Medications for Opioid Use Disorder

Presented by Lance Parks, LCSW 8 CE Credits / Contact Hours

Important Note: We recommend <u>printing the test</u> and completing it as you read to prepare for the online post-test. As you go through the course, hover over or click the yellow 'sticky notes' to reveal helpful study tips. Enjoy the course!

This course is primarily taken from the following citation:

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The content has been edited to make it more appropriate for the length of this course, and also additional, more recent updates have been added and cited in the text and listed in the Bibliography. To see the full unedited TIP, just paste the above citation into your web search bar.

After the TIP Content there are four chapters on "Counseling Clients with Opioid Addiction."

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families TREATMENT IMPROVEMENT PROTOCOL 63

Foreword

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the U.S. Department of Health and Human Services agency that leads public health efforts to reduce the impact of substance abuse and mental illness on America's communities. An important component of SAMHSA's work is focused on dissemination of evidence-based practices and providing training and technical assistance to healthcare practitioners on implementation of these best practices.

The Treatment Improvement Protocol (TIP) series contributes to SAMHSA's mission by providing science-based, best-practice guidance to the behavioral health field. TIPs reflect careful consideration of all relevant clinical and health services research, demonstrated experience, and implementation requirements. Select nonfederal clinical researchers, service providers, program administrators, and patient advocates comprising each TIP's consensus panel discuss these factors, offering input on the TIP's specific topics in their areas of expertise to reach consensus on best practices. Field reviewers then assess draft content and the TIP is finalized.

The talent, dedication, and hard work that TIP panelists and reviewers bring to this highly participatory process have helped bridge the gap between the promise of research and the needs of practicing clinicians and administrators to serve, in the most scientifically sound and effective ways, people in need of care and treatment of mental and substance use disorders.

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration

TIP 63 Update

As a reflection of SAMHSA's commitment to ensuring that people with substance use disorders receive timely, relevant, high-quality care, SAMHSA in May 2021 revised certain areas of all five parts of this TIP to bring the content up to date and make it as useful to readers as possible. These changes will help provide readers with the latest information needed to understand medications for opioid use disorder. These changes include the following:

Updating statistics from SAMHSA, the Centers for Disease Control and Prevention, and other health authorities on opioid-related deaths, overdoses, accidents, and hospitalizations.

Updating the qualifications of practitioners who are eligible to apply for a waiver to prescribe buprenorphine (i.e., clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) to include exceptions under the latest buprenorphine practice guidelines on obtaining a waiver.

Where needed, clarifying whether references to naltrexone refer to the oral formulation or the extended-release injectable formulation.

Adding recent citations that support induction onto extended-release naltrexone of people with positive urine tests for opioids so long as they pass the naloxone challenge.

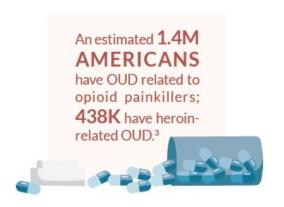
Clarifying that naltrexone can result in decreased opioid cravings.

Removing or replacing broken hyperlinks to online resources.

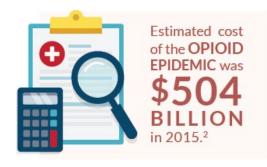
Executive Summary

Introduction

Our nation faces a crisis of overdose deaths from opioids, including heroin, illicit fentanyl, and prescription opioids. These deaths represent a mere fraction of the total number of Americans harmed by opioid misuse and addiction. Many Americans



now suffer daily from a chronic medical illness called "opioid addiction" or OUD.



An expert panel developed the TIP's content based on a review of the literature and on their extensive experience in the field of addiction treatment. Other professionals also generously contributed their time and commitment to this project.

The TIP is divided into parts so that readers can easily find the material they need. Part 1 is a general introduction to providing medications for OUD and issues related to providing that treatment. Some readers may prefer to go directly to those parts most relevant to their areas of interest, but everyone is encouraged to read Part 1 to establish a shared understanding of key facts and issues covered in detail in this TIP.

Following is a summary of the TIP's overall main points and brief summaries of each of the five TIP parts.

Overall Key Messages

Addiction is a chronic, treatable illness. Opioid addiction, which generally corresponds with moderate to severe forms of OUD, often requires continuing care for effective treatment rather than an episodic, acute-care treatment approach.



General principles of good care for chronic diseases can guide OUD treatment.

Approaching OUD as a chronic illness can help providers deliver care that helps patients stabilize, achieve remission of symptoms, and establish and maintain recovery.

Patient-centered care empowers patients with information that helps them make better treatment

decisions with the healthcare professionals involved in their care. Patients should receive information from their healthcare team that will help them understand OUD and the options for treating it, including treatment with FDA-approved medication.

Patients with OUD should have access to mental health services as needed, medical care, and addiction counseling, as well as recovery support services, to supplement treatment with medication.

The words you use to describe OUD and an individual with OUD are powerful. This TIP defines, uses, and encourages providers to adopt terminology that will not reinforce

prejudice, negative attitudes, or discrimination.

There is no "one size fits all" approach to OUD treatment. Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment.

Ongoing outpatient medication treatment for OUD is linked to better retention and outcomes than treatment without medication. Even so, some people stop using opioids on their own; others recover through support groups or specialty treatment with or without medication.

1.6 MILLION
people in the U.S.,
ages 12 and older,
had OUD involving
PRESCRIPTION
OPIOIDS, HEROIN,
or both in 2019.16

The science demonstrating the effectiveness of medication for OUD is strong. For example, methadone, extended-release injectable naltrex- one (XR-NTX), and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for demonstrating efficacy in clinical medicine. Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.



This doesn't mean that remission and recovery occur only through medication. Some people achieve remission without OUD medication, just as some people can manage type 2 diabetes with exercise and diet

alone. But just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness.

Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care at different points in their lives, such as outpatient counseling, intensive outpatient treatment, inpatient

treatment, or long-term therapeutic communities. Patients treated in these settings should have access to OUD medications.

Patients treated with medications for OUD can benefit from individualized psychosocial supports. These can be offered by patients' healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, recovery coaching, mental health services, and other services that may be needed by particular patients.

Expanding access to OUD medications is an important public health strategy. The gap between the number of people needing

opioid addiction treatment and the capacity to treat them with OUD medication is substantial. In 2012, the gap was estimated at nearly 1 million people, with about 80 percent of opioid treatment programs (OTPs) nationally operating at 80 percent capacity or greater.

Improving access to treatment with OUD medications is crucial to closing the wide gap between treatment need and treatment availability, given the strong evidence of effectiveness for such treatments.

Data indicate that medications for OUD are cost effective and cost beneficial.

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

The Approach to OUD Care

According to the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse, **addiction is a chronic, treatable illness.** Opioid addiction, which generally corresponds with moderate to severe forms of OUD (Exhibit 1.1), often requires continuing care for effective treatment rather than an episodic, acute-care treatment approach.

EXHIBIT 1.1. Key Terms

Addiction: As defined by the American Society of Addiction Medicine, "a primary, chronic disease of brain reward, motivation, memory, and related circuitry." It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of **relapse** and **remission.** The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition⁴ (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Medically supervised withdrawal (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

Opioid misuse: The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.⁵

Opioid receptor agonist: A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system (CNS) that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

Opioid receptor antagonist: A substance that has affinity for opioid receptors in the CNS without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioids: All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).

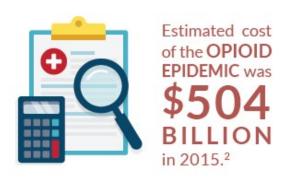
Opioid treatment program (OTP): An accredited treatment program with SAMHSA certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.⁶

Opioid use disorder (OUD): Per DSM-5, a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what DSM-IV termed "opioid abuse" and

The World Health Organization's (WHO's) principles of good care for chronic diseases can guide OUD care:

- Develop a treatment partnership with patients.
- Focus on patients' concerns and priorities.
- Support patient self-management of illness.
- Use the five A's at every visit (assess, advise, agree, assist, and arrange).
- Organize proactive follow-up.
- Link patients to community resources/support.
- Work as a clinical team.
- Involve "expert patients," peer educators, and support staff in the health facility.
- Ensure continuity of care.

Chronic care management is effective for many long-term medical conditions, such as diabetes and cardiovascular disease, and it can offer similar benefits to patients with substance use disorders (SUDs); for example, it can help them stabilize, achieve remission of symptoms, and establish and



maintain recovery. Good con- tinuing care also provides, and links to, other medical, behavioral health, and community and recovery support services.

A noticeable theme in chronic disease management is patient-centered care. Patient-centered care empowers patients with information that helps them make better

treatment decisions with the healthcare profes- sionals involved in their care. Patients should receive information from their healthcare team that will help them understand OUD and the options for treating it, including treatment with FDA-approved medications. Healthcare professionals should also make patients aware of available, appropriate recovery support and behavioral health services.

As is true for patients undergoing treatment for any chronic medical condition, patients with OUD should have access to medical, mental health, addiction counseling, and

recovery support services that they may need to supplement treatment with medication. Medical care should include preventive services and disease management. Patients with OUD who have mental disorders should have access to mental health services.

Treatment and support services should rEffect each patient's individual needs and preferences. Some patients, particularly those with co- occurring disorders, may require these treatments and services to achieve sustained remission and recovery.

The words you use to describe both OUD and an individual with OUD are powerful and can reinforce prejudice, negative attitudes, and discrimination. Negative attitudes held by the public and healthcare professionals can deter people from seeking treatment, make patients leave treatment prematurely, and contribute to worse treatment outcomes. The TIP expert panel recommends that providers always use medical terms when discussing SUDs (e.g., positive or negative urine sample, not dirty or clean sample) and use person-first language (e.g., a person with an SUD, not a user, alcoholic, or addict).

Overview of Medications for OUD

The re is no "one size fts all" approach to OUD treatment. Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment.

Ongoing outpatient medication treatment for OUD is linked to better retention and outcomes than treatment without medication. Even so, some people stop using opioids on their own; others recover through support groups or specialty outpatient or residential treatment with or without medication. Still, FDA-approved medication should be considered and offered to patients with OUD as part of their treatment.

Benefits

The three FDA-approved medications used to treat OUD improve patients' health and wellness by:

Reducing or eliminating withdrawal symptoms: methadone, buprenorphine.

- Blunting or blocking the effects of illicit opioids: methadone, naltrexone, buprenorphine.
- Reducing or eliminating cravings to use opioids: methadone, naltrexone, buprenorphine.

Effectiveness

The science demonstrating the effectiveness of medication for OUD is strong. For example, methadone, extended-release injectable naltrex- one (XR-NTX), and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for demonstrating efficacy in clinical medicine. Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.

This doesn't mean that remission and recovery occur only through medication. Some people achieve remission without OUD medication, just as some people can manage type 2 diabetes with exercise and diet alone. But just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness.

Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care during the course of their lives. These different levels include outpatient counseling, intensive outpatient treatment, inpatient treatment, or long-term therapeutic communities. Patients receiving treatment in these settings should have access to FDA- approved medications for OUD.

Patients treated with OUD medications can benefit from individualized psychosocial supports. These can be offered by patients' healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, contingency management, recovery coaching, mental health services, and other services (e.g., housing supports) that particular patients may need.

The TIP expert panel strongly recommends informing all patients with OUD about the risks and Benefits of treatment of OUD with all FDA- approved medications. Alternatives to these treatments and their risks and benefits should be discussed. Patients should receive access to such medications if clinically appropriate and desired by the patients.

Expanding access to FDA-approved medica- tions is an important public health strategy. A substantial gap exists between the number of people needing OUD treatment and the capacity to treat those individuals with OUD medication. In 2012, the gap was estimated at nearly 1 million people, with approximately 80 percent of OTPs nationally operating at 80 percent capacity or greater. Blue Cross Blue Shield reported a 493 percent increase in members diagnosed with OUD from 2010 to 2016 but only a 65 percent increase in the use of medication for OUD. Improving access is crucial to closing the wide gap between the need for treatment with OUD medications and the availability of such treatment, given the strong evidence of OUD medications' effectiveness.

Methadone

Methadone retains patients in treatment and reduces illicit opioid use more effectively than placebo, medically supervised withdrawal, or no treatment, as numerous clinical trials and meta-analyses of studies conducted in many countries show. Higher methadone doses are associated with superior outcomes. Given the evidence of methadone's effectiveness, WHO lists it as an essential medication.

Methadone treatment has by far the largest, oldest evidence base of all treatment ap-proaches to opioid addiction. Large multisite longitudinal studies from the world over support methadone maintenance's effectiveness. Longitudinal studies have also found that it is associated with:

- Reduced risk of overdose-related deaths.
- Reduced risk of HIV and hepatitis C infection.
- Lower rates of cellulitis.
- Lower rates of HIV risk behavior.
- Reduced criminal behavior.

Naltrexone

XR-NTX reduces illicit opioid use and retains patients in treatment more effectively than placebo and no medication, according to findings from randomized controlled trials.

In a two-group random assignment study of adults who were opioid dependent and involved in the justice system, all participants received brief counseling and community treatment referrals. One group received no medication, and the other group received XR-NTX. During the 6-month follow-up period, compared with the no-medication group, the group that received the medication demonstrated:

- Longer time to return to substance use (10.5 weeks versus 5.0 weeks).
- A lower rate of return to use (43 percent versus 64 percent).
- A higher percentage of negative urine screens (74 percent versus 56 percent).

There are two studies comparing XR-NTX to sublingual buprenorphine. A multisite randomized trial assigned adult residential treatment patients with OUD to either XR-NTX or buprenorphine. Patients randomly assigned to buprenorphine had significantly lower relapse rates during 24 weeks of outpatient treatment than patients assigned to XR-NTX. This finding resulted from challenges in completing XR-NTX induction, such that a significant proportion

of patients did not actually receive XR-NTX. However, when comparing only those partici- pants who started their assigned medication, no significant between-group differences in relapse rates were observed. Because dose induction was conducted with inpatients, findings may not be generalizable to dose induction in outpatient settings, where most patients initiate treatment. A 12-week trial among adults with opioid de- pendence in Norway who were opioid abstinent at the time of random assignment found that XR-NTX was as effective as buprenorphine in retaining patients in treatment and in reducing illicit opioid use.

Oral naltrexone is also available, but it has not been found to be superior to placebo or to no medication in clinical trials. Nonadherence limits its use.

Buprenorphine

Buprenorphine in its sublingual form retains patients in treatment and reduces illicit opioid use more effectively than placebo. It also reduces HIV risk behaviors. A multisite randomized trial with individuals addicted to prescription opioids showed that continued buprenorphine was superior to buprenorphine dose taper in reducing illicit opioid use. Another randomized trial showed that continued buprenorphine also improved treatment retention and reduced illicit prescription opioid use compared with buprenorphine dose taper. Long-term studies of buprenorphine show its effectiveness outside of clinical research proto- cols. Naloxone, a short-acting opioid antago- nist, is also often included in the buprenorphine formulation to help prevent diversion to injected misuse. Because of the evidence of buprenor- phine's effectiveness, WHO lists it as an essential medication. Buprenorphine is available in "transmucosal" (i.e., sublingual or buccal) formulations.

Buprenorphine implants can be effective in stable patients. FDA approved implants (Probuphine) after a clinical trial showed them to be as effective as relatively low-dose (i.e., 8 mg or less daily) sublingual buprenorphine (Suboxone equivalents) for patients who are already clinically stable. More research is needed to establish implants' effectiveness outside of research studies, but findings to date are promising.

FDA approved buprenorphine extended- release injection (Sublocade) in November 2017 to treat patients with moderate or severe OUD who have first received treatment with transmucosal buprenorphine for at least 1 week. This buprenorphine formu- lation is a monthly subcutaneous injection.

Cost Effectiveness and Cost Benefits Cost-effectiveness and cost-benefit analyses can further our understanding of OUD medications' effectiveness.

Data indicates that medications for OUD are cost effective. Cost-effectiveness analyses compare the cost of different treatments with their associated outcomes (e.g., negative opioid urine tests). Such analyses have found that:

 Methadone and buprenorphine are more cost effective than OUD treatment without medication.

- Counseling plus buprenorphine leads to significantly lower healthcare costs than little or no treatment among commercially insured patients with OUD.
- Treatment with any of the three OUD medi- cations this TIP covers led to lower healthcare usage and costs than treatment without medication in a study conducted in a large health plan.

Relatively few cost-benefit analyses have examined addiction treatment with medication separately from addiction treatment in general. Cost-benefit studies compare a treatment's cost with its Benefits. The treatment is cost beneficial if its Benefits outweigh its cost. These Benefits can include:

- Reduced expenditures because of decreased crime.
- Reduced expenditures related to decreases in the use of the justice system.
- Improved quality of life.
- Reduced healthcare spending.
- Greater earned income.

Methadone treatment in OTPs can reduce justice system and healthcare costs.

Requirements and Regulations: Following is a summary of regulations and requirements that apply to the three OUD medications. Part 3 of this TIP discusses the pharmacology and dosing of these medications.

Only federally certifed and accredited OTPs can dispense methadone for the treatment of OUD. Methadone is typically given orally as a liquid. OTPs can dispense buprenorphine under OTP regulations without using a federal waiver. Individual healthcare practitioners can prescribe buprenorphine in any medical setting, as long as they apply for and receive waivers of the special registration requirements defined in the Controlled Substances Act. Several laws and regulations contain information about which healthcare practitioners are eligible to apply for a waiver and how to qualify (www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-forpractitioner-waiver). This information is summarized below.

- Eligible physicians, nurse practitioners, physician assistants, and other qualifying practitioners (clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives) can apply for a waiver.
- At present, clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives are only eligible to apply for a waiver until October 1, 2023.
- For the first year of waiver use, all providers can treat up to 30 patients at one time. However, providers who satisfy additional practice and reporting requirements, and physicians who are board certifed in addiction psychiatry or addiction medicine, may request to treat up to 100 patients at a time in the first year of waiver use. Additionally, practitioners who provide MAT in "qualifed practice settings," as defined in title 42, section 8.615 of the Code of Federal Regulations, may also request to treat up to 100 patients within the first year.
- After the first year of waiver use, all providers may request to increase their patient limit to 100.
- Physicians and other qualifed providers who are board certifed in addiction
 psychiatry or addiction medicine or who satisfy additional practice and reporting
 requirements may apply to increase their patient limit to 275 after a year at the
 100-patient limit.

Prescribing buprenorphine implants requires Probuphine REMS Program certification. Providers who wish to insert or remove implants must obtain live training and certification in the REMS Program. Healthcare settings and pharmacies must get Sublocade REMS Program certification to dispense this medication and can only dispense it directly to healthcare providers for subcutaneous administration.

Naltrexone has no regulations beyond those that apply to any prescription pharmaceutical. Any healthcare provider with prescribing authority, including those practicing in OTPs, can prescribe its oral formulation and administer its long-acting injectable formulation. The Controlled Substances Act contains a few exceptions from the requirement to provide methadone through an OTP or buprenorphine through an OTP or a waivered practitioner. These include (1) administering (not prescribing) an opioid

for no more than 3 days to a patient in acute opioid withdrawal while preparations are made for ongoing care and (2) administering opioid medications in a hospital to maintain or detoxify a patient as an "incidental adjunct to medical or surgical treatment of conditions other than addiction."

Duration of Treatment with OUD Medication

Patients can take medication for OUD on a short-term or long-term basis. However, patients who discontinue OUD medication generally return to illicit opioid use. Why is this so, even when discontinuation occurs slowly and carefully? Because the more severe form of OUD (i.e., addiction) is more than physical dependence. Addiction changes the reward circuitry of the brain, affecting cognition, emotions, and behavior. Providers and their patients should base decisions about discontinuing OUD medication on knowledge of the evidence base for the use of these medications, individualized assessments, and an individualized treatment plan they collaboratively develop and agree upon. Arbitrary time limits on the duration of treatment with OUD medication are inadvisable.

Maintenance Treatment

The best results occur when a patient receives medication for as long as it provides a benefit. This approach is often called "maintenance treatment." Once stabilized on OUD med- ication, many patients stop using illicit opioids completely. Others continue to use for some time, but less frequently and in smaller amounts, which reduces their risk of morbidity and overdose death. OUD medication gives people the time and ability to make necessary life changes associated with long-term remission and recovery (e.g., changing the people, places, and things connected with their drug use), and to do so more safely. Maintenance treatment also minimizes cravings and withdrawal symptoms. And it lets people better manage other aspects of their life, such as parenting, attending school, or working.

Medication Taper

After some time, patients may want to stop opioid agonist therapy for OUD through gradually tapering doses of the medication. Their outcomes will vary based on factors such as the length of their treatment, abstinence from illicit drugs, fnancial and social stability, and motivation to discontinue medication. Longitudinal studies show that most patients who try to stop methadone treatment relapse during or after completing the taper. For example, in a large, population-based retrospective study, only 13 percent of patients who tapered from methadone had successful outcomes (no treatment reentry, death, or opioid-related hospitalization within 18 months after taper). A clinical trial of XR-NTX versus treatment without medication also found increased risk of returning to illicit opioid use after discontinuing medication.

Adding psychosocial treatments to taper regimens may not significantly improve outcomes compared with remaining on med- ication. One study randomly assigned partici- pants to methadone maintenance or to 6 months of methadone treatment with a dose taper plus intensive psychosocial treatment. The maintenance group had more days in treatment and lower rates of heroin use and HIV risk behavior at 12-month follow-up. Patients wishing to taper their opioid agonist medication should be offered psychosocial and recovery support. Primary care physicians are on the front lines of providing office-based treatment with medication for OUD. services. They should be monitored during and after dose taper, offered XR-NTX, and encouraged to resume treatment with medication quickly if they return to opioid use.

Medically Supervised Withdrawal

Medically supervised withdrawal is a process in which providers offer methadone or buprenorphine on a short-term basis to reduce physical withdrawal signs and symptoms. Formerly called detoxifcation, this process gradually decreases the dose until the medication is discontinued, typically over a period of days or weeks. Studies show that most patients with OUD who undergo medically supervised withdrawal will start using opioids again and won't continue in recommended care. Psychosocial treatment strategies, such as contingency management, can reduce dropout from medically supervised withdrawal, opioid use during withdrawal, and opioid use following completion of withdrawal. **Medically supervised withdrawal is necessary for**

patients starting naltrexone, which requires at least 7 days without short-acting opioids and 10 to 14 days without long-acting opioids. Patients who complete medically supervised withdrawal are at risk of opioid overdose.

Treatment Settings

Almost all healthcare settings are appropriate for screening and assessing for OUD and offering medication onsite or by referral. Settings that offer OUD treatment have expanded from specialty sites (certifed OTPs, residential fa- cilities, outpatient addiction treatment programs, and addiction specialist physicians' offices) to general primary care practices, health centers, emergency departments, inpatient medical and psychiatric units, jails and prisons, and other settings.

Sustained public health efforts are essential to address the urgent need for OUD treatment and the risk of related overdose, HIV, and hepatitis C virus epidemics. These efforts must remove barriers and increase access to OUD medication.

OUD medications should be available to patients across all settings and at all levels of care—as a tool for remission and recovery. Because of the strength of the science, a 2016 report from the Surgeon General urged adoption of medication for OUD along with recovery supports and other behavioral health services throughout the healthcare system.

Challenges to Expanding Access to OUD Medication

Despite the urgent need for treatment throughout the United States, only about 21.5 percent of people with OUD received treatment from 2009 to 2013. The Centers for Disease Control and Prevention lists more than 200 U.S. counties as at risk for an HIV or a hepatitis C virus outbreak related to injection drug use.

Resources

Patient success stories are inspirational. They highlight the power of OUD medication to help people achieve remission and recovery. See the "Patient Success Stories" section in Part 5 of this TIP.

Part 5 of this TIP also contains community resources and advocacy resources. The community resources are for OTP, addiction treatment, and office-based providers. The advocacy resources can help patients and others advocate for OUD medication for themselves and in their communities.

<u>Updates 2024–2025:</u>

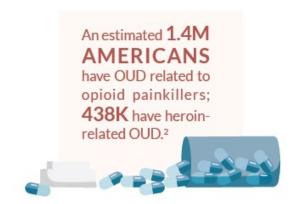
The policy landscape for MOUD has shifted measurably. In February 2024, SAMHSA issued the first comprehensive revision of 42 CFR Part 8 in over two decades, with rules effective April 2, 2024 (compliance Oct 2, 2024). The final rule codifies patient-centered changes for OTPs, modernizes standards, and aims to remove barriers to medications for OUD (SAMHSA, 2024). Access has also been shaped by federal telemedicine policy: DEA and HHS extended COVID-era telemedicine flexibilities through December 31, 2025, allowing many patients to continue initiating/maintaining MOUD by telehealth while agencies finalize permanent rules (DEA, 2024). On the overdose front, provisional CDC data suggest the first major yearover-year improvement since the pandemic: predicted overdose deaths fell nearly 24% for the 12 months ending September 2024 (about 87,000 vs. ~114,000), with declines in most states (CDC, 2025). Expanded naloxone access likely contributed. Beyond the FDA's 2023 OTC approvals, 2024 saw additional lower-cost OTC options, including a Walgreens-branded 4-mg naloxone spray priced at \$34.99, improving consumer access (Sunny, 2024). Taken together, these developments underline the importance of meeting patients where they are—leveraging OTP reforms, telehealth continuity, and widespread naloxone—while maintaining focus on equitable access, retention, and harm-reduction partnerships. Programs should continue to integrate screening for polysubstance exposure and ensure rapid linkage to methadone, buprenorphine, or naltrexone in settings where patients already receive care. As trends remain

heterogeneous and fragile, maintaining these access gains while monitoring local data will be essential to sustain mortality reductions (CDC, 2025). Implementation continues through October 2, 2024 as OTPs align with the rule (SAMHSA, 2024).

Part 2: Addressing Opioid Use Disorder in General Medical Settings

Scope of the Problem

OUD in medical clinics, community health centers, and private practices is increasing. Healthcare professionals in these general settings are in an important position to identify, assess, and treat OUD or to refer patients for treatment. Moreover, patients who are



medically and mentally stable can benefit from receiving OUD medications in integrated care settings, where they often have already established therapeutic relationships with their healthcare providers.

Screening

Screening can identify patients who may have diseases or conditions related to their substance use. Health care in general medical settings routinely includes screening for common, treatable conditions such as cancer that are associated with significant morbidity and mortality. Screening for SUDs is important, as misuse of alcohol, tobacco, and other substances is common among patients in medical settings (Exhibit 2.2).

Screening can identify substance misuse in patients who wouldn't otherwise discuss it or connect it with the negative consequences they're experiencing. Some patients may spontaneously reveal their substance use and ask for help. This is more likely when they're experiencing harmful consequences of substance use. However, screening may identify unhealthy substance use (e.g., binge drinking) and SUDs before patients connect their substance use with their presenting complaint. Screening is also helpful when patients feel ashamed or afraid to reveal their concerns spontaneously.

Every medical practice should determine which screening tools to use and when, how, and by whom they will be administered.

Each practice should also identify steps to take when a patient screens positive. One efficient workflow strategy is to have clinical assistants or nurses administer the screening instrument in an interview or provide patients with a paper or computer tablet version for self-administration. (Self-administration is generally as reliable as interviewer administration.) Providers should be nonjudgmental and rely on established rapport when discussing screening results with patients.

(Exhibit 2.1 on the next page defines key terms in Part 2)

EXHIBIT 2.1. Key Terms

Addiction: As defined by the American Society of Addiction Medicine (ASAM),³ "a primary, chronic disease of brain reward, motivation, memory, and related circuitry." It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of **relapse** and **remission.** The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition⁴ (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Healthcare professionals: Physicians, nurse practitioners (NPs), physician assistants (PAs), and other medical service professionals who are eligible to prescribe medications for and treat patients with OUD (i.e., until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives). The term "prescribers" also refers to these healthcare professionals.

Maintenance treatment: Providing medications to achieve and sustain clinical remission of signs and symptoms of OUD and support the individual process of recovery without a specific endpoint (as with the typical standard of care in medical and psychiatric treatment of other chronic illnesses).

Medically supervised withdrawal (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

Medical management: Process whereby healthcare professionals provide medication, basic brief supportive counseling, monitoring of drug use and medication adherence, and referrals, when necessary, to addiction counseling and other services to address the patient's medical, mental health, comorbid addiction, and psychosocial needs.

Office-based opioid treatment (OBOT): Providing medication for OUD in outpatient settings other than certified opioid treatment programs (OTPs).

Opioid misuse: The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.⁵

Opioid receptor agonist: A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

Opioid receptor antagonist: A substance that has an affinity for opioid receptors in the central nervous system without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioid treatment program (OTP): An accredited treatment program with Substance Abuse and Mental Health Services Administration (SAMHSA) certification and Drug Enforcement Administration (DEA) registration to administer and dispense opioid agonist medications that are approved by the Food and Drug Administration (FDA) to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.⁶

Continued on next page

EXHIBIT 2.1. Key Terms (continued)

Opioid use disorder (OUD): Per DSM-5,7 a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, termed "opioid abuse" and "opioid dependence." An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period. (See Exhibit 2.13 and the Appendix in Part 2 for full DSM-5 diagnostic criteria for OUD.)

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Even individuals with severe and chronic SUDs can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.

Relapse: A process in which a person with OUD who has been in **remission** experiences a return of symptoms or loss of remission. A relapse is different from a **return to opioid use** in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting. The TIP uses relapse to describe relapse prevention, a common treatment modality.

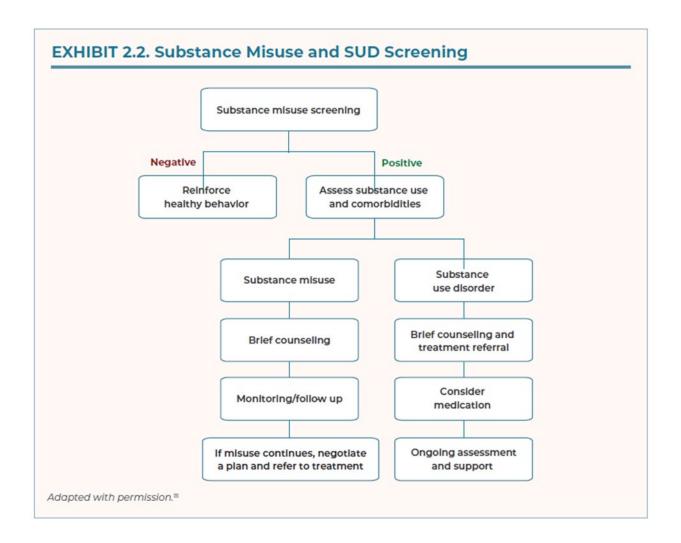
Remission: A medical term meaning a disappearance of signs and symptoms of the disease. DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving). Remission is an essential element of **recovery**.

Return to opioid use: One or more instances of **opioid misuse** without a return of symptoms of OUD. A return to opioid use may lead to **relapse.**

Tolerance: Alteration of the body's responsiveness to alcohol or other drugs (including opioids) such that higher doses are required to produce the same effect achieved during initial use. See also **medically supervised withdrawal.**

Alcohol Screening

Screening for alcohol misuse can identify patients at increased risk for opioid use. When screening patients for opioid misuse, providers should also screen for alcohol misuse and alcohol use disorder (AUD), which cause considerable morbidity and mortality. Providers should warn patients who use opioids that alcohol may increase opioid overdose risk. The U.S. Preventive Services Task Force (USPSTF) recommends screening adults for alcohol misuse, including risky drinking and AUD. USPSTF also recommends brief counseling for patients with risky drinking.



USPSTF recommends the following alcohol screeners:

- The single-item National Institute on Alcohol Abuse and Alcoholism (NIAAA)
 Screener is the briefest tool available (Exhibit 2.3). It can help distinguish at-risk patients who require further screening from those not at risk for AUD. Encourage patients in the latter category to maintain healthy behavior.
- The Alcohol Use Disorders Identification Test (AUDIT) or its briefer version, the AUDIT-Consumption, can elicit more in- formation from patients who screen positive on the single-item screener. The full AUDIT tool (Exhibit 2.4) and its briefer version have demonstrated acceptable reliability in AUD screening.
 Assess patients with positive screens for AUD.

Practitioners should consider medication and referral to counseling for people with AUD. The three FDA-approved medications to treat AUD—acamprosate, disulfram, and naltrexone (oral and extended-release injectable naltrex- one [XR-NTX])—can be prescribed in general medical and specialty SUD treatment settings. (For more information on AUD treatment, see the SAMHSA/NIAAA publication Medication for the Treatment of Alcohol Use Disorder: A Brief Guide.)

EXHIBIT 2.3. NIAAA Single-Item Screener

How many times in the past year have you had five or more drinks in a day (four drinks for women and all adults older than age 65)?



One or more times constitutes a positive screen. Patients who screen positive should have an assessment for AUD.

Adapted with permission.20

Tobacco Screening

More than 80 percent of patients who are opioid dependent smoke cigarettes.

Understanding of the major health consequences and risks associated with tobacco use has grown significantly over the past 50 years. Among preventable causes of premature death, smoking remains most prevalent, with more than 480,000 deaths per year in the United States. In addition, more than 40 percent of all people who smoke are mentally ill or have SUDs.

USPSTF recommends that primary care providers screen for tobacco use, advise patients to quit, and provide counseling and FDA-approved medications for tobacco cessation. The six-item Fagerström Test for Nicotine Dependence assesses cigarette use and nicotine dependence. The maximum score is 10; the higher the total score, the more severe the patient's nicotine dependence. The two-item Heaviness of Smoking Index (Exhibit 2.5) is also useful.

Drug Screening

Screening for illicit drug use and prescription medication misuse is clinically advantageous. USPSTF's position is that adults ages 18 and older (including those who are pregnant) should be routinely screened in primary care for illicit drug use and prescription medication misuse when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referral can be provided. Identifying misuse of prescription or illegal drugs can prevent harmful drug interactions, lead to adjustments

in prescribing practices, improve medical care adherence, and increase the odds of patients getting needed interventions or treatment. Brief screening instruments for drug use can determine which patients need further assessment. Providers should reinforce healthy behaviors among patients who report "no use" and direct those who report "some use" for further screening and assessment to obtain a diagnosis.

Several brief screening instruments for drug use can help primary care practitioners identify patients who use drugs. For example, a single-item screen is available for the general public (Exhibit 2.6). A two-item valid screener is available for use with U.S. veterans (Exhibit 2.7).

Brief drug screens don't indicate specific types of drugs used (nor does the longer Drug Abuse Screening Test). If providers use nonspecific screens, they need to assess further which substances patients use and to what degree.

EXHIBIT 2.4. AUDIT Screener 1. How often do you have a drink containing 6. How often during the last year have you alcohol? needed an alcoholic drink first thing in the morning to get yourself going after a night of (0) Never [Skip to Questions 9–10] heavy drinking? (1) Monthly or less (2) 2 to 4 times a month (0) Never (3) 2 to 3 times a week (1) Less than monthly (4) 4 or more times a week (2) Monthly (3) Weekly (4) Daily or almost daily 2. How many drinks containing alcohol do you 7. How often during the last year have you had a have on a typical day when you are drinking? feeling of guilt or remorse after drinking? Never (0) 1 or 2 Less than monthly 3 or 4 (1) (1) (2) 5 or 6 (2)Monthly 7, 8, or 9 Weekly (3)(3) (4) 10 or more (4) Daily or almost daily 3. How often do you have six or more drinks on 8. How often during the last year have you been unable to remember what happened the night one occasion? before because you had been drinking? (0) Never Less than monthly (1) (2) Monthly Less than monthly (7) (3) Weekly Monthly (2) (4) Daily or almost daily Weekly (3) (4) Daily or almost daily Skip to Questions 9 and 10 if total score for Ouestions 2 and 3 = 04. How often during the last year have you found 9. Have you or someone else been injured as a that you were not able to stop drinking once result of your drinking? you had started? (0) No (0) Never (2) Yes, but not in the last year (1) Less than monthly (4) Yes, during the last year (2) Monthly (3) Weekly (4) Daily or almost daily 10. Has a relative, friend, doctor, or another health 5. How often during the last year have you falled to do what was normally expected from you professional expressed concern about your because of drinking? drinking or suggested you cut down? (O) (1) Less than monthly (2)Yes, but not in the last year Monthly (2) Yes, during the last year (3) Weekly

Note: Add up the points associated with answers. A score of 8 or more is considered a positive test for unhealthy drinking. Adapted from material in the public domain. ³⁵ Available online (http://auditscreen.org).

Daily or almost daily

EXHIBIT 2.5. Heaviness of Smoking Index

Ask these two questions of current or recent smokers:

- How soon after waking do you smoke your first cigarette?
 - · Within 5 minutes (3 points)
 - 5–30 minutes (2 points)
 - 31-60 minutes (1 point)
 - 61 or more minutes (no points)
- 2. How many cigarettes a day do you smoke?
 - 10 or less (no points)
 - 11-20 (1 point)
 - · 21-30 (2 points)
 - 31 or more (3 points)

Total score:

- 1-2 points = very low dependence
- 3 points = low to moderate dependence
- 4 points = moderate dependence
- 5 or more points = high dependence

Adapted with permission.36

EXHIBIT 2.6. Single-Item Drug Screener

How many times in the past year have you used an illegal drug or a prescription medication for nonmedical reasons?

(A positive screen is 1 or more days.)

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EXHIBIT 2.7. Two-Item Drug Use Disorder Screener for Primary Care Clinics Serving U.S. Veterans

Question 1: How many days in the past 12 months have you used drugs other than alcohol? (A positive screen is 7 or more days.) If fewer than 7, proceed with Question 2.

Question 2: How many days in the past 12 months have you used drugs more than you meant to? (A positive screen is 2 or more days.)

Adapted with permission.40

The Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) screens patients for all categories of substance misuse, including alcohol and tobacco. This World Health Organization (WHO) screener also assesses substance-specific risk. The ASSIST's length and rather complex scoring system have hindered its adoption, but a computerized version and a briefer hard copy version (ASSIST- lite) make its use more efficient.

Follow up any positive one-question screen with a brief assessment. An example of a two-step screening and brief assessment is the Tobacco, Alcohol, Prescription Medications, and Other Substance Use (TAPS Tool; see Part 2 Appendix), developed and tested in primary care settings. This tool is based on the National Institute on Drug Abuse (NIDA) Quick Screen V1.0 and a modified WHO ASSIST-lite.

The TAPS Tool screens for clinically relevant heroin and prescription opioid misuse (meeting one or more DSM-5 SUD criteria) and misuse of an array of other substances in primary care patients. However, it may also detect SUDs only for the most often-used substances (i.e., alcohol, tobacco, and marijuana). Patients with positive screens for heroin or prescription opioid misuse need more indepth assessment.

Assessment

Determine the Need for and Extent of Assessment

Assess patients for OUD if:

- They screen positive for opioid misuse.
- They disclose opioid misuse.
- Signs or symptoms of opioid misuse are present.

The extent of assessment depends on a provider's ability to treat patients directly.

If a provider does not offer medication, the focus should be on medical assessment, making a diagnosis of OUD, and patient safety. This allows the provider to refer patients to the appropriate level of treatment. The provider can also conduct:

- Assessment and treatment for co-occurring medical conditions or mental disorders (including HIV and hepatitis C [anti-HCV]).
- Motivational brief interventions to promote safter behavior and foster effective treatment engagement.
- Overdose prevention education and provide a naloxone prescription.
- Education for patients who inject drugs on how to access sterile injecting equipment.
- An in-person follow-up, regardless of referral to specialty treatment.

If the provider offers medication, the patient needs more comprehensive assessment, including:

• A review of the prescription drug monitoring program (PDMP).

- A history, including a review of systems.
- A targeted physical exam for signs of opioid withdrawal, intoxication, injection, and other medical consequences of misuse.
- Determination of OUD diagnosis and severity.
- Appropriate laboratory tests in addition to those recommended by the nontreating provider (e.g., urine or oral fuid drug tests, liver function tests, hepatitis B test).

A comprehensive assessment is intended to:

- Establish the diagnosis of OUD.
- Determine the severity of OUD.
- Identify contraindicated medications.
- Indicate other medical conditions to address during treatment.
- Identify mental and social issues to address.

Set the Stage for Successful Assessment

The medical setting should create a welcoming environment that is nonjudgmental, respectful, and empathetic. Many patients with OUD are reluctant to discuss their opioid use in medical settings. A welcoming environment can help patients feel safe disclosing facts they may find embarrassing. Motivational interviewing strategies, such as asking open-ended questions, foster successful assessment.

Staff should explore patients' ambivalence and highlight problem areas to help them fnd motivations for change. Almost all patients have some ambivalence about their opioid use. They will fnd some aspects pleasant and beneficial, but others problematic, painful, or destructive. By exploring that ambivalence and highlighting problem areas, providers can help patients discover their own motivations for change. Motivational Interviewing: Helping People Change discusses specifc applications of motivational interviewing in health care.

Take a Complete History

Staff should prioritize medical, mental health, substance use, and SUD treatment histories. When obtaining patient histories, staff should address these domains before starting treatment. As providers and staff build trust over future visits, they can get into more detailed elements of the assessment.

Medical history

- Taking a complete medical history of patients with OUD is critical, as it is for
 patients with any other medical condition treatable with medication. Asking about
 patients' medical/surgical history can:
- Reveal medical effects of substance use (e.g., endocarditis, soft tissue infection, hepatitis B or C, HIV infection) that may need treatment.
- Highlight consequences that motivate change.
- Identify medical issues (e.g., severe liver disease) that contraindicate or alter dosing approaches for OUD pharmacotherapies.
- Reveal chronic pain issues.
- Help providers consider interactions among various medications and other substances.

Mental health history

Assessing for comorbid mental illness is critical. **Mental illness is prevalent among people with SUDs; it can complicate their treatment and worsen their prognosis**. In one study, nearly 20 percent of primary care patients with OUD had major depression. SUDs can also mimic or induce depression and anxiety disorders. Although substance-induced depression and anxiety disorders may improve with abstinence, they may still require treatment in their own right after a period of careful observation. Take a history of the relationship between a patient's psychiatric symptoms and periods of substance use and abstinence. Treatment for mental disorders and SUDs can occur concurrently.

Substance use history

Substance use histories can help gauge OUD severity, inform treatment planning, clarify potential drug interactions, and highlight the negative consequences of patients' opioid use.

To help determine the severity of patients' substance use, explore historical features of their use, like:

- Age at first use.
- Routes of ingestion (e.g., injection).
- History of tolerance, withdrawal, drug mixing, and overdose.

Histories should also explore current patterns of use, which inform treatment planning and include:

- Which drugs patients use.
- Comorbid alcohol and tobacco use.
- Frequency, recency, and intensity of use.

Exhibit 2.8 on the next page, lists medical problems associated with opioid misuse.

CATEGORY	POSSIBLE COMPLICATIONS
Cancer	Injection drug use: Hepatocellular carcinoma related to hepatitis C
Cardlovascular	Injection drug use: Endocarditis, septic thrombophlebitis
Endocrine/metabolic	OploIds: Osteopenia, hypogonadism, erectile dysfunction, decreased sperm motility, menstrual irregularity including amenorrhea, infertility
Hematologic	Injection drug use/sharing intranasal use equipment: Hematologic consequences of liver disease from hepatitis C, hepatitis C-related cryoglobulinemia and purpura
Hepatic	Injection drug use/sharing intranasal use equipment: Hepatitis B, C, D; infectious and toxic hepatitis
Infectious	OploIds: Aspiration pneumonia, sexually transmitted infections
	Injection drug use: Endocarditis, cellulitis, necrotizing fasciitis, pneumonia, septic thrombophlebitis, mycotic aneurysm, septic arthritis (unusual joints, such as sternoclavicular), osteomyelitis (including vertebral), epidural and brain abscess, abscesses and soft tissue infections, mediastinitis, malaria, tetanus, hepatitis B, hepatitis C, hepatitis D, HIV, botulism
Neurologic	OploIds: Seizure (overdose and hypoxia), compression neuropathy (following overdose), sleep disturbances
Nutritional	OploIds: Protein malnutrition
Other gastrointestinal	OploIds: Constipation, ileus, intestinal pseudo-obstruction, sphincter of Oddi spasm, nausea
Pulmonary	OploIds: Respiratory depression/failure, bronchospasm, exacerbation of sleep apnea, noncardiogenic pulmonary edema, bullae
	Injection drug use: Pulmonary hypertension, talc granulomatosis, septic pulmonary embolism, pneumothorax, emphysema, needle embolization
Renal	OploIds: Rhabdomyolysis, acute renal failure (not direct toxic effect of opioids but secondary to central nervous system depression and resulting complications), factitious hematuria
	Injection drug use: Focal glomerular sclerosis (HIV, heroin), glomerulonephritis from hepatitis or endocarditis, chronic renal failure, amyloidosis, nephrotic syndrome (hepatitis C)

To diagnose an SUD, assess patients' negative consequences of use, which can affect:

- Physical health.
- Mental health.
- Family relationships.
- Work/career status.
- Legal involvement.

Housing status.

Buprenorphine and methadone can cause complications for patients who misuse or have SUDs involving alcohol or benzodiazepines. Providers should take specifc histories on the use of these substances.

SUD treatment history

Information about a patient's past efforts to get treatment or quit independently can inform treatment planning. The same is true for details about the events and behaviors that led to a patient's return to substance use after periods of abstinence and remission of SUD. Similarly, identifying the features of successful quit attempts can help guide treatment plan decisions. Such features may involve:

- Specifc treatment settings.
- Use of support groups.
- Previous responses to OUD medications.

Social history

Information about a patient's social environments and relationships can aid treatment planning. Social factors that may infuence treatment engagement and retention, guide treatment planning, and affect prognosis include:

- Transportation and childcare needs.
- Adequacy and stability of housing.
- Criminal justice involvement.
- Employment status and quality of work environment.
- Close/ongoing relationships with people with SUDs.
- Details about drug use from people the patient lives or spends time with (obtained with patient's consent).

- Sexual orientation, identity, and history, including risk factors for HIV/sexually transmit- ted infections.
- Safety of the home environment. Substance misuse substantially increases the risk of intimate partner violence; screen all women presenting for treatment for domestic violence.

Family history

Learn the substance use histories of patients' parents, siblings, partners, and children. One of the strongest risk factors for developing SUDs is having a parent with an SUD. Genetic factors, exposure to substance use in the household during childhood, or both can contribute to the development of SUDs.

EXHIBIT 2.9. Signs of Opioid Intoxication

Physical findings

Drowsy but arousable
Sleeping intermittently ("nodding off")
Constricted pupils

Mental status findings

Slurred speech Impaired memory or concentration Normal to euphoric mood

PATIENT TESTIMONY

Opioid Withdrawal

"Severe opioid withdrawal isn't something I'd wish on my worst enemy. The last time I went cold turkey, I was determined to come off all the way. The physical symptoms were just the tip of the iceberg. My mind was a nightmare that I thought I would never wake up from. There were times when I was almost convinced that dying would be better than what I was feeling. I did not experience a moment of ease for the first 3 months, and it was 6 months until I started to feel normal."

Conduct a Physical Examination

Perform a physical exam (or refer for one) as soon as possible if recent exam records aren't accessible.

Assess for:

- Opioid intoxication or withdrawal.
- Physical signs of opioid use.
- Medical consequences of opioid use.

Opioid withdrawal

Opioid withdrawal can be extremely uncomfortable. Symptoms are similar to experiencing gastroenteritis, severe infuenza, anxiety, and dysphoria concurrently.

Severity of withdrawal can indicate a patient's level of physical dependence and can inform medication choices and dosing decisions. The duration of withdrawal depends on the specific opioid from which the patient is withdrawing and can last 1 to 4 weeks. After the initial withdrawal phase is complete, many patients experience a prolonged phase of dysphoria, craving, insomnia, and hyperalgesia that can last for weeks or months.

Assess opioid withdrawal in the physical exam by noting physical signs and symptoms (Exhibit 2.10). Structured measures (e.g., Clinical Opiate Withdrawal Scale [COWS]; Clinical Institute Narcotic Assessment Scale for Withdrawal Symptoms) can help standardize documentation of signs and symptoms to support diagnosis, initial

management, and treatment planning.
See the "Resources" section for links to standardized scales. Part 3 of this TIP covers withdrawal symptom documentation for medication initiation.

The physical signs of opioid misuse vary depending on the route of ingestion:

Patients who primarily smoke or sniff ("snort") opioids or take them orally often have few physical signs of use other than signs of intoxication and withdrawal. However, snorting can cause congestion and damage nasal mucosa.

Patients who inject opioids may develop:

- Sclerosis or scarring of the veins and needle marks, or "track marks," in the arms, legs, hands, neck, or feet (intravenous use).
- Edema in the foot, hand, or both
 (common in injection use, but may occur in oral use).
- Abscesses or cellulitis.
- Jaundice, caput medusa, palmar erythema, spider angiomata, or an enlarged or hardened liver secondary to liver disease.
- Heart murmur secondary to endocarditis.

EXHIBIT 2.10. Physical Signs of Opioid Withdrawal and Time to Onset

STAGE	GRADE	PHYSICAL SIGNS/ SYMPTOMS
Early withdrawal Short-acting opioids: 8–24 hours after last use Long-acting opioids: Up to 36 hours after last use	Grade 1	Lacrimation, rhinorrhea, or both Diaphoresis Yawning Restlessness Insomnia
Early withdrawal Short-acting opioids: 8–24 hours after last use Long-acting opioids: Up to 36 hours after last use	Grade 2	Dilated pupils Piloerection Muscle twitching Myalgia Arthralgia Abdominal pain
Fully developed withdrawal Short-acting opioids: 1–3 days after last use Long-acting opioids: 72–96 hours after last use	Grade 3	Tachycardia Hypertension Tachypnea Fever Anorexia or nausea Extreme restlessness
Fully developed withdrawal Short-acting opioids: 1–3 days after last use Long-acting opioids: 72–96 hours after last use	Grade 4	Diarrhea, vomiting, or both Dehydration Hyperglycemia Hypotension Curled-up position

Total duration of withdrawal:

- · Short-acting opioids: 7-10 days
- Long-acting opioids: 14 days or more

Obtain Appropriate Laboratory Tests

Urine or oral fluid drug testing Urine or oral fluid drug testing is useful before initiating OUD medication. Testing establishes a baseline of substances the patient has used so that the provider can monitor the patient's response to treatment over time. Testing for a range of commonly used substances helps confrm patient histories, facilitates discussion of recent drug use and symptoms, and aids in diagnosing and determining severity of SUDs. Drug testing is an important tool in the diagnosis and treatment of addiction.

A national guideline on the use of drug testing is available from ASAM. Exhibit 2.11 provides guidance on talking with patients about drug testing.

EXHIBIT 2.11. Patient-Provider Dialog: Talking About Drug Testing

Frame drug testing in a clinical, nonpunitive way. For example, before obtaining a drug test, ask the patient, "What do you think we'll find on this test?" The patient's response is often quite informative and may make the patient less defensive than confrontation with a positive test result.

SCENARIO: A provider discusses urine drug testing with a patient being assessed for OUD treatment with medication.

Provider: When we assess patients for medication for opioid addiction, we always check urine samples

for drugs.

Patient: I'll tell you if I used. You don't need to test me.

Provider: Thank you, I really appreciate that. The more we can talk about what's going on with you, the

more I can help. I'm not checking the urine to catch you or because I don't trust you. I trust you. I can see how motivated you are. But I don't trust the addiction because I know how powerful addiction can be, too. To monitor your safety on medication and help determine what other services you may need, it's important for us to test you periodically and discuss

the results. Does that sound okay?

Patient: Yeah, that makes sense.

To assess and manage patients with OUD properly, providers must know which tests to order and how to interpret results. There are many drug testing panels; cutoffs for positive results vary by laboratory. One widely used panel, the NIDA-5, tests for cannabinoids, cocaine, amphetamines, opiates, and phencycli- dine. Additional testing

for benzodiazepines, the broader category of opioids, and specifc drugs commonly used in the patient's locality may be warranted. The typical opioid immunoassay will only detect morphine, which is a metabolite of heroin, codeine, and some other opioids. The typical screen will not detect methadone, buprenorphine, or fentanyl and may not detect hydrocodone, hydromorphone, or oxycodone. Specifc testing is needed to identify these substances.

Co-occurring SUDs require separate, specifc treatment plans.

Testing for substances that can complicate OUD medication is essential. Testing for cocaine, benzodiazepines, and methamphet- amine is clinically important because these and other substances (and related SUDs, which may require treatment in their own right), especially benzodiazepines, can complicate medication treatment for OUD. Benzodiazepine and other sedative misuse can increase the risk of overdose among patients treated with opioid agonists. When assessing benzodiazepine use, note that typical benzodiazepine urine immunoassays will detect diazepam but perhaps not lorazepam or clonazepam. Providers must specifcally request testing for these two benzodiazepines.

Exhibit 2.12 shows urine drug testing windows of detection.

EXHIBIT 2.12. Urine Drug Testing Window of Detection^{61,62}

DRUG	POSITIVE TEST	WINDOW OF DETECTION*	COMMENTS
Amphetamine; methamphetamine; 3,4-methylenedioxy- methamphetamine	Amphetamine	1–2 days	False positives with bupropion, chlorpromazine, desipramine, fluoxetine, labetalol, promethazine, ranitidine, pseudoephedrine, trazadone, and other common medications. Confirm unexpected positive results with the laboratory.
Barbiturates	Barbiturates	Up to 6 weeks	N/A
Benzodia zepines	Benzodiazepines	1–3 days; up to 6 weeks with heavy use of long-acting benzodiazepines	Immunoassays may not be sensitive to therapeutic doses, and most immunoassays have low sensitivity to clonazepam and lorazepam. Check with your laboratory regarding sensitivity and cutoffs. False positives with sertraline or oxaprozin.

^{*}Detection time may vary depending on the cutoff.

Continued on next page

DRUG	POSITIVE TEST	WINDOW OF DETECTION*	COMMENTS
Buprenorphine	Buprenorphine	3–4 days	Will screen negative on opiate screen. Tramadol can cause false positives. Can be tested for specifically.
Cocalne	Cocaine, benzoylecgonine	2–4 days; 10–22 days with heavy use	N/A
Codelne	Morphine, codeine, high-dose hydrocodone	1–2 days	Will screen positive on opiate immunoassay.
Fentanyl	Fentanyl	1–2 days	Will screen negative on opiate screen. Can be tested for specifically. May not detect al fentanyl-like substances. ⁶³
Heroln	Morphine, codeine	1–2 days	Will screen positive on opiate immunoassay. 6-monoacetylmorphine, a unique metabolite of heroin, is present in urine for about 6 hours. Can be tested for specifically to distinguish morphine from heroin, but this is rarely clinically useful.
Hydrocodone	Hydrocodone, hydromorphone	2 days	May screen negative on opiate immunoassay. Can be tested for specifically.
Hydromorphone	May not be detected	1–2 days	May screen negative on opiate immunoassay. Can be tested for specifically.
Marljuana	Tetrahydrocan- nabinol	Infrequent use of 1–3 days; chronic use of up to 30 days	False positives possible with efavirenz, ibuprofen, and pantoprazole.
Methadone	Methadone	2–11 days	Will screen negative on opiate screen. Can be tested for specifically.
Morphine	Morphine, hydromorphone	1–2 days	Will screen positive on opiate immunoassay. Ingestion of poppy plant/ seed may screen positive.

1-1.5 days

Oxymorphone

*Detection time may vary depending on the cutoff.

Oxycodone

Typically screens negative on opiate immunoassay. Can be tested for

specifically.

Positive opioid tests can confrm recent use. Document recent use before starting patients on buprenorphine or methadone. Positive methadone or buprenorphine tests are expected for patients receiving these treatments. Positive opioid tests contraindicate starting naltrexone.

Negative opioid test results require careful interpretation. A patient may test negative for opioids despite presenting with opioid withdrawal symptoms if he or she hasn't used opioids for several days. A negative opioid test in the absence of symptoms of opioid withdrawal likely indicates that the patient has little or no opioid tolerance, which is important information for assessment and treatment planning. Consider that the opioid the patient reports using may not be detected on the particular immunoassay.

Screening tests are not defnitive; false positive and false negative test results are possible. Confirmatory testing should follow all unexpected positive screens. Urine drug testing will detect metabolites from many prescription opioids but miss others, so it is easy to misinterpret results in patients taking these medications. False positives are also common in amphetamine testing. Point-of-service testing provides the opportunity to discuss results with patients immediately. However, cutoffs for positive screens are not standardized across point-of-service tests. Know the specifications of the screens used.

Other laboratory tests

Patients with OUD, particularly those who inject drugs, are at risk for liver disease and blood-borne viral infections. Pregnancy is another important consideration in determining treatment course. Recommended laboratory tests for patients with OUD include:

Pregnancy testing, which is important because:

- It is not advisable for patients to start naltrex- one during pregnancy.
- Pregnant women treated for active OUD typically receive buprenorphine or methadone.
- The American College of Obstetricians and Gynecologists and a recent SAMHSA- convened expert panel on the treatment of OUD in pregnancy

- recommend that pregnant women with OUD receive opioid receptor agonist medication.
- Providers should refer pregnant women to prenatal care or, if qualifed, provide it themselves.

Liver function tests (e.g., aspartate aminotransfer- ase, alanine aminotransferase, bilirubin), which can:

- Guide medication selection and dosing.
- Rule out severe liver disease, which may contraindicate OUD medication (see Part 3 of this TIP).

Hepatitis B and C serology, which can indicate:

- Patients with positive tests (evaluate for hepatitis treatment).
- The need to administer hepatitis A and B and tetanus vaccines, if appropriate.

HIV serology, which can help identify:

- Patients who are HIV positive (evaluate for antiretroviral treatment).
- Patients who are HIV negative (evaluate for preexposure prophylaxis and targeted education).

Review the PDMP

Before initiating OUD medication, providers should check their states' PDMPs to determine whether their patients receive prescriptions for controlled substances from other healthcare professionals. Using the PDMP improves the ability to manage the risks of controlled substances and to identify potentially harmful drug interactions. Although OTPs are not permitted to report methadone treatment to PDMPs, pharmacies that dispense buprenorphine and other controlled substances do report to PDMPs. Medications that need monitoring and required frequency of updates vary by state (for more information about state PDMPs, visit).

Determine Diagnosis and Severity of OUD

Use DSM-5 criteria to make an OUD diagnosis (Exhibit 2.13). Patients who meet two or three criteria have mild OUD. Those meeting four **o**r five criteria have moderate OUD, and those meeting six or more criteria have severe OUD.

Treatment Planning or Referral

Making Decisions About Treatment

Start by sharing the diagnosis with patients and hearing their feedback. Patients with OUD need to make several important treatment decisions:

- Whether to begin medication to treat OUD.
- What type of OUD medication to take.
- Where and how to access desired treatment.

• Whether to access potentially beneficial mental health, recovery support, and other ancillary services, whether or not they choose medication for OUD.

RESOURCE ALERT

Shared Decision-Making Resources for Patients and Family Members

SAMHSA's shared decision-making resource page is a good information source for patients to review before their visit or in the office (www.samhsa.gov/brss-tacs/recovery-support-tools/shared-decision-making). In addition, providers can suggest that family, friends, and other potential recovery supports (e.g., 12-Step program sponsors, employers, clergy) read educational material tailored for them. See Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends (https://portal.ct.gov/-/media/DMHAS/Opioid-Resources/MATInfoFamilyFriendspdf.pdf).

EXHIBIT 2.13, DSM-5 Criteria for OUD73

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

- 1. Opioids are often taken in larger amounts or over a longer period of time than was intended.
- 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- 3. A great deal of time is spent in activities to obtain the opioid, use the opioid, or recover from its effects.
- 4. Craving, or a strong desire or urge to use opioids.
- 5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of opioids.
- 7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- 8. Recurrent opioid use in situations in which it is physically hazardous.
- 9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that's likely to have been caused or exacerbated by the substance.
- 10. Tolerance,* as defined by either of the following:
 - a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect
 - b. A markedly diminished effect with continued use of the same amount of an opioid
- 11. Withdrawal,* as manifested by either of the following:
 - a. The characteristic opioid withdrawal syndrome
 - b. The same—or a closely related—substance is taken to relieve or avoid withdrawal symptoms

*This criterion is not met for individuals taking opioids solely under appropriate medical supervision. Severity: mild = 2–3 symptoms; moderate = 4–5 symptoms; severe = 6 or more symptoms

Offer information to patients about the various treatments for OUD and collaborate with them to make decisions about treatment plans or referrals (Exhibit 2.14). Consider discussing:

- Indications, risks, and Benefits of medications and alternatives to medication for OUD.
- Types of settings that deliver medications (including healthcare professionals' own practice locations, if applicable).
- Availability of and accessibility to treatment (i.e., transportation).
- Alternative treatments without medication (e.g., residential treatment, which often offers medically supervised opioid withdrawal).
- Costs of treatment with OUD medication, including insurance coverage and affordability.

Give patients' expressed preferences significant weight when making decisions. Patient characteristics can't reliably predict greater likelihood of success with one approved medication or another. For detailed information on medications to treat OUD, refer to Part 3 of this TIP.

Strategies to engage patients in shared decision making include:

- Indicating to patients a desire to collaborate with them to fnd the best medication and treatment setting for them.
- Including family members in the treatment planning process, if possible (and only with patients' consent).
- Exploring what patients already know about treatment options and dispelling misconceptions.
- Offering information on medications and their side effects, Benefits, and risks (Exhibit 2.14; Part 3).
- Informing patients of the requirements of the various treatment options (e.g., admission criteria to an OTP; frequency of visits to an OBOT or OTP).
- Offering options, giving recommendations after deliberation, and supporting patients' informed decisions.

Understanding Treatment Settings and Services

Support patient preferences for treatment settings and services. Some patients prefer to receive OUD medication via physicians' offices. Others choose outpatient treatment programs that provide opioid receptor agonist treatment for medically supervised withdrawal (with or without naltrexone) or for ongoing opioid receptor agonist maintenance treatment. Still others may want OUD treatment in a residential program with or without medication (Exhibit 2.15).

Many patients initially form a preference for a certain treatment without knowing all the risks, Benefits, and alternatives. Providers should ensure that patients understand the

risks and Benefits of all options. Without this understand- ing, patients can't give truly informed consent.

Outpatient OUD Treatment Settings

Refer patients who prefer treatment with methadone or buprenorphine via an OTP and explain that:

- They will have to visit the program from 6 to 7 times per week at first.
- Additional methadone take-home doses are possible at every 90 days of demonstrated progress in treatment.
- Buprenorphine take-home doses are not bound by the same limits as methadone.
- Counseling and drug testing are required parts of OTP treatment.
- Some programs also offer case management, peer support, medical services, mental disorder treatment, and other services.

(Scroll down to see Exhibit.)

EXHIBIT 2.14. Comparison of OUD Medications To Guide Shared Decision Making

CATEGORY	BUPRENORPHINE	METHADONE	NALTREXONE
Appropriate patients	Typically for patients with OUD who are physiologically dependent on opioids	Typically for patients with OUD who are physiologically dependent on opioids and who meet federal criteria for OTP admission	Typically for patients with OUD who are abstinent from short-acting opioids for 7 days and long-acting opioids for 10–14 days
Outcome: Retention in treatment	Higher than treatment without medication and treatment with placebo ⁷⁴	Higher than treatment without OUD medication and treatment with placebo ⁷⁵	Treatment retention with oral naltrexone is no better than with placebo or no medication; ⁷⁶ for XR-NTX, treatment retention is higher than for treatment without OUD medication and treatment with placebo ^{77,78}
Outcome: Suppression of illicit opioid use	Effective	Effective	Effective
Outcome: Overdose mortality	Lower for people in treatment than for those not in it	Lower for people in treatment than for those not in it	Unknown
Location/ frequency of office visits	Office/clinic: Begins daily to weekly, then tailored to patient's needs OTP: Can treat with buprenorphine 6–7 days/ week initially; take-homes are allowed without the time-in- treatment requirements of methadone	OTP only: 6–7 days/week initially; take-homes are allowed based on time in treatment and patient progress	Office/clinic: Varies from weekly to monthly
Who can prescribe/ order?	Physicians, NPs,* PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives possessing a federal waiver can prescribe and dispense; also can be dispensed by a community pharmacy or an OTP	OTP physicians order the medication; nurses and pharmacists administer and dispense it	Physicians, NPs,* PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives

^{*}NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives should check with their state to determine whether prescribing buprenorphine, naltrexone, or both is within their allowable scope of practice.

Continued on next page

EXHIBIT 2.14. Comparison of OUD Medications To Guide Shared Decision Making (continued)

CATEGORY	BUPRENORPHINE	METHADONE	NALTREXONE
Administration	Sublingual/buccal; injection; implant by specially trained provider, and only for stabilized patients	Oral	Oral or intramuscular (Note: Oral naltrexone is less effective than the other OUD medications.)
Misuse/diver- sion potential	Low in OTPs or other settings with observed dose administration; moderate for take-home doses; risk can be mitigated by providing take-homes to stable patients only and having a diversion control plan for the practice or program. Appropriate patients may be transitioned to a depot formulation of buprenorphine if and when it is appropriate.	Low in OTPs with directly observed therapy; moderate for take- home doses; risk can be mitigated by a diversion control plan	None
Sedation	Low unless concurrent substances are present (e.g., alcohol, benzodiazepines)	Low unless dose titration is too quick or dose is not adjusted for the presence of concurrent substances (e.g., alcohol, benzodiazepines)	None
Risk of medication- induced respira- tory depression	Very rare; lower than methadone	Rare, although higher than buprenorphine; may be elevated during the first 2 weeks of treatment or in combination with other sedating substances	None
Risk of precipitated withdrawal when starting medication	Can occur if started too prematurely after recent use of other opioids	None	Severe withdrawal is possible if period of abstinence is inadequate before starting medication
Withdrawal symptoms on discontinuation	Present; lower than methadone if abruptly discontinued	Present; higher than buprenorphine if abruptly discontinued	None
Most common side effects	Constipation, vomiting, headache, sweating, insomnia, blurred vision	Constipation, vomiting, sweating, dizziness, sedation	Difficulty sleeping, anxiety, nausea, vomiting, low energy, joint and muscle pain, headache, liver enzyme elevation XR-NTX: Injection site pain, nasopharyngitis, insomnia toothache

D. Coffa, December 2017 (personal communication). Adapted with permission.

Try to arrange OTP intake appointments for patients before they leave the office. If no immediate openings are available, consider starting buprenorphine as a bridge or alternative to the OTP.

Gauge the appropriate intensity level for patients seeking non-OTP outpatient treatment for OUD. These programs range from low intensity (individual or group counseling once to a few times a week) to high intensity (2 or more hours a day of individual and group counseling several days a week). Appropriate treatment intensity depends on each patient's:

- Social circumstances.
- · Severity of addiction.
- Personal preferences.
- Psychiatric/psychological needs.
- Ability to afford treatment at a given intensity.

EXHIBIT 2.15. Treatment Setting Based on Patient's Choice of OUD Medication

MEDICATION	POSSIBLE TREATMENT SETTING
Buprenorphine	Office-based treatment, outpatient or residential SUD treatment programs (prescriber must have a federal waiver), OTP. REMS program participation is required for use of depot formulations.
Methadone	ОТР
Naltrexone	Office-based treatment, outpatient or residential SUD treatment programs, OTP

Outpatient medical settings

Healthcare professionals cannot provide methadone in their clinics.
Only those with

a buprenorphine waiver can provide buprenor- phine. Any healthcare professional with a pre- scribing authority can provide naltrexone.

Once providers obtain the necessary waiver, they should offer buprenorphine treatment to all patients who present with OUD if such treatment is available and

appropriate. Referring them to treatment elsewhere will likely result in delay or lack of

patient access to care. Develop a treatment plan to determine where patients will receive continuing care (see the "Treatment Planning" section). Continue to provide naltrexone for patients who were already receiving it from some other setting (e.g., a prison, a specialty addiction treatment program) or for patients who meet opioid abstinence require- ments and wish to take a medication for relapse prevention.

Residential drug treatment settings

Patients who have OUD, concurrent other substance use problems, unstable living situations, or a combination of the three may be appropriate candidates for residential treatment, which can last from a week to several weeks or more. Inform patients about the services and requirements typical of this treatment setting.

Some patients taking buprenorphine (or methadone) who have other SUDs, such as AUD or cocaine use disorder, can benefit from residential treatment. If such treatment is indicated, determine whether the residential program allows patients to continue their opioid receptor agonist medication while in treatment.

Some residential programs require patients to discontinue these medications to receive residential treatment, which could destabilize patients and result in opioid overdose.

Residential treatment programs typically provide:

- Room and board.
- Recovery support.
- Counseling.
- Case management.
- Medically supervised withdrawal (in some programs).
- Starting buprenorphine or naltrexone (in some programs).
- Onsite mental health services (in some cases).
- Buprenorphine or methadone continuation for patients already enrolled in treatment prior to admission if their healthcare professionals have waivers or their OTP permits.

Transitioning out of residential settings requires careful planning. During a patient's stay in residential treatment, plan for his or her transition out of the program. A good transition plan maximizes the likelihood of continuity of care after discharge. Plans should also address overdose risk. Patients who are no longer opioid tolerant are at heightened risk of opioid overdose if they don't get OUD medication at discharge. Providing XR-NTX, buprenorphine, or methadone during treatment and continuing the medication after discharge can help prevent return to opioid use after discharge. Providing a naloxone prescription and overdose prevention information is appropriate.

Maintaining Confidentiality

Providers who treat patients with addiction must know substance use-related disclosure rules and confidentiality requirements. SAMHSA's webpage lists frequently asked questions on substance use confidentiality and summarizes federal regulations about disclosure and patient records that federal programs maintain on addiction treatment. Key points include:

- Confidentiality regulations prohibit specialty SUD treatment programs from sharing information with healthcare professionals about patients' SUD treatment without specific consent from patients.
- Referrals to other behavioral health services require consent for sharing information on treatment progress.
- Healthcare professionals should discuss confidentiality and consent with patients during the referral process.
- OUD medication prescribers may consider requiring patient consent for communicating with treatment programs as a condition of receiving OUD treatment.

Treatment program staff members can help identify returns to substance use, or risk of such, before the prescriber and can work with the prescriber to stabilize patients.

Determining OUD Service Intensity and Ensuring Follow-Through

Use ASAM placement criteria for guidance on selecting the right level of OUD treatment. ASAM criteria define the level of care and key features that may make a given level (e.g., residential, intensive outpatient, standard outpatient) appropriate for a patient (see the "Treatment Planning" section). To help patients select programs, note that some focus on specifc populations (e.g., gender-specifc programs; parents with children; lesbian, gay, bisexual, transgender, and questioning populations).

Make an appointment with the referral program during the patient's visit rather than giving the patient a phone number to call. Follow up with the patient later to determine whether he or she kept the appointment. Doing so increases the chances of a successful referral.

Referring patients to behavioral health and support services

Discuss patients' potential need for behavioral health, peer support, and other ancillary services, like:

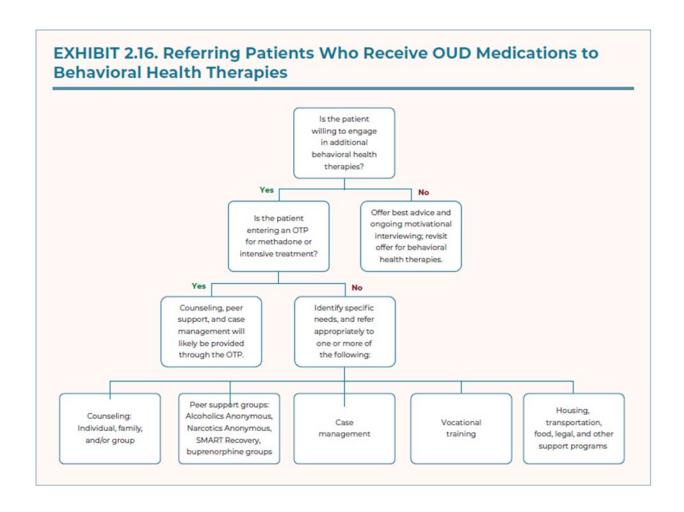
- Drug and alcohol counseling.
- Mental health services.
- Case management.
- Mutual-help groups.
- Peer recovery support services.

Offer referrals to counseling and tailored psychosocial support to patients receiving OUD medication (Exhibit 2.16). Drug Addiction Treatment Act of 2000 legislation requires that buprenorphine prescribers be able to refer patients to counseling, but making referrals is not mandatory. Many patients benefit from referral to mental health services or specialized addiction counseling and recovery support services. However, four randomized trials found no extra benefit to adding adjunctive counseling to well-conducted medical management visits delivered by the buprenor- phine prescriber. There is evidence of Benefits to adding contingency management to medication for OUD.

Make referrals to mutual-help groups. Patients may wish to participate in mutual-help groups (e.g., Alcoholics Anonymous, Narcotics Anonymous, Methadone Anonymous, Medication-Assisted Recovery Services, SMART Recovery) in addition to or instead of specialized treatment. These programs can be highly supportive, but they may pressure patients to stop taking OUD medication. If possible, refer patients to groups that welcome patients who take OUD medication.

Make referrals to medical and mental health services. Respectful, consistent medical care can support patients' efforts to recover from OUD and all other SUDs. As for any patient, providers should make appropriate referrals for patients with OUD to receive medical or mental health services beyond the providers' own scope of practice.

Patients with depression, anxiety disorders, and other mental disorders may be more likely to succeed in addiction treatment if those conditions are managed. If the severity



or type of a patient's psychiatric comorbidity is beyond a provider's scope of practice, the provider should refer the patient to mental health services as appropriate.

Guidance on Providing Integrated Care

Fragmented healthcare services are less likely to meet all patient needs. Integrated medical and behavioral healthcare delivery can effectively provide patient-focused, comprehensive treat- ments that address the full range of symptoms and service needs patients with OUD often have. The key components of integration should be in place to make sure that SUD treatment in a primary care setting works. For more information about how to provide integrated services for individuals taking medication for OUD, see:

The Agency for Healthcare Research and Quality's report Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings (The Agency for Healthcare Research and Quality's Academy for Integrating Behavioral Health and Primary Care.

Make referrals to ancillary services. Besides medical care and mental health services, OUD patients, like patients with other illnesses, may need more support in some areas, including ancillary services such as:

- Case management.
- Food access.
- Vocational training.
- Housing.
- Transportation.
- Legal assistance.

Helping patients who are not ready to engage in OUD treatment

Help reluctant patients be safter and approach readiness. Patients may seem unwilling to discuss their drug use if they're ashamed or fear being judged. Accepting,

nonjudgmental attitudes help patients overcome shame and discuss concerns honestly while also instilling hope. Every visit is a chance to help patients begin healthy changes and move toward treatment and recovery. Patients may not be ready to change right away. Successfully quitting drug use can take many attempts. **Returns to substance use, even after periods of remission, are expected parts of the recovery process**.

Patients with OUD are much more likely to die than their peers, and HIV, hepatitis C, and skin and soft tissue infections are common among this population. Help reduce these OUD- related risks by testing patients for HIV and hepatitis and by educating patients about:

- Using new syringes.
- Avoiding syringe sharing.
- Avoiding sharing other supplies during the injection process.
- Preventing opioid overdose (see the "Preventing Opioid-Related Overdose" section).
- Obtaining overdose prevention infor- mation and resources (e.g., SAMHSA
 Opioid Overdose Prevention Toolkit).
- Obtaining naloxone and instructions for its use.

Preventing Opioid-Related Overdose Every patient who misuses opioids or has OUD should receive opioid overdose prevention education and a naloxone prescription.

Healthcare professionals should educate patients and their families about overdose risk, prevention, identification, and response (Exhibit 2.17). FDA has approved an autoinjectable naloxone device (Evzio) and a naloxone nasal spray (Narcan) for use by patients and others. For information about all forms of naloxone, prescribing, and patient and community education, see the SAMHSA Opioid Overdose Prevention Toolkit.

EXHIBIT 2.17. Opioid Overdose: Risk, Prevention, Identification, and Response

Overdose risk

- Using heroin (possibly mixed with illicitly manufactured fentanyl or fentanyl analogs)
- Using prescription opioids that were not prescribed
- Using prescription opioids more frequently or at higher doses than prescribed
- Using opioids after a period of abstinence or reduced use (e.g., after medically supervised withdrawal or incarceration)
- Using opioids with alcohol, benzodiazepines, or both

Overdose prevention

- · Don't use opioids that were not prescribed.
- · Take medications only as prescribed.
- Don't use drugs when you are alone.
- · Don't use multiple substances at once.
- Have naloxone available and make sure others know where it is and how to use it.
- Use a small "test dose" if returning to opioid use after a period of abstinence, if the substance appears altered, or if it has been acquired from an unfamiliar source. Beware: This doesn't guarantee safety; illicitly manufactured fentanyl or other substances may be present in the drug, and any use may be fatal.

Overdose identification

- · Fingernails or lips are blue or purple.
- · Breathing or heartbeat is slow or stopped.
- · The person is vomiting or making gurgling noises.
- The person can't be awakened or is unable to speak.

Overdose response

- Call 9-1-1.
- Administer naloxone (more than one dose may be needed to restore adequate spontaneous breathing).
- Perform rescue breathing. If certified to provide cardiopulmonary resuscitation, perform chest compressions if there is no pulse.
- Put the person in the "recovery position," on his or her side and with the mouth facing to the side to prevent aspiration of vomit, if he or she is breathing independently.
- Stay with the person until emergency services arrive. Naloxone's duration of action is 30–90 minutes. The person should be observed after this time for a return of opioid overdose symptoms.

Adapted from material in the public domain.96

The United States is experiencing an epidemic of opioid overdose deaths.

Opioids (including prescription opioids and heroin) killed 49,860 people in 2019, more than in any prior year. Less than one-third of overdose deaths involved prescription opioids.⁹⁷ From 2010 to 2018, heroin-related overdose deaths rose about fivefold.^{98,99} Overdose deaths from illicit fentanyl have also risen sharply.¹⁰⁰

Municipalities with community-based naloxone distribution programs have seen substantial decreases in opioid overdose death rates. Many syringe exchange programs also dispense naloxone. For information and resources on prescribing naloxone for overdose prevention, including educational patient handouts and videos, see the "Opioid-Related"

Overdose Prevention" section.

Part 2 — 2024–2025 updates (practice integration)

The federal landscape has continued to ease integration of medications for opioid use disorder (MOUD) across medical and behavioral health settings. SAMHSA's 2024 final rule revising 42 CFR Part 8 modernizes OTP standards, supports patient-centered takehome methadone, and facilitates mobile units—changes that reduce delays in initiation and improve continuity of care when paired with updated admission and screening workflows (SAMHSA, 2024a; SAMHSA, 2024b). In parallel, DEA and HHS extended telemedicine flexibilities through December 31, 2025, allowing many patients—particularly in rural and underserved regions—to initiate or maintain MOUD via telehealth while permanent regulations are finalized (DEA, 2024). Programs should update intake protocols, revise patient education on take-home eligibility, and align pharmacy/OTP coordination to operationalize these changes (SAMHSA, 2024a).

Confidentiality rules affecting coordination also shifted. The 2024 final rule for 42 CFR Part 2 permits a single patient consent for future uses and disclosures for treatment, payment, and health care operations, aligning more closely with HIPAA while preserving strong protections against non-treatment uses (HHS OCR, 2024; Federal Register, 2024). Clinically, protocols should reflect emerging evidence that adequate early dosing matters: higher average daily buprenorphine doses in the first 30 days were associated with significantly lower risk of opioid-involved overdose death over the subsequent year, a finding relevant to induction and stabilization amid fentanyl exposure (Lei et al., 2024). Together, these policy and clinical updates point to a practical agenda: minimize friction at initiation, maintain flexible telehealth access, protect confidentiality while enabling care coordination, and dose effectively to support retention and outcomes (DEA, 2024; HHS OCR, 2024; Lei et al., 2024; SAMHSA, 2024a).

Part 2 Appendix

Stable Resource Toolkit

Audit-C - Overview

The AUDIT-C is a 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of the 10 question AUDIT instrument.

Clinical Utility

The AUDIT-C is a brief alcohol screen that reliably identifies patients who are hazardous drinkers or have active alcohol use disorders.

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are: a = 0 points, b = 1 point, c = 2 points, d = 3 points, c = 4 points

- In men, a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- In women, a score of 3 or more is considered positive (same as above).
- However, when the points are all from Question #1 alone (#2 & #3 are zero), it can be assumed that the patient is
 drinking below recommended limits and it is suggested that the provider review the patient's alcohol intake over
 the past few months to confirm accuracy.
- · Generally, the higher the score, the more likely it is that the patient's drinking is affecting his or her safety.

Psychometric Properties

For identifying patients with heavy/hazardous drinking and/or Active-DSM alcohol abuse or dependence

	MEN ¹	WOMEN ²
≥3	Sens: 0.95 / Spec. 0.60	Sens: 0.66 / Spec. 0.94
≥4	Sens: 0.86 / Spec. 0.72	Sens: 0.48 / Spec. 0.99

For identifying patients with active alcohol abuse or dependence

	MEN ¹	WOMEN ²
≥3	Sens: 0.90 / Spec. 0.45	Sens: 0.80 / Spec. 0.87
≥4	Sens: 0.79 / Spec. 0.56	Sens: 0.67 / Spec. 0.94

Bush K, Kivlahan DR, McDonell MB, et al. The AUDIT Alcohol Consumption Questions (AUDIT-C): An effective brief screening test for problem drinking. Arch Internal Med. 1998 (3): 1789-1795.

Bradley KA, Bush KR, Epler AJ, et al. Two brief alcohol-screening tests from the Alcohol Use Disorders Identification Test (AUDIT): Validation in a female veterans affairs patient population. Arch Internal Med Vol 165, April 2003: 821-829.

Αl	JDIT-C Questionnaire	
Pa	tient Name:	Dates of Visit:
1.	How often do you have a drink containing alcohol? □ a. Never □ b. Monthly or less □ c. 2-4 times a month	
	☐ d. 2-3 times a week ☐ e. 4 or more times a week	
2.	How many standard drinks containing alcohol do you have on a typi a. 1 or 2 b. 3 or 4 c. 5 or 6 d. 7 to 9 e. 10 or more	ical day?
3.	How often do you have six or more drinks on one occasion? a. Never b. Less than monthly c. Monthly d. Weekly e. Daily or almost daily	
AL	IDIT-C is available for use in the public domain.	

Drug Abuse Screening Test (DAST-10)

General Instructions

"Drug use" refers to (1) the use of prescribed or over-the-counter drugs in excess of the directions, and (2) any nonmedical use of drugs. The various classes of drugs may include cannabis (i.e., marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD), or narcotics (e.g., heroin). The questions do not include alcoholic beverages.

you used drugs other than those required for medical r				
you used drugs other than those required for medical r	easons?			
			□ No	☐ Yes
ou use more than one drug at a time?			□ No	☐ Yes
ou always able to stop using drugs when you want to?			□ No	☐ Yes
you had "blackouts" or "flashbacks" as a result of drug	use?		□ No	☐ Yes
ou ever feel bad or guilty about your drug use?			□ No	☐ Yes
your spouse (or parents) ever complain about your invo	lvement with drugs	?	□ No	☐ Yes
you neglected your family because of your use of drug	\$?		□ No	☐ Yes
you engaged in illegal activities to obtain drugs?			□ No	☐ Yes
you ever experienced withdrawal symptoms (i.e., felt s g drugs?	ck) when you stopp	ed	□ No	☐ Yes
you had medical problems as a result of your drug use titis, convulsions, bleeding)?	(e.g., memory loss,		□ No	☐ Yes
s:				
9	you had "blackouts" or "flashbacks" as a result of drug u ever feel bad or guilty about your drug use? your spouse (or parents) ever complain about your invo you neglected your family because of your use of drugs you engaged in illegal activities to obtain drugs? you ever experienced withdrawal symptoms (i.e., felt si drugs? you had medical problems as a result of your drug use itis, convulsions, bleeding)?	you had "blackouts" or "flashbacks" as a result of drug use? u ever feel bad or guilty about your drug use? your spouse (or parents) ever complain about your involvement with drugs' you neglected your family because of your use of drugs? you engaged in illegal activities to obtain drugs? you ever experienced withdrawal symptoms (i.e., felt sick) when you stopped drugs? you had medical problems as a result of your drug use (e.g., memory loss, itis, convulsions, bleeding)?	you had "blackouts" or "flashbacks" as a result of drug use? u ever feel bad or guilty about your drug use? your spouse (or parents) ever complain about your involvement with drugs? you neglected your family because of your use of drugs? you engaged in illegal activities to obtain drugs? you ever experienced withdrawal symptoms (i.e., felt sick) when you stopped drugs? you had medical problems as a result of your drug use (e.g., memory loss, itis, convulsions, bleeding)?	you had "blackouts" or "flashbacks" as a result of drug use? u ever feel bad or guilty about your drug use? No your spouse (or parents) ever complain about your involvement with drugs? No you neglected your family because of your use of drugs? No you engaged in illegal activities to obtain drugs? No you ever experienced withdrawal symptoms (i.e., felt sick) when you stopped drugs? No you had medical problems as a result of your drug use (e.g., memory loss, itis, convulsions, bleeding)?

Interpretation of Score:

Score	Degree of Problems Related to Drug Abuse	Suggested Action
0	No problems reported	None at this time
1-2	Low level	Monitor, reassess at a later date
3–5	Moderate level	Further investigation
6-8	Substantial level	Intensive assessment
9-10	Severe level	Intensive assessment

Adapted with permission. 104,105

DSM-5 Opioid Use Disorder Checklist106

Patient's Name: Date of Birth:

(0	AGNOSTIC CRITERIA pioid use disorder requires that at least 2 criteria be et within a 12-month period.)	MEETS CRITERIA? Yes OR No	NOTES/SUPPORTING INFORMATION
1.	Opioids are often taken in larger amounts or over a longer period of time than intended.		
2.	There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
3.	A lot of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.		
4.	Craving, or a strong desire to use opioids.		
5.	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home.		
6.	Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.		
7.	Important social, occupational, or recreational activities are given up or reduced because of opioid use.		
8.	Recurrent opioid use in situations in which it is physically hazardous.		
9.	Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.		
10.	Tolerance,* as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid		
n.	Withdrawal,* as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome		
	(b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms		

Cianad.	Date:

TAPS Tool Part I

Directions: The TAPS Tool Part 1 is a 4-item screening for tobacco use, alcohol use, prescription medication misuse, and illicit substance use in the PAST YEAR. Question 2 should be answered by males, and Question 3 should be answered by females. Each of the four multiple-choice items has five possible responses to choose from. Check the box to select your answer.

In t	he PA	ST	12 M	IONI	HS.
111 LI	ICIA	131	12 17		113.

1.	How often have you used any tobacco product (for example, cigarettes, ecigarettes, cigars, pipes, or smokeless tobacco)?						
	□ Never	\square Less than monthly	☐ Monthly	☐ Weekly	☐ Daily or almost daily		
2.		ive you had 5 or more drinks o , 1 beer (12 oz), or 1 single sho					
	□ Never	☐ Less than monthly	☐ Monthly	☐ Weekly	☐ Daily or almost daily		
3.	How often have you had 4 or more drinks containing alcohol in 1 day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. (Note: This question should only be answered by females.)						
	□ Never	☐ Less than monthly	☐ Monthly	☐ Weekly	☐ Daily or almost daily		
4.	How often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, or ecstasy/MDMA?						
	□ Never	\square Less than monthly	☐ Monthly	☐ Weekly	☐ Daily or almost daily		
5.	prescribed fo OxyContin, V		s that may be used to e), medications for a	this way include opia inxiety or sleeping (f	an prescribed, or that were not ate pain relievers (for example, for example, Xanax, Ativan, or		
	☐ Never	☐ Less than monthly	☐ Monthly	☐ Weekly	☐ Daily or almost daily		

TAPS Tool Part 2

Directions: The TAPS Tool Part 2 is a brief assessment for tobacco use, alcohol use, illicit substance use, and prescription medication misuse in the PAST 3 MONTHS ONLY. Each of the following questions and subquestions has two possible answers, yes or no. Check the box to select your answer.

In the PAST 3 MONTHS:

1.	Did you smoke a cigarette containing tobacco?		Yes		No
	If "Yes," answer the following questions:				
	 Did you usually smoke more than 10 cigarettes each day? Did you usually smoke within 30 minutes after waking? 		Yes Yes		
2.	Did you have a drink containing alcohol?		Yes		No
	If "Yes," answer the following questions:				
	 Did you have 4 or more drinks containing alcohol in a day?* (Note: This question should only be answered by females.) 		Yes		No
	 Did you have 5 or more drinks containing alcohol in a day?* (Note: This question should only be answered by males.) 		Yes		No
	 Have you tried and failed to control, cut down, or stop drinking? Has anyone expressed concern about your drinking? 	-	Yes Yes		
3.	Did you use marijuana (hash, weed)?		Yes		No
	If "Yes," answer the following questions:				
	 Have you had a strong desire or urge to use marijuana at least once a week or more often? Has anyone expressed concern about your use of marijuana? 		Yes Yes		
4.	Did you use cocaine, crack, or methamphetamine (crystal meth)?		Yes		No
	If "Yes," answer the following questions:				
	 Did you use cocaine, crack, or methamphetamine (crystal meth) at least once a week or more often? Has anyone expressed concern about your use of cocaine, crack, or methamphetamine (crystal 		Yes		No
	meth)?		Yes		No
5.	Did you use heroin?		Yes		No
	If "Yes," answer the following questions:				
	Have you tried and failed to control, cut down, or stop using heroin? Has anyone expressed concern about your use of heroin?		Yes Yes		
_					
6.	Did you use a prescription opiate pain reliever (for example, Percocet or Vicodin) not as prescribed or that was not prescribed for you?		Yes		No
	If "Yes," answer the following questions:				
	 Have you tried and failed to control, cut down, or stop using an opiate pain reliever? Has anyone expressed concern about your use of an opiate pain reliever? 	_	Yes Yes	-	No No

Continued on next page

^{*}One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.

TAPS Tool Part 2 (continued)

7.	Did you use medication for anxiety or sleep (for example, Xanax, Ativan, or Klonopin) not as prescribed or that was not prescribed for you?	☐ Yes	□ No
	If "Yes," answer the following questions:		
	 Have you had a strong desire or urge to use medications for anxiety or sleep at least once a week or more often? 	☐ Yes	□ No
	 Has anyone expressed concern about your use of medication for anxiety or sleep? 	☐ Yes	□ No
8.	Did you use medication for ADHD (for example, Adderall or Ritalin) not as prescribed or that was not prescribed for you?	☐ Yes	□ No
	If "Yes," answer the following questions:		
	 Did you use a medication for ADHD (for example, Adderall or Ritalin) at least once a week or more often? 	☐ Yes	□ No
	 Has anyone expressed concern about your use of medication for ADHD (for example, Adderall or Ritalin)? 	☐ Yes	□ No
9.	Did you use any other illegal or recreational drugs (for example, ecstasy, molly, GHB, poppers, LSD, mushrooms, special K, bath salts, synthetic marijuana ["spice"], or whip-its)?	☐ Yes	□ No
	If "Yes," answer the following question:		
	 What were the other drug(s) you used? (write in response) 		

The complete tool is available online (https://cde.drugabuse.gov/instrument/29b23e2e-e266-f095-e050-bb89ad43472f). Adapted from material in the public domain. 107

Part 3: Medications for Opioid Use Disorder

Scope of the Problem

The United States is experiencing an opioid addiction epidemic. In 2019, an estimated 1.6 million people aged 12 or older had OUD in the United States. Illicit opioid use contributes to the development of OUD, the spread of HIV and hepatitis infections, and increasing numbers of overdose deaths.

OUD is a set of cognitive, behavioral, and physiological symptoms marked by an inability to stop opioid use despite negative consequences. When severe, it can present as a chronic, recurring condition with compulsive opioid use



that is often termed "addiction." It can cause serious physical and mental health, employment, legal, and family problems.

Each FDA-approved medication used to treat OUD can help patients achieve remission and begin or maintain recovery. Medication for OUD should be accompanied by individually tailored medical management and psychosocial and recovery support services as needed and wanted by patients to support their remission and recovery.

Medication supports the efforts of the individual to achieve lasting recovery.

Exhibit 3.1 defines key terms in Part 3. For more definitions, see the glossary in Part 5 of this TIP.

NOTE TO HEALTHCARE PROFESSIONALS

This TIP cannot replace sound clinical judgment and shared decision making based on careful patient assessment. Providers should familiarize themselves with FDA labeling of all OUD medications and current practices standards described here and in other resources such as the Providers' Clinical Support System (https://pcssnow.org/resources/resource-category/clinical-resources/).

EXHIBIT 3.1. Key Terms

Addiction: As defined by the American Society of Addiction Medicine,⁶ "a primary, chronic disease of brain reward, motivation, memory, and related circuitry." It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of **relapse** and **remission.** The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition,⁷ does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Induction: Process of initial dosing with medication for OUD treatment until the patient reaches a state of stability; also called initiation.

Maintenance treatment: Providing medications to achieve and sustain clinical remission of signs and symptoms of OUD and support the individual process of recovery without a specific endpoint (as is the typical standard of care in medical and psychiatric treatment of other chronic illnesses).

Medically supervised withdrawal (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

Medical management: Process whereby healthcare professionals provide medication, basic brief supportive counseling, monitoring of drug use and medication adherence, and referrals, when necessary, to addiction counseling and other services to address the patient's medical, mental health, comorbid addiction, and psychosocial needs.

Office-based opioid treatment: Providing medication for OUD in outpatient settings other than certified OTPs.

Opioid treatment program (OTP): An accredited treatment program with Substance Abuse and Mental Health Services Administration certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.⁸

Key Terms Related to OUD Medication Pharmacology

Abuse liability: The likelihood that a medication with central nervous system activity will cause desirable psychological effects, such as euphoria or mood changes, that promote the medication's misuse.

Bioavailability: Proportion of medication administered that reaches the bloodstream.

Cross-tolerance: Potential for people tolerant to one opioid (e.g., heroin) to be tolerant to another (e.g., methadone).

Dissociation: Rate at which a drug uncouples from the receptor. A drug with a longer dissociation rate will have a longer duration of action than a drug with a shorter dissociation rate.

Half-life: Rate of removal of a drug from the body. One half-life removes 50 percent from the plasma. After a drug is stopped, it takes five half-lives to remove about 95 percent from the plasma. If a drug is continued at the same dose, its plasma level will continue to rise until it reaches steady-state concentrations after about five half-lives.

Continued on next page

EXHIBIT 3.1. Key Terms (continued)

Intrinsic activity: The degree of receptor activation attributable to drug binding. Full agonist, partial agonist, and antagonist are terms that describe the intrinsic activity of a drug.

Opiates: A subclass of opioids derived from opium (e.g., morphine, codeine, thebaine).

Opioid blockade: Blunting or blocking of the euphoric effects of an opioid through opioid receptor occupancy by an opioid agonist (e.g., methadone, buprenorphine) or antagonist (e.g., naltrexone).

Opioid receptor agonist: A substance that has an affinity for and stimulates physiological activity at cell receptors in the nervous system that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose in an opioid-tolerant individual may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists. Methadone and buprenorphine can blunt or block the effects of exogenously administered opioids.

Opioid receptor antagonist: A substance that has an affinity for opioid receptors in the central nervous system without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioids: All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).

Receptor affinity: Strength of the bond between a medication and its receptor. A medication with high mu-opioid receptor affinity requires lower concentrations to occupy the same number of mu-opioid receptors as a drug with lower mu-opioid receptor affinity. Drugs with high mu-opioid receptor affinity may displace drugs with lower affinity.

Chapter 3A: Overview of Medications for Opioid Use Disorder

There are three FDA-approved medications used to treat OUD: the mu-opioid receptor partial agonist buprenorphine, the mu-opioid receptor full agonist methadone, and the mu-opioid receptor antagonist naltrexone.

Discussing medications that can treat OUD with patients who have this disorder is the clinical standard of care and should cover at least:

- The proven effectiveness of methadone, naltrexone, and buprenorphine compared with placebo and with outpatient counseling without medication.
- Risks and Benefits of treatment with all three types of medication, treatment without medication, and no treatment.
- Safety and effectiveness of the medications when used appropriately.
- Pharmacologic properties, routes of administration, and where and how to access treatment with each medication (Exhibit 3A.1).

EXHIBIT 3A.1. OUD Medications: An Overview^{9,10}

CATEGORY	BUPR	ENORPHINE*	METHADONE	XR-NTX**	
	TRANSMUCOSAL	DEPOT			
Appropriate patients	Typically for patients with OUD who are physiologically dependent on opioids.	Typically for patients for whom diversion or safe medication storage are concerns or for patients who must travel large distances to the prescriber.	Typically for patients with OUD who are physiologically dependent on opioids and who meet federal criteria for OTP admission.	Typically for patients with OUD who have abstained from short-acting opioids for at least 7–10 days and longacting opioids for a least 10–14 days.	
Pharmacology	Opioid receptor partial agonist	Opioid receptor partial agonist	Opioid receptor agonist	Opioid receptor antagonist	
	Reduces opioid withdrawal and craving; blunts or blocks euphoric effects of self- administered illicit opioids through cross- tolerance and opioid receptor occupancy.	Reduces opioid withdrawal and craving; blunts or blocks euphoric effects of self-administered illicit opioids through cross- tolerance and opioid receptor occupancy. Note: Patients receiving a depot formulation of buprenorphine must be inducted onto buprenorphine using a transmucosal product.	Reduces opioid withdrawal and craving; blunts or blocks euphoric effects of self- administered illicit opioids through cross- tolerance and opioid receptor occupancy.	Blocks euphoric effects of self- administered illicit opioids through opioid receptor occupancy. Causes no opioid effects. Reduces opioid craving.	
Patient	Tell patients:	Tell patients:	Tell patients:	Tell patients:	
education	That they will need to be in opioid withdrawal to receive their first dose to avoid buprenorphine-precipitated opioid withdrawal. About the risk of overdose with concurrent benzodiazepine or alcohol use, with injecting buprenorphine, and after stopping the medication.	For implantable rods (Probuphine®), they will need to be stable on no more than 8 mg of transmucosal Suboxone or generic equivalents. For subcutaneous injection (Sublocade®), they must first be on a transmucosal form of buprenorphine for at least 7 days at a dose equivalent to 8 to 24 mg of buprenorphine.	That their dose will start low and build up slowly to avoid oversedation; it takes several days for a given dose to have its full effect. About overdose risk in the first 2 weeks of treatment, especially with concurrent benzodiazepine or alcohol use, and after stopping the medication.	That they will need to be opioid free for at least 7–10 days for short-acting opioids and at least 10–14 days for long-acting opioids before their first dose of extended-release naltrexone (XR-NTX) to avoid precipitated withdrawal (which may require hospitalization). About the risk of overdose after stopping the	

EXHIBIT 3A.1. OUD Medications: An Overview (continued)

CATEGORY	BUPF	RENORPHINE*	METHADONE	XR-NTX**
	TRANSMUCOSAL	DEPOT		
Administration	Daily (or off-label less-than-daily dosing regimens) administration of sublingual or buccal tablet or film. Subdermal implants every 6 months, for up to 1 year, for stable patients. Monthly subcutaneous injection of extended-release formulation in abdominal region for patients treated with transmucosal buprenorphine for at least 1 week.	Subdermal implants every 6 months, for up to 1 year, for stable patients. Monthly subcutaneous injection of extended- release formulation in abdominal region for patients treated with transmucosal buprenorphine for at least 1 week.	Daily oral administration as liquid concentrate, tablet, or oral solution from dispersible tablet or powder (unless patients can take some home).	Every 4 weeks or once-per-month intramuscular injection.
Prescribing	Physicians, nurse practitioners (NPs), and physician assistants (PAs) need a waiver to prescribe. Until October 1, 2023, qualified clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives also can obtain a waiver to prescribe. Any pharmacy can fill a prescription for sublingual or buccal formulations. OTPs can administer/dispense by OTP physician order without a waiver.	Prescribers must have a waiver (as for transmucosal buprenorphine) and complete the product's REMS program. Providers of the implantable rods must complete additional training in their insertion and removal. Both the implantable rods and subdermal injections are available via restricted distribution programs and are not available in retail pharmacies. OTPs can be providers of depot formulations of buprenorphine, provided the above criteria are satisfied.	SAMHSA-certified OTPs can provide methadone for daily onsite administration or at-home self- administration for stable patients.	Physicians, NPs, PAs, and, until October 1, 2023, clinical nurse specialists, certifie registered nurse anesthetists, and certified nurse midwives can prescribe or order administration by qualified healthcare professionals.

^{*}Long-acting buprenorphine implants (every 6 months) for patients on a stable dose of buprenorphine are also available through implanters and prescribers with additional training and certification through the Probuphine Risk Evaluation and Mitigation Strategy (REMS) Program. Extended-release buprenorphine monthly subcutaneous injections are available only through prescribers and pharmacies registered with the Sublocade REMS Program.

^{**}Naltrexone hydrochloride tablets (50 mg each) are also available for daily oral dosing but have not been shown to be more effective than treatment without medication or placebo because of poor patient adherence.

Introduction to Medications That Address OUD

Methadone

Methadone is the most used and most studied OUD medication in the world. The World Health Organization (WHO) considers it an essential medication. Many clinical trials and meta-analyses have shown that it effectively reduces illicit opioid use, treats OUD, and retains patients in treatment better than placebo or no medica- tion. (Part 1 of this Treatment Improvement Protocol [TIP] further covers methadone's efficacy.)

In the United States, roughly 1,500 federally certifed opioid treatment programs (OTPs) offer methadone for OUD. Increasingly, they also offer buprenorphine, and some provide XR-NTX. Core OTP services include medical oversight of treatment, direct observation of dose administration, take-home dose dispensing under certain conditions, counseling, and drug testing.

Some OTPs provide other services, including mental health and primary care, HIV and hepatitis C virus care, and recovery support. Even so, significant demand remains for better integration and coordination of care among OTPs, primary care services, and mental health services to treat the range of needs common in people with OUD. Coordination is especially important for people with co-occurring medical, mental, and substance use disorders, who need multiple services and face challenges in treatment access and adherence.

*Although only OTPs can administer or dispense methadone for OUD, all healthcare professionals and addiction and mental health counselors should be familiar with methadone. Their patients may be enrolled in or need referral to OTPs.

Naltrexone

XR-NTX has demonstrated efficacy in reducing return to illicit opioid use, increasing treatment retention, and reducing opioid craving compared with placebo or no

medication in randomized controlled trials. (See Part 1 for more information on XR-NTX's efficacy in OUD treatment.) Because the injectable form was approved more recently by FDA than methadone and buprenorphine, XR-NTX has been less studied than those medications. Physicians, NPs, and, PAs, and, until October 1, 2023, clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives may prescribe or order XR-NTX for administration by qualifed staff members without additional waiver requirements.

NTX initiated prior to release from controlled environments (e.g., jails, prisons, residential rehabilitation programs) may be useful in preventing return to opioid use after release. These settings are typically associated with extended periods of opioid abstinence, so maintaining abstinence for sufficient time to start naltrexone is less challenging than initiating it among outpatients in the community. Short-term pilot studies show that offering XR-NTX under these circumstances can increase treatment engagement after release.

The oral formulation of naltrexone is not widely used to treat OUD because of low rates of patient acceptance and high rates of non-adherence leading to a lack of efficacy. However, consideration should be given to its use in situations where adherence can be ensured, such as with observed daily dosing. Naltrexone is also FDA approved for the treatment of alcohol use disorder and therefore may be useful for patients with both OUD and alcohol use disorder.

Buprenorphine

Buprenorphine is effective in retaining patients in treatment and reducing illicit opioid use, as demonstrated by many clinical trials comparing buprenorphine with placebo or no medication. Buprenorphine treatment is available throughout the world. WHO includes it in its list of essential medicines. (See Part 1 for more information on buprenorphine's efficacy in OUD treatment.)

Buprenorphine is a partial agonist with a ceiling effect on opioid activity. Hence, it is less likely than methadone and other full agonists to cause respiratory depression in an accidental overdose. This property contributed to the decision permitting buprenorphine to be prescribed to treat opioid dependence outside OTPs. That being said, lethal overdose with buprenorphine is possible in opioid-naïve individuals or when it is taken in combination with central nervous system depressants such as benzodiazepines or alcohol.

Transmucosal buprenorphine is available by pre- scription through pharmacies, because the Drug Addiction Treatment Act of 2000 (DATA 2000) created an exception to the Controlled Substances Act to permit FDA schedule III, IV, and V med- ications approved to treat opioid dependence to be prescribed for that purpose outside OTPs. Buprenorphine, in various formulations, is the only medication to which DATA 2000 currently applies.

Qualifying physicians, NPs, and PAs can prescribe buprenorphine if they receive special training, obtain a SAMHSA waiver under DATA 2000, and get a unique Drug Enforcement Administration registration number. Until October 1, 2023, clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives also are waiver- eligible to prescribe buprenorphine.

Additionally, providers who are state licensed and possess a valid Drug Enforcement Agency registration may be exempted from training requirements and the required attestation (about providing patients access to or referrals for psy- chosocial services) that are normally needed to obtain the X waiver. These providers are limited to treating no more than 30 patients. This has greatly increased the number and type of settings where medication for OUD is available and the number of patients in treatment. New settings include non-OTP outpatient addiction treatment programs, as well as general medical and mental health practices or clinics (office-based opioid treatment). OTPs can also provide buprenorphine.

In 2016, FDA approved buprenorphine implants (Probuphine) that last about 6 months for patients stabilized on sublingual or buccal formulations.

Implants have been found to be more effective than placebo in reducing illicit opioid use among opioid-dependent patients receiving counseling. Implants are available in the same settings as other buprenorphine formulations but require waivered providers to receive specifc training from the manufacturer on insertion and removal per the FDA-approved REMS.

In 2017, FDA approved a monthly extended- release buprenorphine injectable formulation (Sublocade) for patients with moderate-to- severe OUD who had been initiated and treated with transmucosal buprenorphine for at least 7 days. The medication is for subcutaneous abdominal injection by a healthcare provider and is intended to be available for ordering and dispensing (not by prescription to patients) in healthcare settings that receive special certifca- tion, pursuant to the FDA-approved REMS.

*DATA 2000 restrictions currently apply only to buprenorphine used to treat OUD. They do not apply to pain treatment using buprenorphine formulations approved to treat pain.

Choosing an OUD Medication

Currently, no empirical data indicate which patients will respond better to which OUD medications. All patients considering treatment should be educated about the effectiveness, risks, and Benefits of each of the three OUD medications, treatment without medication, and no treatment. Emphasize that OUD medications are safe and effective when used appropriately, and point out that these medications can help patients reduce or stop illicit opioid use and improve their health and functioning.

Tailor decisions to patients' medical, psychiatric, and substance use histories; to their preferences; and to treatment availability when deciding which medication and treatment to provide. Consider:

- Patients' prior response to a medication.
- The medication's side effect profle.
- The strength of the published data on safety and effectiveness.

- Patients' use of other substances (e.g., naltrexone is also approved for the treatment of alcohol dependence).
- Patients' occupation. For patients in safety- sensitive occupations, consider XR-NTX.
- Patients' pregnancy status. *
- Patients' physical dependence on opioids. Patients not currently physically dependent on opioids who are returning to the community from a residential treatment program or incar- ceration should have the option of XR-NTX, methadone, or buprenorphine based on which best suits their needs and circumstances (see below for special safety dosing considerations for methadone and buprenorphine in nontoler- ant patients).
- Patients' preferences. Respect patients' preferences for agonist versus antagonist medication. (See Part 2 of this TIP for an in depth discussion of treatment planning.)

*Methadone or buprenorphine maintenance is recommended for OUD treatment during pregnancy, as these medications have better maternal and infant outcomes than no treatment or medically supervised withdrawal. Methadone and buprenorphine are not associated with birth defects and have minimal long-term neurodevelopmental impact on infants. However, neonatal abstinence syndrome can occur, which requires hospitalization. The American College of Obstetricians and Gynecologists notes that limited data exist on the safety and effectiveness of naltrexone in pregnancy. Starting naltrexone rather than opioid agonist treatment in pregnancy is not recommended, given the risk of precipitated withdrawal. An expert panel did not agree on whether women already receiving treatment with naltrexone at the onset of pregnancy should remain on that medication during pregnancy. Patients who were taking naltrexone before their pregnancy should weigh with their providers the risks regarding unknown potential harm to the developing fetus versus the potential Benefits of continuing this medication during pregnancy Pregnant patients who discontinue naltrexone and return to opioid use should be considered for methadone or buprenorphine treatment.

Comparative Effectiveness

A Cochrane review of 5 randomized clinical trials with 788 participants found that, when provided at fixable doses on an outpatient basis, methadone retained patients in treatment longer than buprenorphine. That same review found that methadone and buprenorphine equally reduced illicit opioid use based on 8 studies with urine drug testing data from 1,027 participants and 4 studies with self-reported drug use from 501 participants.

There is not yet a Cochrane review on the comparative effectiveness of XR-NTX and bu- prenorphine. However, in 2017, two randomized trials comparing buprenorphine to XR-NTX were published. A multisite study with 570 partici- pants in the United States compared initiating buprenorphine versus XR-NTX at 8 inpatient treatment programs.

That study found that patients randomly assigned to start buprenor- phine had significantly lower return-to-use rates during 24 weeks of outpatient treatment compared with those patients assigned to start XR-NTX. This finding was because of the known diffculty in successfully completing induction in the XR-NTX group. However, comparing only the subgroups of those participants who did start their assigned medication, there were no significant between-group differences in return- to-use rates. In a 12-week trial in Norway with 159 participants who were opioid abstinent at the time of random assignment, XR-NTX was found to be noninferior to buprenorphine in terms of treatment retention and illicit opioid use. There is no extant literature evaluating the comparative effectiveness of methadone, XR-NTX, buprenor- phine implant, or extended-release buprenor- phine injection to one another.



Duration of Medication

Continued treatment with buprenorphine or methadone is associated with better outcomes than medically supervised withdrawal. Continued treatment with XR-NTX is associated with better outcomes than discontinuing XR-NTX. Patients should be informed of the risks and Benefits of discontinuing medication. Buprenorphine or methadone can be used for medically supervised withdrawal over a period of days to weeks (Exhibit 3A.2) for patients who prefer it to ongoing opioid agonist treatment.

When opioid agonist medications are unavailable, the alpha2-adrenergic agonist clonidine can relieve some withdrawal symptoms, although some clinical trials found it less effective. Pair medically supervised withdrawal with the chance to begin XR-NTX. Discontinuing medication increases risk of return to substance use and overdose death. Stable patients can continue their selected OUD medication indefnitely as long as it is beneficial.

During medically supervised withdrawal, ancillary medications can treat some of the withdrawal symptoms (Exhibit 3A.3).

*The TIP expert panel recommends offering maintenance therapy with medication, not short-term medically supervised withdrawal. The TIP expert panel also supports

maintaining patients on OUD medication for years, decades, and even a lifetime if patients are benefiting.

Principles of OUD Medications

Basic Function

Several factors underlie the development of addiction involving opioids and the diffculty people have in achieving and maintaining abstinence from them. These factors include:

- Short-term direct and indirect mu-opioid receptor agonist effects.
- Neuroplastic changes in the brain.
- Genetic, developmental, and environmental factors (e.g., exposure to high-risk environments, effect of stress on the hypothalamic– pituitary–adrenal axis).

[Scroll down for exhibits.]

EXHIBIT 3A.2. Medically Supervised Withdrawal Using Buprenorphine or Methadone

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

- Prefer it to treatment without medications, after they have been told the risks and benefits of this
 approach compared with treatment with medications.
- Wish to start XR-NTX, which is also FDA approved for the treatment of alcohol dependence.
- Are entering a controlled environment or workplace that disallows opioid agonists.

Data conflict on the ideal duration of medically supervised withdrawal. [60,61,62] Even so, shorter term dose reductions alone (formerly, "detoxification") are rarely effective. [61,64,65]

The TIP expert panel does not recommend short-term medically supervised withdrawal alone because of its high rates of return to illicit opioid use. ^{66,67,68} If patients prefer this approach, it should be provided with psychosocial treatment. ⁶⁹ XR-NTX treatment should always be considered to reduce the likelihood of return to use after medically supervised withdrawal is completed and an adequate period of abstinence achieved, ⁷⁰ as well as to reduce the likelihood of overdose death upon a return to opioid use.

If withdrawal is appropriate for the patient, the TIP expert panel recommends the following strategies:

- Individualize supervised withdrawal duration per patient preference and response to lower medication doses.
- Note that patients may benefit from nonopioid medication (e.g., clonidine, ondansetron, loperamide) or nonsteroidal anti-inflammatory medications to manage withdrawal symptoms near the end of the taper.
- Consider discontinuing dose reduction and increasing the dose if the patient begins to use illicit
 opioids.
- Encourage patients to continue receiving counseling, monitoring, and other psychosocial support after medication discontinuation.
- Urge patients to reenter treatment promptly if they return or think they may return to illicit opioid use.

EXHIBIT 3A.3. Medications for Management of Opioid Withdrawal Symptoms

SYMPTOM	MEDICATION
Nausea	Ondansetron, metoclopramide (avoid promethazine; it potentiates opioids
Diarrhea	Loperamide
Anxiety, irritability, sweating	Clonidine
Insomnia	Diphenhydramine, trazodone
Pain	Nonsteroidal anti-inflammatory drugs

Methadone, buprenorphine, and naltrexone bind to the mu-opioid receptors in the central and peripheral nervous systems, gastrointestinal tract, and vascular system. In the brain, these receptors mediate opioids' analgesic and other effects (e.g., euphoria,

respiratory depression, meiosis). Through modulation of mu-opioid receptor activity in the brain, these medications exert therapeutic efficacy in treating OUD.

Chapter 3B: Methadone

Methadone is the most studied medication for opioid use disorder (OUD). Of all OUD pharma- cotherapies, it is used to treat the most people throughout the world and has by far the longest track record (nearly 50 years).77,78 Numerous clinical trials and meta-analyses have shown that methadone treatment is associated with signif- cantly higher rates of treatment retention and lower rates of illicit opioid use compared with placebo and with no treatment. Other research associates methadone treatment with reduced mortality, criminal behavior, and HIV serocon- version. A Cochrane meta-analysis found that, at fexible doses, methadone compared with buprenorphine retains patients in treatment significantly longer and equally reduces illicit opioid use.

In the United States, OTPs can offer methadone to treat OUD, but <u>all providers who</u> may care for patients with OUD should be familiar with this treatment.

Formulations

There are several formulations of methadone:

- Liquid concentrate, which is the formulation most commonly used in treatment programs.
- Powder, which is dissolved in water and administered as a liquid.
- Dispersible tablets, which are scored tablets that are dissolved in water.
- Tablets, which are most commonly used outside of OTPs for analgesia.

Pharmacology

Methadone, a long-acting mu-opioid receptor full agonist, is a schedule II controlled medica- tion. It is highly plasma—protein bound and binds to proteins within tissues

throughout the body. Through mu-opioid receptor binding and opioid cross-tolerance to other mu-opioid agonists, at adequate doses, methadone reduces opioid craving and withdrawal and blunts or blocks the effects of illicit opioids.

There is wide individual variability in methadone pharmacokinetics. The half-life of methadone can vary from 8 to 59 hours depending on the patient. The average is 24 hours.

Methadone has no ceiling effect. As a full agonist, increasing doses of methadone produce maximal physiological effects at the opioid receptors. Plasma levels reach steady state in about 5 days (i.e., five half-lives). Before achievement of steady state, release from tissue reservoirs can lead to increasing serum plasma levels and toxicity, even if the daily methadone dose is not changed.

Methadone induction, thus, should begin at a low dose and increase gradually with daily monitoring over days or weeks. At stable daily doses, serum levels peak 2 to 4 hours after dosing, then slowly decrease, providing 24 hours without overmedication or withdrawal

Contraindications

Contraindications to treatment with methadone include an allergy to methadone and other instances in which opioids are contraindicated, such as acute asthma, in patients with abnormally high carbon dioxide blood levels (e.g., from pulmonary disease or sleep apnea), or paralytic ileus.

Precautions and Warnings

Respiratory depression

Methadone can cause respiratory depression, particularly during initial dosing and dose titration. The goal of methadone dosing in the first weeks of treatment (i.e., induction) is to relieve withdrawal but avoid oversedation and respiratory depression. Patients who are older or cachectic or who have chronic obstructive pulmonary disease are more susceptible to respiratory depression and should be treated cautiously with lower doses.

*A standard formula for dose induction for all patients, without careful monitoring of response to treatment, and individualized dose adjustment is inadvisable. This can lead to methadone intoxication and overdose death.

Individualize dosing decisions through daily monitoring of patients' responses to treatment. Opioid tolerance cannot be accurately gauged based on patient self-reports of the type, amount, or purity of the opioids they've used or of the severity of their opioid withdrawal symptoms.

best approach to dosing is to start low and go slow. Methadone has a relatively long half-life (24–36 hours or longer). Steady-state serum levels are generally not reached until about five half-lives. This means that patients will not feel the full effect of the initial dose for 4 or more days even if the daily dose is the same. Slow release of methadone from tissues causes serum levels to continue to increase until reaching steady state. Initially a dose may seem appropriate, but the third or fourth day of the same dose can lead to oversedation and even respiratory depression and death.

Concurrent substance use disorders (SUDs) involving benzodiazepines or alcohol

Concurrent misuse of alcohol or benzodiaz- epines with methadone (or buprenorphine) increases respiratory depression risk. Use of alcohol and benzodiazepines (illicit and prescription) is common in patients with OUD. Managing OUD with methadone for patients with alcohol or benzodiazepine use disorders is challenging and should be undertaken with care. A 2017 Food and Drug Administration (FDA) Drug Safety Communication noted that although concomitant use of buprenorphine or methadone with benzodiazepines increases the risk of an adverse reaction, including overdose death, opioid agonist treatment should not be denied to patients solely on the basis of their taking benzodiazepines, because untreated OUD can pose a greater risk of morbidity and mortality. FDA advises that careful medication management by healthcare professionals can reduce risk (see for more information).

Strategies to manage patients with concurrent alcohol or benzodiazepine use disorders include the following (see also Exhibit 3B.1):

- Obtain permission to communicate with the benzodiazepine prescriber to confrm
 the reason for use, adherence to treatment, and prescriber awareness of the
 patient's OUD. It can also help to speak (with permission) with close family
 members or friends to assess the extent and impact of any alcohol or benzodiazepine misuse.
- Ensure that patients understand the risk of potential respiratory depression and un- intentional overdose death when combining methadone with alcohol, benzodiazepines, or other central nervous system (CNS) depressants.
- Determine whether patients require medically supervised withdrawal or tapering from alcohol or benzodiazepines. Patients at risk for serious alcohol or benzodiazepine withdrawal syndrome (including seizures and delirium tremens) may need inpatient medically supervised withdrawal.

 Attempt gradual outpatient medically supervised withdrawal for benzodiazepines when indicated. Some OTPs have the staffing and capacity to provide a supervised outpatient taper from benzodiazepines.

EXHIBIT 3B.1. Strategies for Managing Benzodiazepine Use by Patients in OUD Treatment

- Carefully assess the patient's benzodiazepine use, including:
 - Intent of use.
 - Source (check the state's prescription drug monitoring program [PDMP]).
 - Amount and route of use.
 - Binge use.
 - Prior overdoses.
 - Harms (e.g., car crashes, criminal acts, sleep trouble).
 - Co-use with other substances that further increase risk for respiratory depression and overdose.
 - Withdrawal history (e.g., seizures, delirium).
- Also assess for:
 - Psychiatric and medical comorbidity.
 - Motivation for change.
 - Psychosocial support system (obtain history from a significant other if the patient permits).
- Gauge level of care and setting needed (e.g., residential, outpatient). Inpatient treatment may be best for patients with poor motivation, limited psychosocial support, serious or complicated comorbidity, or injection or binge use.

- Coordinate with other prescribers. Some patients may have taken appropriately prescribed benzodiazepines for years with limited or no evidence of misuse. For such patients, tapering benzodiazepines may be contraindicated and unrealistic.
- Address comorbid mental disorders (e.g., anxiety, depression) with other medications or psychosocial treatments, when feasible.
- Provide medically supervised withdrawal from benzodiazepines or refer to specialty care for same.
- Create a treatment plan with built-in conditions (e.g., urine testing, more frequent visits, short medication supply).
- Frequently review patient progress and objective outcomes, such as:
 - Urine drug testing.
- PDMP reports.
- Psychosocial functioning.
- Reports from significant others.
- Revise treatment plans as needed, and document the rationale for treatment decisions.

Adapted with permission.90

This usually requires use of a long-acting benzodiazepine, management of anxiety and sleeplessness, and careful monitoring with observed dosing and toxicology screening. It may also require lower-than-usual methadone doses. Engage in outpatient medically supervised withdrawal only with patients who are physically dependent on benzodiazepines but do not inject or binge. This may only be successful in a minority of patients. Attempt the taper while continuing treatment with methadone, subject to certain conditions that promote safety and reduce risk.

Consider increasing counseling frequency as appropriate.

Accidental ingestion

Inform patients that accidental ingestion can be fatal for opioid-naïve individuals, particularly children. Patients should safeguard take-home methadone in a lockbox out of the reach of children.

Neonatal abstinence syndrome (NAS)

Ensure awareness among pregnant patients or patients who may become pregnant that NAS can occur in newborns of mothers treated with methadone. Women receiving methadone treatment while pregnant should talk with their healthcare provider about NAS and how to reduce it. Research has shown that the dose of opioid agonist medication is not reliably related to the severity of NAS. Thus, each woman should receive the dose of medication that best manages her illness.

Misuse and diversion

Alert patients to the potential for misuse and diversion of methadone.

Physical dependence

Inform patients that they will develop physical dependence on methadone and will experience opioid withdrawal if they stop taking it.

Sedation

tion patients that methadone may affect cognition and psychomotor performance and can have sedating effects. **Urge patients to be cautious in using heavy**machinery and driving until they are sure that their abilities are not compromised.

Adrenal insufficiency

Adrenal insuffciency has been reported in patients treated with opioids. Ask patients to alert healthcare providers of nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.

Drug Interactions

Methadone has more clinically significant drug–drug interaction than buprenorphine. Carefully monitor each patient's response to treatment if they are prescribed or stop taking a CYP450 34A inducer or inhibitor. Methadone dosages may need to be adjusted up or down depending on the medication and whether treatment is starting or stopping.

Medications that induce CYP450 activity can increase methadone metabolism. Patients may experience craving or opioid withdrawal symptoms between doses if they begin these medications or become sedated if they discontinue them:

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

Other medications can inhibit CYP450 activity and decrease methadone metabolism, causing symptoms of overmedication (e.g., sedation) when the medication is started and possibly withdrawal or cravings when it is stopped.

- Among such medications are:
- Some antibiotics (ciprofoxacin, erythromycin).
- Antacids (cimetidine).
- Antifungals (fuconazole).
- Antidepressants (e.g., fuvoxamine, paroxe- tine, sertraline).

Side Effects

Possible side effects of methadone include the following (methadone FDA labels list all potential side effects and are available at https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=METHADONE

- Constipation
- Nausea
- Sweating
- Sexual dysfunction or decreased libido
- Drowsiness
- Amenorrhea

- Weight gain
- Edema

Assessment

A thorough assessment will help decide whether a patient is appropriate for admission and meets federal and any state regulatory requirements for methadone treatment. (See Part 2 of this TIP for detailed discussion of screening and assess- ment.) Before ordering methadone:

Check the state PDMP for opioid or benzo- diazepine prescriptions from other providers (see for links to state PDMPs). Note that methadone for OUD treatment will not appear in the PDMP because of confidentiality regulations regarding substance use treatment records. Obtain the patient's consent to release infor- mation and speak with treating providers to coordinate care for patient safety.

[Given these treatments involve prescriptions of medications, assessments will need to be provided medical professionals. For the more thorough information for these assessment, see the TIP 63, beginning on page 3-25. Information provided in this course is what has been deemed for treatment and information of interest to those providing mental health counseling services].



EXHIBIT 3B.3. Key Points of Patient Education for Methadone

Before starting OUD treatment with methadone, patients should:

- Be told that the methadone dose is started low and increased slowly over days and weeks with monitoring, because it takes 4 or more days for the body to adjust to a dose change. This is necessary to avoid the risk of overdose.
- Understand that the goal of the first weeks of treatment is to improve withdrawal symptoms without oversedation. Patients should inform providers if they feel sedated or "high" within the first 4 hours after their dose.
- Learn the symptoms of methadone intoxication and how to seek emergency care. The first 2 weeks of treatment have the highest risk of overdose.
- Be aware that rescue naloxone does not last very long, so they should remain in emergency care for observation if they are treated for opioid overdose.
- Know that concurrent alcohol, benzodiazepine, or other sedative use with methadone increases the risk of overdose and death.

- Inform OTP nursing/medical staff about prescribed and over-the-counter medications and herbs (e.g., St. John's wort) they are taking, stopping, or changing doses of to allow assessment of potential drug-drug interactions.
- Inform other treating healthcare professionals that they are receiving methadone treatment.
- Plan to avoid driving or operating heavy machinery until their dose is stabilized.
- Learn about other possible side effects of methadone, including dizziness, nausea, vomiting, sweating, constipation, edema, and sexual dysfunction.
- Agree to keep take-home doses locked up and out of the reach of others. Understand that giving methadone, even small amounts, to others may be fatal.
- · Inform providers if they become pregnant.
- Understand that stopping methadone increases their risk of overdose death if they return to illicit opioid use.

Initiating Methadone Treatment

Observing patients directly when they take doses early in treatment is not just required; it's beneficial. It maximizes adherence, provides a daily opportunity to assess response to the medication, and minimizes the likelihood of medication diversion. Federal OTP regulations permit patients to receive one take-home dose per week, given routine clinic closure on weekends. Patients who demonstrate progress can earn one additional take-home dose per week for the first 90 days of treatment at the OTP medical director's discretion. All other doses are directly observed at the clinic in the first 90 days.

The goal of initiating methadone treatment is to increase the patient's methadone dose gradually and safely, stabilizing the patient and reducing his or her opioid use while recognizing that the risk of dropout or overdose from illicit opioid use may increase if induction is too slow.

Day 1

The first dose should reduce opioid withdrawal symptoms. Perform induction cautiously; it's impossible to judge a patient's level of tolerance with certainty. For patients addicted to prescription opioids, opioid conversion tables should not be relied on to determine methadone dosage.

The first dose for patients tolerant to opioids is generally between 10 mg and 30 mg (30 mg is the maximum first dose per federal OTP regulations). After the first dose, patients should remain for observation for 2 to 4 hours if possible, to see whether the dose is sedating or relieves withdrawal signs. If withdrawal symptoms lessen, the patient should return the next day to be reassessed and to continue the dose induction process.

If sedation or intoxication occurs after the first dose, the patient should stay under observation at the clinic until symptoms resolve. In this case, the patient should be reassessed the following day, and the subsequent day's dose should be substantially reduced. Extremely rarely, the patient will need to be treated for overdose with naloxone. If necessary, begin rescue breathing and call 9-1-1.

withdrawal during the 2- to 4-hour waiting period, administer another 5 mg dose. A final 5 mg dose after another waiting period of 2 to 4 hours can be administered if necessary. The maximum total methadone dose on the first day of treatment should not exceed 40 mg. However, caution dictates against exceeding a total first day's dose of 30 mg except in rare cases. In such cases, the patient should be carefully monitored on subsequent days to rule out oversedation.

Patients transferring from another OTP whose methadone dose and last date of medication administration can be confirmed by the medical staff and documented in the medical record can be continued on the same methadone dose administered in the original OTP, even if the dose exceeds the maximum permitted 40 mg.

The goals of early dose titration for patients with current opioid dependence starting on Day 2 of the first week of treatment through stabilization are to avoid sedation at peak serum levels and to gradually extend time without opioid withdrawal symptoms and craving. When patients attend the program, before dose administration, nursing and/or medical staff members should ask patients whether they felt sedation, opioid intoxication effects, or opioid withdrawal symptoms 2 to 4 hours after their methadone administration the prior day. Doses should be decreased for reports of symptoms of opioid intoxication or oversedation. Dosing must be individualized based on careful patient assessment and generally should not be increased every day, because plasma methadone levels do not reach steady state until about five methadone half-lives.

Dose Titration (Weeks 3 to 4)

Methadone doses can be increased further in 5 mg increments about every 3 to 5 days based on the patient's symptoms of opioid withdrawal or sedation. Patients who miss more than four doses must be reassessed. Their next methadone dose should be decreased substantially and built back up gradually. It may be necessary to restart the dose induction process from Day 1. Be aware of any specific state requirements regarding missed doses.

Dose Stabilization (Week 5 and Beyond)

Once the patient achieves an adequate dose, extended continuation is possible without dose adjustment. Continuing treatment goals are to avoid sedation, eliminate withdrawal and craving, and blunt or block euphoric effects of illicit opioids.

As illicit opioid use stops and stabilization is achieved, the patient may wish to lower the dose to reduce any unpleasant side effects. Typical stabilization doses of at least 60 mg are associated with greater treatment retention; 80 mg to 120 mg is the typical daily range. However, there is wide variation, and some patients benefit from higher daily doses.

Take-Home Medication

OTPs can provide gradually increasing numbers of take-home doses to patients who discontinue illicit drug use and begin achieving treatment goals, commensurate with their tenure in the program. This provides a powerful incentive for patients to achieve treatment goals. It also furthers patients' recovery goals by allowing them to attend work, school, or other activities without daily OTP visits.

Federal OTP regulations describe the conditions under which take-home doses are permitted. Some states have additional regulations. OTPs should be familiar with these regulations and have written procedures to address take-home dosing.

Benefits of take-home doses must outweigh the risks and further patients' rehabilitation goals. When deciding whether patients can handle the responsibility of take-home doses of methadone or buprenorphine, OTP medical directors should consider whether patients demonstrate:

- No recent misuse of substances.
- Regular clinic attendance.
- No serious behavioral problems at the clinic.
- No recent criminal activity (e.g., selling drugs).
- Stability at home and in social relationships.
- Sufficient time in treatment.
- Ability and intent to store take-home medication safely.
- Rehabilitative Benefits from decreasing the frequency of clinic attendance that outweigh the potential risks of diversion.

Federal regulations based on patients' time in treatment determine eligibility to be considered for receiving take-home doses of methadone (but buprenorphine is not bound by these limits):

- One earned dose/week (beyond a weekly clinic closure day or federal holiday, when clinics typically close) in the first 90 days of treatment
- Two doses during the second 90 days
- Three doses during the third 90 days
- Up to 6 doses during the last 90 days

- Up to 2 weeks of doses after 1 year
- Up to 1 month of doses after 2 years

Duration of Methadone Treatment

Longer lengths of stay in methadone treatment are associated with superior treatment outcomes. Leaving methadone treatment is associated with increased risk of death from overdose and other causes. Patients should continue as long as they benefit, want to, and develop no contraindications.

Dose Tapering and Methadone Discontinuation

Discuss risks and Benefits with patients who wish to discontinue treatment. Explore their reasons for wanting to discontinue and solutions for potential barriers to treatment, which may include:

- Logistics (e.g., travel, scheduling). Transportation services, including publicly
 funded ride services, ride sharing, or peer support workers, may be available. If
 not, transferring patients to a closer OTP or to one with more suitable hours of
 operation may resolve the problem.
- Costs. Providers can help patients explore publicly supported treatment options or apply for insurance.
- Side effects. Changing the dose or treating side effects may resolve the problem.
- Opinions of friends or family. When external pressure from family or friends drives the decision, a discussion with the patient and those individuals may help.
- A desire to switch to buprenorphine or XR-NTX treatment. These options should be discussed.

Create a plan collaboratively with stable patients who wish to discontinue treatment that addresses:

- Gradually tapering their dose.
- Increasing psychosocial and recovery supports.

- Discontinuing dose reduction if necessary.
- Returning to medication treatment after discontinuation if they return to illicit opioid use.
- Increasing dosage if destabilization occurs.

Encourage patients to use techniques for preventing return to use, such as participating in recovery support groups and gaining support from counseling and family. Doing so can help patients succeed in tapering off their medication.

Chapter 3C: Naltrexone

The opioid receptor antagonist naltrexone was synthesized in the 1960s to block the euphoric effects of morphine. Oral naltrexone was approved by the Food and Drug Administration (FDA) in 1984 for the blockade of the effects of exogenously administered opioids. Long-acting, sustained-release opioid agonist preparations have been investigated since the 1970s to improve adherence over oral medications. In 2010, FDA approved injectable extended-release naltrexone (XR-NTX) for preventing return to opioid dependence after medically supervised withdrawal.

Despite its potential advantages (e.g., no abuse liability, no special regulatory requirements), oral naltrexone is not widely used to treat opioid use disorder (OUD) because of low rates of patient acceptance, difficulty in achieving abstinence for the necessary time before initiation of treatment, and high rates of medication nonadherence.

Before initiating either formulation of naltrexone, patients must be opioid abstinent for an adequate period of time after completing opioid withdrawal. Medically supervised opioid withdrawal can be conducted on an outpatient or inpatient basis. The latter is often reserved for patients with co-occurring substance use disorders (SUDs) or medical or psychiatric illness.

There are several pharmacological approaches to medically supervised withdrawal. Methadone can be used for this purpose in opioid treatment programs (OTPs) and hospital settings. Patients in opioid withdrawal typically receive an individualized dose between 20 mg and 30 mg per day, gradually reduced over 6 days or more.

Buprenorphine can be used in an adequate dose to lessen withdrawal symptoms and then reduced gradually over several days or more. If an opioid agonist is used for medically supervised withdrawal, an adequate interval of time following the last dose must occur before naltrexone induction.

When it is not possible to use opioid agonists, alpha-2 adrenergic agonists such as clonidine can be used off label at doses from 0.1 mg to 0.3 mg every 6 to 8 hours to treat symptoms.

Side Effects

Possible side effects of XR-NTX include:

- Insomnia.
- Injection site pain.
- Hepatic enzyme abnormalities.
- Nasopharyngitis.

Assessment

Thorough assessment helps determine whether naltrexone treatment is appropriate for a patient. (Part 2 of this Treatment Improvement Protocol [TIP] covers screening and assessment in more detail.)

Patients who have been abstinent from short-acting opioids (including tramadol) for 7 to 10 days or long-acting opioids (e.g., methadone, buprenorphine) for 10 to 14 days can initiate naltrexone following assessment that includes:

Checking the state prescription drug monitoring program database.

Taking the patient's history.

- Conduct a medical, psychiatric, substance use, and substance use treatment history.
- Assess recent opioid use, including frequency, quantity, type, route, and last day of use. Confirm an adequate opioid abstinence period.
- Establish OUD diagnosis.
- Assess for other SUDs, including those that involve alcohol, benzodiazepines, or stimulants.

Obtaining laboratory tests.

- Conduct drug and alcohol tests. Use reliable urine tests for opioids (including morphine, methadone, buprenorphine, and oxycodone), benzodiazepines, cocaine, and other drugs commonly used in the area. Use a breathalyzer to estimate the patient's blood alcohol content.
- Conduct a pregnancy test. Naltrexone is not recommended for OUD treatment in pregnancy. Refer pregnant patients to prenatal care.
- Assess liver function. Obtain liver function tests followed by periodic monitoring at 6or 12-month intervals during treatment.
- Obtain kidney function tests (e.g., creatinine) for people who inject drugs.
- Conduct hepatitis and HIV tests. Hepatitis B and C are common among patients entering naltrexone treatment. HIV infection is also prevalent. Everyone ages 15 to 65 should be tested at least once for HIV.

Conducting a physical exam.

 Assess for signs and symptoms of intoxication. Do not give a first dose to a patient who is sedated or intoxicated. Assess and treat him or her appropriately. - Assess for evidence of opioid withdrawal and physiological dependence.

Persons at higher risk, such as people who use drugs by injection, should be tested annually for hepatitis C. Anyone who is injecting or has ever injected drugs, even once, no matter how long ago, should be tested for hepatitis C, regardless of their intention to seek treatment for SUD. The Centers for Disease Control and Prevention recommends hepatitis B vaccine for individuals seeking treatment for SUDs.

During assessment, discuss with patients the risks and Benefits of naltrexone and alternative treatment approaches. Explore patients' moti- vation to initiate medication treatment and to adhere to the dosing regimen. Start naltrexone if the patient:

- Meets Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, criteria for OUD.
- Understands risks and Benefits.
- Reports opioid abstinence for 7 to 10 days (short acting) or 10 to 14 days (long acting).
- Reports no allergies to naltrexone or the components of the XR-NTX preparation.
- Does not have a coagulation disorder.
- Will not soon require opioid analgesia.
- Has a negative pregnancy test.
- Has a negative urine opioid screen for morphine, methadone, buprenorphine, oxycodone, and other opioids.
- Is free of current opioid withdrawal signs and symptoms (Exhibit 3C.2).
- Has liver function test results that do not indicate acute hepatitis or liver failure.
- Has a negative naloxone challenge result.

Patient selection

No evidence clearly predicts which patients are best treated with XR-NTX versus other OUD medications. A secondary analysis of the data from a randomized trial of XR-NTX versus placebo conducted in Russia found no significant baseline predictors of

successes among the 25 variables examined, including demographics, clinical severity, level of functioning, craving, and HIV serostatus.

Inform patients of all their treatment options and the settings in which they are available. OTPs may be best for patients needing more structure. Tailor decisions about which medication to use to patients' medical and substance use histories, patient preferences, and treatment availability.

Pregnant women are not appropriate candidates for XR-NTX treatment.

Potentially suitable candidates for XR-NTX treatment include patients who:

- Do not wish to take opioid agonists.
- Have been opioid abstinent for at least 1 week, have recently been or will soon
 be released from controlled environments (e.g., incarceration, residential
 addiction treatment), and do not wish to initiate (or are not able to access) opioid
 agonist treatment. For patients requesting opioid agonist treatment, methadone
 or buprenorphine must be started at much lower doses and increased much
 more slowly than for opioid-tolerant patients (see sections on methadone and
 buprenor- phine dosing).
- Have not responded well to prior adequate treatment with opioid agonist therapy
- Are part of an overall program with external monitoring and significant, immediate
 external consequences for lack of adherence (because these patients [e.g.,
 healthcare professionals, pilots, probationers, parolees] may show higher rates of
 retention with XR-NTX because of required external monitoring).
- Have home locations or work schedules making daily or almost-daily OTP visits impossible or risky (e.g., job loss).

One study demonstrated that stable patients who were able to taper to 8 mg or less of buprenorphine may be successfully started on XR-NTX using a regimen consisting of a buprenorphine taper and ancillary medications to palliate withdrawal symptoms. The study employed a hybrid outpatient and residential care model and excluded patients who consistently tested positive for illicit or nonprescribed opioids.

EXHIBIT 3C.2. Signs and Symptoms of Opioid Withdrawal

Signs

Symptoms

Runny nose Skin crawling
Tearing Abdominal cramps
Yawning Temperature changes
Sweating Nausea
Tremor Vomiting

Vomiting Diarrhea
Piloerection Bone or muscle pain
Pupillary dilation Dysphoria

Craving for opioids

Administration

Administer XR-NTX every 4 weeks or once a month as a 380 mg IM gluteal injection. Alternate buttocks for each 4-week injection. Given the risk of severe injection site reactions, FDA requires a risk evaluation and mitigation strategy for XR-NTX including a patient counseling tool, a patient medication guide, and a visual aid to reinforce proper XR-NTX injection technique.

EXHIBIT 3C.3. Key Points of Patient Education for XR-NTX

- Do not use any opioids in the 7 to 10 days (for short acting) or 10 to 14 days (for long acting) before starting XR-NTX, to avoid potentially serious opioid withdrawal symptoms. Opioids include:
 - _ Heroin.
 - Prescription opioid analgesics (including tramadol).
 - Cough, diarrhea, or other medications that contain codeine or other opioids.
 - Methadone.
 - _ Buprenorphine.
- Seek immediate medical help if symptoms of allergic reaction or anaphylaxis occur, such as:
 - _ Itching.
 - Swelling.
 - Hives.
 - Shortness of breath.
 - Throat tightness.
- Do not try to override the opioid blockade with large amounts of opioids, which could result in overdose.
- Understand the risk of overdose from using opioids near the time of the next injection, after missing a dose, or after stopping medications.
- · Report injection site reactions including:
 - Pain.
 - Hardening.
 - Lumps.

- Blisters.
- Blackening.
- _ Scabs.
- An open wound.

Some of these reactions could require surgery to repair (rarely).

- Report signs and symptoms of hepatitis (e.g., fatigue, abdominal pain, yellowing skin or eyes, dark urine).
- Report depression or suicidal thoughts. Seek immediate medical attention if these symptoms appear.
- Seek medical help if symptoms of pneumonia appear (e.g., shortness of breath, fever).
- Inform providers of naltrexone treatment, as treatment differs for various types of pneumonia.
- Inform all healthcare professionals of XR-NTX treatment.
- · Report pregnancy.
- Inform providers of any upcoming medical procedures that may require pain medication.
- Understand that taking XR-NTX may result in difficulty achieving adequate pain control if acute medical illness or trauma causes severe acute pain.
- Wear medical alert jewelry and carry a medical alert card indicating you are taking XR-NTX. A patient wallet card or medical alert bracelet can be ordered at 1-800-848-4876.

Follow-up care after first dose

Examine patients within a week of administering their first XR-NTX dose. It can be clinically beneficial to maintain weekly contact in the first month to:

- Provide supportive counseling.
- Assess ongoing drug or alcohol use.
- Monitor side effects.
- Obtain drug testing.
- Follow up on status of referrals to counseling or other services.

Patients who test the opioid blockade of XR-NTX may discontinue use because of the blocking of the euphoric effects of illicit opioids. Patients who miss a dose can restart medication (use procedures outlined earlier in this section) after an adequate period of opioid abstinence (7 to 14 days).

The TIP expert panel cautions that, based on current data, arbitrary time limits on XR-NTX are inappropriate.

See Chapter 3E for information on the manage- ment of patients taking naltrexone in office- based treatment settings.

Duration of treatment

Barring contraindications, patients should continue taking XR-NTX as long as they benefit from it and want to continue. Data are limited on the long-term effectiveness of XR-NTX compared with methadone or buprenorphine.

Treatment discontinuation

When patients wish to discontinue naltrexone, **engage in shared decision making** and **explore**:

- Their reasons for wanting to discontinue.
- . The risks and Benefits of discontinuing.
- Problem-solving strategies that can help them make an informed choice.
 - Their appropriateness for buprenorphine or methadone treatment.

Discourage patients who are not yet stable from discontinuing treatment, because of the high rate of return to illicit opioid use and the increased chance of overdose death.

Signs that a patient may be ready to discontinue medication include:

- Sustaining illicit drug abstinence over time.
- Having stable housing and income.
- Having no legal problems.
- Having substantially reduced craving.

Attending counseling or mutual-help groups.

Patients who discontinue should have a recovery plan that may include monitoring as well as adjunctive counseling and recovery support. If they return to opioid use, encourage them to return for assessment and reentry into treatment.

Given the high risk of return to illicit opioid use, offer patients information about opioid overdose prevention and a naloxone pre- scription they can use in case of overdose. When patients stop using naltrexone, they will have no tolerance for opioids. Their risk of overdose is very high if they use again.

Rapid naltrexone induction

Patients with OUD need to discontinue opioids and wait 7 to 14 days after last opioid use (including any given for with- drawal treatment) before receiving XR-NTX.

As described above, they can do so through medically supervised withdrawal in a controlled environment, such as an inpatient unit, residen- tial addiction treatment program, correctional facility, or hospital, or on an outpatient basis.

Financial issues and managed care constraints may infuence patients' access to controlled treatment environments. The alternative— abstaining long enough after outpatient medically supervised withdrawal—is challeng- ing. Thus, various approaches to rapid naltrexone induction have been developed and more recently refned in research settings.

Consider rapid induction in specialty addiction treatment programs, not general medical settings. It may be hard for providers in general medical settings to start XR-NTX successfully with patients who need medically supervised opioid withdrawal. Rapid induction approaches are likely beyond the scope of general outpatient settings. However, patients can successfully initiate XR-NTX in a general outpatient medical setting if they:

- Have been abstinent for suffcient time and pass the naloxone challenge.
- Started taking XR-NTX elsewhere and are due for the next injection.

Chapter 3D: Buprenorphine

Buprenorphine and buprenorphine/naloxone formulations are effective treatments for opioid use disorder (OUD). Numerous clinical studies and randomized clinical trials have demonstrated buprenorphine's efficacy in retaining patients in treatment and reducing illicit opioid use compared with treatment without medication and medically supervised withdrawal. Other research has associated it with reduction in HIV risk behavior and risk of overdose death, and its effectiveness has been shown in primary care settings. Buprenorphine is on the World Health Organization (WHO) list of essential medications.

The Treatment Improvement Protocol (TIP) expert panel recommends offering the option of Food and Drug Administration (FDA)- approved buprenorphine formulations to appropriate patients with OUD, considering patient preferences for and experience with other medications or no medication. These recommendations align with Department of Veterans Affairs guidelines.

Pharmacology

Buprenorphine, an opioid receptor partial agonist, is a schedule III controlled medication derived from the opium alkaloid thebaine. Through cross-tolerance and mu-opioid receptor occupancy, at adequate doses, buprenorphine reduces opioid withdrawal and craving and blunts the effects of illicit opioids. Buprenorphine binds tightly to the mu-opioid receptor because of its particularly high receptor affnity. This prevents other opioids with lower affnity (e.g., heroin) from binding. The net result is a blunting or blocking of the euphoria, respiratory depression, and other effects of these opioids.

Buprenorphine has less potential to cause respiratory depression, given its ceiling effect. As a partial agonist, buprenorphine's maximum effect on respiratory depression is more limited than full agonists. Once reaching a moderate dose, its effects no longer increase if the dose is increased.

Contraindications

Buprenorphine is contraindicated in patients who are allergic to it. Patients with true allergic reactions to naloxone should not be treated with the combination buprenorphine/naloxone product. Allergy to naloxone is infrequent.

Some patients may falsely or mistakenly claim an allergy to naloxone and request buprenorphine monoproduct. Carefully assess such claims and explain the differences between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone; the monoproduct has more abuse liability than buprenorphine/naloxone.

Drug Interactions

Buprenorphine has fewer documented clinically significant drug interactions than methadone.

Side Effects

Buprenorphine's side effects may be less intense than those of full agonists. Otherwise, they resemble those of other mu-opioid agonists. Possible side effects include the following:

- Oral hypoesthesia (oral numbness)
- Constipation
- Glossodynia (tongue pain)
- Oral mucosal erythema
- Vomiting
- Intoxication
- Disturbance in attention
- Palpitations
- Insomnia
- Opioid withdrawal syndrome
- Excessive sweating
- Blurred vision

Assessment

No evidence clearly predicts which patients are best matched to buprenorphine versus other OUD medications. Thorough assessment helps determine whether buprenorphine treatment is appropriate for a patient. (Part 2 of this TIP covers screening and assessment in more detail.)

Patient Selection

No evidence clearly predicts which patients are best treated with buprenorphine versus other OUD medications. Inform all patients with OUD about treatment with transmucosal buprenorphine and where it's available. (See "Treatment Planning or Referral" in Part 2 of this TIP for more on shared decision making.)

Patients who responded well to buprenorphine in the past should be considered for this treatment. Prior use of diverted buprenorphine doesn't rule out OUD treatment with buprenorphine. Diverted buprenorphine is often associated with an inability to access treatment, and it's often used to self-treat opioid withdrawal rather than to "get high."

Unsuccessful treatment experiences with buprenorphine in the past do not necessarily indicate that buprenorphine will be ineffective again. Motivation and circumstances change over time. Also, treatment varies by provider, clinic, and setting, as it does for other medical illnesses. Records from previous providers can contextualize the extent of past treatment.

Pregnant women should be considered for transmucosal buprenorphine treatment.

Stable patients are the best candidates for buprenorphine implants. Implants are indicated for patients who have already achieved illicit opioid abstinence and clinical stability while taking transmucosal buprenorphine for at least 90 days. Their current dose should be 8 mg/ day or less. There is no absolute defnition of clinical stability, but per the implant package insert, patients may be stable if they are:

- Abstaining currently from illicit opioids.
- Having little or no craving for illicit opioids.

EXHIBIT 3D.5. Key Points of Patient Education for Buprenorphine

Before starting OUD treatment with buprenorphine, patients should:

- Tell providers the prescribed and over-thecounter medications they take to allow drug interaction assessment.
- Understand the goal of the first week of treatment: To improve withdrawal symptoms without oversedation.
- Tell providers if they feel sedated or euphoric within 1 to 4 hours after their dose.
- Be given the appropriate buprenorphine medication guide.
- · Know possible side effects, including:
 - _ Headache.
 - Dizziness.
 - Nausea.
 - _ Vomiting.
 - Sweating.
 - Constipation.
 - Sexual dysfunction.
- Agree to store medication securely and out of the reach of others.
- Alert providers if they discontinue medications, start new ones, or change their medication dose.
- Understand that discontinuing buprenorphine increases risk of overdose death upon return to illicit opioid use.
- Know that use of alcohol or benzodiazepines with buprenorphine increases the risk of overdose and death.
- Understand the importance of informing providers if they become pregnant.
- Tell providers if they are having a procedure that may require pain medication.
- Be aware of resources through which to obtain further education for:
 - Themselves: Decisions in Recovery: Treatment for Opioid Use Disorder (https:// store.samhsa.gov/product/SMA16-4993)
 - Their families and friends: Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends (https://portal.ct.gov/-/media/DMHAS/Opioid-Resources/ MATInfoFamilyFriendspdf.pdf)

- Living in a stable environment.
- Participating in a structured job or activity.
- Engaging in a positive social support system.
- Lacking recent hospitalizations, emergency department visits, or crisis interventions for substance use or mental illness.
- Adhering to clinic appointments and other aspects of treatment and recovery plans.

Initiating Buprenorphine Treatment

It can be helpful to use a buprenorphine treatment agreement for patients treated in office-based settings

Induction can occur in the office or at home.

Most clinical trials were conducted with office-based induction, and extant guidance recommends this approach. However, office-based induction can be a barrier to treatment initiation. Home induction is increasingly common.

Office-Based Induction

Providers can perform office-based induction by ordering and storing induction doses in the

office or by prescribing medication and instructing patients to bring it to the office on the day of induction. Office-based induction allows providers to:

- Ensure that patients know how to take medication without swallowing or spitting it
 out if they have too much saliva or experience unpleasant tastes. Tell them to
 wait to eat or drink until the medication is totally dissolved.
- Enhance the therapeutic relationship.
- Verify the presence of opioid withdrawal and absence of precipitated opioid withdrawal.
- Ensure the lack of sedation 1 to 2 hours after the first dose in patients taking sedatives.
- Use time between doses for patient self- assessment.

Home Induction

Home induction can be safe and effective. Retention rates are similar to office inductions, but no comparison data from large randomized controlled studies exist. The American Society of Addiction Medicine National Practice Guideline recommends home induction only if the patient or prescriber has experience with using buprenor- phine. Clinical experience indicates that patients suitable for home induction:

- Can describe, understand, and rate withdrawal.
- Can understand induction dosing instructions.
- Can and will contact their provider about problems.

Educate patients about how to assess their withdrawal, when to start the first dose, how to take the medication properly, and how to manage withdrawal on induction day.

Instruct patients to take their first dose when they experience opioid withdrawal at least 12 hours after last use of heroin or a short-acting prescription opioid.

Effectively switching from methadone to buprenorphine can be challenging. This should generally be started with office-based induction. Consult with a medical expert knowledgeable about methadone in these situations until experi- ence is gained.

Withdrawal can include:

Goose bumps.

- Nausea.
- Abdominal cramps.
- · Running nose.
- Tearing.
- Yawning.

Be available for phone consultation during the induction period and for an in-office evaluation should the need arise.

Advise patients to abstain from tobacco before dosing. Many patients with OUD use tobacco products.

Nicotine causes vasoconstriction, decreasing the surface area of blood vessels that absorb buprenorphine.

Induction

Patients who are currently physically dependent on opioids

Patients should begin buprenorphine when they are exhibiting clear signs of opioid withdrawal. If patients experience sedation upon first dose, stop and reevaluate the following:

Most patients tolerated this dose induction, and the mean daily dose exceeded 8 mg per day by the fifth week.

Dose Stabilization

Stabilization occurs when there is evidence of:

- Markedly reduced or eliminated illicit opioid use.
- Reduced craving.
- Suppression of opioid withdrawal. Buprenorphine treatment should substantially
- Minimal side effects.
- Patient-reported blunted or blocked euphoria during illicit opioid use.

Once patients have stabilized, continue to screen and evaluate for mental disorders and psychosocial problems that may need to be addressed (e.g., having a spouse or cohabitant who is using illicit opioids). Support patients' engagement in prosocial activities and progress toward treatment goals and recovery as they decrease use of illicit substances.

Offer psychosocial referrals to help decrease and manage cravings.

Offer referrals for adjunctive counseling and recovery support services as needed. It may not be possible to eliminate opioid craving completely, regardless of the dose. Counseling can help patients reduce and manage craving. A more important measure of dose adequacy than craving is whether patients report that the feeling of euphoria associated with self-administered illicit opioids is blunted or blocked. Patients who were not interested in adjunctive addiction or mental health counseling during induction may become receptive to it when they are feeling more stable.

Duration of Buprenorphine Treatment

There is no known duration of therapy with buprenorphine (or methadone or XR-NTX) after which patients can stop medication and be certain not to return to illicit opioid use. Those who stay in treatment often abstain longer from illicit opioid use and show increasing clinical stability. Long-term treatment outcomes up to 8 years after buprenorphine treatment entry show lower illicit opioid use among those with more time on medication. Patients should take buprenorphine as long as they benefit from it and wish to continue.

Successful Buprenorphine Treatment

goal of buprenorphine treatment is full remission from OUD. Maintaining illicit opioid abstinence is ideal, but imperfect abstinence does not preclude treatment benefits. Patients should do better in treatment than before treatment. If not, seek alternatives. Do not judge treatment progress and success on the amount of medication a patient needs or how long treatment is required. Rather, gauge

treatment progress and success based on patients' achievement of specific goals that were agreed on in a shared decision-making and treatment planning process.

Consider this analogy: A patient with poorly controlled diabetes was previously unable to work and was admitted to the hospital several times for diabetic ketoacidosis. When taking insulin regularly, the patient worked part time, had fewer hospitalizations for diabetic ketoaci- dosis despite a nondiabetic diet, and had lower (but still high) hemoglobin A1C. This patient's treatment with insulin is not a "failure" because perfect control and function were not restored, and the patient would not be discharged from care against his or her will.

<u>Chapter 3E: Medical Management Strategies for Patients Taking OUD</u> <u>Medications in Office-Based Settings</u>

Management of patients taking medications for opioid use disorder (OUD) varies by setting. Whereas OBOT stabilizes patients on buprenorphine or naltrexone, providers focus on medication management and treatment of other substance use, medical comorbidities, and psychosocial needs. Treatment of comorbid conditions should be offered onsite or via referral and should be verifed as having been received.

EXHIBIT 3E.1. Key Terms

In addition to the key terms defined in Exhibit 3.1 of this Treatment Improvement Protocol (TIP), these terms appear in Chapter 3E:

Psychosocial support: Ancillary services to enhance a patient's overall functioning and well-being, including recovery support services, case management, housing, employment, and educational services.

Psychosocial treatment: Interventions that seek to enhance patient's social and mental functioning, including addiction counseling, contingency management, and mental health services.



Patient Selection

To assess patients' chances of success with standard office-based treatment, consider:

- Concurrent substance use disorder (SUD) involving alcohol or benzodiazepines.
 Benzodiazepine (illicit and prescription) and alcohol use are common in patients
 with OUD. This use presents clinical challenges, including increased risk of
 respiratory depression and unintentional overdose or death. Some patients may
 have taken appropriately prescribed benzodiazepines for years with limited or no
 evidence of misuse. For such patients, tapering benzodiazepines may be
 contraindicated and unrealistic. Others may require treatment for a
 benzodiazepine use disorder
- Although concomitant use of buprenorphine with benzodiazepines increases the
 risk of an adverse reaction, including overdose death, opioid agonist treatment
 should not be denied to patients solely because they take benzodiazepines,
 because untreated OUD can pose a greater risk of morbidity and mortality. The
 Food and Drug Administration (FDA) advises that careful medication management by healthcare professionals can reduce risk (see for more
 information).

Approaches to addressing concurrent benzodiazepine use include:

- Get patients' permission to contact their benzodiazepine prescribers to confrm their histories. Speaking with close family members or friends (with patients' permission) can also help in evaluating evidence of alcohol or benzodiazepine misuse (e.g., intoxication, accidents, withdrawal seizures).
- Make sure patients understand that combining buprenorphine with alcohol, benzodiazepines, or other central nervous system depressants risks potential respiratory depression and unintentional overdose death. Overdose death with buprenorphine is most often associated with intravenous benzodiazepine and heavy alcohol use.
- For patients misusing benzodiazepines (e.g., taking in high doses, bingeing, using intravenously), the TIP expert panel recommends referral to higher intensity addiction treatment with medically supervised benzodiazepine withdrawal if available (e.g.,

intensive outpatient programs, residential treatment). Do not rule out concurrent use of buprenorphine or extended-release injectable naltrexone (XR-NTX) for treatment of OUD in more structured settings for these patients.

Referral to counseling and other psychosocial supports

Prescribers of buprenorphine must be able to refer patients for appropriate adjunctive counseling and ancillary services as needed according to federal law. (However, patients can still receive buprenorphine treatment even if they do not use such services.) There's no such referral requirement for naltrexone treatment, but patients should receive medical management and be referred as needed for adjunctive addiction, mental health, or recovery services.

To achieve clinical stability and abstinence from illicit drug use, many patients need psychosocial counseling and support services beyond what their buprenorphine prescriber's practice offers. For example, patients with mental disorders (e.g., depression, posttraumatic stress disorder) should be assessed and treated with appropriate medications (as indicated) and adjunctive mental health services.

Some patients are reluctant to engage in addiction counseling or recovery support groups until they stabilize on medication. Once stabilized, they may see Benefits to participating in these supports. Recommend additional addiction, mental health, and social services as appropriate if patients:

- Do not achieve full remission.
- Continue to misuse nonopioid substances.
- Do not reach their treatment goals with medication management alone.

Behavioral treatment with contingency management (e.g., rewards for illicit drug abstinence) is highly effective and is offered in some specialty treatment programs. It can motivate the patient to reduce illicit drug use, including opioids and stimulants, and increase medication adherence.

Alcoholics Anonymous, Narcotics Anonymous, Self-Management and Recovery Training, and other peer recovery support groups can be helpful to patients, especially if they find groups with accepting attitudes toward OUD medication and people who take it. Some peer recovery support groups consider patients taking methadone and buprenorphine for OUD treatment as not being abstinent from opioids. Check with local groups before referring a patient. Groups not accepting of OUD medications are not appropriate for patients taking them. Patients are most likely to benefit from peer support programs if they actively participate in offered recovery activities. Monitor recovery activities to ensure that patients are accessing appropriate supports and are benefiting from them.

Patients may need many other psychosocial services. Case managers can help patients obtain:

- Housing support.
- Medicaid or other health insurance.
- Income support.
- Food assistance services.
- Vocational and educational services.
- Mental health and family therapy.

Refer to psychosocial services as appropriate. Get patient consent to share information and make provider introductions, just as referrals to other medical specialists would occur. Strategies include:

- Referring per program availability, affordability, and patients' needs, preferences, and treatment responses. Ensure referrals to programs that accept and support patients receiving OUD medication.
- If possible, personally introducing patients to the new behavioral health service providers or peer recovery support specialists if changing settings, to encourage a successful transition.
- Developing and maintaining a list of referral resources, including:
 - Drug and alcohol counselors.
 - Inpatient, residential, and outpatient addiction counseling programs.

- OTPs.
- Inpatient/outpatient behavioral health programs.
- Primary care and mental health providers.
- Community-based services.
- Recovery support groups.
- Using active referral procedures (e.g., linking patients directly via phone to a specific program staff member) instead of passive ones (e.g., giving a patient a name and a phone number to call).
- Avoiding leaving patients to fnd their own referrals.
- Monitoring patients' follow-through via phone contact or at the next office visit.

[Scroll down for exhibit]

EXHIBIT 3E.3. Key Elements of an OBOT Clinic Diversion Control Plan³⁸⁹

New Patients

Check the state's PDMP before admission to determine whether patients are receiving opioids or benzodiazepine prescriptions from other providers.

Ask patients to sign a release of information to speak with the other prescribers. Patients who are unwilling to sign a release of information are poor candidates for outpatient treatment.

Review the clinic diversion control policy with new patients. This should include counseling patients to:

- Keep buprenorphine locked up and out of children's reach.
- Never share medication with anyone.
- Never sell medication to anyone.
- Acknowledge giving or selling medication to others as illegal.
- Take medication only as prescribed.
- Review, understand, and agree to the practice's buprenorphine treatment agreement before they start.

Prescribe buprenorphine/naloxone when possible rather than monoproduct. Exceptions include prescribing the monoproduct for pregnant women with OUD.

Prescribe an adequate but not excessive dose. Most patients respond to doses at or below 24 mg per day. Carefully evaluate requests for higher doses and confirm, document, and assess medication adherence continuously.

Ongoing Patients

Periodically check the state's PDMP.

Conduct random urine tests that include a wide spectrum of opioids—including morphine, oxycodone, and buprenorphine—and periodically include buprenorphine metabolites. This will help monitor response to treatment and determine whether patients are taking at least some of their prescribed buprenorphine.

Use **unobserved** specimen collection to preserve patient privacy and dignity:

- Do not let patients bring backpacks, jackets, or other items into the bathroom.
- · Do not let others enter bathrooms with patients.
- · Temperature test the urine sample.

Use **observed** specimen collection (obtained by a staff member of the same gender) or oral fluid testing if there is reason to suspect tampering or falsification.

Contact patients at random; ask them to bring in their medication within a reasonable period (24 to 48 hours) to count the tablets/films to ensure that all medication is accounted for.

Provide a limited number of days of medication per prescription without refills (e.g., several days or I week per prescription) until the patient has demonstrated stability and lowered diversion risk.

Chapter 3F: Medical Management of Patients Taking OUD Medications in Hospital Settings

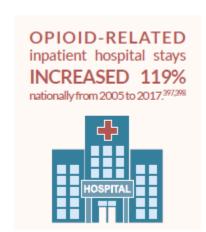
Patients with opioid use disorder (OUD) who present to emergency departments (EDs) or are admitted to hospitals for acute medical or psychiatric care can benefit from medication to treat OUD in the hospital setting. During acute medical illness, patients experiencing consequences of opioid use may be motivated to change. Hospital-based providers can take this opportunity to initiate long-term medication maintenance.

Unfortunately, less than one-quarter of patients with an opioid-related hospitalization are offered Food and Drug Administration-approved medication for OUD within 30 days of discharge. Patients who already take OUD medication may also present to the hospital. Thus, a broad understanding of how to manage their OUD medication during hospitalization is necessary.

The keys to effective patient management in general hospital settings are:

- Balancing medication for OUD with other medical concerns (e.g., surgery, pain manage- ment) during hospitalization.
- Careful management after discharge.
- Seamless transfer to opioid treatment via an opioid treatment program (OTP) or office- based opioid treatment (OBOT) provider after discharge.

Hospitalized or ED Patients Taking Medication for OUD



Buprenorphine, methadone, and naltrexone may be ordered in EDs or inpatient hospital units. It's essential for the patient to continue receiving OUD medication while hospitalized.

Pain Management

Pain management for hospitalized patients who take OUD medication is a key element of medical management.

Discuss pain management and engage in a shared

decision-making process with patients being treated for OUD with buprenorphine, methadone, or naltrexone.

Patients may have strong preferences and opinions about pain and use of opioid analgesics for pain treatment. Some patients may want to avoid opioid analgesics. For others, **inadequately treated pain may be a trigger for illicit drug use**. Involve primary care pain specialists and addiction treatment providers in discussing options for managing OUD medication and pain during patient hospitalization.

Buprenorphine

The hospital team will need to manage buprenorphine for patients who present to the ED or are hospitalized on buprenorphine maintenance. Physicians in inpatient settings can legally order buprenorphine without a waiver if a patient is admitted primarily for other medical reasons. Key medication management strategies include:

- Obtaining written consent to contact the patient's providers, including:
 - Primary care provider.
 - Buprenorphine prescriber.
 - Pharmacy.
- Confirming the patient's outpatient buprenorphine dose by:
 - Checking prescribing records.
 - Contacting the prescriber or pharmacy.
 - Examining recent prescription bottles.
 - Checking the prescription drug monitoring program database before administering buprenorphine.
- Providing the usual daily dose to the patient, once that dose is confrmed.
- Ensuring the patient's outpatient prescriber understands the reason for any missed visits.
- Informing the patient's outpatient prescriber that the patient may test positive for opioids if treated with opioid analgesics while in the hospital.
- Maintaining contact with the patient's prescriber, especially when a buprenorphine dose change is considered and in discharge planning.

Patients with pain may continue their buprenorphine while in the hospital. For mild-to-moderate pain, dividing the patient's usual buprenorphine dose three times per day

(TID) may provide sufficient pain relief. In some cases, increased buprenorphine dose may be appropriate. For moderate-to-severe pain, additional analgesia will be necessary. Two approaches to consider:

- 1. Continue buprenorphine treatment and use full agonist opioids for added pain relief. Because of the partial blockade caused by buprenorphine, higher-than-usual doses of opioids will probably be required for pain relief. Fentanyl, hydromorphone, and morphine have relatively high binding affnities for the muopioid receptor and are most likely to displace buprenorphine from receptors and provide improved analgesia. Once the painful condition has improved, if mild-to-moderate pain persists, bu- prenorphine can be divided TID to manage residual pain. This approach is usually successful and allows the patient to remain stable on buprenorphine.
- 2. Discontinue buprenorphine upon hospitalization and use full agonist opioids to treat pain and prevent withdrawal. This approach avoids the blockade effect of buprenorphine on the mu-opioid receptors but leaves the patient vulnerable to a return to illicit opioid use. It may be useful if the first approach does not achieve adequate pain control. Consider a consult by an addiction medicine, psychiatric, or pain management provider if appropriate and available.

Pregnant women on buprenorphine can continue buprenorphine through their labor. Labor pain for pregnant patients on buprenorphine can be managed effectively with epidural analgesia or intravenous opioids. Spinal anesthesia is effective in patients on buprenorphine; patients can receive general anesthesia if needed.

Perioperative pain management of patients on buprenorphine requires further study, but multiple approaches have been found effective. Most patients can continue buprenorphine through the operative period. Treat postoperative

pain with regional anesthesia, nonopioid pain management, or full agonist opioids. Remember that higher doses are likely to be necessary. Some data suggest that buprenorphine divided TID may even be as effective as morphine for postopera- tive pain control. Alternatively, buprenorphine can be discontinued 72 hours before a

planned surgery and restarted after resolution of acute postoperative pain. The risk of this approach is that it leaves the patient vulnerable to a return to use of illicit opioids.

Methadone

The hospital team will need to manage methadone for patients who present to the ED or are hospitalized on methadone maintenance treatment. This includes pregnant women. Generally, only physicians in OTPs can order methadone to treat OUD. However, physicians in an inpatient setting can legally order methadone administration to patients admitted primarily for other reasons.

Contact the patient's OTP directly to confrm the outpatient methadone dose, the last day of dose administration, and whether the patient was dispensed take-home doses (and how many doses) after the last dose administration at the OTP. This is to avoid double dosing and to avoid providing a full dose to a patient who hasn't been to the OTP for several days. Notify the OTP of the patient's admission and discharge so that OTP staff is aware of:

- The patient's upcoming missed visits.
- Medications received during hospitalization.
- Medications prescribed at discharge.

Patients in pain should receive their full usual daily dose of methadone, barring contraindi- cations. This is their baseline dose and should not be considered a dose for pain management.

They'll need pain medication in addition to their usual methadone dose. If their condition is painful enough to require opioids, prescribe short-acting opioids as scheduled, not asneeded, treatment. Because these patients are already opioid tolerant, they'll likely require higher doses of opioids than patients without tolerance. However, as with any patient, use nonopioid multimodal pain management when possible to minimize reliance on opioids and maximize pain control.

It is important to tell patients who receive take-home doses that they should not take their own medication while in the hospital. They will receive methadone from the treatment team. Patients can be asked to lock their take-home medications with their other valuables. It is also important to monitor these patients closely after the initial and subsequent methadone administration in the hospital. Some patients who receive take-home doses do not take their entire dose every day, so they may display signs of intoxication or frank overdose if the hospital staff gives them the full dose.

Naltrexone

Patients taking oral naltrexone for OUD treatment may continue naltrexone when admitted to the hospital if they do not have and are not at risk for developing a painful condition requiring opioid analgesia. Oral naltrexone provides full blockade of opioid receptors for up to 72 hours. Extended-release injectable naltrexone (XR-NTX) provides mea- surable naltrexone levels for 1 month or longer. Thus, managing acute pain in patients taking XR-NTX is complicated.

In patients who have taken naltrexone, manage severe pain intensively via nonopioid approach- es, such as regional anesthesia or injected non- steroidal anti-infammatory drugs. Naltrexone blockade can be overcome with very high doses of opioids, but patients must be closely monitored for respiratory depression in a setting with anesthesia services. This is especially true upon discontinuation of oral naltrexone, which dissociates from opioid receptors.

Hospitalized or ED Patients Not Taking Medication for OUD

Patients with OUD who present to the ED or are admitted to the hospital for an acute medical problem may benefit from initiating medications for OUD during their hospitalization. A thoughtful and respectful discussion of treatment options and patient-centered provision of medication can be a critical entry point into care. Research supports the

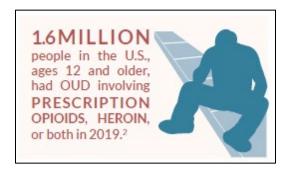
efficacy of initiating either buprenorphine or methadone during acute hospital stays and starting patients on buprenorphine in the ED.

Substance Abuse and Mental Health Services Administration

Part 4: Bringing Together Addiction Treatment Counselors, Clients, and Healthcare Professionals Overview and Context

Scope of the Problem

Opioid misuse has caused a growing nationwide epidemic of OUD and unintentional overdose deaths. This epidemic affects people in all regions, of all ages, and from all walks of life. Opioid misuse devastates families, burdens emergency



departments and first responders, fuels increases in hospital admissions, and strains criminal justice and child welfare systems.

Counselors can play an integral role in addressing this crisis. Counseling helps people with OUD and other substance use disorders (SUDs) change how they think, cope, react, and acquire the skills and confidence necessary for recovery. Counseling can provide support for people who take medication to treat their OUD. Patients may get counseling from prescribers or other staff members in the prescribers' practices or by referral to counselors at specialty addiction treatment programs or in private practice.

Counselors and peer recovery support specialists can work with patients who take OUD medication and refer patients with active OUD to healthcare professionals for an assessment for treatment with medication.

Part 4 uses "counselor" to refer to the range of professionals—including recovery coaches and other peer recovery support services specialists—who may counsel, coach, or mentor people who take OUD medication, although their titles, credentials, and range of responsibilities vary. At times, Part 4 refers to individuals as "clients." For

other key terms, see Exhibit 4.1. Part 5 of this TIP provides a full glossary and other resources related to the treatment of OUD.

- Counseling clients who take OUD medication requires understanding:
- Basic information about OUD.
- The role and function of OUD medications.
- Ways to create a supportive environment that helps clients work toward recovery.
- Counseling's role within a system of whole-person, recovery-oriented OUD care.

Key Terms

Addiction: As defined by the American Society of Addiction Medicine, "a primary, chronic disease of brain reward, motivation, memory, and related circuitry" (p. 1). It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Care provider: Encompasses both healthcare professionals and other professionals who do not provide medical services, such as counselors or providers of supportive services. Often shortened to "provider."

Healthcare professionals: Physicians, nurse practitioners, physician assistants, and other medical service professionals who are eligible to prescribe medications for and treat patients with OUD (i.e., until October 1, 2023, clinical nurse specialists, certifed registered nurse anesthetists, certifed nurse midwives). The term "prescribers" also refers to these healthcare professionals.

Maintenance treatment: Providing medications to achieve and sustain clinical remission of signs and symptoms of OUD and support the individual process of recovery without a specific endpoint (as is the typical standard of care in medical and psychiatric treatment of other chronic illnesses).

Mutual-help groups: Groups of people who work together on obtaining and maintaining recovery. Unlike peer support (e.g., the use of recovery coaches), mutual-help groups consist entirely of people who volunteer their time and typically have no official connection to treatment programs. Most are self- supporting. Although 12-Step groups such as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) are the most widespread and well-researched type of mutual-help groups, other groups may be available in some areas. They range from groups affliated with a religion (e.g., Celebrate Recovery, Millati Islami) to purely secular groups (e.g., SMART Recovery, Women for Sobriety).

Opioid misuse: The use of prescription opioids in any way other than as directed by a doctor; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.

Opioid receptor agonist: A substance that has an affnity for and stimulates physiological activity at cell receptors in the central nervous system (CNS) that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

Opioid receptor antagonist: A substance that has an affnity for opioid receptors in the CNS without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioids: All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).

Opioid treatment program (OTP): An accredited treatment program with Substance Abuse and Mental Health Services Administration (SAMHSA) certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement

of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, termed "opioid abuse" and "opioid dependence." An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period. (See Exhibit 2.13 and the Appendix in Part 2 for full DSM-5 diagnostic criteria for OUD.)

Peer support: The use of peer support specialists in recovery to provide nonclinical (i.e., not requiring training in diagnosis or treatment) recovery support services to individuals in recovery from addiction and to their families.

Peer support specialist: Someone in recovery who has lived experience in addiction plus skills learned in formal training. Peer support specialists may be paid professionals or volunteers. They are distinguished from members of mutual-help groups because they maintain contact with treatment staff. They offer experiential knowledge that treatment staff often lack.

Prescribers: Healthcare professionals who are eligible to prescribe medications for OUD.

Psychosocial support: Ancillary services to enhance a patient's overall functioning and well-being, including recovery support services, case management, housing, employment, and educational services.

Psychosocial treatment: Interventions that seek to enhance a patient's social and mental functioning, including addiction counseling, contingency management, and mental health services.

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Even individuals with severe and chronic SUDs can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.

Recovery capital: The sum of the internal (e.g., motivation, self-efficacy, spirituality) and external (e.g., access to health care, employment, family support) resources that an individual can draw upon to begin and sustain recovery from SUDs.

Recovery-oriented care: A service orientation that supports individuals with behavioral health conditions in a process of change through which they can improve their health and wellness, live self- directed lives, and strive to reach their full potential.

Relapse: A process in which a person with OUD who has been in remission experiences a return of symptoms or loss of remission. A relapse is different from a return to opioid use in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting. The TIP uses relapse to describe relapse prevention, a common treatment modality.

Remission: A medical term meaning a disappearance of signs and symptoms of the disease. DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving). Remission is an essential element of recovery.

Return to opioid use: One or more instances of opioid misuse without a return of symptoms of OUD. A return to opioid use may lead to relapse.

Setting the Stage

Since the 1990s, dramatic increases in controlled medication prescriptions—particularly opioid pain relievers—have coincided with increases in their misuse. Since the mid-2000s, heroin and fentanyl (mainly illicit formulations) consumption has also sharply increased. People who turn to illicit drugs after misusing opioid medications have driven greater use of heroin and fentanyl, which are cheaper and easier to obtain.

Approximately 1,500 OTPs currently dispense methadone, buprenorphine, or both. They may also offer naltrexone. Historically, OTPs were the only source of OUD medication and offered only methadone.

Buprenorphine is increasingly available in general medical settings. Physicians, nurse practitioners, and physician assistants (whether or not they're addiction specialists) can get a federal waiver to prescribe buprenorphine. These healthcare professionals can also prescribe and administer naltrexone, which does not require a waiver or OTP program certification. Until October 1, 2023, qualifed clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives also can obtain a waiver to prescribe and administer buprenorphine in office-based settings.

People with OUD should have access to the medication most appropriate for them. Medication helps establish and maintain OUD remission. By controlling withdrawal and cravings and blocking the euphoric effects of illicit opioids, OUD medication helps patients stop illicit opioid use and resolve OUD's psychosocial problems. For some people, OUD medication may be lifesaving. Ideally, patients with OUD should have access to all three FDA-approved pharmacotherapies. (See the "Quick Guide to Medications" section for an overview of each medication.)

Many patients taking OUD medication benefit from counseling as part of their treatment. Counseling helps people with OUD change how they think, cope, react, and acquire the skills and confidence needed for recovery. Patients may get counseling from medication prescribers or staff members in prescribers' practices or by referral to counselors at specialty addiction treatment programs or in private practice. Exhibit 4.2 discusses recommending versus requiring counseling as part of medication treatment for OUD.

*The counselor's role with clients who take OUD medication is the same as it is with all clients who have SUDs: Help them achieve recovery by addressing addiction's challenges and consequences.

<u>Distinguishing OUD From Physical Dependence on Opioid Medications</u>

According to DSM-5, OUD falls under the general category of SUDs and is marked by:

- Compulsion and craving.
- Tolerance.
- Loss of control.
- Withdrawal when use stops.
- Continued opioid use despite adverse consequences.

Properly taken, some medications cause tolerance and physical dependence. Medications for some chronic illnesses (e.g., steroids for systemic lupus erythematosus) can make the body build tolerance to the medications over time. If people abruptly stop taking medications on which they've become physically dependent, they can experience withdrawal symptoms. This can be serious, even fatal.

Physical dependence on a prescribed, properly taken opioid medication is distinct from OUD and opioid addiction. OUD is a behavioral disorder associated with loss of control of opioid use, use despite adverse consequences, reduction in functioning, and compulsion to use. The professionals who revised DSM-5 diagnostic criteria for OUD made several significant changes. Among the most notable was differentiating physical dependence from OUD:

- Tolerance or withdrawal symptoms related to FDA-approved medications appropriately prescribed and taken to treat OUD (buprenorphine, methadone) don't count toward diagnostic criteria for OUD.
- If the individual is being treated with an OUD medication and meets no OUD criteria other than tolerance, withdrawal, or craving (but did meet OUD criteria in the past), he or she is considered in remission on medication.

EXHIBIT 4.2. Recommending Versus Requiring Counseling

The TIP expert panel affirms that counseling and ancillary services greatly benefit many patients. However, such counseling and ancillary services should target patients' needs and shouldn't be arbitrarily required as a condition for receiving OUD medication (although they are required by regulations in OTPs), especially when the benefits of medication outweigh the risks of not receiving counseling.

The TIP expert panel recommends individualized treatment. Patients who choose to start medication and medication management with their prescriber without adjunctive counseling and don't adequately respond to such treatment should be referred to adjunctive counseling and more intensive services as needed.¹⁶

The law requires buprenorphine prescribers to be able to refer patients taking OUD medication to counseling and ancillary services. Buprenorphine prescribers may meet this requirement by keeping a list of referrals or by providing counseling themselves. The law doesn't require naltrexone prescribers to refer patients to additional services. However, FDA labels for both medications recommend counseling as part of treatment.

Some treatment environments require counseling by regulation or contractual obligation. In other cases, a healthcare professional may believe that a patient taking OUD medication would benefit from counseling. Some healthcare professionals may require counseling, particularly if patients aren't responding well to medication.

*OUD is often a chronic medical illness. Treatment isn't a cure.

Accepting this distinction is essential to working with clients taking OUD medication. One common question about patients taking medication for OUD is "Aren't they still addicted?" The new DSM-5 distinction makes the answer to this question "No, they're not still addicted." A person can require OUD medication and be physically dependent on it but still be in remission and recovery from OUD.

Understanding the Benefits of Medication for OUD

Medication is an effective treatment for OUD. People with OUD should be referred for an assessment for medication unless they decline. To be supportive and effective when counseling clients who could benefit from or who take medication for OUD, know that:

- Treatment with methadone and buprenorphine is associated with lower likelihood of overdose death compared with not taking these medications.
- Medication helps people reduce or stop opioid misuse. As Jessica's story in Exhibit 4.3 shows, even if people return to opioid use during treatment or don't achieve abstinence in the short term, medication lessens misuse and its health risks (e.g., overdose, injection-related infections).
- Patients taking FDA-approved medication used to treat OUD can join residential
 or outpatient treatment. Decades of clinical experience in OTPs, which must
 provide counseling, suggest that patients taking OUD medication can fully
 participate in group and individual counseling, both cognitively and emotionally.
 Patients with concurrent SUDs (involving stimulants or alcohol) can benefit from
 residential treatment while continuing to take their OUD medication.
- Randomized clinical trials indicate that OUD medication improves treatment retention and reduces illicit opioid use. Retention in treatment increases the opportunity to provide counseling and supportive services that can help patients stabilize their lives and maintain recovery.
- The longer patients take medication, the less likely they are to return to opioid use, whereas short-term medically supervised withdrawal rarely prevents return to use:
 - Conducting short-term medically supervised withdrawal may increase the risk of unintentional fatal overdose because of decreased tolerance after withdrawal completion.
 - Providing short-term medical treatment for OUD is the same as treating a heart attack without managing the underlying coronary disease.
 - Providing longer courses of medication that extend beyond withdrawal can allow patients to stabilize.
 - Getting stabilized, which may take months or even years, allows patients to focus on building and maintaining a healthy lifestyle.

 Patients taking OUD medication can achieve long-term recovery. People who continue to take medication can be in remission from OUD and live healthy, productive lives.

EXHIBIT 4.3. Jessica's Story About Medication

Jessica is a 32-year-old who unsuccessfully quit heroin dozens of times. She had been in and out of treatment but says, "It just never stuck. I'd always start using again when I left the program." Three years ago, her primary care doctor started prescribing her buprenorphine. Now Jessica says:



Some days I pinch myself. I can't believe I got my life back.

I tried quitting so many times but always got pulled back into the scene. Ever since I've been on buprenorphine, I haven't had any cravings. Even when I'm around triggers, they just don't set me off the same way. I've been able to get a job and I'm starting to build a community of friends who don't use. The hardest part about being on buprenorphine is that my emotions aren't masked anymore. I have to feel all of the sadness and fear that I was avoiding all these years. But it's good. I'm getting a chance to work through it."

Reviewing the Evidence on Counseling in Support of Medication To Treat OUD

Dedicated counseling can help clients address the challenges of extended recovery. For clients who seek a self-directed, purposeful life, counseling can help them:

- Improve problem-solving and interpersonal skills.
- Find incentives for reduced use and abstinence.
- Build a set of techniques to resist drug use.
- Replace drug use with constructive, rewarding activities.

Moreover, evidence shows that counseling can be a useful part of OUD treatment for people who take OUD medication. Impact studies of counseling for people with SUDs show that:

 Motivational enhancement/interviewing is generally beneficial. This approach helps get people into treatment. It also supports behavior change and, thus, recovery.

- Cognitive—behavioral therapy (CBT) has demonstrated efficacy in the treatment of SUDs, whether used alone or in combination with other strategies. Clinical trials have not shown that CBT added to buprenorphine treatment with medical management is associated with significantly lower rates of illicit opioid use. However, a secondary analysis of one of those trials found that CBT added to buprenorphine and medical management was associated with significantly greater reduction in any drug use among participants whose OUD was primarily linked to misuse of prescription opioids than among those whose OUD involved only heroin. Thus, CBT may be helpful to those patients receiving buprenorphine treatment who have nonopioid drug use problems.
- Case management helps establish the stability necessary for SUD remission.
 Case management helps some people in SUD treatment get or sustain access to services and necessities, such as:
 - Food.
 - Shelter.
 - Income support.
 - Legal aid.
 - Dental services.
 - Transportation.
 - Vocational services.
- Family therapy can address SUDs and various other family problems (e.g., family confict, unemployment, conduct disorders). Several forms of family therapy are effective with adolescents and can potentially address family members' biases about use of medication for OUD.
- There is more research on combined methadone treatment and various psychosocial treatments (e.g., different levels of counseling, contingency management) than on buprenorphine or naltrexone treatment in office-based settings. More research is needed to identify the best interventions to use with specific medications, populations, and treatment phases in outpatient settings.
- Motivational intervention, case management, or both can improve likelihood of entry into medication treatment for OUD among people who inject opioids,

- according to a systematic review of 13 studies plus data from a prior systematic review.
- Clinical trials have shown no differences in outcomes for buprenorphine with medical management between participants who get adjunctive counseling and those who don't (i.e., prescriber-provided guidance focused specifically on use of the medication).

RESOURCE ALERT

Principles of Effective Treatment

In its Principles of Drug Addiction Treatment, the National Institute on Drug Abuse lists 13 principles of effective treatment (p. 2). Two principles that pertain to counseling are:

- "No single treatment is effective for everyone.
 Treatment varies depending on the type of drug and the characteristics of the patients. Matching treatment settings, interventions, and services to an individual's particular problems and needs is critical to his or her ultimate success
- in returning to productive functioning in the family, workplace, and society."
- "Effective treatment attends to multiple needs
 of the individual, not just his or her drug
 abuse. To be effective, treatment must address
 the individual's drug abuse and any associated
 medical, psychological, social, vocational,
 and legal problems. It is also important that
 treatment be appropriate to the individual's
 age, gender, ethnicity, and culture."

Yet those trials:

- Relied on well-structured medical management sessions that may not be typical in practice.
- Excluded patients with certain co-occurring disorders or factors that complicated treatment.

Benefits from counseling may depend on factors such as the number of sessions and adherence.

Using a Recovery-Oriented Approach to Treating Patients With OUD

Counseling for OUD gives patients tools to manage their illness, achieve and sustain better health, and improve their quality of life. There are limits to how much medication alone can accomplish. OUD medication will improve quality of life, but many clients in addiction treatment have complex issues that may decrease quality of life, such as:

- Other SUDs (e.g., alcohol use disorder, cannabis use disorder).
- Mental distress (i.e., high levels of symptoms) and disorders (e.g., major
- Depressive disorder, posttraumatic stress disorder).
- Medical problems (e.g., hepatitis, diabetes).
- History of trauma.
- Poor diet, lack of physical activity, or both.
- Lack of social support.
- Unemployment.

Acknowledge many pathways to recovery

Recovery occurs via many pathways. OUD medication may play a role in the beginning, middle, or entire continuum of care.

Support clients in making their own informed decisions about treatment. Counselors don't need to agree with clients' decisions but must respect them. Educate new clients about:

- Addiction as a chronic disease influenced by genetics and environment.
- How medications for OUD work.
- What occurs during dose stabilization.
- The Benefits of longer-term medication use and the risks of abruptly ending treatment.

SAMHSA'S GUIDING PRINCIPLES OF RECOVERY

Recovery emerges from hope.

- Recovery is person driven.
- Recovery occurs via many pathways.
- Recovery is holistic.
- Recovery is supported by peers and allies.
- Recovery is supported through relationships and social networks.
- Recovery is culturally based and infuenced.
- Recovery is supported by addressing trauma.
- Recovery involves individual, family, and community strengths and responsibilities.
- Recovery is based on respect.

Promote recovery for clients with OUD. Focus on addressing personal and practical problems of greatest concern to clients, which can improve their engagement in treatment. Recovery supports can sustain the progress clients made in treatment and further improve their quality of life. Addressing the full range of client needs can improve clients' quality of life and lead to better long-term recovery outcomes. A recovery-oriented approach to traditional SUD counseling may help address client needs.

Increasing recovery capital supports long-term abstinence and improved quality of life, especially for clients who decide to stop medication. Clients with substantial periods of abstinence from illicit drugs identify these strategies for increasing recovery capital as helpful:

- Forging new relationships with friends/family
- Obtaining support from friends, family, partners, and communities
- Using positive coping strategies
- Finding meaning or a sense of purpose in life
- Engaging in a church or in spiritual practices
- Pursuing education, employment, or both
- Engaging in new interests or activities (e.g., joining a community group, exercising)
- Building confidence in ability to maintain abstinence (i.e., increasing abstinencerelated self-efficacy)

Finding ways to help other individuals who are new to recovery

Help clients further grow recovery capital by offering or connecting them to a range of services, such as:

- Ancillary services (e.g., vocational rehabilitation, supported housing).
- Additional counseling.
- Medical services.
- Mental health services.

Provide person-centered care

Clients' confidence in their ability to stay away from illicit substances, or self-efficacy, is an important factor in successful change. In person-centered care, also known as patient- centered care:

- Clients control the amount, duration, and scope of services they receive.
- They select the professionals they work with.
- Care is holistic; it respects and responds to clients' cultural, linguistic, and socioenviron- mental needs.
- Providers implement services that recognize patients as equal partners in planning, devel- oping, and monitoring care to ensure that it meets each patient's unique needs.

*The confrontational/expert model that characterized much of SUD treatment in the past may harm some patients and inhibit or prevent recovery

A person-centered approach to OUD treatment empowers clients in making decisions, such as:

- Whether to take OUD medication.
- Which medication to take.

Which counseling and ancillary services to receive.

Fragmented healthcare services are less likely to meet the full range of patients' needs. Integrated medical and behavioral healthcare delivery provides patient-focused, comprehensive treatment that meets the wide range of symptoms and service needs that patients with OUD may have. Significant demand remains for better integrated and coordinated SUD treatment (including OTP), medical, and mental health services. Such improvements are particularly important for the many individuals with co-occurring substance use and mental disorders who receive OUD medication. In a randomized trial of methadone patients with co-occurring mental disorders receiving onsite versus offsite mental health services, those receiving services onsite had less psychiatric distress at follow-up.

Promote family and social support

Support from family and friends can be the most important factor in long-term recovery, according to many people who have achieved long-term recovery from OUD. Support from intimate partners helps all clients, especially women, avoid return to opioid use. But the more people in clients' social networks who use drugs, the more likely clients are to return to use.

Most clients are willing to invite a substance- free family member or friend to support their recovery. Most have at least one nearby family member who does not use illicit drugs. A client's community may provide a cultural context for their recovery and culturally specific supports that may not otherwise be available in treatment.

Help clients develop and support positive relations with their families by:

- Suggesting that clients invite family and friends to aid in the recovery planning process (Exhibit 4.4).
- Emphasizing the importance of relationships with family and friends who actively support recovery.
- Supporting clients in mending broken relationships with loved ones.

- Helping clients cut ties with individuals who still use drugs or enable clients' drug
 use.
- Encouraging clients to build new relationships that support recovery.

EXHIBIT 4.4. Engaging Reluctant Family Members in a Client's Treatment

If the client agrees and has signed the appropriate releases, help even reluctant family members engage in the client's treatment to offer support. To reach out to family members who hesitate to engage, try to:

- Recognize that they have been harmed by their family member's substance use and that their participation in his or her recovery can help them heal too.
- Ask them to recall some positive experiences they have had with the client.
- Introduce them to mutual-help groups and other supports for families (e.g., Nar-Anon, Learn to Cope, Parents of Addicted Loved Ones Group).
 Ensure that suggested groups don't have a negative option medication bias.
- Help them understand OUD, the treatment process, and medication's role in recovery.
 This knowledge can keep family members from pressuring the client to taper medication prematurely.
- Hold multifamily therapy groups or informal discussion sessions for families (with or without clients present) so that family members can learn from one another and share their experiences.
- Offer family or couples therapy as an option for additional support.

Provide trauma-informed care

Trauma-informed service requires providers to realize the significance of trauma.

According to SAMHSA, trauma-informed counselors know what trauma is and also:

- Understand how trauma can affect clients, families, and communities.
- Apply knowledge of trauma extensively and consistently in both practice and policy.
- Know ways to promote recovery from trauma.
- Recognize the signs and symptoms of trauma in clients, families, staff members, and others.
- Resist things that may retraumatize or harm clients or staff.

Incorporate trauma-informed principles of care into recovery promotion efforts, because:

- Trauma histories and trauma-related disorders may increase clients' risk for various problems, including early drop-out from treatment and greater problems with pain.
- Childhood trauma is highly prevalent among people with OUD.
- People often suffer multiple traumas during opioid misuse.
- An intervention that integrated trauma treatment and standard care (which goes further than the trauma-informed care detailed here) had better outcomes than standard care alone in a diverse group of women treated in various settings, including an OTP.

Quick Guide to Medications

This section introduces the neurochemistry and biology of OUD and the medications that treat it. Reading this section will familiarize counselors with terminology healthcare professionals may use in discussing patients who take OUD medication (see also Exhibit 4.1 and the comprehensive glossary in Part 5).

Understanding the Neurobiology of OUD Opioid receptors are a part of the body's patural endorphin system. Endorphins are chemicals our bodies release to help reduce our experience of pain. They can also contribute to euphoric feelings like the "runner's high" that some people experience. When endorphins or opioids bind to opioid receptors, the receptors activate, causing a variety of effects.

After taking opioids, molecules bind to and activate the brain's opioid receptors and release dopamine in a brain area called the nucleus accumbens (NAc), causing euphoria. Like opioid receptors, the NAc has a natural, healthy function. For example, when a person eats, the NAc releases dopamine to reinforce this essential behavior. The NAc is a key part of the brain's reward system.

opioid use leads to an above-normal release of dopamine, essentially swamping the natural reward pathway and turning the brain strongly toward continued use. The brain also learns environmental cues associated with this dopamine release. It associates specific people, places, and things (e.g., music, drug paraphernalia) with the euphoria; these environmental cues then become triggers for drug use.

Intermittent opioid use causes periods of euphoria followed by periods of withdrawal. The brain's strong draw toward euphoria drives repeated and continued use. Few people with OUD reexperience the euphoria they obtained early in their opioid use, yet they continue to seek it.

Changes in brain function that result from repeated drug use cause a person who once took the drug for euphoria to seek it out of habit, then compulsion. People with OUD use opioids to stave off withdrawal. Without opioids, the person feels dysphoric and physically ill, only feeling normal by taking opioids again. At the same time, other areas of the brain begin to change:

- The amygdala, which is associated with feelings of danger, fear, and anger, becomes overactive.
- The frontal cortex, which is associated with planning and self-control, becomes underactive.
- The ability to control impulses diminishes, and drug use becomes compulsive.
- The need to escape the discomfort and intensely negative emotional states of withdrawal becomes the driving force of continued use.

Even after opioid use stops, brain changes linger. A person's ability to make plans and manage impulses stays underactive. That's why return to substance use is very common even after a period of abstinence.

Medications for OUD promote emotional, psychological, and behavioral stabilization. By acting directly on the same opioid receptors as misused opioids (but in different ways), medications can stabilize abnormal brain activity.

Learning How OUD Medications Work

The following sections describe how each of the OUD medications functions (Exhibit 4.5; see also Part 3 of this TIP for greater detail). Discuss questions or concerns about

a patient's medication, side effects, or dosage with the patient's prescriber after getting the patient's consent.

EXHIBIT 4.5. FDA-Approved Medications Used To Treat OUD: Key Poin	EXHIBIT 4.5	. FDA-Approved	Medications Use	d To Treat OUD: Ke	y Points
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MEDICATION	HOW IT'S TAKEN	WHY IT WORKS	SIDE EFFECTS	NOTES
Buprenorphine	Tablet dissolved under the tongue or film dissolved under the tongue or against the inside of the cheek. Taken once daily, every other day, or 3 times a week. It also comes as an implant that lasts 6 months or as an injection that lasts 1 month.	Partially activates the opioid receptor. Reduces craving and blocks the euphoric effect of opioids.	Can cause constipation, headache, nausea, insomnia, excessive sweating, or opioid withdrawal. Overdose is possible but less likely than with methadone. Overdose death risk is increased if buprenorphine is taken with alcohol or intravenously in combination with benzodiazepines or other CNS depressants. Neonatal abstinence syndrome (NAS)	Less sedating than methadone. Prescribers must have a special SAMHSA waiver but don't need to be part of a federally certified OTP. Can be prescribed through pharmacies or provided via OTPs. The implant and injection can only be prescribed by waivered providers who have completed REMS training.
Methadone	Liquid or tablet once daily. Dose may be divided for twice- daily dosing if medically necessary.	Fully activates the opioid receptor. Reduces craving and blocks the euphoric effect of opioids.	Can cause constipation, sleepiness, sweating, swelling of hands and feet, sexual dysfunction, heart arrhythmias, low blood pressure, fainting, and substance misuse. Can cause overdose death if increased too rapidly, taken in a much higher than usual dose, or taken concurrently with some substances and medications, particularly CNS depressants such as alcohol or benzodiazepines. NAS	Initially requires visits 6 to 7 times per week to an OTP. Patients can decrease attendance gradually based on time in treatment and clinical stability
Naltrexone	Daily tablet (can also be taken 3 times a week) or monthly injection in buttock.	Occupies the opioid receptors. Reduces craving and blocks the euphoric effect of opioids.	Can cause nausea, headache, dizziness, fatigue, liver toxicity, depression and suicidality, muscle cramps, fainting, and loss of or decreased appetite or other appetite disorders; in the extended-release injectable formulation, can cause pain, swelling, and other complications at the injection site. Patient must complete withdrawal and stay opioid abstinent for at least 7 days before starting naltrexone and longer (e.g., 10 or more days) for long-acting opioids, such as methadone.	Tablets are rarely effective. Monthly injections are more effective than tablets.

Buprenorphine

Buprenorphine reduces opioid misuse, HIV risk behaviors, and risk of overdose death. Buprenorphine only partially activates opioid receptors; it is a partial agonist. It binds to and activates receptors suffciently to prevent craving and withdrawal and to block the effects of illicit opioids. Appropriate doses of buprenorphine shouldn't make patients feel euphoric, sleepy, or foggy headed.

Buprenorphine has the benefit of a ceiling effect. Its effectiveness and sedation or respiratory effects don't increase after a certain dosing level, even if more is taken. This lowers risk of overdose and misuse. Groups at particular risk for buprenorphine overdose include children who accidentally ingest the medication and patients who also use CNS depressants like benzodiazepines or alcohol. (See Part 3 of this TIP for more information on concurrent use of CNS depressants and buprenorphine.)

Buprenorphine is available outside of OTPs, through non-OTP healthcare settings (e.g., physicians' offices, outpatient drug treatment programs). Healthcare professionals (including nurse practitioners and physician assistants, per the Comprehensive Addiction and Recovery Act of 2016, and, until October 1, 2023, qualifed clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives, per the SUPPORT for Patients and Communities Act of 2018) can prescribe it outside of an OTP, provided they have a specifc federal waiver. This is often referred to as "being waivered" to prescribe buprenorphine.

Buprenorphine can cause opioid withdrawal in patients who have recently taken a full opioid agonist (e.g., heroin, oxycodone). This occurs because buprenorphine pushes the full opioid activator molecules off the receptors and replaces them with its weaker, partially activating effect. For this reason, patients must be in opioid withdrawal when they take their first dose of buprenorphine.

The most common buprenorphine formulation contains naloxone to reduce misuse. Naloxone is an opioid antagonist. It blocks rather than activates receptors and lets no opioids sit on receptors to activate them. Naloxone is poorly absorbed under the

tongue/against the cheek, so when taking the combined medication as directed, it has no effect. If injected, naloxone causes sudden opioid withdrawal.

Buprenorphine comes in two forms that melt on the inside of the cheek or under the tongue: flms (combined with naloxone) or tablets (buprenorphine/naloxone or buprenorphine alone). For treatment of OUD, patients take the flms or tablets once daily, every other day, or three times a week. Various companies manufacture these forms of the medication. Some are brand name, and some are generic. The different kinds vary in strength or number of milligrams, but they have been designed and tested to provide roughly the same amount of medication as the first approved product.

Buprenorphine is also available in a long-acting implant and long-acting injection that specially trained healthcare professionals place under the skin (subdermal implant) and an extended-release formulation that is administered under the skin (subcutaneous injection). The implant is appropriate for patients who have been stable on low doses of the flms or tablets. It lasts for 6 months and can be replaced once after 6 months. The extended release injection lasts for 1 month and can be repeated monthly. It is appropriate for patients who have been stabilized on the flms or tablets for at least 7 days.

Healthcare professionals with waivers can prescribe buprenorphine. Physicians who take an 8-hour training and get a waiver can prescribe buprenorphine. Nurse practitioners and physician assistants are eligible to apply for waivers after 24 hours of training. Until October 1, 2023, clinical nurse specialists, certifed registered nurse anesthetists, and certifed nurse midwives also are eligible to apply for waivers after 24 hours of training. Recent buprenorphine practice guidelines provide an exemption to providers who are state licensed, possess a valid DEA registration, and wish to treat no more than 30 patients with buprenorphine. The "traditional" pathway of obtaining a waiver by undergoing the 8-hour training still exists and is required for providers who wish to treat more than 30 patients. Providers who wish to deliver buprenorphine implants must receive special training on how to insert and remove them.

Buprenorphine can cause side effects including constipation, headache, nausea, and insomnia. These often improve over time and can be managed with dosage adjustments or other approaches.

Methadone

Methadone is highly effective. Many studies over decades of research show that it:

- Increases treatment retention.
- Reduces opioid misuse.
- Reduces drug-related HIV risk behavior.
- Lowers risk of overdose death.

Methadone is slow in onset and long acting, avoiding the highs and lows of short-acting opioids. It is a full agonist. Patients who take the same appropriate dose of methadone daily as prescribed will neither feel euphoric from the medication nor experience opioid withdrawal.

Methadone is an oral medication that is taken daily under observation by a nurse or pharmacist and under the supervision of an OTP physician. Methadone is available as a liquid concentrate, a tablet, or an oral solution made from a dispersible tablet or powder.

Methadone blunts or blocks the euphoric effects of illicit opioids because it occupies the opioid receptors. This "opioid blockade" helps patients stop taking illicit opioids because they no longer feel euphoric if they use illicit opioids. When on a proper dose of methadone, patients can:

- Keep regular schedules.
- Lead productive, healthy lives.
- Meet obligations (family, social, work).

Methadone can lead to overdose death in people who use a dose that's considerably higher than usual, as methadone is a full agonist. People who don't usually take opioids or have abstained from them for a while could overdose on a fairly small

amount of methadone. Thus, patients start on low doses of methadone and gradually adjust upward to identify the optimal maintenance dose level.

Patients must attend a clinic for dose administration 6 to 7 days per week during the start of treatment. Healthcare professionals can thus observe patients' response to medication and discourage diversion to others. Visit frequency can lessen after patients spend time in treatment and show evidence of progress.

Methadone can cause certain side effects. Common potential side effects of methadone include:

- Constipation.
- Sleepiness.
- Sweating.
- Sexual dysfunction.
- Swelling of the hands and feet.

Sleepiness can be a warning sign of potential overdose. Patients who are drowsy should receive prompt medical assessment to determine the cause and appropriate steps to take—which may require a reduction in methadone dose. Some patients may appear sleepy or have trouble staying awake when idle, even if there is no immediate danger of evolving overdose. These patients may need a lower dose or may be taking other prescribed or nonprescribed medications (e.g., benzodiazepines, clonidine) that are interacting with the methadone.

Naltrexone

Naltrexone stops opioids from reaching and activating receptors, preventing any reward from use. Naltrexone is an antagonist of the opioid receptors—it does not activate them at all. Instead, it sits on the receptors and blocks other opioids from activating them. Naltrexone appears to reduce opioid craving but not opioid withdrawal (unlike buprenorphine and methadone, which reduce both craving and withdrawal). Someone starting naltrexone must be abstinent from short-acting opioids for at least 7 days and from long-acting opioids for 10 to 14 days before taking the first dose. Otherwise, it will

cause opioid withdrawal, which can be more severe than that caused by reducing or stopping opioid use.

Naltrexone comes in two forms: tablet and injection.

- Patients take oral naltrexone as tablets daily or three times per week. Tablets are rarely effective, as patients typically stop taking them after a short time.
- Highly externally monitored populations in remission may do well with the tablet, such as physicians who have mandatory frequent urine drug testing and are at risk of losing their licenses.
- The injected form is more effective than the tablet because it lasts for 1 month.
 Patients can come to a clinic to receive an intramuscu- lar injection in their buttock.

Naltrexone can produce certain side effects, which may include:

- Nausea.
- Headache.
- Dizziness.
- Fatigue.

For the extended-release injectable formulation, potential reactions at the injection site include:

- Pain.
- Bumps.
- Blistering.
- Skin lesions (may require surgery).

The following sections will help explain the role healthcare professionals play in providing each OUD medication as part of collaborative care. Part 3 of this TIP offers more detailed clinical information.

Administer buprenorphine

their first dose in the prescriber's office so the prescriber can observe its initial effects. Increasingly often, patients take their first dose at home and follow up with prescribers by phone. Most people are stable on buprenorphine dosages between 8 mg and 24 mg each day.

Patients who take buprenorphine visit their prescriber regularly to allow monitoring of their response to treatment and side effects and to receive supportive counseling. The visits may result in specifc actions, such as adjusting the dosage or making a referral for psychosocial services. Stable patients may obtain up to a 30-day prescription of this medication through community pharmacies. Visits may include urine drug testing. Early in treatment, patients typically see their prescribers at least weekly. Further along, they may visit prescribers every 1 to 2 weeks and then as infrequently as once a month or less.

The prescriber will make dosage adjustments as needed, reducing for side effects or increasing for unrelieved withdrawal or ongoing opioid misuse. OTPs that provide buprenorphine will typically follow a similar process, with the principal difference being that the program will administer or dispense the medication rather than the patient flling a prescription at a pharmacy.

Administer methadone

Only SAMHSA-certifed OTPs may provide methadone by physician order for daily observed administration onsite or for self- administration at home by stable patients. The physician will start patients on a low dose of methadone. People in early methadone treatment are required by federal regulation to visit the OTP six to seven times per week to take their medication under observation. The physician will monitor

patients' initial response to the methadone and slowly increase the dose until withdrawal is completely relieved for 24 hours.

A prescriber can't predict at the start of treatment what daily methadone dose will work for a patient. An effective dose is one that eliminates withdrawal symptoms and most craving and blunts euphoria from self- administered illicit opioids without producing sedation. On average, higher dosages of methadone (60 mg to 100 mg daily) are associated with better outcomes than lower dosages. That said, an effective dose of methadone for a particular patient can be above or below that range.

The prescriber will continue to monitor the patient and adjust dosage slowly up or down to find the optimum dose level. The dose may need further adjustment if the patient returns to opioid use, experiences side effects such as sedation, starts new medications that may interact with methadone, or has a change in health that causes the previously effective dose to become inadequate or too strong.

If patients taking methadone drink heavily or take sedatives (e.g., benzodiazepines), physicians may:

- Treat the alcohol misuse.
- Refer to a higher level of care.
- Address comorbid anxiety or depression.
- Decrease dosage to prevent overdose.
- Administer naltrexone

To avoid severe withdrawal, prescribers will ensure that patients are abstinent from opioids at least 7 to 10 days before initiating or resuming naltrexone. Prescribers may require longer periods of abstinence for patients tran- sitioning from buprenorphine or methadone to naltrexone.

Prescribers typically take urine drug screens to confrm abstinence before giving naltrexone. Healthcare professionals can confrm abstinence through a "challenge test" with naloxone, a short-acting opioid antagonist. Healthcare professionals manage withdrawal symptoms with nonopioid medication. Prescribers are prepared to handle withdrawal caused by naltrexone despite a period of abstinence. Ideally, they administer the first injection before patients' release from residential treatment or other controlled settings (e.g., prison) so qualifed individuals can monitor them for symptoms of withdrawal.

Healthcare professionals typically see patients at least monthly to give XR-NTX injections. For those taking oral naltrexone, prescribers schedule visits at their discretion. Thus, urine drug testing may be less frequent for these patients than for patients taking buprenorphine. But periodic drug testing should occur.

There is only one dose level for injected naltrexone, so prescribers cannot adjust the dose. However, they can slightly shorten the dosing interval if the medication's effectiveness decreases toward the end of the monthly dosing interval. If the patient is having side effects or intense cravings, the prescriber may recommend switching to a different medication.

Set expectations

Ideally, prescribers will collaborate with counselors and other care providers involved in patients' care to set reasonable patient expectations. Medications can effectively treat OUD, but they don't treat other SUDs (save naltrexone, also FDA-approved to treat alcohol use disorder). Patients may still need:

- Counseling for psychosocial issues.
- Social supports/treatment to get back on track.
- Medications, therapy, or both for co-occurring conditions.

Collaboration between all involved healthcare providers helps patients understand the OUD treatment timeline, which generally lasts months or years. Courses of medically supervised withdrawal or tapering are considerably less effective than longer term maintenance treatment with buprenorphine or methadone and are often associated with return to substance use and a heightened risk of overdose.

*Patients may still benefit from the counseling you can offer in addition to care from other providers, even if you can't communicate with those providers directly.

Counselor-Prescriber Communications

OUD medication can support counselors' work with clients who have OUD, and counseling supports the work prescribers do with them.

Good communication facilitates mutually supportive work (Exhibit 4.6). A counselor will probably:

- See patients more frequently than prescribers.
- Have a more complete sense of patients' issues.
- Offer providers valuable context and perspective.
- Help patients take medications appropriately.
- Ensure that patients receive high-quality care from their other providers.

Obtaining Consent

Get written consent from patients allowing communication directly with their providers (unless the counselor and the providers work in the same treatment program). The consent must explicitly state that the patient allows the counselor to discuss substance-use-related issues. It should also specify which kinds of information the counselor can share (e.g., medical records, diagnoses). Consent forms must comply with federal and state confidentiality laws that govern the sharing of information about patients with SUDs.

Carefully protect any identifying information about patients and their medical and treatment information. Don't send such information through unsecured channels, such as:

- Text messaging.
- Unsecure, unencrypted emails.
- Faxes to unsecured machines.

Phone calls are the most secure way to discuss patient cases, although it may be more convenient to reach out to healthcare professionals first through email.

Counselor:	Dr. Smith, thank you for referring Jeff to my counseling practice. I'd like to review with you the elements of the treatment plan we've developed.	
Prescriber:	That would be really helpful.	
Counselor:	We agreed to meet weekly while he's getting stabilized on the buprenorphine. The initial focus of our sessions will be helping Jeff expand his recovery support network.	
Prescriber:	I'm glad to hear that you're following up on that. My nurse reported that he's alone in t waiting room before his appointments, and he also mentioned to me that he doesn't have anybody to talk with.	
Counselor:	I suggested a support group for people taking buprenorphine that's in his neighborhood. We've also begun talking about recreational activities that can help him fill the time he used to spend with drug-using friends.	
Prescriber:	I'll reinforce your suggestions when he comes in this Friday.	
Counselor:	Also, he seems confused about where the film goes in his mouth. I urged him to discuss that with you.	
Prescriber:	I'll make a note to go over that with him again on Friday.	

Structuring Communications With Prescribers

Regular, structured communication can improve the flow of information between treatment teams. Some multidisciplinary programs produce regular reports for prescribers about patient progress. Exhibit 4.7 provides some strategies for discussing patient care with healthcare professionals.

EXHIBIT 4.7. Tips for Discussing Patient Care With Prescribers

- Identify the patient. Once the counselor has established secure communication through encrypted email or by phone, he or she should state the patient's name, date of birth, and medical record number (if obtained).
- Let prescribers know up front the purpose of the call. Begin by clearly describing the question or concern leading to the call. If it is simply to establish contact because of a shared patient, that's fine.
- Share any relevant information about the patient (if the patient has consented). If there is a concern
 about a side effect, for example, describe observed changes to the healthcare professional. If there is a
 concern about return to opioid use, describe which elements of the patient's behavior are worrisome.
- Work together to build a shared understanding of the patient's situation. The counselor likely has key
 information about the patient that the prescriber does not have, and vice versa.
- Discuss next steps with the healthcare provider before ending any communication to help coordinate
 patient care. Consider scheduling a check-in with each other to assess patient progress.

Helping Clients Overcome Challenges in Accessing Resources

By collaborating with healthcare professionals in OUD care, counselors can help clients overcome challenges they face in obtaining treatment, such as:

- Ability to pay for OUD medication. Counselors are often already skilled in helping
 clients address treatment costs (e.g., facilitating Medicaid applications, linking
 them to insurance navigators). Try to refer clients who face diffculty meeting
 prescription costs or copays back to the agency's financial department for sliding
 scale adjustments and ability-to-pay assessments. Also try to help patients fnd
 and apply for relevant pharmaceutical company medication prescription plans.
- Transportation. Options to offer clients may include:
 - Providing vouchers for public transportation.
 - Providing information on other subsidized transportation options.
 - Linking clients to peer support specialists and case managers who can arrange transportation.
 - Assisting eligible clients in navigating Medicaid to obtain transportation services.
 - If available, arranging for telehealth services to overcome clients' transportation barriers.
- Access to medication in disaster situations. Counselors can review options with
 patients for obtaining prescription replacements and refills or daily medicine dosing
 under various scenarios. This could include if their usual clinic or primary pharmacy
 is closed or if they're relocated without notice because of an unforeseen emergency.
 Also advise patients on the items to take with them in such scenarios to facilitate
 refills from a new medication-dispensing facility.

Key materials include:

Photo identification.

- Medication containers of currently pre- scribed medications (even if empty).
- Written prescriptions.
- Packaging labels that contain dosage, prescriber, and refll information.
- Any payment receipts that contain medication information.

To overcome systemic barriers, help enact collaborative policies and procedures. Work with program management and the community at large to address the following issues:

- Connection to treatment: Counselors may be able to participate in community
 efforts to ensure that information on how to obtain treatment for OUD is available
 wherever people with OUD:
 - Gather (e.g., all-night diners, bars, free health clinics, injection equipment exchanges).
 - Seek help (e.g., emergency departments, houses of worship, social service agencies).
 - Reveal a need for help (e.g., encounters with law enforcement and child welfare agencies).

Encourage buprenorphine prescribers to make known their availability if they are prepared to accept new patients. Help disseminate lists of addiction treatment providers and share their information via peer recovery specialists (see Part 5).

Rapid assessment and treatment initiation: Try to help OUD medication providers, partic- ularly in OTPs, streamline counseling intake processes to help patients receive medication efficiently. The expert panel of this TIP recognizes that same-day admission of patients with OUD may not be possible in all settings, but it's a worthwhile goal. Every program should streamline its intake processes and expedite admissions.

Return to treatment: When patients discontinue treatment prematurely and return to use of opioids, it can be hard for them to reengage in treatment because of the shame they feel or because there is a waiting list for admission. The waitlist problem may not be

solvable because of capacity limitations, but all collaborative care team members—including counselors and prescribers—should:

- Inform patients from intake onward that the program will readmit them even if they drop out.
- Encourage patients to seek readmission if they return to opioid use or feel that they are at risk for returning to opioid use.
- Inform patients of the importance of overdose prevention (see the "Counseling Patients on Overdose Prevention and Treatment" section).
- Provide continued monitoring if possible; it can range from informal quarterly check-ins to regularly scheduled remote counseling or peer support (e.g., from a recovery coach).
- Offer an expedited reentry process to encourage patients to return if they need to.
- Engage in active outreach and reengagement with OTP patients, which can be effective. Try to contact patients who have dropped out to encourage them to return.

<u>Creation of a Supportive Counseling Experience</u>

Maintaining the Therapeutic Alliance The therapeutic alliance is a counselor's most powerful tool for influencing outcomes. It underlies all types and modalities of therapy and helping services. A strong alliance welcomes patients into treatment and creates a sense of safety.

COUNSELING PATIENTS WITH OUD WHO DON'T TAKE MEDICATION

Patients who don't take an OUD medication after withdrawal are at high risk of return to opioid use, which can be fatal given the loss of opioid tolerance. Provide these patients with overdose prevention education and the overdose-reversal medication naloxone, or educate them about naloxone and how they can obtain it in their community. Advise

them to report a return to opioid use or a feeling that they are at risk of relapsing. Work with them and their care team to either resume medication for OUD or enter a more intensive level of behavioral care.

Certain counselor skills help build and maintain a therapeutic alliance, including:

- Projecting empathy and warmth.
- Making patients feel respected and understood.
- Not allowing personal opinions, anecdotes, or feelings to infuence the counseling process (unless done deliberately and with therapeutic intention).

These skills are relevant for working with all patients, including those taking medication for OUD. Apply them consistently from the very first interaction with a patient through the conclusion of services. For example, recognize and reconcile personal views about medication for OUD so that they don't infuence counseling sessions.

Educating Patients About OUD and a Chronic Care Approach to Its Treatment

- Help ensure that patients understand the chronic care approach to OUD and their:
- Diagnosis.
- Prognosis.
- Treatment options.
- Available recovery supports.
- Prescribed medications.
- Risk of overdose (and strategies to reduce it).

Seek to understand patients' preferences and goals. Doing so can help convey information meaningfully so patients understand the choices available to them. Also, help communicate patients' preferences and goals to healthcare professionals and family members.

Educate colleagues and other staff members so they can help create a supportive experience for patients with OUD:

- Provide basic education to colleagues about medications for OUD and how they work.
- Share evidence on how these medications reduce risky behavior, improve outcomes, and save lives.
- Note that major U.S. and international guidelines affirm use of medication to treat OUD.
- Ask about and address specifc fears and concerns.
- Provide resources for additional information.

Counseling Patients on Overdose Prevention and Treatment

Know how to use naloxone to treat opioid overdose; share this information with patients and their family members and friends. Available by prescription (or without a prescription in some states), naloxone is an opioid antagonist that has successfully reversed many thousands of opioid overdoses. It comes in auto-injector and nasal spray formulations easy for laypeople to administer immediately on the scene of an overdose, before emergency responders arrive.

Ask patients if they have a naloxone prescription or help them get it without one if possible. Providers may prescribe naloxone in addition to OUD medication. Counselors should check state laws to learn their jurisdiction's naloxone prescription and dispensation policies (see "Resource Alert: Overdose Prevention/ Treatment").

Inform clients and their friends and families of any Good Samaritan laws in the jurisdiction, which protect against drug offenses for people who call for medical help while experiencing or observing overdose.

Emphasize that a person given naloxone to reverse overdose must go to the emergency department, because overdose can start again when naloxone wears off.

Consider working with the program administrator to place a naloxone rescue kit in the office, if one is not already available. To be ready for an emergency, learn:

- The signs of overmedication (which may progress to overdose) and overdose itself.
- What to do if an overdose is suspected.
- How to administer naloxone.

Consider working with the program administrators to set up a program to distribute naloxone directly to patients. Many states allow organizations to do this under a standing order from a physician. Clients are more likely to access naloxone if their program provides it directly to them rather than sending them to another organization to get it.

Helping Patients Cope With Bias and Discrimination

Patients taking medication for OUD must deal with people—including family members, friends, colleagues, employers, and community members—who are misinformed or biased about the nature of OUD and effective treatments for it (Exhibit 4.8).

Mother of Patient:	They want to put my son on methadone, but it's going to rot his teeth.
Father of Patient:	Yeah. I don't want him to look like he's on drugs when he's finally off them.
Counselor:	You have the impression that people who use drugs have bad teeth. And in many cases, that's true. But there are a lot of reasons why people with a substance use disorder develop teeth and gum problems—such as a high-sugar diet, co-occurring depression that prevents them from taking good care of themselves, poor health that allows oral disease to develop, and lack of access to preventive dental care or treatment. But if your son practices good oral hygiene, his mouth will stay healthy while he takes methadone.
Mother of Patient:	What do you mean by "oral hygiene"?
Counselor:	Like all of us, he'll have to limit his sweets and brush and floss regularly. Methadone can reduce the flow of saliva, which means that not as much of the bacteria on his teeth will get washed away. So, he'll want to get good dental advice on how to address dry mouth if that's a problem for him. Regular dental checkups will be really important, too.
Father of Patient:	So, he won't trade his teeth for his recovery. Thanks—that's one less thing to worry

Wherever possible, such as in a counseling session or a community education forum, counter misunderstandings with accurate information. Emphasize the message that addiction is governed by more powerful brain forces than those that determine habits.

As a result, having a lot of positive intent, wanting to quit, and working hard at it sometimes won't be enough.

Remind patients about building recovery capital and sticking with their treatment plan and goals. A particularly good opportunity to do so arises when patients ask how to "get off medication." Statements such as "The longer you take medication, the more of your life you can get back and the less likely you are to return to opioid use" and "We usually recommend continuing medication long term because it helps people maintain recovery" can help clients understand that they are following medical recommendations and doing a good job of caring for themselves (Exhibit 4.9).

*People may think that addiction is just a bad habit or willful self-destruction and that someone who has diffculty stopping opioid misuse is lazy. They may view OUD medication as "just another drug" and urge patients to stop taking it.

Review a client's motivation for tapering or quitting medication (Exhibit 4.10) and have a conversation about the best timing for such a change (Exhibit 4.11). If the client has consented to communication with other providers, inform the client's prescriber about the client's desires or intent so that shared decision making can take place.

Be proactive in dispelling myths and providing facts about medications for OUD when countering misconceptions and judgmental attitudes. Point out that multiple organizations consider individuals to be in recovery if they take OUD medication as prescribed, including:

- The American Medical Association.
- The American Society of Addiction Medicine.
- The National Institute on Drug Abuse.
- The Office of the Surgeon General.
- The World Health Organization.

Explain that alcohol and opioids are different substances with different effects on the body and brain. This counters the mistaken belief that people receiving buprenorphine or methadone are always "high" and as impaired as if they drank alcohol all day. People

acquire tolerance to impairments that drinking causes in motor control and cognition.

But this tolerance is partial; alcohol consumption always results in some deficits.

Opioids don't have the same motor or cognitive effects. Complete tolerance develops to the psychoactive effects and related motor impairments opioids cause.

If a person takes a therapeutic dose of opioid agonist medication as prescribed, he or she may be as capable as anyone else of driving, being emotionally open, and working productively. Some people worry that OUD medication causes a "high" because they've seen patients taking OUD medication whose behavior was affected by other substances (e.g., benzodiazepines). Others may assume that someone is high on a medication for OUD who isn't taking any such medication at all.

EXHIBIT 4.9. Addressing the Misconception That an Opioid Medication Is "Just Another Drug"

Concerned Colleague: These patients are just replacing one drug with another. Instead of heroin, they're

using buprenorphine or methadone.

Counselor: Actually, there's substantial research that medication for opioid use disorder

helps patients stop feeling withdrawal and craving and allows them to get their life back on track. These medications keep patients in treatment and reduce

crime and HIV risk behavior.

Concerned Colleague: Yeah, but aren't they still addicted?

Counselor: Physically dependent, yes; but addicted, no. There's an important difference.

Someone addicted to heroin has to take the drug several times a day to avoid withdrawal. This usually leads to craving, loss of control, and taking more than intended. Drug-seeking behavior causes loss of family and friends. It makes the

person unable to perform daily roles and meet obligations.

Concerned Colleague: Yes, I know how addiction works. But isn't taking methadone an addiction, too?

Counselor: Patients only take methadone once a day, and its makeup is different from

heroin. Daily methadone lets the body stabilize so patients don't have the highs and lows that come from heroin use. If patients use heroin, the methadone blocks its effects; they don't get high. Methadone is taken orally, so there isn't the same danger of infection that comes with injection drug use. Taking methadone as part of a treatment program lets patients feel normal and focus on changing

the other aspects of their lives that led to drug use.

Concerned Colleague: But you just said they take methadone every day.

Counselor: Yes. That is true of most medications for any disease, if you think about it. Patients

have a physical dependence on the medication but are in remission from addiction.

Point out that many thousands of people are prescribed medication for OUD every year, are receiving appropriate treatment, and are indistinguishable from other people. People taking OUD medication rely on it to maintain daily function, like people with diabetes rely on insulin. Nevertheless, some people think that individuals taking buprenorphine or methadone are still addicted to opioids (Exhibit 4.9), even if they don't use illicit

EXHIBIT 4.10. When a Patient Wants To Taper Medication or Stop Altogether

- Review the decision with the patient to determine the motivation for tapering or quitting medication and the best timing for such a change.
- Tell the prescriber that the patient wants to taper; shared decision making should guide the patient's decision.
- Avoid encouraging tapering, which can imply that recovery can only truly occur off of the medication.

drugs. For people with OUD, the medication addresses the compulsion and craving to use. It also blocks the euphoric effects of illicit opioids, which over time helps people stop attempting to use. For people with diabetes, medication addresses the problems caused by inadequate production of insulin by the pancreas. Medication allows both populations to live life more fully.

EXHIBIT 4.11. Responding to a Patient's Desire To Taper Medication for OUD

Patient: I want to taper off the buprenorphine.

Counselor: You'd like to taper—can you tell me why?

Patient: I'm getting married. I want a fresh start.

Counselor: You're saying you'd like to have this all behind you for the new phase in your life.

Patient: Yeah, that's it.

Counselor: Would it be alright if I share my concerns about that?

Patient: Okay.

Counselor: A big change—whether it's having a baby, getting a new job, or getting married like

you're about to do—can be very exciting. But it can also be surprisingly stressful. You may want to consider staying on the medication during this transition to make sure you maintain your recovery. I'm just suggesting postponing a taper decision until you start

getting settled into married life.

Patient: I hear you. The last thing I want to do is mess up my marriage right away by using again.

^{*}It would be inappropriate for a medical team to refuse radiation for cancer patients because the team believes chemotherapy is always needed, or to refuse chemotherapy because they believe that radiation is always needed, regardless of each patient's diagnosis and condition. It would be just as inappropriate to refuse evidence- based

treatment with medication for a patient with OUD, when that may be the most clinically appropriate course of treatment.

Focus on common ground—all patients want a healthy recovery, and judging or isolating someone for return to use doesn't aid anyone's recovery. A divide may occur between patients in a group setting over return to opioid use. People in the OUD community typically are forgiving of return to opioid use and recognize that it can occur on the path to long-term recovery. However, some people in mutual-help communities judge those who return to use (see the "Helping Clients Find Accepting Mutual-Help Groups" section). Address judgmental attitudes through this analogy: People with diabetes whose blood sugar spikes aren't condemned and ejected from treatment.

Dispel the myth that OUD medications make people sick. In fact, methadone and buprenorphine relieve opioid withdrawal, even if patients don't feel complete relief in the first few days. Taking naltrexone too soon after opioid use can cause opioid withdrawal, but withdrawal symptoms can generally be managed successfully. Point out that people taking medication for OUD sometimes get colds, the fu, or other illnesses, like everyone else. A similar misconception is that OUD medications make all patients sleepy. Exhibit 4.12 offers a sample dialog for responding to this misconception.

When return to opioid use comes up in a group counseling setting, messages about

Concerned Colleague:	A patient in my group was falling as leep. I think his methadone dose is too high.
Counselor:	That's an important observation. That certainly is possible, although there are many other possible explanations. What makes you think it's the medication and not lack of sleep or some other reason?
Concerned Colleague:	Because everyone taking methadone falls asleep in group.
Counselor:	Our medical staff members work hard to make sure that each patient is on the right dose. If a patient is falling asleep in group, you should alert the patient's physician right away, regardless of what medication they're taking. But I'm wondering if anything besides medication could be causing this issue.
Concerned Colleague:	Well, this patient is struggling with having an all-night job.
Counselor:	It may be helpful to talk to the patient about moving to a group that meets at a time when he can be more rested. In any case, to be safe, you should call the patient's prescriber about reassessing him.

getting back on track and avoiding shaming and blaming apply just as much to the

patients taking OUD medication as to other participants. This topic is an opportunity to address the dangers of overdose, especially the dangers of using an opioid after a period of abstinence or together with other CNS depressants.

Helping Patients Advocate for Themselves

Educate clients so they can advocate for their treatment and personal needs. Key topics include:

- Addiction as a chronic disease influenced by genetics and environment.
- The ways that medications for OUD work.
- The process of dose stabilization.
- The Benefits of longer-term medication use and risks of abrupt treatment termination.
- The role of recovery supports (e.g., mutual-help groups) in helping achieve goals.

Offer clients' family and friends education on these topics, as well, so that they can advocate for their loved ones. Encourage patients to let family and friends know how important they are and how valuable their support is. Also urge patients to ask loved ones to help them express concerns or fears.

Role-playing can help patients self-advocate. It allows them to practice what to say, what reactions to expect, and ways to respond. Coach patients in active listening and in focusing on solutions rather than problems. Exhibit 4.13 gives an example of a counselor helping a client self-advocate.

Urge patients to advocate for themselves beyond one-on-one conversations. Options include sharing educational pamphlets, inviting loved ones to a counseling session, or referring them to websites.

<u>Addressing Discrimination Against Clients Who Take OUD Medication</u>

Patients can face discriminatory actions when dealing with individuals, organizations, or systems that make decisions based on misinformation about, or biases against, the use of medication for OUD. The following sections highlight issues patients taking OUD medication may face and how counselors can help.

Patient:	My mom is driving me to my back surgery. I'm worried that she'll find out I'm taking buprenorphine.	
Counselor:	It sounds like you're worried she'll reject you and be upset if she knows you're taking medication.	
Patient:	I think she'll be disappointed in me. She thinks people who take addiction medication are still on drugs.	
Counselor:	What would you think about finding a time before your surgery to tell your mother the you're taking buprenorphine? You can explain how it works and remind her how well you've been doing maintaining your job, regaining custody of your children, and living a balanced and healthy life. That may help ease her fears.	
Patient:	Thanks. I'll give that a try.	
Counselor:	If you want, you could invite her to one of our sessions so that I can answer any questions she has.	
Patient:	Yeah, she may hear it better from you. I like the idea of having her come in after I've told her.	
Counselor:	When would be a good time to bring up this topic?	
Patient:	She's driving me to my pre-op appointment on Friday. Maybe I'll suggest we go for coffee after.	
Counselor:	That's a good idea. How about we practice that conversation? I'll play the role of your mom.	

Help clients address employment- related issues

Under the Americans With Disabilities Act, employers cannot discriminate against patients taking medication for OUD. However, the law doesn't always stop employers from taking such action. For example, some employers conduct workplace urine drug testing, either before offering employment or randomly during employment. The OUD medication they test for most frequently is methadone, but it's possible to test for buprenorphine. Naltrexone is generally not tested for. The TIP expert panel concludes, based on multiple patient experiences, that patients who take OUD medication fnd it intimidating to explain to their employers why their urine test results are positive for opioids. Yet if they offer no explanation, they don't get the callback for the job or are let go from the job they have.

Direct patients to legal resources and help them consider how to respond to discrimination at work based on misinterpreted drug tests. Offer to speak with their prospective/current employers to address concerns and misperceptions about OUD medication and its effect on their ability to do work tasks.

Understand potential legal issues

This section describes issues that can affect access to care for patients involved in the justice system who take buprenorphine or methadone for OUD. These issues usually don't apply for naltrexone.

Many jails (short term) and prisons (long term) restrict or disallow access to OUD medication despite the federal mandate that people who are incarcerated have access to medical care. For example:

- A jail may not continue methadone treatment or allow methadone delivery by patients' OTPs.
- Patients' medication may be seized upon arrest.
- Jail health offcials may deny patients' buprenorphine prescriptions.

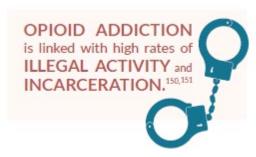
Help negotiate patient access to OUD medication during incarceration. Negotiating access to OUD medication can be problematic and often requires multiple meetings between care providers and jail staff members to resolve successfully. Patients taking OUD medication may be forced to go without medication during incarceration. This increases their risk for opioid overdose if they return to use after reentering the community, given the decreased tolerance that results from interrupted treatment.

Encourage patients to reengage in treatment as soon as they're released. People with OUD released from prison or jail who don't take OUD medication have higher risk of overdose death during their first few weeks in the community. Early after release, they are at very high risk of overdose, given possible:

- Decrease in opioid tolerance while incarcerated.
- Lack of appropriate OUD therapy while incarcerated.
- OUD medication initiation right before release.

Release without coordination or a slot for community-based treatment.

Patients who aren't opioid tolerant need a lower starting dose that prescribers will increase more slowly than usual. Extended-release injectable naltrexone can be an effective alternative for these patients.



Support patients in getting legal advice or counsel via their OUD medication prescribers' healthcare organization. Members of the TIP expert panel have observed situations in which law enforcement personnel arrested patients leaving methadone clinics and charged them with driving under the infuence or arrested them after finding buprenorphine prescription bottles in their cars. Discussions among treatment organizations and local law enforcement leadership can help address such situations.

Address concerns and advocate for addiction specialists to select treatments best suited for each patient. Sometimes, authorities insist that patients enter a particular kind of treatment or follow particular rules related to their OUD. To ensure a patient-centered focus, help involve addiction specialists in determining what kind of treatment best meets patients' needs. This kind of advocacy works best when counselors and the programs for which they work have preexisting relationships with personnel in local employ- ment, law enforcement, drug court, and child welfare facilities.

Address issues in dealing with healthcare providers

Misunderstandings about OUD and its treatment aren't rare among healthcare providers:

- Patients admitted to the hospital for medical issues may face prejudice from hospital staff members.
- Providers may not know how to manage patients' OUD medication during their hospital stay.
- Some providers don't know how to manage pain in someone taking medication for OUD.

Help communicate issues to patients' prescribers, who can advocate for proper handling of OUD medication. It is also possible to help hospital staff members see the patient as a whole person who deserves respect and to provide them with essential information about treatment for OUD.

Inpatient SUD treatment facilities may refuse admission until patients are off buprenorphine or methadone. Sometimes, patients taking OUD medication seek admission to inpatient facilities for treatment of an additional SUD, a mental disorder, or both. If a facility won't accept someone on OUD medication, call on local or state regulatory authorities (e.g., the State Opioid Treatment Authority) and patients' healthcare professionals to intervene with the facility's professional staff and management.

Demonstrate awareness of pregnancy and parenting issues

Healthcare professionals may be unaware of current guidelines for treating pregnant women with OUD (Exhibit 4.14). As a result, they may inappropriately:

- Deny OUD medication to pregnant women.
- Discourage breastfeeding by mothers taking OUD medication.
- Direct women who become pregnant while taking OUD medication to undergo with- drawal from their medication and attempt abstinence.

Hospital policies on screening infants for prenatal substance exposure vary considerably. A positive screen may trigger involvement of Child Protective Services. This may occur even when the positive screen results from treatment with OUD medication under a physician's care rather than opioid misuse.

Help pregnant and postnatal clients in these situations by:

- Educating them and encouraging them to share pertinent information and resources with healthcare professionals involved in their care.
- Coordinating with their prescribers to help them get prenatal and postnatal care from well-informed healthcare professionals.

• **Getting involved in efforts to educate the local healthcare community** about best practices for the care of pregnant and postnatal women with OUD.

EXHIBIT 4.14. Summary of Current Guidance for the Treatment of Pregnant Women With OUD

- An obstetrician and an addiction treatment provider should comanage care, and the woman should receive counseling and supportive services as needed to assist her in achieving a stable life.
- Treatment with methadone or buprenorphine without naloxone during pregnancy is recommended.
 Treatment with naltrexone is not recommended during pregnancy.
- Medically supervised withdrawal during pregnancy is typically not advisable. If not done with great
 care in a controlled setting, it can cause premature labor, fetal distress, and miscarriage. Attempts at
 abstinence from opioids without the support of medication are generally not advised because of the
 risk of return to opioid use, which can adversely affect both mother and fetus.
- Newborns of women who take OUD medication often show symptoms of NAS, which is treatable. NAS
 from opioid agonist treatment is not as harmful to the fetus as continued use of illicit opioids during
 pregnancy.
- · Mothers stabilized on medication for OUD are encouraged to breastfeed.

Summarized from SAMHSA's publication A Collaborative Approach to the Treatment of Pregnant Women With Opioid Use Disorders (https://store.samhsa.gov/product/A-Collaborative-Approach-to-the-Treatment-of-Pregnant-Women-with-Opioid-Use-Disorders/SMA16-4978). 82

Legal problems can arise if Child Protective Services or legal personnel don't understand that parents receiving OUD medication are fully capable of caring for children and contributing to their families. Judges, probation or parole officers, or Child Protective Services workers may inappropriately request that patients discontinue medication as a condition of family reunification. Such orders are medically inappropriate and should be challenged. Possible ways to help:

- Write letters to judges and lawyers explaining how effective OUD medication can be.
- Send judges and lawyers literature about current medical recommendations (including this TIP).
- Testify in court, if necessary.

Helping Clients Find Accepting Mutual- Help Groups

Voluntary participation in 12-Step groups can improve abstinence and recovery-related skills and behaviors for some people with SUDs. Greater involvement (e.g., being a 12-Step sponsor) can increase these Benefits. However, not much research has explored

less widespread types of groups (e.g., groups that follow a given religion's principles, secular groups that downplay the spiritual aspects of 12-Step groups). Research exploring longitudinal outcomes for people with OUD who attend NA is limited, but findings link more frequent atten- dance with abstinence.

Clients taking medication for OUD may face challenges in attending mutual-help groups. For example:

- NA, the most widely available program, treats illicit opioids and OUD medications equally in gauging abstinence and recovery. NA doesn't consider people taking OUD medication "clean and sober."
- Local chapters of NA may decide not to allow people taking OUD medication to participate at meetings or may limit their participation (e.g., not allowing service work).
- Clients attending some NA meetings may encounter hostile attitudes toward the use of medication.
- AA's official policy is more accepting of the use of prescribed medication, but clients may still encounter negative attitudes toward their use of medications for OUD.
- Other groups, such as some religious mutual-help programs, SMART Recovery, and LifeRing Secular Recovery, also have policies that could challenge clients for taking medication for OUD.

Prepare clients who take medication for OUD to attend mutual-help meetings

Clients will be better able to fnd supportive mutual-help groups if their counselor and program:

- Evaluate attitudes toward medication for OUD among local mutual-help groups.
- Keep on hand information about all mutual-help options available in the clients' area.
- Recruit volunteers from mutual-help groups to help clients find and attend meetings
- (e.g., by providing transportation, serving as "sponsors," introducing clients).

- Do not mandate meeting attendance. Recommending participation is just as effective.
- Keep track of clients' experiences at different groups to ensure that meetings remain welcoming.
- Help clients start onsite mutual-help groups.
- Ask staff members to evaluate their own feelings and beliefs about mutual-help groups.

Facilitate positive mutual-help group experiences

- Educate clients about mutual-help groups. Explore group types, risks and Benefits of participation, and limitations of research in support of those risks and Benefits.
- Suggest buddying up. Clients can attend meetings with other people who take medication for OUD.
- Review with clients their understanding of and prior experience with mutual help.
- Explore clients' understanding of the Benefits and risks of disclosure about taking OUD medication.
- Develop a risk-reduction plan for disclosure if clients want to share their use of OUD medication (e.g., talking with an individual group member instead of disclosing to the entire group).
- Help clients anticipate and learn to handle negative responses:
 - Develop sample scripts clients can use when questioned about their medication.
 - Role-play scenarios in which clients respond to questions about their use of medication.
- Respect the privacy of clients' participation in mutual-help groups and recognize that some groups ask that participants not discuss what occurs in meetings.

- Make sure clients know they can talk about their experiences in mutual-help groups but don't pressure them to disclose in these groups that they take OUD medication.
- Consider mutual-help participation using groups more open to OUD medication (e.g., attending AA even if the client has no alcohol use disorder; attending groups for co- occurring substance use and mental disorders, such as Dual Recovery Anonymous or Double Trouble in Recovery). Clients with OUD who attend AA and not NA have similar recovery-related outcomes and retention rates.

Online mutual-help groups

Before recommending an online group, check its content and tone on the use of medication. Mutual help using the Internet (either through real-time chat rooms or discussion boards where one posts and waits for responses) has been growing in popularity. This is an especially valuable resource for clients living in rural and remote areas. Groups range from general meetings for people with a particular SUD (e.g., online AA meetings) to those that are very specifc (e.g., Moms on Methadone). Moderated groups are preferable to unmoderated groups. TIP 60, Using Technology-Based Therapeutic Tools in Behavioral Health Services, addresses many of the pros and cons of online support groups. Part 5 of this TIP gives links for several groups that the TIP expert panel has identifed as helpful.

Mutual-help groups specifc to OTPs

Although these meetings occur mostly on the premises of OTPs, it may be possible to use the models developed by OTPs in more general SUD treatment settings. Because they serve only patients receiving medication to treat OUD, OTPs can create and sustain onsite mutual- help groups specifc to this population. Such groups include Methadone Anonymous (MA), other variations on a 12-Step model, and the mutual-help component of Medication-Assisted Recovery Services (MARS). MARS is a recovery community organization, not just a mutual-help program. MARS members design, implement, and evaluate a variety of peer-delivered recovery support services in

addition to providing meetings. More information on these programs is in the articles cited and online resources presented in Part 5.

Facilitating Groups That Include Patients Taking OUD Medication

Foster acceptance via attitude and behavior when facilitating groups that include patients taking OUD medication:

- Establish ground rules about being respectful, avoiding negative comments about group members, and keeping statements made in the group confdential as with any group.
- Be proactive. State up front that ground rules apply to everyone, regardless of a given person's decisions about whether to include OUD medication in his or her path to recovery.
- Ask members to discuss how to address any negative comments, should they
 occur. This is especially important for mixed groups.
- Ask group members to affrm that they will abide by the rules.
- Provide consistent reminders throughout each session about the ground rules.

Group members may still make negative comments about medication for OUD. Avoid feeding the negativity with attention, which can worsen the situation. Reframe negative comments to express underlying motivations, often based on fear or misunderstanding. Remain positive; model expected behavior, which can benefit the person who made the negative remark (Exhibit 4.15).

Petra:	How can you say Joni is in recovery when she's still taking a drug every day? I struggled every day and never took anything for 10 years.	
Counselor:	I hear your concern for Joni. You want her recovery to follow the same path you took in yours.	
Petra:	Right! And she's taking methadone, which is an opioid. People use opioids to get high.	
Counselor:	In this treatment program, we see addiction as a brain disease. Methadone treats the brain disease part of addiction. It stabilizes the brain and allows the person to focus or learning new ways of thinking and reacting. It works by blocking the effects of other opioids. Patients on a proper dose can't get high even if they try to use. This helps discourage future drug use. Joni, would you like to add anything?	
Joni:	Petra, it's great that you stopped using opioids and stayed in recovery without medication—but everyone has a different path to recovery. For me, medication helps me hold a job, take care of my kids, stay focused in my counseling sessions, and feel normal.	

Additional tips for leading mixed groups include the following:

- Treat patients taking OUD medication the same as other patients in the group.
 Patients taking medication can participate in and benefit from individual and group counseling just like other patients. There is no need to have separate counseling tracks based on OUD medication status, nor should that status limit a participant's responsibilities, leadership role, or level of participation.
- Meet with patients taking OUD medication in advance to prepare them for mixed-group settings. Advise them that they don't have to disclose their medication status to the group, just as they don't have to disclose any other health issues.
 Counsel them that if they choose to talk about their medication status, it helps to talk about how medication has helped shape their personal recovery.
- Don't single out patients taking OUD medication. Let participants decide whether
 to tell the group about any issue they want to share, including medication status.
 If a patient chooses to disclose that status, follow up after the session to ensure
 that he or she is in a positive space and feels supported.
- Keep the session's focus on the topic and not on the pros and cons of medication for OUD. If the person receiving medication for OUD or other group members have specific questions about such medications, have them ask their healthcare professionals.

- Reinforce messages of acceptance. During the wrap-up discussion at the end of a session, members may comment on points that stood out for them. This is a chance to restate information accurately and model respect for each patient's road to recovery, whether it includes OUD medication or not.
- Review confidentiality rules. Affirm that patients' OUD medication status will not be shared with other group members. Remind participants to think carefully before sharing personal details such as their medication status with the group, because other participants may not respect confidentiality even if they have agreed to do so as part of the group guidelines.

Other Common Counseling Concerns

Patients must sign releases to permit ongoing conversations between care providers in accordance with federal regulations on confidentiality of medical records for patients in treatment for an SUD (42 CFR Part 2). When patients' primary care providers, prescribers of medication for OUD, and addiction-specifc counselors don't work for the same entity, patients must consent for them to share information.

It can be challenging when a patient refuses to consent to collaborative communication among his or her healthcare team members. In these cases, the professionals involved must decide whether they will continue to provide either medication or counseling services without permission to collaborate. In other words, is cross-communication among all providers required for collaborative care? The answer to this complicated question depends on each patient's circumstances.

*The TIP expert panel recommends communication among providers as the standard of care for OUD treatment and recovery support. Carefully consider deviations from this standard, which should occur only rarely. That said, individualize decisions about collaborative communication among providers to each patient's unique preferences, needs, and circumstances.

Patients may not consent to communication among providers if they:

Have experienced discrimination in health-care systems.

- Have developed OUD after taking opioid pain medication.
- Have legitimate cause not to trust providers (e.g., perceiving themselves as having been abused by a healthcare professional).
- Are not ready to make primary care providers aware of their disorder, even (or especially) if those providers have been prescribing opioid pain medication.
- Encounter problems in making progress toward recovery. After typically consenting to communication among providers, a patient's sudden revocation may signal trouble in recovery.

EXHIBIT 4.16. Common Collaborative Care Issues and Possible Counselor Responses

ELATED ISSUE	COUNSELOR RESPONSE
The patient complains of continued cravings.	Talk with the patient about his or her medication adherence. Review with the patient strategies for overcoming cravings using a CBT model. Communicate with the prescriber to see whether dosage can be adjusted to subdue the cravings.
A patient taking methadone does not appear engaged in counseling sessions and seems drowsy during conversations.	Ask the patient whether drowsiness is caused by lack of sleep, disturbed sleep, substance use, or overmedication. Consider obtaining a spot urine test (if available). In all cases of drowsiness, alert the prescriber immediately so that the cause can be determined. This is particularly important during the first few weeks of treatment.
The patient is at risk for return to opioid use.	Inform the prescriber if the patient appears at risk for return to use given cravings, life stressors, changes in social circumstances, new triggers, or the like. This alerts the prescriber to monitor the patient more closely and consider medication changes to reduce likelihood of return to use.
The patient has recently returned to opioid misuse after a period of abstinence.	Gather details about circumstances surrounding the incident of use and, in collaboration with the prescriber and the patient, adjust the treatment plan accordingly. Reinforce the patient's understanding of the increased risk of opioid overdose given altered levels of tolerance.

EXHIBIT 4.16. Common Collaborative Care Issues and Possible Counselor Responses (continued)

ELATED ISSUE	COUNSELOR RESPONSE
The patient is discussing chronic pain with the counselor.	Direct the patient to a healthcare professional for assessment of pain and medical treatment as necessary. If indicated as appropriate by a healthcare professional, provide CBT for dealing with pain or instruct the patient in adjunct methods for pain relief (e.g., meditation, exercise, physical therapy).
The patient is asking the counselor for medical advice on what dose to take, side effects, how long to stay on the medication, and the like.	Answer questions based on your knowledge of medications for treatment of OUD but don't provide medical advice. Refer the patient to the prescriber for that. As appropriate, contact the prescriber with the patient to have a three-way discussion.
The counselor or patient is concerned that the prescriber is not giving quality care.	As appropriate, advocate for the patient with the prescribing medical team.
The patient discloses use of other drugs.	Use motivational interviewing techniques to have a collaborative conversation about the details of this drug use. For example, give a response like "Tell me more about this," followed by questions about the specific drugs used, why they were used, and what the patient's thoughts are about changing that drug use.
The patient discloses that she is pregnant.	Advise the patient to contact her prescriber immediately no matter what medication she is taking. Work with her to help her get access to prenatal care (if she doesn't have it already) and other health services related to pregnancy as needed.
The patient has a positive urine screen.	Using motivational interviewing tools, discuss with the patient the context of the substance use and what implications this use may have for the treatment plan. If the patient denies the substance use, reconsider the patient's readiness to change and how it affects the treatment plan.

[Part 5 which contains a long list of resources and tools will not be included in this course. It is available at the cited location of the TIP.]

The next section of the course will have a more pointed focus on providing counseling services to clients.

Counseling Clients with Opioid Addiction

Chapter 1: The Human Experience of Opioid Addiction

1.0 Vignette: "When the Ache Becomes a Voice"

Marisol wakes before dawn, the quiet of her small apartment broken only by the soft hum of the heater. Her body feels hollow, as though a vacuum has been carved through her chest and belly. The pain began six years ago, after the back injury that ended her work in construction. At first it was manageable—"take a pill, keep working," she told herself. But by the time her prescription ran dry, the empty days stretched into desperation.

She slips out of bed and pads to the bathroom. Her hands shake. She sees the thin track marks on her arms—fresh, from last night when she thought she could manage "just one more dose." She remembers lying in the ER, sweat beading on her forehead as she coughed and vomited, straining to breathe. The doctors called it "acute opioid withdrawal," but to her it felt like being hollowed out from the inside.

She wraps her arms around herself in the mirror, staring at her own eyes—haunted, hollow, pleading. She thinks of her daughter, six years old now, sleeping in the next room. She pictures the last time her little hand reached for hers in the morning, asking, "Are you better today, Mama?" Marisol swallowed her guilt, her shame, her fear—and slipped back into bed, trying to will the ache away.

1.1 The Landscape of Opioid Addiction

Marisol's story is not an anomaly. Across the United States, communities of all sizes—from rural towns to dense urban centers—are grappling with the reverberations of opioid use disorder (OUD). To counsel effectively, one must first orient to the scope, shifts, and structural forces shaping this epidemic.

Over the past two decades, the United States has endured successive waves of opioid overdose mortality. The first wave was fueled by liberal prescribing of pain medications

in the late 1990s, the second by heroin as prescription access tightened, and the third by the rise of potent synthetic opioids such as illicit fentanyl (CDC, 2025; "Understanding the Opioid Overdose Epidemic," 2025). At its peak, more than 105,000 deaths from drug overdose were recorded in a single year, with approximately 76 % of those tied to opioids (CDC, 2025). But in recent data, preliminary reductions in overdose deaths suggest cautious hope: the U.S. recorded a nearly 24 % drop in overdose fatalities in the twelve months ending September 2024 compared to the prior year (CDC, 2025).



Even with that promising trend, the human toll remains staggering. Daily, hundreds lose their lives; many families are left haunted by grief; and countless individuals wrestle with the day-to-day demands of addiction. The epidemic does not distribute its burden evenly. Communities facing economic decline, poverty, inadequate health access, and social dislocation are disproportionately affected. Recent research underscores how social vulnerability—such as high rates of unemployment, lack of insurance, unstable housing, and limited educational resources—correlates strongly with higher rates of opioid mortality (Deas et al., 2024).

Within the larger canvas of the epidemic, certain patterns stand out. First, the shift from prescription opioids to illicit synthetic opioids (most notably fentanyl) has made the risk landscape more lethal and less predictable. A user may believe they are ingesting heroin or a prescription opioid, but potent fentanyl analogues are often present, raising overdose risk dramatically with minimal margin for error. Second, many who develop opioid addiction begin in medical settings—after surgery, injury, or chronic pain management—with doses intended for relief. An estimated 3–12 % of people on long-term opioid therapy may develop problematic use or addiction (Psychiatry.org, 2025).

Yet treatment access remains a critical bottleneck. Although medications for opioid use disorder (MOUD)—such as methadone, buprenorphine, and naltrexone—are evidence-based and effective, only a minority of people in need receive them (Psychiatry.org, 2025). Barriers include stigma (both social and internalized), regulatory constraints, provider shortages, geographic deserts in rural regions, and fragmented systems of care. In some areas, the nearest clinic offering methadone may be dozens of miles away; in others, regulations limiting prescribers' ability to dispense buprenorphine constrain access.

As counselors, we must understand that the "landscape" is not a static map of numbers but a shifting terrain of risk, resource, and resilience. In any given community, you may see waves of overdose, cycles of relapse, families torn by shame, and hopeful recovery in close proximity. Recognizing how macro forces—like socioeconomic inequality, policy decisions, and drug supply dynamics—intersect with individual lives is essential. When you meet clients like Marisol, you are not entering a void but stepping into a landscape shaped by histories, systems, and possibilities.

1.2 The Lived Experience

On a rainy Tuesday afternoon, Marcus sat slumped in the corner of a bus shelter, his hood pulled low to block both the drizzle and the gaze of passersby. At forty-two, his body carried the weariness of someone much older. His hands bore small scars from years of construction work, and his knees ached from the long days of kneeling on concrete. A decade ago, when a scaffold collapsed and crushed his ankle, doctors

prescribed opioids to manage the unrelenting pain. At first, the pills brought relief, a kind of reprieve that let him walk his children to school and finish a day's work without grimacing. But gradually, the line blurred. One extra dose on a bad day. Another to ease the restless nights. Soon the prescription became harder to refill, and Marcus discovered that pills purchased on the street filled the gap more quickly than waiting weeks for another doctor's appointment.

His story is familiar in countless counseling rooms. The body grows tolerant; withdrawal looms like a shadow; and shame coils itself around even the most ordinary moments. Marcus describes waking each morning with a singular thought—how to find enough to avoid being sick by nightfall. He knew he was caught, but the fear of withdrawal outweighed nearly everything else. Researchers describe this narrowing of daily life as the "hijacking" of reward pathways, where seeking and using opioids becomes the brain's organizing principle (Volkow et al., 2024). For Marcus, it meant missing birthdays, skipping work, and pulling further away from his wife and children.

Yet he also carried an ember of longing. He still remembered sitting at the dinner table, laughing as his daughter recounted her first day of middle school. That image tugged at him on the loneliest days. It is this kind of thread—attachment to family, the memory of dignity—that counselors can help clients rediscover. Research suggests that a strong therapeutic alliance, particularly when grounded in empathy and respect, predicts better retention in treatment for opioid use disorder (Watkins et al., 2024).

When Marcus first walked into a counseling session at a community clinic, he did so reluctantly, coaxed by a probation requirement after a possession charge. He expected judgment and lectures. Instead, he found a counselor who asked not only about his drug use but about his children, his work, his injuries, and his hopes. For the first time in years, Marcus felt seen beyond the narrow label of "addict." That encounter did not end his use overnight, but it shifted the ground beneath him. He began to imagine recovery not as punishment but as a path back to being the man his children once knew.

The lived experience of opioid addiction is rarely linear. It is filled with moments of clarity and collapse, courage and despair. Clients carry both the neurological imprints of

dependence and the emotional wounds of stigma, loss, and fractured trust. When counselors enter into these stories, they are stepping into a complex human landscape where empathy, patience, and hope become as vital as clinical technique.

1.3 Vignette: Daniel's Descent

Daniel never thought of himself as someone who would get "hooked." At twenty-nine, he was a new father and a rising electrician in his company. His days were long, but he carried a quiet pride in being able to provide for his family. The accident came on an ordinary Wednesday: a fall from a ladder, a sharp crack in his lower back, and weeks of hospital visits and physical therapy that left him restless and sore. The



prescription for oxycodone felt, at first, like a blessing—relief that allowed him to lift his infant son without grimacing, to sit upright during family dinners, to fall asleep without hours of tossing in pain.

The line between relief and reliance blurred slowly. At first, he took the pills as prescribed. But soon, one didn't last long enough, and doubling the dose seemed harmless. He found himself calling for refills earlier each month. His doctor's concern grew; the prescriptions tapered. Daniel reassured himself that he could handle it, that he wasn't like "those addicts" he read about in the news. When the pills ran out, the back pain returned with a vengeance—accompanied by sweats, shaking, and a gnawing restlessness that seemed to come from deep inside his bones.

A friend at work offered him a pill from a relative's bottle, and when those dried up, someone else suggested heroin as a cheaper, stronger alternative. At first, Daniel recoiled, convinced that was a step too far. But one night, desperate for sleep and trembling with withdrawal, he said yes. What followed was a cycle he had never

imagined: chasing the high, warding off sickness, lying to his wife, and slipping further from the steady man he once was.

Daniel's story is echoed in thousands of clinical encounters. Many individuals who develop opioid use disorder began with prescriptions for legitimate pain, gradually finding themselves trapped in a cycle that reconfigured their daily lives (Volkow et al., 2024). For Daniel, the shame was perhaps the heaviest weight. He could tolerate the nausea, the restless nights, even the risk of losing his job. But each time he looked at his son, he felt the ache of failing as a father. This sense of shame and stigma is well documented in research as a barrier that prevents many from seeking help, even when the desire for change is present (Kennedy-Hendricks et al., 2023).

The first time Daniel walked into a counselor's office, he sat rigid, arms crossed, expecting to be scolded. Instead, his counselor spoke gently about pain—both physical and emotional—and acknowledged that dependence is not a sign of moral weakness but the predictable result of neurobiology and exposure. Daniel cried that day, not because of withdrawal, but because he realized someone believed he was more than his worst choices. Establishing this kind of trust, rooted in empathy and clinical clarity, is often the opening that makes recovery imaginable (Watkins et al., 2024).

Daniel's descent into opioid use was slow, insidious, and deeply human. His story illustrates the invisible line between treatment and dependency, the crushing burden of stigma, and the essential role counselors play in creating space for honesty, dignity, and the fragile beginnings of recovery.

1.4 The Role of Counselors: Meeting Clients with Empathy and Realism

When Marisol walked into her first counseling session, she carried the same guarded posture she wore on the bus or in the grocery store—head lowered, voice soft, shoulders hunched as if bracing for judgment. Her counselor, Ms. Green, didn't begin with a checklist or a lecture. Instead, she invited Marisol to sit comfortably, offered a glass of water, and asked a simple question: "What do you want me to understand about your story today?" The question lingered in the quiet room, and for the first time in months, Marisol felt like someone was asking about her, not just her use.

This moment captures the essence of what counselors offer in the opioid epidemic: a space where dignity is restored, where the crushing shame of addiction meets the steady presence of another human being. Counseling does not erase the neurobiological challenges of opioid use disorder, nor does it replace the evidence-based medications that often make recovery possible. But research shows that the therapeutic relationship is one of the strongest predictors of engagement and retention in care, particularly when it is grounded in empathy and nonjudgment (Watkins et al., 2024).

Counselors are uniquely positioned to bridge the personal and the systemic. They sit in the tension between individual suffering and structural forces such as poverty, racial disparities, and gaps in healthcare access. They accompany clients through relapses and renewals, helping them make sense of what may feel like endless cycles. Recent studies emphasize the importance of trauma-informed care in this population, recognizing that many who struggle with opioid addiction carry deep histories of trauma, loss, and relational rupture (Substance Abuse and Mental Health Services Administration [SAMHSA], 2023). When counselors create safe, respectful, and compassionate spaces, clients are more likely to risk honesty, engage in treatment, and begin imagining life beyond opioids.

The role is not without its weight. Counselors often witness repeated relapses, court-mandated sessions filled with resistance, or clients who vanish after a single meeting. Burnout and compassion fatigue are real hazards. Yet alongside the heartbreak are moments of profound transformation: the first time a client arrives sober to session, the reunion of a parent with their child, the spark of laughter returning to someone's face after years of numbness. These glimpses of resilience affirm why the work matters.

As the opioid crisis continues to evolve, the counselor's role remains both ancient and urgent. It is the work of listening, accompanying, and believing in the possibility of change even when the client cannot. In every story—whether Daniel's descent, Marcus's struggle, or Marisol's hesitant hope—the counselor stands as a witness and companion, offering both realistic guidance and unwavering empathy. In this

intersection of science and compassion lies the possibility of recovery, dignity, and renewed life (Volkow et al., 2024; Kennedy-Hendricks et al., 2023).

Transitional Summary

Chapter 1 has explored the lived human experience of opioid addiction, weaving together the stories of Marisol, Marcus, and Daniel to illustrate how ordinary lives can be overtaken by pain, dependence, and stigma. Through these vignettes, we see how opioid use disorder is rarely a matter of choice alone; it is deeply intertwined with medical histories, structural inequalities, trauma, and the neurobiology of dependence. The epidemic itself remains vast and shifting, shaped by the rise of synthetic opioids, gaps in treatment access, and persistent stigma.

For counselors, these stories highlight the profound importance of presence, empathy, and resilience. The role is not only to guide clinical interventions but also to bear witness to suffering, hold hope when clients cannot, and walk alongside individuals as they navigate both relapse and recovery. This human-centered foundation sets the stage for Chapter 2, where we turn from the broader landscape to the counseling relationship itself—how trust is built, how resistance is met, and how therapeutic models can be adapted to support those seeking freedom from opioid addiction.

Chapter 2. Therapeutic Approaches and Relational Dynamics

2.1 Building Trust: Establishing Rapport with Clients Who May Fear Judgment

When Darius arrived for his first counseling session, he sat close to the door, his arms crossed and his eyes darting toward the clock on the wall. He had been through intake before, had spoken to doctors, probation officers, and even a judge, all of whom seemed more interested in paperwork than in him. He expected this to be another lecture about responsibility, another recitation of what he should or should not do. When the counselor simply said, "I'm glad you came today," Darius felt a flicker of something unexpected—relief.



For many individuals with opioid use disorder, the first hurdle is not the craving or even the withdrawal, but the crushing weight of stigma. People often enter counseling already carrying the belief that they are broken, unworthy, or destined to fail. This internalized stigma has been shown to reduce treatment engagement and worsen mental health outcomes (Kennedy-Hendricks et al., 2023). Establishing trust, therefore, is not a preliminary step to treatment but

the treatment itself in its earliest form.

Counselors build rapport not by glossing over the pain but by creating an atmosphere where honesty feels possible. Research on therapeutic alliance consistently demonstrates that clients who perceive their counselors as empathic, nonjudgmental, and collaborative are more likely to remain in treatment and achieve positive outcomes (Watkins et al., 2024). In the context of opioid addiction, where ambivalence and relapse are common, that alliance becomes an anchor during turbulent periods.

Trust is fragile, particularly for those who have experienced betrayal, loss, or punitive responses from systems meant to help. Many clients arrive with histories of trauma—emotional, physical, or systemic—and approach new relationships with protective distance (SAMHSA, 2023). Counselors who are attuned to this reality understand that rapport is not built in a single session but cultivated over time through consistent respect, reliability, and presence.

Returning to Darius, the turning point in his counseling did not come when he committed to abstinence or enrolled in a medication program. It came weeks earlier, when he tested the waters by admitting he had used again over the weekend. He braced for

disappointment, even dismissal. Instead, his counselor leaned forward and said, "Thank you for trusting me with that. Let's talk about what you learned and what you need now." In that moment, Darius began to believe that counseling might not be another arena of judgment but a space where his humanity could be seen alongside his struggles.

Building trust is slow, delicate work, but it is also profoundly transformative. For clients burdened by the stigma of opioid addiction, even a single relationship rooted in respect can shift the possibility of recovery. As we continue through this chapter, we will examine how therapeutic models and counselor self-reflection deepen this foundation, allowing trust to blossom into motivation, resilience, and growth.

2.2 Counseling Modalities: CBT, Motivational Interviewing, Trauma-Informed Care, and Integrated Models

Cognitive-Behavioral Therapy: Rewriting the Inner Story

When Lila first entered counseling, she was twenty-six and already carried the weariness of someone decades older. Her heroin use had begun three years earlier, after her prescription for oxycodone was cut off. She described her days as a cycle: wake with a knot of dread, scramble for money, find the next fix, and collapse into a restless sleep. Her counselor noticed how Lila described herself in absolute terms—"I'm worthless," "I'm a failure," "I'll never get better." These thoughts weren't casual; they were the architecture of her self-image, reinforced by years of disappointment and shame.

Cognitive-behavioral therapy begins here, at the level of thoughts and their ripple effects. The central idea is deceptively simple: what we think influences how we feel and what we do. For someone like Lila, the thought "I'm a failure" led to feelings of despair, which drove her behavior of using to numb those feelings. Breaking that loop required examining the thought itself, testing whether it was entirely true, and experimenting with alternative ways of thinking.

In their early sessions, her counselor asked her to recall times when she had shown resilience. At first, Lila resisted—her mind skipped immediately to every broken promise and relapse. But with gentle persistence, she recalled how she had once worked two jobs to keep her apartment, how she had cared for her younger brother when their mother was sick, how she had gone almost three months without using during her pregnancy. These memories didn't erase the shame, but they complicated the story. Slowly, her black-and-white thinking began to give way to more nuanced narratives: I've failed, but I've also succeeded. I've used, but I've also tried to stop. I'm not only my worst moments.

CBT provides clients with practical tools to disrupt the automatic chain between trigger and behavior. Counselors help clients identify high-risk situations—an argument with a partner, walking past a corner where dealers gather, payday afternoons—and then rehearse alternative responses. For Lila, one trigger was finishing her late-night restaurant shift, exhausted and craving. Her usual thought was *I can't handle this without using*. Together with her counselor, she developed a replacement script: *I've gotten through nights before. I can call my sponsor first. I can walk to the bus stop on the other side of the block.* Each time she practiced this, her confidence grew.

The counselor's role is part teacher, part coach, and part witness. They introduce skills like thought records—journaling automatic thoughts, the emotions that follow, the evidence for and against those thoughts, and alternative interpretations. They model problem-solving strategies, such as breaking overwhelming tasks into smaller steps. They role-play scenarios so clients can rehearse refusing offers or calming themselves under stress. Over time, these tools shift from being "exercises in therapy" to habits that clients use in daily life.

Research continues to affirm CBT's value for people with opioid use disorder. A recent meta-analysis found that CBT, particularly when combined with medication-assisted treatment, significantly improves abstinence rates and reduces relapse frequency (McHugh et al., 2023). What makes it effective is not only its structure but also its adaptability. Counselors can tailor CBT to individual needs, weaving in cultural considerations, family dynamics, and co-occurring mental health concerns.

One of the overlooked gifts of CBT is how it restores a sense of agency. Addiction often convinces people that they are powerless passengers in their own lives, driven by cravings they cannot resist. CBT gently counters this by showing clients that their thoughts and choices matter—that while cravings may arise, how they respond is not predetermined. For Lila, this realization came the night she walked past her old dealer's block and called her counselor instead of stopping. She recounted the story in session with trembling pride: "I didn't think I had it in me. But I did." The counselor leaned in and said, "That's what recovery looks like—not perfection, but moments like this."

The journey with CBT is not about erasing negative thoughts altogether. It is about teaching clients to notice them without surrender, to question them without judgment, and to replace them with more balanced perspectives. This skill-building offers protection against relapse, but more than that, it nurtures dignity. For someone who has spent years believing they are broken beyond repair, CBT opens the possibility that change is not only possible but already unfolding within them.

As we move deeper into the landscape of counseling, it is important to recognize that CBT is one voice in a larger chorus of therapeutic approaches. Its strength lies in clarity, structure, and skill-building, but it often finds its fullest power when paired with other modalities. In the next section, we will explore motivational interviewing, a model that approaches change less through skills and more through the delicate art of evoking a client's own reasons for hope.

Motivational Interviewing: Finding the Spark of Change

When Andre first sat down with his counselor, he made it clear he wasn't there by choice. The court had ordered him to attend sessions after a possession charge, and his opening words were blunt: "I don't have a problem. The system has a problem with me." His arms were folded tight across his chest, his gaze fixed just past the counselor's shoulder. Many counselors know this posture—the defensive shield of someone expecting to be told what's wrong with them.

Traditional approaches might have confronted Andre with the evidence: his failed drug tests, his missed work, his arrest record. Motivational interviewing takes a different

route. Instead of trying to argue someone into change, MI listens for the whispers of ambivalence already alive within them. Andre insisted he didn't have a problem, but when asked what he wanted most out of life, he hesitated before admitting, "I just want my daughter to look at me again without disgust." That flicker of desire became the spark the counselor leaned into.

At its core, MI is a collaborative, person-centered style of counseling that honors autonomy. It assumes that clients are the ones who will ultimately decide if and how they change. The counselor's role is not to persuade or instruct but to evoke the client's own reasons for change, amplifying them until they outweigh the pull of staying the same (Miller & Rollnick, 2023). For people struggling with opioid addiction, this can be profoundly liberating. Many have grown accustomed to being told they are failures, criminals, or patients defined only by diagnosis. MI counters this by treating them as agents of their own story.

The process unfolds through four guiding principles, often described as engaging, focusing, evoking, and planning. With Andre, the early sessions were about engaging—building a working relationship where he felt safe enough to explore. The counselor reflected his resistance without judgment: "It sounds like you're tired of people telling you what to do." Andre nodded, relaxing slightly. This acknowledgment opened the door to focusing, gently steering the conversation toward what mattered most to him: his relationship with his daughter.

Evoking came next. The counselor asked, "What would it mean to you if she saw you as trustworthy again?" Andre's eyes softened as he replied, "It would mean everything." This statement, called "change talk" in MI, is the seed from which motivation grows. By reflecting and affirming such moments, counselors help clients hear themselves articulate hope. Planning, the final stage, emerges naturally when motivation has ripened. For Andre, that meant sketching out practical steps to reduce his use, reconnect with his daughter, and explore treatment options.

One of MI's most powerful elements is its ability to roll with resistance. Instead of viewing resistance as opposition, MI sees it as information about where the client is in

their readiness for change. When Andre bristled at the idea of joining a recovery group, the counselor didn't push. Instead, she reflected, "You don't see yourself fitting in there." This validation reduced defensiveness, keeping the dialogue open. Weeks later, Andre brought up the group on his own, wondering aloud whether it might help him rebuild trust with his probation officer.

Research consistently supports MI as an effective approach for engaging individuals with opioid use disorder, particularly those ambivalent about treatment. A recent randomized trial found that clients exposed to MI were more likely to initiate medication-assisted treatment and showed higher retention rates compared to those receiving standard intake procedures (Santa Ana et al., 2023). Importantly, MI doesn't require clients to declare absolute commitment before beginning. It respects the messy, incremental process of change, where relapse and hesitation are expected rather than condemned.

From the counselor's perspective, practicing MI demands humility and patience. It requires listening more than talking, asking open-ended questions, and resisting the urge to "fix." For counselors accustomed to more directive methods, this can feel counterintuitive. Yet it often yields moments of profound honesty. In one session, Andre admitted, "I don't even know who I am without drugs." Rather than rushing in with reassurance, the counselor asked, "Would you like to explore who that person might be?" In that question lay an invitation, not an instruction—a door opening onto possibility.

The strength of MI lies in its respect for human dignity. By treating ambivalence as a natural part of change rather than a failure, it helps clients reframe their own hesitations as steps in the process. For someone burdened by the shame of opioid addiction, hearing their own voice speak of hope, however tentative, can be life-altering.

For Andre, the journey was far from linear. He relapsed twice within the first six months, each time returning to counseling with a mix of guilt and resignation. His counselor responded with the same steady curiosity: "What did you learn about yourself this time?" These conversations gradually helped Andre see relapse not as proof of

hopelessness but as information about triggers, patterns, and vulnerabilities he could address moving forward.

Months later, when his daughter agreed to meet him for coffee, Andre described the moment in counseling with tears in his eyes. "She didn't smile right away, but she didn't look at me with disgust either. That's progress." For him, progress was not abstinence alone—it was the rebuilding of trust, the reawakening of hope, the quiet possibility that his story was not over.

Motivational interviewing shines brightest in such stories, where the counselor's belief in the client's capacity for change allows the client to begin believing it too. In a landscape marked by stigma and despair, MI offers a reminder: change begins not with being told, but with being heard.

Trauma-Informed Care: Healing the Wounds Beneath the Use

Elena was twenty-three when she came into counseling, referred from an emergency department after an overdose scare. She spoke softly, almost whispering, her eyes fixed on the floor. When asked about her history, she paused, then admitted that her opioid use was less about pain from a car accident, as she had told doctors, and more about escaping memories of childhood abuse. "When I use," she said, "the memories get quiet. It's the only time they leave me alone."

Stories like Elena's are common. Research indicates that individuals with opioid use disorder have disproportionately high rates of trauma exposure, including physical abuse, sexual assault, and chronic neglect (Hanson et al., 2024). Trauma doesn't simply coexist with opioid addiction; it often drives it, as people discover that opioids temporarily numb intrusive memories, soothe hyperarousal, or blunt overwhelming emotions. Without addressing this trauma, treatment risks becoming another surface-level intervention—helping clients reduce use without healing the wounds that fuel it.

Trauma-informed care begins by recognizing this reality. It reframes the central question of counseling from "Why are you using?" to "What has happened to you, and how has it shaped your choices?" This shift may sound subtle, but for clients who have lived with

blame and shame, it is transformative. Elena had grown accustomed to hearing she was reckless, weak, or selfish. When her counselor said instead, "It sounds like opioids became your way of surviving unbearable pain," Elena's tears flowed freely. For the first time, she felt understood rather than judged.

The principles of trauma-informed care are often summarized as safety, trustworthiness, choice, collaboration, and empowerment (SAMHSA, 2023). For counselors, this means creating environments where clients do not feel re-traumatized by the very process meant to help them. Something as simple as asking permission before beginning sensitive questions, or offering choices about where to sit in the counseling room, can restore a sense of control for clients who have had it stripped away.

Elena's counselor worked deliberately to build safety. Instead of plunging directly into her trauma narrative, sessions began with grounding exercises: noticing her breath, identifying something in the room that felt safe, practicing brief relaxation techniques. These weren't distractions; they were essential tools for helping Elena regulate her nervous system. When she later shared fragments of her past abuse, she was able to do so without becoming overwhelmed, knowing she had skills to return to calm.

Counselors practicing TIC must also recognize that trauma often appears in the room indirectly. Clients may miss appointments, react with anger to limits, or disengage when topics feel threatening. Without a trauma lens, these behaviors might be labeled "noncompliance" or "resistance." With a trauma lens, they are understood as protective adaptations—ways the client has learned to survive. This understanding shifts the counselor's response from frustration to compassion.

Empirical evidence supports the integration of trauma-informed principles into opioid treatment. A recent longitudinal study found that clients in programs with explicit TIC training showed significantly higher retention rates and reduced relapse compared to those in standard care (Knight et al., 2023). The presence of trauma-sensitive counselors created environments where clients felt safe enough to disclose vulnerabilities, which in turn allowed deeper healing.

From the counselor's perspective, TIC requires both patience and self-awareness. It means being alert not only to the client's triggers but to one's own. Elena's counselor, for example, noticed feeling a wave of protective anger when hearing about her abuse. Rather than acting on this impulse, the counselor acknowledged it internally and redirected that energy into creating a steady, reliable presence for Elena. Counselors who do not tend to their own reactions risk inadvertently overwhelming clients or stepping into rescuing roles that disempower rather than heal.

Over months, Elena's story began to change. She still struggled with cravings, but she no longer described opioids as her "only escape." She learned to identify when memories were rising and to use grounding techniques instead of reaching automatically for drugs. In one session, she reflected, "I'm starting to see that my past explains me, but it doesn't have to define me." That statement marked a turning point—the recognition that she had choices, that her identity was larger than her trauma or her addiction.

Trauma-informed care is not a discrete technique but a way of being with clients. It requires counselors to embody compassion, to prioritize safety, and to approach each behavior with curiosity rather than condemnation. For those battling opioid addiction, TIC acknowledges that substance use often began as a solution—albeit one with devastating consequences—to unbearable emotional pain. By honoring that complexity, counselors help clients loosen shame and reclaim agency.

For Elena, the work was slow, fragile, and at times painful. Yet each time she left counseling with a sense of calm rather than chaos, she reinforced the truth that healing was possible. Her counselor's task was not to erase her memories but to accompany her in learning to carry them differently. That journey, supported by trauma-informed care, became a cornerstone of her recovery.

Integrated Models: Weaving the Strands Together

When Jamal entered treatment, he had already cycled through detox programs three times in five years. Each time he completed withdrawal, he felt hopeful for a few weeks, only to relapse once stress mounted. "I know I can stop for a while," he said, "but I don't

know how to *live* without it." His words point to the central challenge of opioid addiction: stopping is not the same as sustaining recovery. What he needed was not just another attempt at abstinence, but a model of care that addressed his cravings, his thoughts, his ambivalence, and his history of trauma in a coordinated way.

Integrated treatment models provide exactly this kind of comprehensive approach. Rather than treating opioid use disorder as an isolated problem, they view it as a complex, multifaceted condition that requires interventions across biological, psychological, and social domains. This means combining counseling modalities like CBT, motivational interviewing, and trauma-informed care with medications for opioid use disorder (MOUD) and supportive services such as housing, peer mentorship, and vocational training.



For Jamal, this looked like a patchwork quilt of supports stitched together into a cohesive plan. He began buprenorphine under medical supervision, which stabilized his withdrawal and reduced cravings. In counseling, he engaged in CBT to challenge the thought patterns that convinced him he was doomed to fail, MI sessions to explore his ambivalence about staying in treatment, and trauma-informed work to gently address the violence he had witnessed growing up. At the same

time, his counselor referred him to a peer support group and connected him with a local workforce development program. The combination of medication, therapy, and social supports provided multiple safety nets, ensuring that no single setback unraveled the entire process.

Research consistently underscores the effectiveness of such integrated approaches. Clients receiving MOUD alongside psychosocial support are more likely to remain in treatment, avoid relapse, and reduce mortality compared to those receiving either intervention alone (Volkow et al., 2024). Integrated models also recognize the

importance of context: recovery is not just about removing opioids but about building a meaningful life that reduces the pull of return. For Jamal, securing stable employment was just as critical as learning cognitive restructuring skills or attending group sessions.

One of the strengths of integrated models is flexibility. Not all clients need the same combination at the same time. For some, beginning with MOUD may be essential to create enough stability for counseling to be effective. For others, initial work may focus on motivational interviewing to build readiness before exploring trauma history. The counselor's task is to act as a kind of conductor, helping to weave together the right blend of interventions in harmony with the client's needs.

Integrated care also extends beyond the walls of the counseling room. Counselors often collaborate with physicians, social workers, probation officers, and peer recovery specialists. This collaboration can transform what might otherwise feel like fragmented, even conflicting systems into a unified web of support. For clients accustomed to being lost in bureaucracies, this coordination signals respect and safety.

A counselor reflecting on Jamal's progress described the moment he brought in his daughter to meet the team that had supported his recovery. "This is the first time I've felt like people weren't just fixing me but helping me live," he said. That distinction matters. Integrated care does not reduce people to their addiction; it recognizes their humanity and addresses the broad set of conditions—biological, psychological, and social—that shape their lives.

From a clinical standpoint, integrated models require ongoing communication, shared decision-making, and humility. No single professional holds all the answers. Counselors working in these models must be comfortable both leading therapeutic interventions and collaborating within interdisciplinary teams. The benefit, however, is profound: clients receive consistent messages, coherent plans, and multiple forms of support reinforcing one another.

For Jamal, integrated treatment did not mean an end to struggle. He still faced cravings, conflict at home, and moments of doubt. But unlike past attempts, this time he wasn't navigating recovery alone or relying on a single fragile strategy. Instead, he had

medication to reduce physical cravings, counseling to reshape thoughts and address trauma, motivational interviewing to sustain his own reasons for change, and tangible support to rebuild his life. Together, these strands formed a net strong enough to catch him when he stumbled—and resilient enough to carry him forward.

Integrated models embody the essence of what modern counseling for opioid addiction can offer: not a single silver bullet, but a tapestry of interventions woven together in compassion and science. They remind us that recovery is not simply about stopping use but about creating a life that feels worth sustaining. For counselors, embracing integration means embracing the full humanity of clients, recognizing that change comes not in isolation but in community, collaboration, and care.

Transitional Summary

In this section, we explored the breadth of counseling modalities that form the backbone of effective care for individuals struggling with opioid addiction. Cognitive-behavioral therapy offers practical tools for reshaping thoughts and behaviors, giving clients the agency to disrupt old cycles and write new narratives. Motivational interviewing, in contrast, honors ambivalence and seeks to evoke change from within, helping clients like Andre discover their own reasons for moving forward. Trauma-informed care reminds us that substance use often begins as a survival strategy in the face of unbearable pain, and that healing requires safety, compassion, and empowerment. Finally, integrated models bring these strands together with medications, peer supports, and community resources, ensuring that recovery is supported across biological, psychological, and social dimensions.

Each modality carries unique strengths, but together they form a tapestry of care that is flexible, comprehensive, and profoundly human. Counselors who weave these approaches with warmth and precision create spaces where clients can move from shame to dignity, from despair to possibility. As we transition to the next section, Maria's story will illustrate how these principles come alive in practice—how counseling, in the context of relapse prevention, can nurture turning points that change the trajectory of a life.

2.3 Vignette: Maria's Turning Point

Maria sat in the waiting room, her leg bouncing furiously, hands clutched tight around a Styrofoam cup of coffee. It was her third attempt at treatment in two years. Each time she had begun with determination, vowing to her teenage son that this time she would get clean. Each time, a relapse had followed within months. Now, as she waited to see her counselor again, she wondered if there was any point. The shame was heavy, and the thought that echoed in her mind was simple: *Maybe I'm just not the kind of person who gets better*.

When she walked into her counselor's office, she braced for disappointment. Instead, the counselor smiled warmly and said, "I'm glad you came back." Those four words became the opening Maria needed to breathe. Instead of judgment, she encountered acceptance. Her counselor explained relapse not as a moral failure but as part of the chronic, relapsing nature of opioid use disorder (Volkow et al., 2024). For Maria, that shift was monumental. She had spent years seeing each relapse as proof of weakness. Hearing it reframed as information—an opportunity to learn about her triggers and vulnerabilities—gave her permission to try again.

In their sessions, the counselor used cognitive-behavioral therapy to help Maria examine the chain of events that led to her last relapse. She remembered the fight with her sister, the loneliness that followed, and the thought that whispered in her mind: *If I use just once, I won't feel so alone.* Together, they broke down that thought, tested its accuracy, and rehearsed alternative responses. Maria practiced writing thought records, learning to slow down her automatic beliefs. One day she reported proudly that she had caught herself mid-thought and instead of calling her dealer, she called her sponsor. "It wasn't easy," she admitted, "but I felt stronger afterwards."

The counselor also drew on motivational interviewing when Maria expressed doubts about whether staying sober was worth the effort. Rather than arguing, the counselor asked, "What are some things that matter most to you?" Maria grew quiet, then said, "My son. He deserves a mom who shows up." That moment became her own reason to keep trying. In later sessions, whenever her motivation wavered, the counselor gently

returned to her words: "You said your son deserves a mom who shows up. What would showing up look like this week?" By evoking her own values, the counselor kept her motivation rooted in her personal identity, not external pressure (Miller & Rollnick, 2023).

Yet it was trauma-informed care that provided the deeper breakthrough. In one session, Maria described the violence she had witnessed in her childhood home. For years, she had carried those memories in silence, believing they explained why she turned to opioids. When the counselor responded, "It makes sense that you found something to quiet that pain," Maria wept. Instead of shame, she felt compassion—for the first time directed inward. Recognizing that her use had been an attempt to survive, not proof of weakness, helped her begin to release the self-loathing that had fueled so many relapses (Knight et al., 2023).

An integrated treatment plan tied these pieces together. Maria began buprenorphine, which helped ease her cravings enough to focus in counseling. She attended a women's trauma group once a week, where she learned grounding techniques and shared her story with others who understood. Her counselor coordinated with her primary care physician and referred her to a local parenting class where she and her son could rebuild trust through shared activities. Over time, Maria no longer described treatment as something she was enduring, but as a network of support holding her up.

Her turning point came one rainy evening. She had a terrible day at work, her boss scolding her for being late. On the drive home, the thought emerged: *Just one pill, and this day will go away.* She pulled into a gas station and sat with her keys in her hand, phone in her lap, heart pounding. For nearly twenty minutes she sat there, fighting the pull. Then she dialed her counselor's voicemail and left a simple message: "I wanted to use, but I didn't." In session the next day, she described the moment with tears in her eyes. "I didn't think I could ever stop myself. But I did. Even just once."

That small victory became her anchor. Each success reinforced the possibility of the next. Her son began to notice changes, telling her, "You're different now. You keep your promises." Maria still struggled with cravings, and relapse remained a possibility, but the

narrative had shifted. Instead of being defined by failure, she began to see herself as someone capable of resilience.

Maria's story illustrates how relapse prevention is not about perfection but about building a web of supports—cognitive tools, motivational anchors, trauma healing, and integrated care—that together sustain recovery. Her turning point was not dramatic; it was the quiet decision to call for help instead of reaching for a pill. Yet in that small, ordinary moment, a new story began to unfold.

2.4 Navigating Resistance and Ambivalence: When Clients Are Not Ready for Change

In his first counseling session, Kevin leaned back in his chair, arms crossed, eyes narrowed. Every question seemed to meet a wall. When asked about his opioid use, he shrugged and muttered, "I don't think it's that big a deal." His parole officer had required treatment, but Kevin made it clear he wasn't convinced he needed to be there. For counselors, this is a familiar scenario: a client who is physically present but emotionally resistant, hovering between recognition and denial.

Resistance and ambivalence are not signs of failure. They are part of the fabric of addiction itself. Opioid use disorder hijacks the brain's reward system, rewiring motivation so that immediate relief outweighs long-term consequences (Volkow et al., 2024). Clients often enter treatment with genuine conflict: part of them longs for relief from the chaos, while another part clings to the drug as a lifeline. The counselor's task is not to "break through" resistance with force, but to meet it with curiosity, patience, and respect.

For Kevin, resistance wasn't hostility so much as self-protection. Years of stigma had taught him that admitting to a problem meant opening himself up to judgment. His counselor chose to lean into his ambivalence instead of pushing past it. When Kevin said, "It's not that bad," the counselor replied, "On some days it feels manageable. But I also wonder if there are times it feels out of control?" The question planted a seed. Kevin didn't respond immediately, but the next week he admitted, almost reluctantly, "There are mornings when I wake up sick and think, 'How did I get here?"

Ambivalence is often the doorway to change. Clients like Kevin may swing between denial and despair, sometimes in the same conversation. Motivational interviewing techniques are especially useful here, helping counselors highlight the discrepancy between what clients value and how their substance use interferes with those values (Miller & Rollnick, 2023). Kevin often spoke about his daughter, whom he hadn't seen in months. When the counselor reflected, "You want to be the kind of father who shows up, and sometimes your use gets in the way of that," Kevin grew quiet. He didn't argue—because it was true.

Resistance can also take subtler forms: missing appointments, avoiding eye contact, changing the subject when use is discussed. Trauma-informed care teaches counselors to interpret these behaviors not as defiance but as survival strategies. Many clients learned early in life that disclosure brought pain, not safety. For them, mistrust is rational. Counselors who take this lens are less likely to respond with frustration and more likely to explore what the client needs to feel safe enough to engage (SAMHSA, 2023).

A key principle in navigating ambivalence is pacing. Clients may want the counselor to prove that recovery is possible before they risk trying. Others may test the counselor with hostility or silence, waiting to see if they will remain steady. Kevin skipped two sessions in his second month. Instead of scolding, his counselor called and left a message: "I missed seeing you this week. You're welcome back whenever you're ready." Two weeks later, Kevin returned. "I thought you'd give up on me," he admitted. That moment of persistence on the counselor's part chipped away at his resistance more than any lecture could have.

Research highlights that dropout rates from opioid treatment programs are highest in the first month, when ambivalence is strongest (Santa Ana et al., 2023). Counselors who respond with empathy rather than judgment increase the likelihood of retention and long-term outcomes. One study found that clients who reported feeling respected by their counselor in the first session were twice as likely to remain in treatment six months later (Watkins et al., 2024).

Counselors also need to recognize that their own responses shape the dynamic. Resistance often provokes frustration—especially when the counselor sees the danger of overdose looming. But pressing harder can backfire, reinforcing the client's defenses. Kevin's counselor practiced reflective listening, even when Kevin dismissed his own progress. When he said, "I'm never going to change," she responded, "Part of you feels hopeless, and part of you is still here talking about it." By naming both sides, she gave voice to his ambivalence without demanding resolution.

Over time, Kevin's resistance softened. He began to share stories of exhaustion, of mornings when he woke up determined to quit, only to find himself using by afternoon. The counselor framed these not as failures but as evidence of the powerful grip of opioids. Together, they explored harm reduction strategies—safe use practices, overdose prevention with naloxone, and small steps toward cutting back. Meeting Kevin where he was allowed him to experience success, however modest, which built momentum for greater change.

Ambivalence does not resolve in a straight line. Clients may lean into change one week and pull back the next. What matters is that the counseling relationship remains a constant, steadying presence. For Kevin, the turning point came unexpectedly. He described watching his daughter play soccer from a distance, too ashamed to approach her. "I wanted to walk away, but I couldn't move. That's when I knew—I don't want to miss her life." That moment of clarity didn't eliminate his resistance overnight, but it gave him a reason to keep showing up.

Navigating resistance is, in many ways, the art of counseling itself. It requires patience to sit with silence, humility to let go of control, and faith in the client's capacity to change. For those battling opioid addiction, ambivalence is not the enemy but the terrain on which change is forged. By walking with clients through that terrain—steady, compassionate, and unhurried—counselors create the conditions where transformation can begin.

2.5 The Counselor's Self-Reflection: Managing Countertransference and Compassion Fatigue

On a Tuesday evening, after back-to-back sessions, Jordan sat in her office long after her last client had left. She felt heavy, her chest tight as she replayed the stories she had heard that day—relapse, loss of custody, another overdose scare. She thought of Marcus, who had promised to stay safe, only to call two days later from the hospital. She thought of Elena, whose trauma disclosures stirred feelings of both sadness and protective anger. Jordan found herself asking a question many counselors eventually face: How do I keep carrying these stories without being crushed by them?

Counselors who work with individuals struggling with opioid addiction are immersed daily in suffering. They witness the devastation of overdose, the fracturing of families, and the relentless cycles of relapse. In this context, self-reflection is not a luxury; it is a necessity. Without it, countertransference and compassion fatigue can quietly erode the counselor's effectiveness and well-being (Figley, 2023).

Countertransference refers to the counselor's own emotional reactions to clients, shaped by personal history, values, and vulnerabilities. In opioid counseling, these reactions may be especially intense. A counselor with a family history of substance use may feel frustration when a client relapses, interpreting it as personal betrayal. Others may feel compelled to rescue clients, overextending themselves in ways that ultimately undermine both counselor and client. Jordan noticed this in herself with Elena. Hearing about Elena's childhood abuse stirred memories of her own adolescence. She caught herself wanting to rush in with advice, to push Elena toward disclosure before she was ready. Recognizing this as countertransference, Jordan brought it to supervision, where she reflected on her triggers and found strategies to stay grounded.

Compassion fatigue is another hazard. Sometimes called "the cost of caring," it describes the emotional exhaustion that arises when counselors are continually exposed to suffering without adequate replenishment (Ray et al., 2024). Counselors may begin to feel numb, detached, or cynical. They may dread sessions or feel their empathy thinning. With opioid addiction, where relapse is common and progress can feel tenuous, compassion fatigue is an especially persistent risk. One counselor described it as "carrying hope for so many people that sometimes I forget where my own hope ends and theirs begins."

Self-reflection begins with awareness. Counselors must learn to recognize the early signs of strain: irritability after sessions, difficulty sleeping, fantasizing about leaving the profession. Journaling, mindfulness practices, and regular supervision provide mirrors where these signs can be noticed before they harden into burnout. For Jordan, keeping a reflective journal helped her notice patterns: she was most drained on days when clients canceled at the last minute, which stirred her fear of being ineffective. Naming this pattern allowed her to explore it in supervision, reducing its unconscious pull.

Boundaries are another vital aspect of reflection. Counselors in opioid treatment often feel the urge to be endlessly available, especially when clients are in crisis. While accessibility matters, blurring boundaries can create unsustainable pressure. Self-reflection allows counselors to ask: *Am I responding out of clinical wisdom or out of anxiety that I'm not enough?* Jordan learned to set clear availability policies, reassuring clients that they were still cared for even when she was not on call at all hours.

Resilience also grows through connection. Peer consultation, supervision, and professional networks provide spaces where counselors can share the weight of their work. Research shows that clinicians who engage in reflective supervision report lower rates of burnout and higher job satisfaction (Lawson & Venart, 2023). These spaces remind counselors that they are not alone, that the challenges they face are shared, and that support is available.

Self-reflection does not mean detachment from clients' pain. Rather, it means holding that pain with enough distance to remain present without being consumed. For Jordan, one practice was ending each day by naming not only the hardest moment but also one moment of hope—a client's smile, a small step forward, a courageous disclosure. This ritual anchored her attention in resilience as well as suffering.

Ultimately, counselors are not immune to the human toll of opioid addiction. They feel grief when clients die, frustration when relapse occurs, and joy when recovery blooms. Self-reflection is the practice that allows them to carry these emotions wisely, neither suppressing nor being overwhelmed by them. It is an act of humility, acknowledging that counselors, too, are shaped by the work they do.

Jordan often returned to a phrase from her supervisor: "You can't pour from an empty cup." She learned that caring for herself—through rest, reflection, and boundaries—was not selfish but essential. By tending to her own well-being, she was better able to sit with clients in their darkest hours, offering not just clinical skill but genuine presence. In this way, self-reflection becomes both a safeguard for the counselor and a gift to the client: the ability to remain steady, compassionate, and resilient in the face of immense suffering.

Chapter 2 Transitional Summary

In this chapter, we explored the heart of the counseling relationship with clients living through opioid addiction. We began with the fragile work of building trust, recognizing that stigma and shame often precede clients into the counseling room. We then turned to the counseling modalities that form the backbone of effective practice. Cognitive-behavioral therapy offers clients the skills to notice and reshape the thought patterns that perpetuate use. Motivational interviewing honors ambivalence and gives space for clients to discover their own reasons for change. Trauma-informed care reframes opioid use as, in many cases, an attempt to survive overwhelming pain, and reminds counselors to approach every behavior with compassion rather than condemnation. Integrated models bring these threads together, combining counseling with medication, peer support, and community resources to sustain long-term recovery.

The chapter also highlighted the human stories behind these modalities. Maria's turning point illustrated how relapse prevention grows from a network of supports rather than willpower alone. Kevin's ambivalence reminded us that resistance is not a barrier but the terrain where change takes root. Finally, Jordan's reflection underscored the necessity of counselor self-care. Without attention to countertransference, compassion fatigue, and boundaries, the work risks consuming those who offer it.

Taken together, these sections affirm that counseling in the opioid crisis is as much about presence as it is about technique. Counselors offer not only skills but also a steady belief in the client's dignity and capacity for growth. As we turn to Chapter 3, we

will widen the lens beyond the individual, exploring how family systems, communities, and broader social contexts shape the journey of both addiction and recovery.

Chapter 3. The Web of Recovery: Family, Community, and Systems 3.1 Family Systems and Opioid Addiction

When Sofia discovered that her twenty-year-old son, Mateo, had been using fentanyl, she felt as if the ground beneath her collapsed. She had noticed the late nights, the missing money, the hollowed look in his face, but she had convinced herself he was simply under stress at school. Now, sitting in a counselor's office with her husband and younger daughter beside her, Sofia whispered, "I don't know how we got here." Her family carried the strain in different ways—her husband with anger, her daughter with silence, Sofia herself with tears.

Stories like this are not unusual. Opioid addiction is often described as an "individual" disease, but in reality it is a family illness. The behaviors associated with opioid use—lying, secrecy, financial instability, unpredictable moods, legal problems—ripple outward, affecting partners, children, parents, and siblings. Families often experience cycles of trust and betrayal, hope and despair, enmeshment and detachment. Understanding these dynamics is essential for counselors who work with clients in recovery.

Families as Systems

Family systems theory reminds us that families function as interconnected units; when one member changes, the entire system is affected (Bowen, 1978/2023). In the context of opioid addiction, this interconnectedness can manifest in ways that both hinder and help recovery. Some families adapt by becoming hypervigilant, monitoring every move of the member with addiction. Others withdraw, leaving the individual isolated. Still others unconsciously enable, providing money or covering up consequences in the hope of protecting their loved one. None of these responses are malicious—they are

attempts to cope with overwhelming stress—but they can inadvertently reinforce the addiction cycle.

Counselors often encounter families caught between extremes. In one case, a father told his daughter, "I'm done with you until you get clean," while her mother continued to slip her money for food, knowing it might be spent on drugs. These contradictory responses left the daughter both abandoned and enabled, trapped in a cycle that strained every relationship.



Impact on Children

Children in families affected by opioid use disorder are especially vulnerable. Research indicates that children exposed to parental substance use have higher risks of anxiety, depression, behavioral problems, and eventual substance use themselves (Choi et al., 2024). Many children adopt roles—caretaker, peacemaker, invisible child—in an effort to stabilize the family system. A counselor working with Sofia's daughter noticed that the girl rarely spoke during sessions. When asked directly about her feelings, she said, "If I say anything, it will make things worse." Her silence was her way of preserving fragile stability, but it also meant her own needs were overlooked.

Grief, Shame, and Hope

Families living with opioid addiction often describe the experience as a kind of ambiguous loss. They grieve the person their loved one once was, even while that person is still alive (Boss, 2022). Sofia cried when she told her counselor, "I don't even recognize my son anymore." This grief intertwines with shame. Parents may feel they failed, partners may blame themselves, siblings may distance themselves out of embarrassment. Stigma compounds this pain, as many families hesitate to seek support for fear of judgment.

Yet families also hold profound potential for healing. Studies show that family involvement in treatment improves retention and long-term recovery outcomes for individuals with opioid use disorder (Rowe & Liddle, 2023). Families can provide accountability, encouragement, and a sense of belonging that counters the isolation fueling addiction.

Counseling Interventions with Families

For counselors, working with families requires both sensitivity and skill. Family sessions provide opportunities to educate relatives about the nature of opioid use disorder, helping them see relapse as part of a chronic illness rather than a moral failing. Counselors can guide conversations about boundaries—how to offer support without enabling, how to hold accountability without severing connection.

In Sofia's family, sessions became a space where anger, silence, and grief could be spoken aloud. Her husband admitted, "I'm scared my son will die, and anger is the only way I know to show it." Her daughter whispered, "I just want us to have dinner together without fighting." Over time, these conversations shifted the family's dynamic. Instead of each member reacting in isolation, they began to act with more unity—agreeing on consistent boundaries, practicing open communication, and finding support groups for themselves as well as for Mateo.

The Counselor's Role

Counselors must balance advocacy for the individual with attention to the system as a whole. They are tasked with holding space for multiple truths: that Mateo is responsible for his recovery, and that his family is deeply impacted; that families can help, but they cannot control; that love persists, even when trust has frayed. Interventions may include family therapy sessions, psychoeducation, referrals to groups like Nar-Anon, and ongoing support for children.

Closing Reflection

Opioid addiction disrupts not only the body and mind of the individual but also the relational fabric of families. Yet within that disruption lies opportunity. When families are supported, educated, and empowered, they can become vital partners in the recovery process. For Sofia and her family, the shift did not happen overnight. But slowly, they began to rediscover connection—not by pretending the addiction had not happened, but by learning to face it together.

3.2 Community Resources: Peer Support, Recovery Groups, and Wraparound Services

When Leonard left inpatient treatment after ninety days, he carried both hope and fear. In treatment, every day had a rhythm—group therapy in the morning, counseling in the afternoon, shared meals, curfews. Now, walking into his small apartment with its silence and unstructured time, he felt the pull of cravings return almost immediately. "I know

what I'm supposed to do," he told a friend, "but I don't know how to do it out here." What made the difference for Leonard was not only his counselor but the network of community resources that caught him before he slipped back into isolation.

For many individuals in recovery, the transition from structured treatment into daily life is one of the most vulnerable periods. Community resources—peer support groups, recovery housing, vocational programs, faith-based initiatives, and harm-reduction services—form the scaffolding that sustains recovery when professional counseling alone is not enough. Research underscores that individuals with access to strong community supports are more likely to maintain sobriety and less likely to relapse (Laudet & Humphreys, 2023).

Peer Support and Recovery Groups



Peer support groups such as Narcotics Anonymous (NA) or SMART Recovery provide something formal counseling cannot fully replicate: the lived wisdom of others who have walked the same path. In these spaces, the language of "I understand" carries a credibility born from shared struggle. Leonard recalled sitting in his first NA meeting, arms crossed, certain he didn't belong. Then a man across the circle spoke about waking up sick, swearing he would stop,

and using again by noon. Leonard felt his body jolt with recognition. "It was like he was telling my story," he said later. That moment of recognition became his entry point into belonging.

Peer recovery coaches extend this model by providing one-on-one mentorship from individuals in long-term recovery. Unlike counselors, who are trained professionals, peer coaches draw primarily on lived experience. They walk alongside clients in daily life—

helping them navigate appointments, model coping strategies, and offer encouragement when cravings surge. A recent study found that individuals paired with recovery coaches had higher rates of treatment retention and reduced emergency department visits compared to those without such support (Eddie et al., 2024).

Recovery Housing

Housing instability is another critical barrier to sustained recovery. Returning to environments where drug use is prevalent or where conflict dominates the home can unravel progress. Recovery housing offers a middle ground—structured living environments where sobriety is the expectation, but autonomy is encouraged. Residents share chores, attend house meetings, and support one another through the ups and downs of daily life.

For Marisol, whose story opened Chapter 1, recovery housing was her lifeline after detox. "At home, I was surrounded by reminders," she said. "In the house, I was surrounded by people who understood." Over time, the sense of accountability—knowing that her choices affected not just herself but her housemates—helped her rebuild routines of responsibility. Studies confirm that residents of recovery housing have higher rates of abstinence and employment compared to individuals returning directly to independent living (Polcin et al., 2023).

Vocational and Educational Programs

Recovery is not simply the absence of drugs; it is the presence of purpose. Employment and education provide meaning, structure, and financial stability—key protective factors against relapse. Community programs that assist with job training, resume building, or GED completion often serve as bridges back into society.

Take Andre, who after months of counseling still feared idle time. "When I don't have something to do, that's when I get into trouble," he admitted. His counselor referred him to a local nonprofit that partnered with unions to provide construction apprenticeships for people in recovery. The first months were grueling—early mornings, physical labor—

but Andre found that exhaustion replaced restlessness. "For the first time in years," he said, "I feel proud to bring home a paycheck."

Harm Reduction Services

Not all community resources require abstinence as a condition of participation. Harm reduction programs, such as syringe service programs, naloxone distribution, and safeuse education, aim to reduce the immediate risks of opioid use while supporting pathways to treatment. While controversial in some communities, research demonstrates that harm reduction services lower rates of infectious disease, prevent overdoses, and increase the likelihood of eventual entry into treatment (CDC, 2025).

Elena, still early in her recovery, carried naloxone provided by a local outreach worker. "They didn't judge me," she recalled. "They just wanted me to stay alive long enough to have a chance." That simple act of compassion became a stepping stone toward her eventual entry into treatment.

Faith and Community-Based Initiatives

In many towns, especially rural areas with limited formal services, faith-based organizations and grassroots groups provide essential support. These might take the form of weekly support circles in church basements, food pantries, transportation assistance, or volunteer opportunities. For clients who feel alienated from mainstream systems, these community-based initiatives often provide the first point of trust.

Leonard found a men's Bible study at a small local church. He admitted he wasn't sure what he believed, but the consistency of weekly gatherings, the sense of being welcomed, and the opportunity to share his struggles in a safe environment became another thread holding him in recovery.

The Web of Community

Community resources do more than provide practical support—they counter the isolation that fuels addiction. Clients often describe opioid use as narrowing their world

until nothing remains but the next dose. Community, in its many forms, expands that world again. It provides connection, accountability, purpose, and hope.

For Leonard, recovery was not the result of one counselor or one program but of a web of support: NA meetings, a peer coach, stable housing, and a job program. Each resource played a role; together they created the environment in which recovery became not just possible but sustainable.

3.3 Vignette: The Ramirez Family

On a humid summer evening in Texas, the Ramirez family sat crowded together in a small living room. The blinds were half-closed, a quiet attempt at privacy in a neighborhood where everyone seemed to know one another's business. At the center of the gathering was Carlos, a thirty-four-year-old father who had struggled with opioid addiction for nearly a decade. Around him were his wife, Rosa, their two children, and his mother, who had moved in after her husband's death. Each family member carried a different weight, but all of them bore the mark of Carlos's addiction.

For years, Rosa had lived in the push and pull of anger and hope. She remembered the man she married—playful, hardworking, devoted to his children. But the last few years had been a blur of broken promises, sleepless nights, and financial strain. "I love him," she told the counselor, "but sometimes I don't recognize him anymore." Their teenage son, Diego, carried his pain in silence. He avoided bringing friends home, ashamed of the tension that clung to the house. Their younger daughter, Sofia, swung between clinginess and defiance, sensing the instability but unable to name it.

Carlos's mother, Lourdes, approached the problem differently. She defended her son fiercely, insisting that his addiction was not his fault. "He just needs more time," she told the counselor, her eyes brimming with tears. "He's been through so much." The generational dynamic was palpable—Lourdes wanting to protect her son, Rosa yearning for accountability, the children caught in the middle.

The counselor invited the family to share how Carlos's addiction had touched their lives. Rosa spoke first, her voice trembling: "I'm tired of carrying everything. The bills, the kids, the lies. I can't do this alone anymore." Diego finally admitted, "I don't even talk to my dad at school when he shows up. I'm scared people will know." Sofia, clutching a stuffed animal, whispered, "I just want Daddy to stop being sick."

Carlos sat with his head in his hands. For years, he had justified his use—first as pain management after an injury, then as a way to cope with stress. Hearing his family's words stripped away those defenses. "I didn't realize how much I was breaking all of you," he murmured. In that moment, the family's pain became a mirror in which he could see himself more clearly.

Research affirms that involving families in treatment increases retention and improves outcomes for individuals with opioid use disorder (Rowe & Liddle, 2023). Yet the benefits extend beyond the person using; family therapy offers a space for relatives to voice their own grief, anger, and needs. In the Ramirez family, sessions gradually shifted from blame to dialogue. Rosa expressed her need for honesty and stability. Lourdes shared her fear of losing her son and her struggle to let go of control. Diego admitted he wanted to trust his father again but didn't know how. Sofia, in her child's simple language, reminded everyone of the hope still present.

Over time, the family began practicing small but significant changes. Rosa agreed to attend a support group for spouses. Lourdes began to recognize that protecting Carlos from consequences was not the same as loving him. Diego joined a group for teens affected by addiction, where he discovered he was not alone. Carlos, with the support of medication and counseling, began to rebuild his credibility, one step at a time.

The Ramirez family's story underscores the reality that opioid addiction is not an individual struggle but a multigenerational experience. Each member of the system adapts—some by enabling, some by distancing, some by over-functioning—and each needs support to heal. By bringing the whole family into the process, treatment acknowledges that recovery is not only Carlos's journey but theirs as well.

3.4 Collaboration with Medical and Legal Systems: Counselors as Bridges

When Anthony walked into the counseling office, he carried a stack of paperwork under his arm: a probation order requiring treatment, discharge instructions from a recent hospitalization after an overdose, and a referral from his primary care doctor. His life was no longer his own—it was mediated by courts, clinics, and case managers. "I feel like I'm just a file being passed around," he muttered. His counselor nodded gently, aware that for many clients with opioid addiction, the path to recovery winds through both medical and legal systems, often with little coordination between them.

Anthony's experience reflected a common reality. Opioid addiction is not just a clinical issue—it is a public health crisis that collides with the legal system at almost every turn. Many clients arrive in counseling through court mandates, probation requirements, or child protective services. Others come after medical crises—overdose, infections, or chronic pain. The overlap between these systems is profound, but for clients it can feel disjointed, confusing, even adversarial. Counselors often become the connecting thread, translating between systems and advocating for care that is both humane and effective.

Medical Collaboration

Medical providers play a critical role in opioid treatment. Medications for opioid use disorder (MOUD)—such as methadone, buprenorphine, and naltrexone—are evidence-based treatments that significantly reduce relapse and mortality (Volkow et al., 2024). Yet clients frequently report fragmented care: a physician prescribes medication, but there is little communication with the counselor; or a hospital treats an overdose, but no referral is made for follow-up therapy.

For Anthony, the hospital had stabilized him after an overdose but discharged him with only a pamphlet and a hotline number. It was his counselor who coordinated directly with a buprenorphine provider, ensuring that medication and therapy were aligned. This kind of collaboration can be life-saving. Recent studies show that patients receiving both MOUD and counseling are far more likely to remain engaged in treatment compared to those receiving either intervention alone (Wakeman et al., 2023).

Effective medical collaboration requires counselors to understand the basics of MOUD, respect the expertise of prescribers, and maintain open communication. It also means advocating for clients when stigma or gaps in care arise. One counselor recalled calling a pharmacy after a client was denied buprenorphine by a skeptical pharmacist. "He's in recovery," she explained firmly, "and this medication is part of his treatment." Such advocacy transforms abstract collaboration into tangible care.

Legal Collaboration

The legal system is another frequent touchpoint for clients with opioid addiction. Many enter treatment under probation orders, drug court mandates, or child welfare requirements. These referrals can feel coercive, but they can also create opportunities for intervention. Drug courts, for example, often combine judicial oversight with treatment mandates, aiming to reduce recidivism and promote recovery.

Anthony's probation officer required regular counseling reports. Initially, Anthony bristled at the intrusion, but over time he began to see the accountability as a form of structure. His counselor, acting as a bridge, reported progress honestly but also advocated for support rather than punishment when setbacks occurred. When Anthony relapsed briefly, the counselor emphasized to the court that relapse was part of the recovery process, recommending intensified treatment rather than incarceration. Research supports this approach: drug court participants who receive both supervision and comprehensive treatment show significantly lower rates of re-arrest compared to those receiving supervision alone (Mitchell et al., 2023).

Collaboration with legal systems is not without tension. Counselors must balance confidentiality with mandated reporting, navigate clients' fears of disclosure, and ensure that treatment remains therapeutic rather than punitive. For Anthony, knowing that his counselor respected his privacy—sharing only what was legally required—helped him trust the process rather than resist it.

Building Integrated Pathways

The challenge, and the opportunity, lies in creating integrated pathways where medical, legal, and counseling systems do not operate in silos. Too often, a client like Anthony is seen through separate lenses: the patient in a hospital bed, the defendant in a courtroom, the addict in a counseling office. Integration asks: *What if all these perspectives worked together toward the same goal—recovery, stability, dignity?*

Some communities are moving toward such integration. Models like "hub-and-spoke" systems coordinate MOUD providers, counselors, probation officers, and case managers, ensuring continuity of care (Brooklyn et al., 2024). Others use recovery-oriented systems of care (ROSC), where multiple agencies collaborate around shared principles of client-centered support. These efforts reduce duplication, close gaps, and create a more seamless experience for clients navigating complex systems.

For Anthony, the turning point was not a single intervention but the convergence of many. His counselor coordinated with his physician, communicated constructively with his probation officer, and connected him with a peer recovery group. Instead of being a "file passed around," Anthony began to feel like a person surrounded by a team. "For once," he told his counselor, "I feel like everyone is on the same side."

3.5 Addressing Social Determinants: Poverty, Housing Instability, and Employment Challenges in Recovery

When Denise left a residential treatment program after six months, she felt ready. She had stabilized on buprenorphine, reconnected with her children, and practiced coping strategies in counseling. But within weeks, the stability she had worked so hard to build began to unravel. The landlord of her small apartment raised the rent beyond her reach. Her part-time job at a diner provided irregular hours and no benefits. The stress mounted, and the cravings followed. "I didn't relapse because I wanted to," Denise later explained. "I relapsed because life pushed me into a corner."

Her story reflects a truth often overlooked: recovery does not occur in a vacuum. Social determinants—poverty, unstable housing, unemployment, lack of healthcare—are not

just background conditions but central forces shaping whether recovery can be sustained. Research shows that individuals with opioid use disorder who face social vulnerabilities are more likely to relapse, less likely to access treatment, and more likely to experience overdose (Deas et al., 2024). Addressing these realities is therefore not peripheral to treatment—it is essential.

Poverty and Economic Stress

Economic strain magnifies every other challenge. For many clients, financial instability means choosing between food, rent, and treatment. Transportation costs alone can derail recovery; a bus ticket to a clinic or a day missed at work for an appointment can tip the balance. Poverty also intersects with stigma, as clients navigating low-income systems often report being treated as "less deserving" of care (Kennedy-Hendricks et al., 2023).

Denise's counselor noticed how much of their sessions focused not on cravings or triggers, but on unpaid bills and overdue notices. Together, they explored community resources, such as rental assistance programs and food pantries. These supports did not solve everything, but they reduced immediate stress enough for Denise to remain engaged in treatment. Her story illustrates what research affirms: when basic needs are unmet, the cognitive and emotional load of survival overwhelms the capacity to focus on recovery (Deas et al., 2024).

Housing Instability

Stable housing is one of the most powerful predictors of recovery success. Without it, clients often cycle between shelters, friends' couches, and the streets—environments that increase exposure to drugs and heighten stress. A longitudinal study found that individuals with opioid use disorder who secured stable housing were nearly twice as likely to remain abstinent at one-year follow-up compared to those experiencing homelessness (Polcin et al., 2023).

For Marcus, housing instability became his greatest obstacle. After a relapse, his partner asked him to leave, and he bounced between relatives who welcomed him

reluctantly. Each environment carried its own risks—relatives who used, neighborhoods where drugs were readily available, overcrowded conditions that left no room for privacy. Only after being accepted into a recovery housing program did he find enough stability to focus again on treatment. "Having a bed I could count on," he said, "was what gave me the strength to keep going."

Employment and Purpose

Employment is more than a paycheck. It provides structure, purpose, and identity— elements that counteract the emptiness addiction often creates. Yet many clients face barriers to employment: criminal records, gaps in work history, lack of transportation, or physical limitations from injuries. These barriers can become demoralizing, reinforcing the belief that life outside of addiction holds no place for them.

Jamal, introduced earlier, had applied for dozens of jobs without success. Each rejection deepened his frustration. "They see my record and toss the application," he said. His counselor connected him with a vocational program specializing in second-chance employment for individuals with justice involvement. Within months, Jamal was working as an apprentice electrician. "It's not just work," he reflected. "It's proof that I can belong somewhere again."

Programs that link treatment with job training and education have shown significant promise. Clients who engage in vocational supports are more likely to maintain abstinence and report higher life satisfaction (Laudet & Humphreys, 2023). Employment restores not only financial stability but also self-worth, reinforcing the belief that recovery is more than survival—it is growth.

Intersections of Inequality

Social determinants are rarely isolated. Poverty often coincides with unstable housing, food insecurity, and limited healthcare access. These conditions disproportionately affect marginalized populations, including racial and ethnic minorities, rural residents, and those involved in the criminal justice system (Brooklyn et al., 2024). For these clients, recovery requires navigating not only personal cravings but systemic inequities.

Denise's relapse after losing her housing was not simply about willpower. It was about the cumulative weight of poverty, lack of affordable housing, and limited job security. Without addressing these layers, recovery programs risk setting clients up for failure. This recognition has led to the expansion of recovery-oriented systems of care (ROSC), which integrate medical, counseling, and social supports into a single framework (Brooklyn et al., 2024). Such systems view housing, employment, and healthcare not as adjuncts to treatment but as central pillars.

A Broader Vision of Recovery

Addressing social determinants requires creativity and collaboration. Counselors connect clients with housing agencies, advocate for second-chance hiring, and coordinate with social workers and case managers. Peer recovery coaches often guide clients through the maze of applications and waiting lists. While these efforts do not erase systemic inequities, they create openings where clients can breathe, stabilize, and imagine new possibilities.

For Denise, the turning point came when she secured transitional housing through a community partnership. With her rent stabilized and a case manager helping with childcare, she was able to focus again on counseling. "It wasn't that I suddenly wanted recovery more," she said. "It was that recovery finally felt possible."

Her words capture the essence of addressing social determinants. Recovery is not only about abstaining from opioids—it is about building a life where abstinence can be sustained. Poverty, housing instability, and unemployment are not side issues; they are the terrain on which recovery is either built or broken. By acknowledging and addressing these realities, communities give individuals not just a chance to survive, but a chance to thrive.

Chapter 3 Transitional Summary

Chapter 3 has widened the lens beyond the individual to the broader contexts in which opioid addiction and recovery unfold. Families, as we saw in the Ramirez story, are not bystanders but participants, each member shaped by the strain and capable of

contributing to healing. Community resources such as peer support groups, recovery housing, and vocational programs demonstrate that recovery is sustained not only through individual resolve but through webs of belonging and accountability. Collaboration with medical and legal systems highlighted the importance of integration—ensuring that care is not fragmented but aligned across institutions that often hold power over clients' lives. Finally, we examined the social determinants that underpin the recovery journey, showing how poverty, housing instability, and unemployment can undermine progress unless addressed directly.

Taken together, these sections affirm that opioid addiction is not a solitary struggle but a systemic challenge. Recovery requires coordinated responses that include families, communities, institutions, and policies. Counselors stand at the intersection of these systems, helping clients navigate complexity while keeping the focus on dignity, resilience, and hope. With this understanding of context, we now turn to Chapter 4, where we explore the non-linear nature of recovery, the reality of relapse, and the long-term work of sustaining growth.

Chapter 4. Hope, Relapse, and Long-Term Growth

4.1 The Non-Linear Nature of Recovery

When Thomas completed a year of counseling and celebrated twelve months of sobriety, his friends and family gathered with pride. They brought cake, balloons, and congratulations. "You did it!" his sister exclaimed, hugging him tightly. But weeks later, after an unexpected layoff and the return of back pain, Thomas relapsed. Sitting once again in his counselor's office, he whispered, "I thought I was past this. Maybe I'll never be free."

His words capture one of the most difficult truths about opioid addiction: recovery is not linear. It does not progress neatly from treatment to abstinence to lifelong stability. Instead, it is often cyclical, with periods of progress interrupted by setbacks.

Counselors, families, and clients themselves may long for a straight path forward, but

the reality is more complex. Relapse rates for opioid use disorder are comparable to those of other chronic illnesses such as diabetes and hypertension (Volkow et al., 2024). This reality does not mean treatment has failed—it means that recovery, like other chronic conditions, requires ongoing management, adjustment, and resilience.

Relapse as Part of the Process



For many clients, relapse carries profound shame. Thomas saw his slip as proof that his progress meant nothing, that the year of sobriety had been erased. But research and clinical wisdom affirm otherwise: relapse does not erase growth; it offers information about vulnerabilities, triggers, and the ongoing need for support (McHugh et al., 2023). When clients and families reframe relapse as part of a non-linear journey rather than as failure, hope is preserved.

Maria, whose turning point was described earlier, had also relapsed several times before finding stability. Each time, her counselor encouraged her to explore what had led to the

lapse. Was it unstructured time? Conflict at home? Physical pain? These reflections allowed her to prepare differently the next time. Rather than viewing relapse as the end of recovery, her counselor framed it as another chapter in a longer story—an approach consistent with trauma-informed and motivational models of care.

The Myth of the "Rock Bottom"

Popular culture often promotes the idea that people must "hit rock bottom" before they can recover. But this narrative oversimplifies and stigmatizes the process. Many individuals recover without catastrophic loss, and others relapse even after devastating consequences. Recovery is not ignited by a single dramatic moment; it is nurtured by repeated opportunities for change, layered supports, and compassionate persistence (Laudet & Humphreys, 2023).

Thomas's relapse after a year of sobriety did not mean he had not "hit bottom" deeply enough; it meant that new stressors—job loss, pain—activated vulnerabilities that required fresh strategies. Acknowledging recovery as non-linear makes space for these realities, reducing the burden of shame and allowing clients to re-engage without losing dignity.

Cycles of Change

The Transtheoretical Model of Change (often called the "Stages of Change") provides a useful lens for understanding the non-linear nature of recovery (Prochaska & DiClemente, 2023). Clients may move from precontemplation ("I don't have a problem") to contemplation ("Maybe I should cut back"), to preparation and action, and then into maintenance. Relapse often returns them to earlier stages, but not to the very beginning. Each cycle brings new awareness, new skills, and new motivation.

Diego, a young man in treatment, described it this way: "Every time I fell, I learned something. I didn't go back to zero—I went back with more knowledge." Counselors who normalize this cyclical process help clients view relapse not as erasure but as part of growth.

The Role of Resilience

Resilience is what allows clients to re-engage after relapse. It is built through supportive counseling relationships, peer networks, family involvement, and access to community resources. Thomas's counselor reminded him of his year of sobriety, his rebuilding of family trust, his ability to manage cravings before. "That year is not gone," she told him.

"It is proof of what you are capable of." That reframing helped Thomas return not with despair but with renewed determination.

Research supports the importance of resilience-building strategies—mindfulness, self-compassion, social support—in sustaining long-term recovery even amid setbacks (Ray et al., 2024). These practices buffer against the hopelessness that relapse can generate, making it possible to reframe the narrative from failure to persistence.

Holding Hope in the Spiral

Recovery often resembles a spiral more than a straight line. Clients circle back to old patterns, but at a higher level of awareness each time. Counselors hold hope during the moments when clients cannot see their own progress. Families, too, are invited to shift perspective—from expecting perfection to supporting persistence.

For Thomas, the relapse that once felt like proof of failure became a turning point when reframed as part of the journey. He began to see recovery not as a fragile achievement that could be lost, but as a lifelong practice of learning, adapting, and returning to center. His story, like so many others, reminds us that recovery is not defined by the absence of relapse but by the ability to rise after each fall.

4.2 Vignette: Thomas's Relapse and Return

Thomas had always been the dependable one in his family. A mechanic by trade, he worked long hours, coached his nephew's Little League team, and was the first to show up when a neighbor's car wouldn't start. But an injury at work left him with chronic back pain, and what began as prescribed opioids slowly became dependence. When the prescriptions ran out, illicit pills and eventually heroin filled the void.

By the time he entered treatment, Thomas had lost his job, drained his savings, and strained his marriage nearly to breaking. Yet when he completed a year of counseling and celebrated twelve months of sobriety, it felt like a rebirth. His wife cried as she

hugged him, his church group brought food and flowers, and Thomas himself said, "I finally feel like myself again."

But recovery is rarely linear. Just three weeks after his one-year milestone, Thomas's shop announced layoffs. He was one of the first to go. The news crushed him. His sense of identity—as provider, worker, dependable man—was shaken. On top of that, his back pain flared under the stress. "I told myself I'd just take one," he admitted later. "One to get through the night." That one stretched into weeks, and soon he was using daily again.

When he returned to his counselor, shoulders slumped and voice barely above a whisper, his shame was palpable. "I ruined everything," he said. "All that work, all that time—gone." His counselor leaned forward gently: "That year is not gone. It is proof that you can do this. Relapse doesn't erase progress—it shows us where you need more support."

This reframing was crucial. Thomas had internalized the idea that relapse meant failure, an idea that research shows often leads individuals to abandon treatment entirely (McHugh et al., 2023). By normalizing relapse as part of a chronic condition, his counselor kept the door open for renewed engagement.

Together, they mapped out what had led to his return to use. Job loss was the first trigger, stripping him of both income and identity. Chronic pain was the second, reminding him of the physical vulnerability that had started his opioid use years before. Stress and shame piled on, convincing him that a slip meant inevitable collapse.

The counselor integrated multiple approaches. Using cognitive-behavioral strategies, they worked to identify and challenge Thomas's automatic thoughts—*I'll never change, I'm worthless without my job.* Through motivational interviewing, the counselor drew out Thomas's values: being present for his wife, returning to coaching, rebuilding trust with his family. Trauma-informed care allowed Thomas to name the fear beneath his relapse—the fear of helplessness—and to learn grounding strategies for the moments when panic surged.

Equally important was reconnecting Thomas to community supports. His counselor referred him to a vocational rehabilitation program, where he began retraining for a less physically demanding job. He rejoined his church recovery group, where peers reminded him that relapse was not the end of the story. He also saw a physician to adjust his pain management plan, integrating non-opioid medications and physical therapy.

Over time, Thomas began to regain equilibrium. One evening, he stood again on the sidelines of his nephew's baseball game. "I thought I'd lost the right to be here," he told his counselor afterward. "But being here sober feels even better than it did the first time."

Thomas's story illustrates the reality of recovery as a process of falling and rising, learning and returning. His relapse was not a sign that treatment had failed; it was evidence that stressors and pain required ongoing strategies. With support, he discovered that recovery was not about never stumbling, but about getting back up, again and again, each time a little stronger.

4.3 Sustaining Long-Term Recovery

After nearly three years of sobriety, Jasmine described her life as "both ordinary and extraordinary." Ordinary, because she worked a steady job at a grocery store, paid her bills, and walked her dog each evening after dinner. Extraordinary, because just five years earlier she had lived in the chaos of opioid addiction—nights of desperation, mornings of withdrawal, and a future she believed she had lost forever. "Sometimes I have to remind myself," she told her counselor, "that ordinary life is the miracle."

Sustaining long-term recovery requires more than initial treatment or the achievement of abstinence. It is the ongoing work of creating a stable, meaningful life that can withstand the inevitable stressors and transitions of adulthood. Counselors who walk with clients through these later stages recognize that the challenges of long-term recovery are not about learning how to guit, but about learning how to live.

Building Daily Routines

Jasmine emphasized how much structure mattered to her recovery. In early sobriety, idle time had been her greatest enemy. Now, routines anchored her days: waking at the same time, making coffee, journaling before work, attending a weekly recovery meeting, setting aside Sunday afternoons for family dinners. Research affirms the importance of daily structure, showing that consistent routines reduce relapse risk and improve psychological well-being among those with substance use disorders (Hser et al., 2023).

For many clients, these routines are not glamorous but essential. Work schedules, exercise habits, meal planning, and sleep hygiene become protective factors. Over time, they form the scaffolding on which a new identity is built—one rooted not in survival but in stability.

Maintaining Social Connections



Long-term recovery also relies on the cultivation of healthy relationships. For Jasmine, this meant carefully pruning her social circle. She no longer spent time with old friends who still used opioids, even when they begged her to reconnect. Instead, she invested in relationships that supported her growth—her sister, colleagues from work, and peers from her recovery group.

Social connectedness is one of the most consistent predictors of sustained recovery. A longitudinal study found that individuals with strong social support networks were significantly more likely to maintain abstinence at five-year follow-up (Kelly et al., 2024). Counselors can help

clients assess their relational worlds—identifying which connections nurture and which threaten their recovery.

Addressing Co-Occurring Conditions

For many clients, sustaining recovery also means managing mental health conditions such as depression, anxiety, or PTSD. Left untreated, these conditions can resurface as relapse triggers. Jasmine, for instance, struggled with persistent anxiety. In her first year of recovery, she often described feeling "wired and restless," which made cravings worse. With integrated care—counseling, mindfulness practices, and non-addictive medication—she learned to manage her anxiety without returning to opioids.

The integration of mental health and substance use care is increasingly recognized as essential. Studies show that clients with untreated co-occurring disorders relapse at higher rates, while those in integrated programs achieve longer periods of sobriety (Watkins et al., 2024). Sustained recovery therefore requires ongoing assessment and treatment that address the whole person, not just the substance use.

Purpose and Identity

Perhaps most transformative is the shift in identity that long-term recovery allows. In early treatment, many clients describe themselves primarily through the lens of addiction: "I'm an addict," "I'm broken," "I'm hopeless." Over time, as sobriety is sustained, new identities emerge: worker, parent, friend, artist, volunteer. These identities provide not only self-worth but also anchors that help weather relapse risks.

Jamal, who once believed he had no future beyond day-to-day survival, now introduces himself as an electrician's apprentice. "That's who I am now," he said proudly. "Not just someone who used to use." Research on recovery capital—the internal and external resources individuals accumulate over time—emphasizes that purpose and identity are key predictors of sustained recovery (Best & Aston, 2023).

Relapse Prevention as Lifelong Practice

Even in long-term recovery, relapse remains a possibility. Sustaining sobriety requires ongoing vigilance—recognizing warning signs, managing stress, and staying connected to supports. Many clients develop personalized relapse prevention plans, updating them as life circumstances change. Jasmine kept hers written in the back of her journal: a list of triggers, coping strategies, and names she could call in crisis.

Her counselor reminded her that relapse prevention is not about fear but about readiness. "It's like keeping a fire extinguisher in the kitchen," she explained. "You hope you'll never need it, but having it gives you confidence." This approach reduces anxiety while empowering clients to take ownership of their recovery.

The Quiet Miracles

Long-term recovery is often less dramatic than early sobriety. It is measured not in milestones but in the quiet persistence of ordinary days. Jasmine described it best: "It's not about fireworks anymore. It's about waking up, going to work, cooking dinner, and knowing I don't need opioids to get through the day."

For counselors, supporting long-term recovery means honoring these ordinary victories as extraordinary. It means helping clients sustain routines, nurture relationships, manage co-occurring conditions, and cultivate purpose. Most of all, it means affirming that recovery is not just about surviving addiction, but about living fully beyond it.

4.4 The Role of Counselors in Lifelong Recovery Support: From Crisis Intervention to Thriving

When Maya answered the phone late one evening, she recognized the voice immediately. It was Andre, the client who had called her years earlier in tears after a relapse, convinced he had lost everything. This time, his voice carried a different weight: steady, grounded. "I just wanted you to know," he said, "I got promoted at work today. Five years sober. I couldn't have imagined this back then."

Counselors walk with clients across the spectrum of recovery—from the chaos of overdose crises to the quiet victories of long-term thriving. Their role is not static; it shifts as clients move through different phases of recovery. In early moments, counselors may act as lifelines, grounding individuals in the midst of crisis. Over time, their role often becomes one of scaffolding—helping clients build skills, connections, and identities strong enough to sustain themselves.

Crisis Intervention

In the earliest encounters, the counselor's task may be as urgent as keeping someone alive. Overdose prevention, safety planning, and connection to emergency resources are often first priorities. For clients in acute withdrawal or high-risk environments, counselors provide stabilization: orienting them to immediate supports, reducing shame, and instilling the smallest spark of hope. Research emphasizes that rapid connection to treatment after crisis events significantly increases survival rates and engagement (Wakeman et al., 2023).

Sustaining Recovery

As clients stabilize, the counselor's role expands into teaching and reinforcing coping strategies. Modalities like CBT and motivational interviewing equip individuals to handle cravings, manage stress, and navigate ambivalence. Trauma-informed approaches help clients understand the roots of their use and learn to carry their histories without being crushed by them. Counselors also bridge gaps between systems—coordinating with medical providers, probation officers, and social workers to ensure continuity of care.

For Jasmine, introduced earlier, her counselor became a steady presence not just through her first year but into her third and fourth, reminding her that relapse prevention was not about fear but about readiness. "You believed in me before I believed in myself," Jasmine told her counselor. That belief became an anchor, allowing Jasmine to transition from fragile sobriety into sustained recovery.

Thriving Beyond Sobriety

In long-term recovery, the counselor's role often shifts again. The focus is less on crisis and relapse prevention and more on flourishing. Clients begin to explore new goals: returning to school, building careers, repairing relationships, or developing spiritual practices. Counselors support these aspirations by fostering resilience, encouraging community engagement, and celebrating the quiet victories that mark thriving.

Andre's late-night phone call reflected this stage. Once consumed by cravings and legal crises, he now spoke as a man proud of his accomplishments. His counselor's role had transformed from crisis responder to cheerleader, someone who could reflect back the progress Andre himself had sometimes struggled to see.

In this way, counselors embody continuity across the nonlinear journey of recovery. They meet clients at their lowest points, walk beside them through setbacks, and celebrate when ordinary life becomes extraordinary again. Their task is not to carry clients indefinitely but to walk alongside until clients can carry themselves—and even then, to remain a trusted presence when needed.

4.5 Closing Reflections: Holding Space for Hope, Resilience, and Dignity

As this course draws to a close, it is worth pausing to remember the human faces behind the clinical terms. Marisol, the mother desperate to escape the cycle of relapse; Marcus, the worker numbing both pain and memories; Elena, the survivor of trauma learning to reclaim safety; Maria, finding her turning point; Thomas, falling and rising again; Jasmine, celebrating the miracle of ordinary life. Their stories remind us that opioid addiction is not an abstract epidemic—it is lived in homes, families, and communities every day.

Counselors stand in a unique position. They are witnesses to despair but also to resilience. They hear the darkest confessions and the first fragile whispers of hope. They see clients stumble and rise, again and again, and they hold faith when clients cannot yet hold it for themselves. This work requires skill, yes, but even more, it requires presence—the ability to sit with suffering without flinching, to reflect dignity

back to those who have lost sight of it, and to carry hope like a lantern through dark terrain.

The opioid crisis will not end tomorrow. Relapse will remain common, overdose rates will continue to challenge communities, and families will keep wrestling with grief and survival. Yet in the midst of this, recovery stories unfold every day. A parent reunites with a child. A client returns to work. A family sits down to dinner without fear. These moments are not small; they are profound acts of healing.

For counselors, the invitation is to keep holding space—for crisis and for thriving, for relapse and for resilience, for despair and for dignity. In doing so, they become not just practitioners of treatment but companions in the lifelong journey of recovery.

Conclusion

Chapter 4 reminded us that recovery from opioid addiction is rarely straightforward. We began by exploring the non-linear nature of recovery, reframing relapse not as failure but as part of a chronic, cyclical process that provides opportunities for learning and growth. Through Thomas's journey, we saw how relapse and return can become pivotal turning points when met with compassion and persistence rather than shame. Sustaining long-term recovery emerged as an ongoing practice of structure, connection, purpose, and resilience—measured not only in milestones but in the quiet miracles of ordinary life.

In the final sections, we reflected on the role of counselors as enduring companions in this journey. From crisis intervention to long-term thriving, counselors adapt alongside their clients, offering presence, advocacy, and belief in dignity when it is most needed. Closing reflections brought us back to the core: that behind every statistic are lives worth honoring, families worth strengthening, and communities worth healing. By holding space for both suffering and resilience, counselors not only support recovery—they embody hope itself.

End of the course!