Missouri Department of Mental Health
Division of Behavioral Health

Provider Implementation Guide for
the
State Opioid Response Grant
(Opioid SOR)

July 2020

Developed by the Missouri Department of Mental Health, Division of Behavioral Health, and members of the Opioid SOR team
# Table of Contents

Introduction ......................................................................................................................................... 3  
General Overview of Grant and Grant Requirements ................................................................. 3  
Important Points to Remember ................................................................................................... 4  
DBH Policy Expectations for the Use of Medications for OUD ................................................ 6  
Clinical Guide for Intake and Psychosocial/Supportive Services .............................................. 7  
Appendix A. Eligibility Determination Memorandum ............................................................... 12  
Clinical Guide for Medical Treatment of Opioid Use Disorder ............................................. 13  
Phases of Medical OUD Treatment .............................................................................................. 13  
1. Induction ................................................................................................................................... 14  
2. Stabilization ............................................................................................................................ 16  
3. Maintenance ........................................................................................................................... 17  
4. Tapering and Discontinuing Buprenorphine with Patients .................................................. 19  
CIMOR Procedures for Client Admission, Enrollment, and Billing ........................................ 23  
Guide for Opioid SOR Program Data Reporting ........................................................................ 24  
Appendix B. The Evidence of Medical vs Abstinence Treatment for Opioid Use Disorder .... 32  
Appendix C. Services Not Reimbursable under SOR ................................................................. 35  
Appendix D. Recovery Community Center Contact Information ............................................ 36  
Appendix E. Example Opioid SOR Phone Screening ................................................................. 37  
Appendix F. Example Initial Screen for Opioid Use Presentation ............................................ 38  
Appendix G. Points to Cover in Overdose Education and Naloxone Distribution (OEND) ....... 40  
Appendix H. Overdose Education and Naloxone Distribution Fact Sheet ............................... 41  
Appendix I. Overdose Field Report ............................................................................................ 42  
Appendix J. Addiction vs. Dependence: Medical Treatment for Addiction Group Exercise ...... 52  
Appendix K. Recovery Housing Information ............................................................................ 54  
Appendix L. SOR Funded Recovery Housing Memorandum .................................................... 56  
Appendix M. Transportation Services ....................................................................................... 57  
Appendix N. Outreach Service Codes ....................................................................................... 58  
Appendix O. Sample Brochure Outlining Buprenorphine Clinic Protocols ............................ 59  
Appendix P. Resources for the Use of Methadone and Naltrexone ......................................... 60  
Appendix Q. GPRA Information ................................................................................................. 71
Introduction

This guide is intended to help providers deliver treatment and supportive services to individuals with Opioid Use Disorder (OUD) under the State Opioid Response Grant (Opioid SOR). The DMH and Opioid SOR team have developed this Provider Implementation Guide to outline clear and consistent guidance with step-by-step clinical and administrative instructions on grant utilization. While the guide addresses specifics about the SOR grant, most of the content is applicable to any agencies serving individuals with OUD.

This guide is divided into multiple sections, as many provider staff are involved in the consumer experience and the billing process and have distinct roles. We encourage you to distribute particular sections to the staff who could most benefit from the information. These sections include the following:

- General Overview of Grant and Grant Requirements
- Important Points to Remember
- DBH Policy Expectations for the Use of Medications for OUD
- Clinical Guide for Intake and Psychosocial Supportive Services
- Clinical Guide for Medical Treatment of OUD
- Customer Information Management, Outcomes and Reporting (CIMOR) Procedures for Client Admission, Enrollment, and Billing
- Guide for Data Reporting

General Overview of Grant and Grant Requirements

The Opioid STR project was a $20 million two-year award from the Substance Abuse and Mental Health Services Administration (SAMHSA), using funds provided by the 21st Century Cures Act federal legislation. Missouri Opioid STR expanded access to integrated prevention, treatment, and recovery support services for individuals with OUD throughout the state. The primary focus for SOR continues to be on rigorous, multidisciplinary provider training and education on the medical treatment of OUD, and the provision of evidence-based treatment services to uninsured individuals diagnosed with OUD who present for care to state-funded programs.

Missouri received $36 million through the SOR project for FY 2018 and 2019, with an additional $9.5 million in supplemental funding. Primary prevention activities are centered on increased awareness and decreased availability of opioids, led by local agencies in high-risk areas. Prevention of overdose deaths is accomplished through training clinical providers and at-risk individuals on Overdose Education and Naloxone Distribution practices, and providing telemedicine didactic and consultation services to primary care providers treating chronic pain. Numerous lives have been saved in initial grant years as a result of this training and naloxone distribution.

Recovery support services are provided in the form of Recovery Community Centers, recovery housing, and recovery management checkups, all delivered by peer support specialists in an effort to increase consumer engagement in treatment and long-term recovery. The Missouri
Department of Mental Health (DMH) leads the project, with administration, implementation, and evaluation activities provided by the University of Missouri, St. Louis - Missouri Institute of Mental Health (UMSL-MIMH), as well as healthcare agencies, additional academic institutions, and content experts throughout the state. The primary goals of the Opioid SOR project are the following:

1. Increase provider and student-focused opioid misuse and overdose prevention initiatives and programs;

2. Increase access to evidence-based medical treatment for uninsured individuals diagnosed with OUD through provider training, direct service delivery, healthcare integration, and improved transitions of care;

3. Increase the number of individuals diagnosed with an OUD who receive recovery support services; and,

4. Enhance sustainability through policy and practice changes, as well as demonstrate clinical- and cost-effectiveness of grant-supported protocols.

**Important Points to Remember**

Basic information of which providers should be aware:

1. The primary goal of this grant is to **SAVE LIVES**.

2. Medication in conjunction with behavioral health services is considered the most effective treatment for OUD (See Appendix B).

3. **SOR funds cannot supplant** other funds. Given the prior point, additional individuals shall be served in all programs accessing SOR funds.

4. SOR funds are to be used for individuals without Medicaid. **CIMOR will not verify Medicaid eligibility, meaning all encounters will process as non-Medicaid.** Providers must be sure they are enrolling non-Medicaid consumers. All efforts should still be made to have potential Medicaid eligible clients apply for Medicaid, and if a client becomes Medicaid eligible post-SOR enrollment, they should be seamlessly moved to CSTAR. If an SOR consumer becomes Medicaid eligible, they will need to be enrolled in a CSTAR program on the date of eligibility, and services from date of eligibility must be billed to the CSTAR program.

5. Opioid SOR program services may be billed when **Eligibility Determination is complete** and the diagnosis is signed off on by a licensed diagnostician. The **Eligibility Determination for SOR consumers** in the Medication First approach only consists of the

   A. initial diagnosis (physician or other qualified provider’s diagnosis),
   B. initial treatment recommendations, and
   C. initial treatment goals (to meet immediate needs) for the first 45 days of treatment. Often this requirement is met during the first visit with the doctor under the Medication First approach.
6. The **GPRA** is required upon intake for ALL Opioid SOR consumers. GPRA must be entered in CIMOR before services can be billed (CIMOR business rules have been relaxed through the end of SOR year 2, September 30, 2020 to allow providers ability to backdate GPRAs originally collected via paper format while CIMOR enhancements were made to allow for SOR GPRAs) See Appendix Q.

7. For individuals served in the Opioid SOR program, neither **Treatment Episode Data Set (TEDS) data**, nor a completed **Daily Living Assessment 20 (DLA-20)**, are required to bill the Eligibility Determination. However, a **GAF score will be required** on the CIMOR diagnosis tab. (See #6 under CIMOR Procedures for Client Admission, Enrollment, and Billing section.)

8. **TEDS** data will be required within the first **30 days of treatment** and **upon discharge** only (CIMOR business rules were changed to allow for this).

9. The **DLA-20 is not required** for SOR consumers, but DMH recommends it be completed following medical stabilization and within 30 days of the date of the Eligibility Determination.

10. There are **no treatment levels in SOR**. The **frequency and intensity of services must be based on the individualized needs identified in the assessment**. Consumers may initiate and proceed with treatment at the frequency and intensity most appropriate to meet their needs. Some consumers may not need intensive psychosocial support services (lower “threshold”), though all should be offered the full menu of available and appropriate services. Individuals prescribed medication will not be “mandated” to attend or participate in an arbitrary number of services in order to continue to be prescribed medications to treat their OUD. Agencies have reported that the use of **peer supports** at the time of medication induction and thereafter has been very helpful in engaging consumers in psychosocial services.

11. There is a selection of services that may be provided to individuals served through the SOR grant, but that **SOR funds will not pay for**. For this specific set of services (see Appendix C), the provider’s regular allocation will be used. The SOR grant supports the services with the strongest evidence base (e.g., medication), as well as those that are considered best practices for the treatment of any substance use disorder (e.g., family therapy).

12. Multiple episodes of care (EOCs) or program assignments do **NOT** need to be opened in CIMOR for the provider to be reimbursed for non-SOR funded services. Payment for these services will default to the provider’s contract associated with the location where SOR services are provided.

13. Agencies serving individuals with OUD should utilize and collaborate with SOR funded **Recovery Community Centers** (Appendix D) and Recovery Housing (Appendix K). For more information please visit: [https://www.nomodeaths.org/recovery-community-centers](https://www.nomodeaths.org/recovery-community-centers) and [https://www.nomodeaths.org/recovery-housing](https://www.nomodeaths.org/recovery-housing)
DBH Policy Expectations for the Use of Medications for OUD

“10 Do’s and Don’ts of Medical Treatment for OUD”

1. Do not initiate a taper or discontinuation of buprenorphine or methadone in response to any client “infraction” (e.g., missing therapy sessions).

2. (Other side of #1) Do not mandate participation in individual or group counseling as a requirement for continued medical treatment. See #10.


4. Do not encourage 'rapid' buprenorphine taper protocols with the goal of transitioning to antagonist medications or no medications at all.

5. Do not discharge a client based on positive drug test results for illicit substances.

6. Do not discharge a client from a residential setting without enough medication to supply them to their first outpatient physician visit.

7. Do not withhold medical treatment if the treatment provider does not have staffing capacity to provide psychosocial services at the time the client presents.

8. Do not switch a client from Injectable Naltrexone (XR-Naltrexone) to oral naltrexone solely for cost saving purposes.

9. Do individualize dose decisions based on individual client factors, particularly craving intensity and environmental support (i.e., be wary of underdosing – most clients do best when stabilized between 16mg-24mg of buprenorphine per day).

10. Do increase client accountability measures (e.g., drug testing, frequency of medication/dosing visits) -- if and when adherence to treatment protocols becomes disrupted by client behaviors described above -- without discontinuing the needed medications. Use motivational interviewing and make clear the rationale for the recommendation of individualized psychosocial supports. Peer support services can also be effective in helping a consumer engage in needed services.

Compiled from guidelines within the following sources:
- The FDA Drug Safety Communication (2017)
The SOR grant has provided an opportunity to reevaluate our intake process, particularly as it relates to serving those diagnosed with OUDs. Historically, an individual had to have a comprehensive assessment and multiple other forms completed prior to seeing a physician; however, we have implemented a “Medication First” approach minimizing the burden of paperwork on the front end. Many times individuals with OUD present in the early stages of withdrawal, which is an opportune time to get them connected with a medical professional, stabilized, and then engaged in care planning. Thus, the goals of this re-imagined intake process are to 1) provide rapid access to medical treatment by eliminating known barriers; and, 2) prevent providers from losing reimbursement if an individual enrolls in services but does not return to complete the comprehensive assessment and treatment plan.

The following represent “steps” to take in terms of engaging an individual in services supported through SOR:

1. The individual seeking services makes **first contact with the organization**. *(Note: There is no “wrong door.” First contact could be through outpatient clinic, crisis stabilization site, withdrawal management unit, etc.)*

2. If first contact is **by phone, the provider will conduct their typical pre-admission screening in addition to supplemental brief screening on opioid use**. *(See Appendix E; only triggered if individual reports uses opioids in pre-admission screening)* If the individual answers yes to any questions on the opioid supplemental screening, the provider will schedule the consumer for first available medical appointment.

   **The in-person brief screening (described below) will take place when the individual arrives for his/her first appointment prior to the medical appointment.**

   The individual is designated as an **emergent** client for immediate treatment access.

3. **Alert appropriate staff of client contact and need for emergent medical visit** and proceed with scheduling medical visit. *(Prior to the initial medical visit, the individual is administered a brief screening (see Appendix F for an example) by a medical staff coordinator (or other qualified staff) to determine presenting concerns and experience of current opioid withdrawal symptoms. The screening may include information such as the following:*

   a. Date of birth
   b. Vital signs
   c. Results of a drug screen
   d. Report of substances used in the past 30 days, frequency of use, date/amount of last use, and route of administration
   e. Report of prior overdose events
   f. Current medications
4. If the individual is in **active opioid withdrawal** and/or has used opiates within the past five (5) days:
   a. Connect individual with a prescriber who is onsite, via telehealth, or local.
   b. If the individual must travel for the appointment and has no means of transportation, facilitate transportation as needed and appropriate. If accompanied by a care coordinator, community support specialist, or peer specialist because their presence is needed (rationale documented appropriately), the time traveled by the coordinator or CSS is billable through SOR at standard community support/peer support service rates.

5. **Prescriber initiates** methadone (in an OTP) or buprenorphine (in clinic or at home) **induction** and **prescribes naloxone** and other ancillary **medications** as clinically indicated. (XR-Naltrexone cannot be started if a person is in withdrawal. Medication protocols are detailed in the following section, “Clinical Guide for Medical Treatment of OUD.”)
   (Note: the naloxone is for take-home purposes and is **billable to Opioid SOR** under the CIMOR code: NALOX.)
   a. **DMH strongly encourages the provision of overdose education and a naloxone prescription upon the earliest possible contact with a consumer, given the high risk of overdose before, during, and after treatment episodes. (See step 7, below.)** Ideally, this service would be provided during the first visit (following receipt of stabilizing medication); if not possible, please complete at the second visit.

   Whenever possible include a family member or caregiver in the discussion about naloxone use – **people who overdose cannot administer naloxone to themselves.**

6. Complete the **Eligibility Determination as soon as possible.** Required information includes:
   a. **Diagnoses**, including substance use and mental health disorders, medical conditions, and notation for psychosocial and contextual factors (*rendered by physician or other eligible licensed diagnostician*). SOR-eligible diagnoses are included in the CIMOR procedure section later in the document. Services leading up to the diagnosis and submission of the Eligibility Determination are reimbursable (e.g., if diagnostic services are provided on Tuesday, but the diagnosis is not entered into CIMOR until Thursday, the Tuesday services will still be covered).

   The following **mental health professionals are approved to render diagnoses** in accordance with the current edition of the Diagnostic and Statistical Manual of Mental Disorders:
   - Physicians (including psychiatrists);
   - Psychologists (licensed or provisionally licensed);
   - Advanced Practice Nurses;
   - Physician Assistants
   - Professional Counselors (licensed or provisionally licensed);
   - Marital and Family Therapists (licensed or provisionally licensed);
   - Licensed Clinical Social Workers;
• Licensed Master Social Workers who are under registered supervision with the Missouri Division of Professional Registration for licensure as a Clinical Social Worker. (LMSWs not under registered supervision for their LCSW credential cannot render a diagnosis).

b. **Initial treatment recommendations.** These are rendered by physician and/or agency staff who is coordinating care in this early treatment stage.

c. **Initial treatment goals to meet immediate needs within the first 45 days of service.** Goals are established with individual prior to, during, or following visit with prescriber. Goals established prior to the medical visit will be by agency staff providing service coordination.

7. The care coordinator, nurse, or other appropriately trained staff conducts **Overdose Education and Naloxone Distribution (OEND) training** with the individual and natural supports whenever possible.

OEND is a 10-15 minute conversation about overdose risk and response, including instructions on naloxone administration. *(See Appendix G-I for an outline of what should be covered and handouts for clients, and visit the “Training” tab on www.mohopeproject.org to request staff OEND training.)*

   a. Review overdose prevention, recognition, and response strategies, including how to use naloxone.
   b. Prescribe naloxone (recommended forms are AdaptPharma Narcan nasal spray and intramuscular injection naloxone hydrochloride).
   c. Instruct client to pick up naloxone at the pharmacy at the same time other medications are collected.

8. **Schedule appointments** with staff whose services are identified as needed (e.g., counselor, community support specialist, peer specialist).

9. Facilitate the **comprehensive assessment within 30 days of the date of Eligibility Determination** *(see other DMH policy documents regarding the assessment components).* The assessment does NOT need to be completed within 72 hours for residential or three outpatient office visits. Clinically, it is not appropriate to do a “comprehensive” assessment while the individual is in active withdrawal or before s/he is stabilized on medication.

10. Develop the **comprehensive treatment plan within 45 days of the date of Eligibility Determination** *(see other DMH policy documents regarding treatment plan components).*
   a. The treatment plan should be a working document, with goals added and dropped as they are identified and achieved, with the involvement of the individual served.
   b. Services are billable if they relate to an identified need in the assessment and are included on the treatment plan.
   c. Make sure the treatment plan addresses all life domains affected by the OUD.
11. Collect and enter into CIMOR the **TEDS data within 30 days** of program assignment.

12. **Provide comprehensive, person-centered, individualized services.** To highlight just a few:

   a. **Community Support** for those with needs related to entitlements, housing, employment, social supports, legal problems, physical health and wellness, etc. There are 25 service functions under the Community Support Service -- be sure to use this service for all those who have identified needs in life domains. *(Reference: *Community Support Definitions and Key Service Functions:* [https://dmh.mo.gov/media/pdf/community-support-definitions-and-key-service-functions-handout](https://dmh.mo.gov/media/pdf/community-support-definitions-and-key-service-functions-handout)*)

   b. **Individual Counseling** must be highly individualized. *Motivational interviewing* should be utilized. *Cognitive-behavioral therapies and interventions* have the best outcomes in the literature, particularly those focusing on craving management and behavior modification. Remember that individuals with specialized needs may benefit from Co-Occurring and/or Trauma-Specific Individual Counseling when provided by qualified staff. *(Included in Appendix J is a helpful psychosocial exercise: Addiction Versus Dependence: Medical Treatment for Addiction.)*

   c. **Peer Support** is a required service under Opioid SOR, as recognition of its benefits is increasingly widespread. Peers have been used successfully in outreach, active treatment, and recovery services. *(Reference: *Clinical Services Bulletin #30 Peer Support Services:* [https://dmh.mo.gov/media/pdf/030-peer-support-services](https://dmh.mo.gov/media/pdf/030-peer-support-services)*)

   d. **Recovery Housing** should be provided for individuals treated through Opioid SOR who have been through medical stabilization but need a safe, healthy environment to support engagement in treatment (including but not limited to medication services). Opioid SOR can be billed for housing services at locations approved by the National Alliance for Recovery Residences (NARR) and certified as an Opioid SOR housing provider by DBH *(for updating listings of approved housing units, visit: [https://www.nomodeaths.org/recovery-housing](https://www.nomodeaths.org/recovery-housing)*)

   A condition of DBH housing approval is that the housing entity does not discriminate against and is accepting of individuals on all forms of medication for the treatment of OUD. *(More information on housing services in Appendix K.)*

   e. **Transportation.** Individuals who lack adequate transportation should receive this service through community provider agencies. This is billable through SOR *(see Appendix M).*

   f. **Medically Monitored Inpatient Detoxification (MMID)** may be indicated for a subset of individuals served. However, MMID should not include traditional “detox” and tapering protocols, but rather induction and stabilization on a therapeutic dose of buprenorphine for continued dosing through outpatient maintenance.
g. Social setting detox is NOT supported in the literature as an appropriate intervention for individuals in opioid (or alcohol or benzodiazepine) withdrawal. [See TIP 45: “…hospitalization (or some form of 24-hour medical care) is generally the preferred setting for detoxification based on principles of safety and humanitarian concerns.”]
Every effort should be made to have a consumer seen by a physician (or other prescribing provider), and addiction medication initiated, PRIOR to admission to a SSD setting. Clients would self-administer medication (as they would any other prescribed medication in this setting), communicating as directed with the prescriber/staff (as they would with an at-home induction).

h. Client-specific Outreach can be used to facilitate and maintain client engagement (re-engagement efforts that are not billable as community support). (See Appendix N for revised service codes.) This service may involve recovery management check-ups, which involve reviewing the individual’s recovery and progress in the areas of substance use, housing, employment, criminal justice, and social connectedness.

i. Recovery Community Centers are available as a resource in St. Louis, Kansas City, and Springfield. (For a complete list of SOR funded RCC’s see Appendix D or visit https://www.nomodeaths.org/recovery-community-centers) Recovery Community Centers offer supportive services such as peer-to-peer support, support groups, overdose education and naloxone distribution, housing referrals, monthly telephone check-ups, and substance-free social activities.

13. Continue providing comprehensive, person-centered, individualized services. There is no established timeframe for engagement in treatment for substance use disorders. There is not a finite number of hours of treatment one must complete. Neither are there timeframes established for how long an individual should take medications prescribed for his/her chronic medical illness(es), addiction being one of them.

Individuals should continue in services (which may include maintenance medications) as long as needed, receiving no more and no less treatment than is indicated by their individualized needs. That will look different for everyone!

14. Transition to other care settings through warm hand-offs. Individuals on maintenance medication for OUD who have stable environments and do not require a high level of care may not be best suited for ongoing care in an SUD specialty setting. Instead, an outpatient setting like primary care or an Opioid Treatment Program (OTP) may be used to continue maintenance. Once the referral is made to an alternate care setting, the consumer should have an adequate supply of medication and remain engaged with the Opioid SOR provider until it has been verified that the consumer presented for his/her first appointment with the new provider(s). If circumstances change and the individual requires a higher level of care in the future, he/she should readily resume care at the SUD agency. This requires bi-directional “warm handoff” relationships between appropriate agencies, as well as a potential revision of discharge policies and procedures.
Appendix A. Eligibility Determination Memorandum

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Official Memorandum

Date: September 3, 2019

To: All DBH Contracted Providers

From: Nora K. Bock, DBH Deputy Director of Adult Community Treatment  
Corinne Cahalan, DBH Director of Children's Services

Re: Assessment Billing – No Recoupment after Eligibility Determination

Affected Programs: SOR, CPR, CSTAR, JRI

There are no CIMOR business rules tied to the comprehensive assessment and billing of other services. The diagnosis and functional assessment score are required to be in CIMOR.

If an individual’s Eligibility Determination has been completed and s/he receives services, but then discontinues services prior to the completion of the comprehensive assessment (within the first 30 days), the services billed and paid for will not be recouped. Providers should bill for all services rendered.

If you have any questions, you may email the CIMOR DBH Support Center by logging in and selecting the Help Ticket option found on the left side menu of the portal, https://portal.dmh.mo.gov

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Clinical Guide for Medical Treatment of Opioid Use Disorder

The frequency and extent of treatment and rehabilitation services shall be adjusted based on individual patient needs.

Individuals enrolled in the Opioid SOR program need not receive treatment in accordance with levels of care. Consumers may initiate and proceed with treatment at the frequency and intensity most appropriate to meet their needs. Some consumers will not need intensive psychosocial support services, though all should be offered the full menu of appropriate services, consistent with their individualized needs.

It should be noted that the majority of the following guidance is in reference to induction, stabilization, and maintenance on buprenorphine. Buprenorphine has been found to be highly effective for OUD stabilization and maintenance.

Methadone and XR-Naltrexone remain appropriate treatments for many individuals and these medications are supported by DMH and reimbursed through Opioid SOR. However, because methadone is administered in a controlled OTP setting (by clinicians well-versed in Federal OTP guidelines and state standards of care), and because XR-Naltrexone is a non-controlled substance that has been increasingly used within the DMH treatment system since 2011, this guidance document does not go into significant detail about either medication.

A subset of patients may require Modified Medical Inpatient Detoxification (MMID). Patients who also use high doses of benzodiazepines, alcohol, or other substances with risk of respiratory depression, along with opioids, should be considered for MMID. However, MMID should not include tapering protocols, but rather induction and stabilization on a therapeutic dose of buprenorphine for continued dosing through outpatient maintenance. Arrangements for discharge and follow-up appointments should begin on Day 1 of MMID. Upon discharge from MMID, patients should be prescribed an adequate supply of medication to last until their first follow-up outpatient appointment with a prescriber. Following MMID, patients should engage in standard Opioid SOR treatment protocol, outlined below.

Phases of Medical OUD Treatment:

The descriptions and guidelines presented in this section reflect best practices and guidance provided by the:


For comprehensive, yet succinct guidance for physicians, nurse practitioners (NPs), and physician assistants (PAs) regarding medication induction, stabilization, and maintenance protocols, DMH recommends frequent consultation of ASAM’s pocket guide.
1. **Induction:**

The goal of the induction is to find the patient's ideal daily dose of buprenorphine that safely suppresses opioid withdrawal and drug craving as rapidly as possible. For most opioid-dependent patients, the daily dose with the most therapeutic benefit is 16-24 mg/day of the buprenorphine + naloxone combination film or tablet. Induction usually takes 2 to 4 days to complete. Buprenorphine + naloxone combination is preferred except for use in special populations such as pregnant women (in pregnancy, use of buprenorphine monoproduct [or methadone] are best practice). The following recommendations are for buprenorphine + naloxone combination tablets or films.

Induction can either be done in the outpatient clinic setting or in the patient's home environment. Office-based induction is recommended if the physician/prescriber or patient is unfamiliar with the process, or either of them do not feel comfortable with initiating home induction with buprenorphine. However, more experienced providers may feel confident and comfortable facilitating home induction, with good nursing support to intermittently guide the patient through the process over the phone or through telehealth.

**Induction Steps:**

- The first dose of buprenorphine + naloxone combination pill or film should be administered when an opioid-dependent individual has abstained from opioids for 12 to 24 hours and is in moderate withdrawal (If using the Clinical Opiate Withdrawal Scale ([COWS](#)), a score of 12 or 13).
- Day 1 of induction: Opioid-dependent patients should be inducted with a 4mgs dose of buprenorphine, and observed for 1-2 hours. If withdrawal symptoms are not well controlled or they reappear, an additional 4mgs should be given. Additional doses in increments of 2mgs can be given up to a dose of 12 to 16mgs.
- For office based induction, it is helpful to allow a 2-4 hour window of office time on the first day of induction. A nurse or medical assistant can perform the monitoring and titrate the medication based on the withdrawal symptoms, based on the physician/prescriber’s order. The patient is not necessarily required to sit in the office the entire time.
- For off-site/home induction, on Day 1, remote support should be offered by a nurse (through phone or telehealth) to help assess withdrawal symptoms and determine readiness for induction. This could include but is not limited to assessment of discomfort, agitation, joint pain, stomach upset, diarrhea, chills, restlessness, and other common withdrawal symptoms. The Subjective Opioid Withdrawal Scale ([SOWS](#)) can be used by the nurse to assist with the assessment of opioid withdrawal symptoms via the phone.
- If the patient experiences continued withdrawal symptoms and cravings after Day 1, dosage should be increased on Day 2 in increments of 2-4 mg up to 16 mg. Some patients may need titration up to 24mgs. By Day 3 or 4, the dosage needed to fully control the withdrawal symptoms should be determined. There is limited evidence for the efficacy of doses greater than 24 mg, but some patients may benefit from doses up to 32 mg. Doses higher than this will not harm the patient but will do little to decrease patients’ cravings, due to a ceiling effect.
If switching from methadone to buprenorphine, the dosage of methadone needs to be tapered down to 30 mgs per day of methadone before the buprenorphine induction. It may take more than 36 hours after the last dose of methadone for the patient to be in mild or moderate withdrawal. Also, start with a 2 mg dose of buprenorphine and titrate by 2mgs to decrease risk of precipitating acute withdrawal.

Important things to note:

- Initial and maintenance dosing depend on several patient use factors. **Avoid under-dosing on both induction and maintenance dose.** Under-dosed patients are at increased risk of overdose. (Severity of factors below suggest higher induction dose and maintenance dose)
  - Types of opioids
  - Quantity of opioids
  - Other addictive substances used routinely or episodically
  - Age of onset of use of addictive substances

- At a minimum, weekly visits are recommended with the physician/prescriber during the induction phase.
- Between follow-up appointments with the physician/prescriber, patients can be assessed by nursing support staff.
- During the office visits, urine drug screens or salivary drug screens for other substances and for the presence of buprenorphine or its metabolites should be administered.
- Other recommended labs: liver function tests, and pregnancy test for female patients.
- The role of community support specialists, peers, care managers, and other psychosocial support staff during the induction phase should focus on:
  - Motivational enhancement
  - Treatment engagement
  - Craving management
  - Other strategies to support the patient during what is often a physically distressing period
  - Securing a safe environment

- Extensive talk therapy sessions or assessments may serve as a barrier to treatment at this point and should be avoided until the patient has stabilized.

**Note:** Though Opioid SOR services are available for uninsured individuals only, **DMH recommends this protocol be utilized for all individuals, no matter their payer source.** For individuals with insurance (MO HealthNet, private, or other), prior authorization for the initial buprenorphine prescription may be required. This underscores the importance of having a partnership with a nearby pharmacy to streamline the prescription process and, for individuals with Medicaid, being familiar with MO HealthNet prior authorization rules and practices.

For individuals with MO HealthNet coverage requiring a Prior Authorization from the treatment provider, call this toll-free number and listen to the menu of options. Phone: (800) 392-8030; Fax: (573) 636-6470.
2. **Stabilization:**

**Goals:**

- To determine the appropriate stabilizing dose of medication needed to:
  - block the effects of illicit opioids
  - eliminate or greatly reduce opioid craving and illicit opioid use
  - facilitate patient engagement in recovery-oriented activities including psychosocial interventions
- To inform the patient of the variety of psychosocial support services available through the treatment program.

**Stabilization Steps:**

- The next 6-8 weeks after the induction is the stabilization period, during which time patients should be maintained at their daily dose with close monitoring and adjustments as needed.
- At an ideal daily dose, the patient should experience no withdrawal symptoms and no cravings.
- Regular and frequent clinic visits (recommended: weekly) should continue until the patient stabilizes medically and psychosocially.
- Continue urine or salivary drug screens for buprenorphine, illicit opioids, and other substances relevant to the patient’s treatment.
- Deliver individualized treatment and recovery support services.
- Begin to address environmental and psychosocial needs (e.g., peer and community support, housing, counseling), with the understanding that medical stability remains the treatment priority and psychosocial services should not serve as a barrier to medical treatment.
- Take reasonable steps to reduce the chances of diversion while keeping patient care, functioning, and stability as the top treatment priorities. Strategies to reduce diversion include:
  - Requiring frequent office visits (e.g., every three days instead of weekly)
  - Drug testing
  - Observed dosing
  - Recall visits for medication/pill counts
  - Conduct “wrapper counts” for Suboxone; match serial numbers with records
  - Patient education on strategies to secure medication and prevent theft

**A special note about drug testing and treatment implications:**

At this time, it is widely recommended that drug testing is done at each medication-related visit and includes testing for buprenorphine.

- If patients test positive for illicit opioids, the following may increase compliance and improve engagement:
  - Increased buprenorphine dose (after assessment for cravings and need for on-going use of illicit opioids)
  - Increased medical visit frequency
  - Motivational interviewing/peer support
Important things to note:

Most patients will eliminate their illicit opioid use \textit{gradually} as they stabilize on buprenorphine and develop confidence in its therapeutic effects. Some will continue to use other substances but will nevertheless experience significant improvements in functioning. Discontinuing buprenorphine therapy is generally not clinically indicated if its use is associated with any decrease in illicit opioid use.

Patients should be educated about the risk of combining buprenorphine with alcohol or benzodiazepines, but a high degree of caution should be exercised before discontinuing buprenorphine due to drug or alcohol misuse. Discontinuing buprenorphine is very likely to precipitate a relapse to heroin or prescription opioid misuse and the associated risk to patients.

Consider some creative dosing in prescriptions, for example:

- Write prescriptions and instruct patients to allow for an extra 5-10 days of 4 mg Suboxone
- Discuss other medications and/or non-medication tools to help on higher craving days

3. Maintenance:

The maintenance phase is reached when the patient is functioning well on a steady dose of buprenorphine with little or no cravings and little or no illicit opioid use. The maintenance phase will continue indefinitely for most patients. Long-term maintenance is recommended due to high relapse rates.

While it is best to maintain a patient on the lowest effective dose of any therapeutic agent, be mindful, particularly in the first year of maintenance, that patients will have good days and bad days, higher craving days, and changes in their lives. This is a normal part of the recovery process.

Goals:

- Prevent or decrease risk of relapse.
- Retain patients in treatment.
- Avoid under-dosing Assist patients in making continued improvements in functioning and quality of life
- If the patient is medically, socially, and environmentally stable, facilitate a warm handoff to continue maintenance treatment with a community provider with ability to continue buprenorphine prescription.
- If the patient is medically, socially, and environmentally stable, AND expresses wishes to taper off medication or transition to XR-Naltrexone/long-acting naltrexone, assist with this gradual and highly collaborative process.
Maintenance Steps:

- Continue medical visits approximately monthly or more frequently if a patient demonstrates non-adherence.
- Monitor the patient’s cravings for opioids and develop strategies for effective management of cravings.
- Labs:
  - Monthly urine toxicology screens including buprenorphine
  - After the initial pregnancy tests for all women of childbearing age, ask each month thereafter if the patient thinks they may be pregnant, or test the patient as indicated. Request to be notified if they think they are pregnant.
  - Liver function tests every 6 months if the initial test was abnormal, or with liver disease

- When a patient resumes use of illicit substances, steps should be taken to re-engage them and provide medical stabilization as quickly as possible. Resumed use will often require patients to return for the induction and stabilization phases of treatment.
- Continue implementing the individualized care plan, including but not limited to medical care coordination, community support, peer engagement, vocational training, housing support, individual counseling, and other services as needed.

However, *psychosocial support services should never function as a barrier to treatment*. For example, if an individual requests less frequent psychosocial visits because the current appointments interfere with procuring or maintaining employment, accommodations should be made to continue providing medical services while reducing the frequency of psychosocial visits.

- If the patient is medically, socially, and environmentally stable, facilitate a warm handoff to continue maintenance treatment at an office-based treatment facility:
  - Many Federally Qualified Health Centers (FQHCs), Community Mental Health Centers (CMHCs), Opioid Treatment Programs (OTPs) and other state-contracted and private treatment facilities are now offering buprenorphine treatment for OUD and could serve as excellent referral destinations for patients.

- If a patient plans to transfer to another care setting:
  - The patient should have a buprenorphine prescription/supply to last until their appointment with a prescribing provider at the new facility.
  - Should the patient later require a higher level of care, they should resume treatment at the SUD treatment facility with minimal wait time and barriers. This “cooperative” model of specialty and primary care will likely require alterations to existing protocols and the development of memoranda of understanding between cooperating agencies.
A Note about Accountability Structures:

Explain to patients initially – and repeat frequently – that accountability structures are ways to promote patient safety. They are NOT intended to be punishments. Urine drug screens, PDMP alerts, wrapper counts, etc., are conversation starters, not sledgehammers. Alarming results, including indications of diversion, should be met with a question, “What’s going on?” “Can you help me understand your situation?”

Explore options with the treatment team to promote accountability-oriented communications. These may include:

- Utilizing a brochure with guidelines based in contingency-management (See Appendix O for an example that can be modified to suit the needs of your agency)
- Support staff counting Suboxone wrappers since the client’s last visit
- Routine outreach, recovery management checkup, and appointment reminder calls
- Utilize a Treatment Agreement.
  - Discussing rules and expectations is an important step when starting a client on buprenorphine treatment. Some providers choose to use a printed and signed Treatment Agreement (see this example from ASAM. Note – this content may differ from your clinic’s protocol. Review and revise as necessary before use.)

4. Tapering and Discontinuing Buprenorphine with Patients:

Things to note prior to initiating a taper:

- Tapering and discontinuing buprenorphine for a patient who wants buprenorphine maintenance and is responding well to buprenorphine therapy is not recommended.
- There is a high risk for relapse when medical treatment is discontinued, even if a patient has been in maintenance treatment for months or years.
- Discontinuing buprenorphine, methadone, or XR-Naltrexone is not required. Patients can continue medication therapy indefinitely so long as:
  - They choose to;
  - They experience no significant adverse events that would render treatment contraindicated;
  - The treatment improves their functioning and/or decreases their risk for morbidity and mortality.
- Illicit opioid use should not be grounds for terminating buprenorphine treatment. Alternative responses include checking on proper use of buprenorphine and dose, increasing the frequency of medical and/or monitoring visits, and offering additional psychosocial support services.
- Assess for under dosing as a driver for desire to discontinue (i.e., the medication
is prescribed at too low a dose to achieve optimal therapeutic benefit
• If anyone on the treatment team becomes aware that a patient wants to discontinue Suboxone, inform the prescribing provider and the RN or staff member coordinating the patient’s care.

Having the conversation*:

(*to be facilitated by both medical and psychosocial providers):

Although the majority of patients who discontinue buprenorphine do so involuntarily, some may choose to discontinue and may request the prescriber to taper and discontinue the medication. If a patient expresses an interest in discontinuing the use of addiction medications, providers should engage in a collaborative decision-making process with the patient (and key primary support persons, if possible).

• When a patient is considering a buprenorphine or methadone taper, or a discontinuation of injectable naltrexone, providers should invite them and their loved ones to reflect on the role the medication has had on their recovery and their lives. For example, providers might ask:

“What are your reasons for wanting to discontinue medical treatment?”

“How effective has this medication been in helping you stop your opioid use?”

“How has your life improved as a result of this change?”

“Would you want to stop the medication if you knew these positive gains might be lost?”

• It is important to inform patients that although it may seem like the gains they have achieved with the help of medication can be maintained in its absence, evidence strongly suggests that, for the majority of patients, this perception is not accurate.

Indeed, for the majority of patients, the medication works when you take it and stops working when it is discontinued (not unlike hypertension or cholesterol medication!).

○ For patients who have maintained abstinence from illicit opioids for 5 years or more, their likelihood of maintaining future abstinence is substantially higher than that for those who have been abstinence for <5 years.

• Providers should assess and address patients’ motivations for wanting to discontinue medical treatment, paying attention to the degree to which these motivations are intrinsic (coming from internal factors) or extrinsic (coming from external factors). External factors that are impacting a patient’s decision to discontinue medications might include: pressure from family or peers, negative social stigma,
discrimination in the workplace or the job or housing market, etc. Providers should validate these real concerns and provide support to continue the medication, if such support is something the patient is lacking. Of course, the provider’s primary role in this exchange is to offer medical advice based on empirical evidence.

- **For buprenorphine specifically, providers should indicate that continuing buprenorphine therapy will (conservatively) decrease by 2 to 3 times their risk for relapse, overdose, and death.** Explicitly share that Suboxone discontinuation is associated with a 50-90% relapse rate. The protective effect of buprenorphine is likely to be greater for patients who injected heroin or have other risk factors for overdose (such as previous overdose events, co-occurring mental health diagnoses, prior suicide attempts, etc.).

- Patients should be informed that discontinuation of the medication is especially contraindicated if they are experiencing instability in any key domain of functioning (e.g., mental/emotional health, primary support system, housing, employment) and if they do not have in place elements of a robust non-medical recovery plan (e.g., consistent and active involvement in a recovery community, a 12-step sponsor).

- **Risk of relapse and overdose will increase following the discontinuation of any medication** (though relative risk of overdose following buprenorphine or methadone is less than the risk following abstinence or naltrexone/XR-Naltrexone treatment). Patients’ tolerance to opioids has decreased and, should they resume use, they must start at much lower doses than they used prior to initiating treatment.

**Tapering Steps:**

If, following discussion of the above, the patient and provider agree to proceed with discontinuation, the provider should note the following and share this information with the patient:

- The more gradual the taper, the less likely that the patient will experience significant craving and withdrawal symptoms. **Therefore, the more gradual the taper, the safer the taper.**
- Tapers should be paced based on patients’ ability to tolerate each decrease. As such, providers should increase the frequency of office visits during the taper process to regularly assess craving and withdrawal symptoms.
- The length of tapering steps and the magnitude of dose reductions should be individualized to the patient’s response and, ideally, would take place over several months.
- In general, decreases should not comprise more than 25% of the current dose and not take place more frequently than every 10 days.
  - Some patients will benefit from even smaller and less frequent dose reductions. For example, a patient may be able to step down 4mg every two weeks when...
tapering from 24mg to 12mg, but need to step down 2mg every two weeks from 12mg to 4mg, and 1mg every two weeks from 4mg to 0mg.

- Often, the final reductions (lower than 4mg) take as long to taper down as the initial reductions. Go much slower when tapering down from 4 mg and monitor closely for cravings and withdrawal symptoms.
- Some patients can taper down to 2 or 4 mg but cannot discontinue the medication completely without uncomfortable withdrawal symptoms or a sharp increase in cravings. This possibility should be discussed with each patient.
- It is always safer to titrate back up to a higher dose (vs. continue with tapering) if a patient starts experiencing strong cravings to use illicit opioids.
- Offer the option of XR-Naltrexone (long-acting naltrexone), if appropriate, for continued treatment of OUD. This option can further improve patients’ chances of preventing relapse.
- Prior to starting XR-Naltrexone (long-acting naltrexone shot), the patient should be off buprenorphine for about 7-10 days to prevent precipitation of acute opioid withdrawal, and providers should utilize a “naltrexone/naloxone challenge” to confirm the patient is sufficiently detoxed/opioid-free. (A naltrexone/naloxone challenge refers to the administration of a small amount of naltrexone to determine if opioids are still in an individual’s system; if they are, the naltrexone will result in the experience of precipitated withdrawal symptoms in the patient). The treatment plan should consider additional supports needed during this period to prevent a relapse.
- Patients who discontinue buprenorphine or any addiction medication should be monitored and assessed for cravings by medical and psychosocial support staff for as long as they remain engaged in any form of care.
- Patients should be encouraged to return for maintenance medical treatment if strong or persistent cravings develop.

*Naltrexone/Naloxone (i.m.) Challenge Procedure

- Obtain baseline COWS, if 4 or less proceed with the challenge
- Administer naloxone 0.4 mg (1 cc) i.m. to deltoid and observe for 20 minutes. (OR, administer 25mg of an oral naltrexone tablet [half of a 50mg tablet])
- If no change in COWS administer additional 0.8 mg (2 cc) to the other deltoid and monitor for additional 20 minutes
- Test is considered positive if there is a COWS increase of 2 or more from the pre-injection score
- In case of positive challenge, do not administer XR-naltrexone, wait 1-2 days and repeat the challenge
- If the test is negative, proceed with the XR-Naltrexone injection.

For more information about topics such as tapering and pain, emergency tapering, or to create a tapering schedule, providers and their patients can visit:

XR-Naltrexone: A Step-by-Step Guide (from PCSS)
CIMOR Procedures for Client Admission, Enrollment, and Billing

Remember:

1. **CIMOR will not verify Medicaid eligibility.** All encounters will process as if non-Medicaid.
   a. If an SOR consumer becomes Medicaid eligible, they will need to be enrolled in a CSTAR program on the date of eligibility and services from date of eligibility must be billed to the CSTAR program. *(DBH staff run monthly reports to check for Medicaid eligibility of SOR consumers and will notify agencies if consumers have not been switched in CIMOR).* Any services already billed during a period of Medicaid eligibility will be voided by DBH staff and must be re-billed by agency staff under the correct CSTAR program. If a consumer loses Medicaid eligibility they may be transferred back to their Opioid SOR program assignment.

2. For individuals in the Opioid SOR program, **neither TEDS data nor a complete DLA-20** is required to submit the Eligibility Determination. The Eligibility Determination only consists of the initial diagnosis (usually rendered by the physician or prescribing provider), initial treatment recommendations, and initial treatment goals for the first 45 days of treatment services to meet immediate needs.

3. **TEDS data will be required** within the first 30 days of treatment and upon discharge only (CIMOR business rules have been changed to allow for this). The DLA-20 is not required for individuals in the Opioid SOR program, but its completion is recommended. At a minimum, the diagnosis and functional assessment score must be completed; see #4.

4. CIMOR requires the diagnosis and the functional assessment score be entered on the “Diagnosis List” screen prior to billing for services. As a work-around in CIMOR, it is acceptable for diagnosticians to use the Global Assessment of Functioning rating (GAF) utilized in the DSM IV rather than the DLA-20© functional assessment to identify the functional assessment score to be added in CIMOR. When the DLA-20© is completed at a later date, then this revised score should be added as the updated functional assessment score on the “Diagnosis List” screen in CIMOR.

5. There are **no “levels of care”** in the Opioid SOR program. *(Note, even within CSTAR programming, clients can be enrolled at any level of care and there are no “minimum” numbers of hours of required services of any kind! Clinical treatment of OUD, if based on the treatment evidence, should look very similar in CSTAR and SOR consumers.)*

6. **Group services, residential services, day treatment, and social setting detox are not covered with SOR funds.** These services may be delivered and will be billed under the SOR grant service category, but will be funded out of sites’ CSTAR or existing allocations. *(The complete list of exempt services is in Appendix B.)*
7. Opioid SOR programs may not overlap with CSTAR programs in CIMOR. (With the exception of OTPs to allow for individuals to receive Methadone medication at an Opioid Treatment Program and other psychosocial supportive services at another SOR contracted site.)

Guide for Opioid SOR Program Data Reporting

Entering diagnosis and functional assessment score after enrolling in CIMOR and Episode of Care opened:

Click on Diagnosis
Click on ICD-10 Tab
Click Add
Enter into CIMOR:

**Diagnosis Date Time** (mm/dd/yyyy HH:MM AM/PM)

**Diagnosis Code** (eligible diagnoses listed below)
- Initial diagnosis of Opioid Withdrawal may be entered. The diagnosis from a physician or nurse practitioner on day 1 qualifies as eligible diagnosis.

**Diagnostician** (name and credentials of staff providing diagnosis)

**Status**

**Eligible diagnoses include:**

<table>
<thead>
<tr>
<th>Code</th>
<th>ICD 10</th>
<th>Description</th>
<th>Code</th>
<th>DSM-5</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F11.23</td>
<td>Opioid dependence with withdrawal</td>
<td>F11.23 Opioid withdrawal</td>
<td>F11.10</td>
<td>Opioid use disorder, Mild</td>
<td>Opioid use disorder, Moderate</td>
</tr>
<tr>
<td>F11.24</td>
<td>Opioid abuse with intoxication delirium</td>
<td>F11.121 Opioid intoxication delirium with moderate or severe use disorder</td>
<td>F11.93</td>
<td>Opioid use, unspecified with intoxication delirium</td>
<td>Opioid intoxication delirium without use disorder</td>
</tr>
<tr>
<td>F11.25</td>
<td>Opioid dependence with intoxication delirium</td>
<td>F11.221 Opioid intoxication delirium w moderate or severe use disorder</td>
<td>F11.92</td>
<td>Opioid use, unspecified with intoxication delirium</td>
<td>Opioid intoxication delirium without use disorder</td>
</tr>
<tr>
<td>F11.26</td>
<td>Opioid abuse with intoxication with perceptual disturbance</td>
<td>F11.122 Opioid intoxication w perceptual disturbs w mild use disorder</td>
<td>F11.92</td>
<td>Opioid use, unspecified with intoxication, unspecified</td>
<td>Opioid intoxication w perceptual disturbances w/o use disorder</td>
</tr>
<tr>
<td>F11.27</td>
<td>Opioid dependence w intoxication with perceptual disturbance</td>
<td>F11.222 Opioid intoxication w perceptual disturbs w mod severe use disdr</td>
<td>F11.92</td>
<td>Opioid use, unspecified with intoxication, unspecified</td>
<td>Opioid intoxication w perceptual disturbances w/o use disorder</td>
</tr>
<tr>
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<td>F11.129 Opioid intoxication w/o perceptual disturbs w mild use disorder</td>
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<td>Opioid intoxication w perceptual disturbances w/o use disorder</td>
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<tr>
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<td>F11.229 Opioid intoxication w/o perceptual disturbs w mod severe use disdr</td>
<td>F11.92</td>
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<td>Opioid intoxication w perceptual disturbances w/o use disorder</td>
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<td>Opioid use disorder, Moderate</td>
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<td>F11.20 Opioid use disorder, Moderate</td>
<td>F20.1</td>
<td>Contact with and (suspected) exposure to tuberculosis</td>
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<tr>
<td>Z20.1</td>
<td>Contact with and (suspected) exposure to tuberculosis</td>
<td>F11.20 Opioid use disorder, Moderate</td>
<td>F11.93</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
Contact w and (suspected) exposure to human immunodef virus

Click Save
After saving, information for diagnosis date time, code, description, source, status, principal, map fields should populate.

**Functional Assessment Tab:**

Enter into CIMOR:

**Diagnostician**

**Diagnosis Date/Time**

**Current Functional Assessment Score**
Program Assignment:

Under Episode of Care select **Program**
Choose **Add**

Program assignment: **ADA Opioid SOR Grant**
Status is “**Assigned**”
Enter **From Date** and **From Time**
Choose **Living Arrangement**
Click **Save**

Program assignment information should populate when saved.
Adding Services:

Click **Add Non-Authorized Encounter**

Enter **From Date**
Select **List Contracts**
Select **Contract**
Select **Provider Site**
Select **Service Category** (ADA Opioid SOR Grant) Select **Procedure Code** for service being entered Record **# of Units Provided**
**Unit Rate** should populate
**Dollar Amount** will populate unless code is as prescribed. If not populated, actual cost must be entered
Click **Save** or **Save & Add** to stay on that screen to add another service.

Service information should populate once saved.
Appendix B.

The Evidence of Medical Vs. Non-Medical Treatment for Opioid Use Disorder

Extensive research demonstrates people with opioid addiction who follow detoxification with complete abstinence are likely to relapse (e.g., Bart, 2012, Mattick et al., 2008 & 2009, Volkow et al., 2014). Though relapse is a common and expected step on the path to recovery, it can also be life threatening, raising the risk for a fatal overdose. Thus, an important way to reduce mortality and support recovery from heroin or prescription opioid addiction is to maintain abstinence from those drugs using medications that reduce the negative effects of withdrawal and craving. Use of these medications is commonly referred to as Medication Assisted Treatment, or, preferably, medical treatment for opioid use disorder (OUD).

Medications commonly used to treat OUD include:

- Methadone
- Buprenorphine (e.g., Suboxone®)
- Extended-release injectable naltrexone (e.g., Vivitrol®)

National and international professional bodies consider medical treatment for OUD the evidence-based best practice for treating OUD. This includes the National Association of State Alcohol and Drug Abuse Directors (NASADAD), the American Academy of Addiction Psychiatry (AAAP), the American Society of Addiction Medicine (ASAM), the World Health Organization (WHO), and the Substance Abuse and Mental Health Services Administration (SAMHSA). Understanding substance use disorder as a brain disease is widely accepted. It is considered a disease that has “cognitive, behavioral, and physiological characteristics that contribute to continued use of drugs despite the harmful consequences.” (NIDA, 2012).

The Effectiveness of Methadone

Methadone is a synthetic opioid agonist that eliminates withdrawal symptoms and relieves drug cravings by acting on opioid receptors in the brain. When appropriately dosed, methadone improves treatment retention, decreases relapse and overdose mortality (e.g., Clausen, Anchersen, & Waal, 2008; Connock et al., 2007), as well as the health and criminal problems associated with illicit opioid use (see Cochrane Review, Mattick et al., 2009). Long-term methadone (i.e., taken over the course of many months or years) maintenance therapy is more effective than either detoxification with methadone or medication-free treatment in decreasing heroin use and retaining patients in treatment (Mattick et al., 2009; Sees et al., 2000). A review of the literature showed that, in 11 clinical trials involving 1,969 people, methadone improved treatment retention and reduced heroin use compared with non-medication treatment (Mattick et al., 2009). A recent report in the Annals of Internal Medicine found treatment with methadone following a non-fatal overdose event was associated with a 60% decreased mortality rate in the 12 months following the overdose (Larochelle, et al., 2018). Additionally, Bhati et al. (2008) found if outpatient methadone treatment were expanded to all eligible offenders, 3.3 million nondrug crimes could be averted. Every dollar spent on ongoing methadone treatment yields almost $38 in benefits through reduced crime, better health, and gainful employment (Zarkin et al., 2005).
The Effectiveness of Buprenorphine

Buprenorphine is a partial opioid agonist, meaning it partially binds to opioid receptors, the same receptors that other opioids such as heroin, morphine, and opioid pain medications activate. Buprenorphine activates these receptors less strongly than full agonists (i.e., methadone).

Similar to methadone, maintenance buprenorphine is more effective than abstinence-based treatment or placebo in the treatment of OUD (e.g., Fielen et al., 2014; Mattick et al., 2008; Veillux, 2010). Studies comparing the effectiveness of buprenorphine to that of methadone have been mixed. Buprenorphine does appear to be as effective as moderate doses of methadone. However, buprenorphine is unlikely to be as effective as higher doses of methadone and therefore may not be the treatment of choice for patients with higher levels of physical dependence. Magura et al. (2009) found that among people who were incarcerated, most preferred buprenorphine to methadone when released back into the community. A recent report in the *Annals of Internal Medicine* found treatment with buprenorphine following a non-fatal overdose event was associated with a 40% decreased mortality rate in the 12 months following the overdose (Larochelle, et al., 2018).

It is important to understand that methadone and buprenorphine are maintenance medications, not cures. A maintenance medication is one taken to stabilize and control an illness or symptoms of illness over time. It is effective only for as long as the patient takes it. Some individuals may be able to discontinue methadone or buprenorphine and continue in recovery without it. However, long-term maintenance with methadone or buprenorphine yields the best results and is considered the standard of care.

The Effectiveness of Extended-Release Injectable Naltrexone

Naltrexone is an opioid antagonist, which means it works by blocking the activation of opioid receptors. Instead of controlling withdrawal and cravings, it treats addiction by preventing any opioid drug from producing rewarding effects, such as euphoria.

Extended-release injectable naltrexone (Vivitrol®) has not been studied for as long as either methadone or buprenorphine, but results of its use in certain settings are promising. Studies have found the injectable form of naltrexone can increase treatment retention (Bart, 2012; Comer et al., 2006; Krupitsky et al., 2011). Treatment retention is particularly important because it provides clinicians sufficient time to engage patients in psychotherapy or counseling so they can learn to make psychological and social adjustments that support a life without opioids (Comer et al., 2006).

Injectable naltrexone has been found to be effective in reducing relapse and re-incarceration among people involved in the criminal justice system (Lee et al., 2016; Crits-Christoph, 2015; Gordon et al., 2015). A recent comparison study of buprenorphine versus of XR-Naltrexone treatment found of XR-Naltrexone to be more difficult for patients to initiate, even within an inpatient treatment setting. However, once patients were stabilized, outcomes for the two medications to be comparable once individuals at six month follow-up (Lee et al., 2017). Of
note, no published studies have yet compared of XR-Naltrexone to buprenorphine or methadone in outpatient settings or studied comparisons in patients for longer than six months.

**Conclusion**

The standard of care for OUD is medical treatment with maintenance medication, rather than mandated abstinence with psychosocial support only. Compared to traditional, non-medical abstinence-based treatment, utilization of this chronic care model improves treatment retention, reduces relapse, controls cravings, and, most critically, significantly reduces mortality.

**Footnotes and References**

This document is primarily adapted from SAMHSA – Adult Drug Courts and Medication-Assisted Treatment for Opioid Dependence (2014), and NIDA – Medications to Treat Opioid Addiction (2017).

**References**


SAMHSA. (2014). Adult Drug Courts and Medication-Assisted Treatment for Opioid Dependence. 8(1).


Appendix C.

Services NOT Reimbursable Under SOR

* provider’s regular allocation will be used when these services are billed

Day Treatment – H2012

Group Counseling (Associate Addiction Counselor) – H0005 HM

Group Counseling (QAP) – H0005 HN

Group Counseling (Collateral Relationship) – H0005 UK

Group Education – H0025

Group Education (Trauma Related) – H0025 ST

Residential Support (Women & Children – for child) – T2048 UK

Residential Support (Women & Children) – T2048 HD

Room & Board – T2046

Supportive Housing (Community Based) – H0044

Detoxification (Social Setting) – H0010
Appendix D.

Recovery Community Center Contact Information

Recovery Community Centers receiving funding and support through SOR are listed below.

Services offered include but are not limited to: substance use support groups, peer-to-peer support, naloxone and overdose reversal training, treatment referrals, housing referrals, and substance-free social activities.

**Missouri Network for Opiate Reform**
4022 S. Broadway  
St. Louis, MO 63118  
(844)-REBEL UP (844-732-3587)  
[www.Monetwork.org](http://www.Monetwork.org)
Drop-in Hours: Monday – Friday (10:00 am – 5:00 pm) and Saturday – Sunday (12:00 pm – 6:00 pm)
See website for groups and activities.

**St. Louis Empowerment Center**
1908 Olive Street  
(will change to 907 Dock St., off North Broadway, in March 2020)  
St. Louis, MO 63101  
(314) 652-6100
[www.Dbsaempowerment.org](http://www.Dbsaempowerment.org)
Drop-in Hours: Every day (9:00 am – 3:00 pm)
See website for groups and activities.

**Springfield Recovery Community Center**
1925 E. Bennet St.  
Springfield, MO, 65804  
(417) 368-0852
[https://www.betterlifeinrecovery.com/srcc](https://www.betterlifeinrecovery.com/srcc)
Drop-in Hours: Monday – Friday (9:00 am – 9:00 pm) and Saturday (6:00 pm – 10:00 pm)
See website for groups and activities.

**Healing House**
4602 St. John Avenue  
Kansas City, MO 64123  
(816) 920-7181
[www.Healinghousekc.org](http://www.Healinghousekc.org)
Drop-in Hours: Monday – Friday (9:00 am – 4:30 pm) and Sunday (1:00 pm – 3:00 pm)
See website for groups and activities
Appendix E.

Example Opioid SOR Phone Screening

Client Name: ________________________________
Date of Birth: ________________________________
Address: ____________________________________________________________________________
Insurance Type: ________________________________

Check All That Apply

1. Opioids

☐ Patient uses heroin or fentanyl

☐ Patient uses prescription opioids recreationally (such as OxyContin, Vicodin, Hydrocodone, Percocet, Morphine, Suboxone, etc.)

☐ Patient uses prescription opioids as prescribed by a doctor, but wants to discontinue these meds

2. Other

☐ Patients drug of choice is not opioids, but sometimes uses opioids

If ANY of the above are checked patient is a candidate for medication for their OUD and should be sent for evaluation by a physician immediately
Appendix F.  
Example Initial Screen for Opioid Use Presentation

Date:______________ Time:______________ Referral Source: ____________________________

Client’s Name________________________________________ Date of Birth/Age______________

Address______________________________________________
City/State/Zip________________________________________

Blood Pressure: _______ Pulse: _______ Respiration: _______ Temperature: ____________

Drug Screen Results: ________________________________
Alcohol Breathalyzer Results: _________________________

Last Treatment (when/where):

<table>
<thead>
<tr>
<th>Name of presenting substance/s (all substances used within the last 30 days)</th>
<th>Age First Used</th>
<th>Describe any difficulty the client has had when they stopped using this substance in the past</th>
<th>Date Last Used</th>
<th>Quantity and Duration of Use</th>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medical, psychological, physical problems (including current withdrawal symptoms and thoughts of self-harm or harm to others):
Previous suicide attempts (method, date):

Summary/Initial Treatment Goals/Recommendations based on the screening:

Signature of Staff Person (name and title): ________________________________
Appendix G.
Points to cover in Overdose Education and Naloxone Distribution (OEND) trainings
(Document for clinicians)

**Acute risk factors:**
- Periods of abstinence (decreased tolerance)
- Mixing with other sedatives (benzos, alcohol)
- Injecting
- Change in supplier/dosage
- Increased purity; presence of fentanyl
- Using alone or in a new environment

**Recognize signs:**
- Cold, clammy skin
- Shallow breathing/no breathing
- Unresponsive
- Gurgling/snoring
- Small “pinpoint” pupils

**Rescue response/ how to use naloxone:**
- Check for breathing/clear airways
- Administer Narcan nasal spray
- Call 911
- Administer rescue breaths, turn person on side in recovery position
- Administer 2nd dose if no response in 2-3 minutes
- Stay with person until medical help arrives to ensure safety and prevent repeat use/overdose

**Tips for prevention:**
- Share this information with family/loved ones
- If you choose to use: don’t use alone, avoid mixing, start small, be extra cautious when sick/in poor respiratory health
- Keep naloxone accessible and out of extreme temperatures

**MO-HOPE Overdose Field Report:**
- **Walk through materials:**
  - Field Report Instruction Card
  - Field Report Business Card (wallet size for convenience)
  - Mini Field Report (to take notes for later web entry)
- **How to complete the overdose field report:**
  - Access the field report using one of the following methods listed on the field report instruction card *(also, on back of this sheet)*:
    1) Enter the survey link, OR
    2) If you have an app on your phone that is capable of scanning QR codes, scan the QR code.
- **Once you have accessed the survey, add link to home screen** (see back of field report instruction card)
Appendix H.

Overdose Education and Naloxone Distribution (OEND) Fact Sheet

(Document for clients and community members)

- What are risk factors for an overdose?
  - Previous overdose
  - Period of abstinence/sobriety (e.g., following rehab or jail) → Decreased tolerance
  - A change in strength, amount, supplier of the opioid, or location of use
  - Being physically ill/respiratory disease (flu, pneumonia, bronchitis)
  - Mixing opioids with other substances (benzodiazepines, sedatives, alcohol)
  - Using alone
  - Injecting

- How can you tell if someone’s overdosing:
  - Cold, clammy skin
  - Shallow breathing/no breathing
  - Unresponsive
  - Gurgling/snoring
  - Small “pinpoint” pupils

- What to do if someone overdoses:
  1. Check for breathing/clear airways
  2. Administer Narcan nasal spray
  3. Call 911
  4. Administer rescue breaths, turn person on side in recovery position
  5. Administer 2nd dose if no response in 2-3 minutes
  6. Stay with person until medical help arrives to ensure safety and prevent repeat use/overdose
  7. Complete the Overdose Field Report

- Tips for prevention:
  - Share this information with family/loved ones
  - If you choose to use: know your tolerance, don’t use alone, avoid mixing drugs, start small, be extra cautious when sick/in poor respiratory health
  - Keep naloxone accessible and out of extreme temperatures

- How to complete the overdose field report (see back of sheet):
  - Access the field report using one of the following methods (see back of sheet):
    - Enter the survey link, OR
    - If you have an app on your phone that is capable of scanning QR codes, you may scan the QR code.
  - Once you have accessed the survey, answer the questions as honestly as possible remembering that all information will be kept confidential.
Appendix I.

Overdose Field Report

If you experience, witness, or are informed of an overdose event, please complete the MO-HOPE field report as soon as you are able to do so.

To start the survey, you may use any of the choices below:

<table>
<thead>
<tr>
<th>Use the Survey Link:</th>
<th>Scan the QR Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open your browser and go to this web address:</td>
<td>If you have a device that has an app capable of reading QR codes, you may, scan the QR code below:</td>
</tr>
<tr>
<td>mohopeproject.org/ODreport</td>
<td><img src="image" alt="QR Code" /></td>
</tr>
</tbody>
</table>

To add the survey to your home screen:

Once you have opened the field report survey on your phone you can save the link to your home screen for quick, easy access later when you are in the field.

Instructions for Apple:

Tap the share button on the browser’s toolbar - that’s the rectangle with an arrow pointing upward. It’s on the bar at the top of the screen on an iPad, and on the bar on the bottom of the screen on an iPhone or iPod Touch. Tap the Add to Home Screen icon in the Share menu. A new icon should now appear on your home screen that with take you directly to the field report.

Instructions for Android:

Tap the menu button and tap Add to Home screen. You’ll be able to enter a name for the shortcut and then Chrome will add it to your home screen. This will take your directly to the field report.

For questions about evaluation, contact:

MOHOPEproject@mimh.edu
(314) 516-8420

MO-HOPE Project
Overdose Field Report

*for visual purposes only – can only be submitted online at: mohopeproject.org/ODreport*

1. Date and time: __________________________
2. Zip Code of Overdose Event: __________________________
3. Your relation to the person who overdosed:
   - Emergency Responder (Agency: __________)  
   - Parent  
   - Partner or Spouse  
   - Friend  
   - Other family member (non-partner, non-parent)  
   - Clinician or Provider  
   - Self  
   - Other (specify: __________)

4. Individual’s state of primary residence: ________________  
5. In what county did the overdose occur? ________________

6. Incident Location: A home or residence/ A treatment facility / A public place (specify: __________)/ Other (specify: __________)
8. Individual’s sex: Male/ Female/ Intersex/ Unsure
9. Individual’s race (select all that apply): White/ Black or African American/ Asian/ American Indian or Alaskan Native/ Native Hawaiian or Pacific Islander/ Unsure/ Other (specify: __________)
10. Is the individual Hispanic? Yes/ No/ Unsure

11. Type of drugs involved (circle all that apply): Heroin/ Prescription Painkiller/ Fentanyl/ Benzos (e.g., Xanax)/ Alcohol/ Unsure/ Other (specify: __________________________)

12. Was naloxone administered? Yes/ No (If no, skip to question 13)
   If yes, who administered naloxone?
   - EMS  
   - Fire Crew  
   - Police  
   - Other ER (specify: __________)  
   - A parent  
   - A partner or spouse  
   - A friend  
   - Another family member  
   - A clinician or provider  
   - A stranger  
   - Someone else (specify: __________)

   What form of naloxone was used and how many doses were given? (Circle all that apply)
   - AdaptPharma Narcan nasal spray (Doses: 1 / 2 / 3 / 4+ / Unsure)
   - Evzio auto-injector (Doses: 1 / 2 / 3 / 4+ / Unsure)
   - Other intranasal device (with vial and atomizer) (Doses: 1 / 2 / 3 / 4+/ Unsure)
   - Intravenously (IV) (Doses: 1 / 2 / 3 / 4+/ Unsure)
   - Other intramuscular device (with vial and syringe) (Doses: 1 / 2 / 3 / 4+/ Unsure)
   - Unsure

   Where was naloxone obtained? (Skip question if you are an emergency responder)
   - Unsure, Naloxone was administered by someone else/ Pharmacy (specify: __________)/
   - Treatment program (specify: __________)/ Recovery Community Center (specify: __________)/
   - Jail or treatment court program (specify: __________)/ Other (specify: __________)

   Were there any post-naloxone withdrawal symptoms? (circle all that apply)
   - None/ Physically combative/ Irritable or angry/ Vomiting/ Dope sick (e.g., nauseated, muscle aches, runny nose, and/or watery eyes)/ Other (specify: __________________________)

13. Was 911 called? Yes/ No/ Unsure
14. To the best of your knowledge, did the individual survive the overdose? Yes/ No/ Unsure
15. Was the individual transported to the hospital? Yes/ No, escorted to treatment center/ No, escorted to residence/ No, transported elsewhere/ No, declined transport/ Unsure
Appendix J.

Addiction vs. Dependence: Medical Treatment for Addiction Group Exercise

This exercise is meant to help clients (and sometimes agency staff!) understand addiction as an attachment that causes them to compromise their own priorities. It also helps clients distinguish between the effects of medication and illicit drug use.

A. Take a moment to list the most important things in human life. There are no wrong answers, just start listing things as they come to you. Persons with or without addiction tend to create very similar lists of human priorities. Here is an example list:

- Relationships
- Emotional Well-being
- Reputation
- Health Family
- Friendship Spirituality
- Career Success
- Financial
- Shelter
- Community
- Security
- Food
- Religion Integrity
- Purpose
- Emotional Safety
- Loyalty
- Self-esteem
- Principles
- Commitments
- Physical Safety
- Legal status

B. Which of the things we've listed on the board have you sacrificed or significantly compromised due to addiction? Among persons seeking treatment, the almost unanimous response is: “All of the above.” Persons with addiction can easily perceive that they have compromised almost everything of value for the sake of their addiction. Sometimes the “functional alcoholic” in the room will protest that they’ve never lost their job. But upon probing, they usually agree that their relationships, values, self-esteem, and even work performance have suffered as a result of alcoholism. Question “B” also allows you to contrast minor dependencies such as caffeine dependence with addiction. People may routinely drink a cup of coffee in the morning and get a headache when they try to abstain. But even if coffee became hard to acquire, few people would steal from their families or sell their possessions to obtain it. Coffee causes mild physical dependence but rarely causes addiction.

C. Which of the things on the board have you sacrificed or significantly compromised by taking your OUD medication? Typically clients are a bit confused by this question because the medication has begun to help them pursue and invest in their priorities; it has not caused them to sacrifice or compromise them. On medication, clients typically start attending to the things they value—like their relationships, basic needs, and management of their mental and physical health. Helping clients to see that medication supports recovery can help them deflect the stigma they often face for taking OUD medications. This exercise can be especially helpful when a client is starting to think that they should stop their medication. When they realize what a huge difference the medication has made in their life, they often reconsider their desire to discontinue it.
Appendix K.

Recovery Housing Information

Recovery housing should be provided for individuals treated through Opioid SOR within a participating DMH SUD treatment program who have been through medical stabilization but need a safe, healthy environment to support engagement in treatment (including but not limited to medication services). Opioid SOR can be billed for housing services at locations accredited by the National Alliance for Recovery Residences (NARR) and approved by DBH (for updated listing of approved housing, visit: https://www.nomodeaths.org/recovery-housing).

All Opioid SOR program housing must accept people no matter their medication status and place no requirements for step-down dosing or medication tapering. Other key characteristics of the recovery housing model include:

a. Participation is generally self-initiated with individuals having a preference for living in a recovery-focused environment;

b. Holistic services and peer supports are available to housing participants;

c. A “slip” or “lapse” are not treated as an automatic cause for eviction, and relapse prevention and management are supported; and

d. Assistance is provided in finding permanent housing.

Recovery housing will be coordinated by the treatment provider in accordance with the individual’s treatment plan. The treatment provider will:

- Assess that the individual with OUD served is in need of recovery housing;
- Review the list of NARR-accredited and DBH-approved agencies; and
- Contact the recovery residence to determine space availability;
- Establish a written agreement with the recovery residence to determine payment and coordination of care.

Once the treatment provider has placed an individual in the recovery residence the provider can be reimbursed $25.88 per day through CIMOR code Supportive Housing (Transitional) 12000. The treatment provider will then make payments to the recovery residence. The entirety of the $25.88 per day rate must be paid to the recovery housing entity.

A 7% administrative fee will be paid quarterly to the treatment provider for processing invoices and verifying documentation on subcontracts or memorandums of understanding with separate recovery housing entities. The administrative processing fee will not be paid for processing payments to housing owned and operated by the treatment provider. A new code for the providers who do their own housing (12000 HW) has been added to contracts. Based on
housing encounters (procedure code 12000) invoiced during the previous quarter, a 7% administration fee will be added to your agency’s invoice by DBH Central Office.

**Documentation:** There is an expectation that the treatment providers and the housing providers will sign a written agreement that would include how the treatment agency can ensure that consumers were present each night to bill for Transitional Housing – 12000. Documentation of Recovery Housing should include nightly logs with client or staff signatures confirming services. Acceptable supporting documentation includes treatment staff verified individual resided at recovery house on billed nights or Recovery House Manager signature indicating individual resided at recovery house on billed dates.
DATE: September 3, 2019

TO: All DBH Contracted Providers

FROM: Nora K. Bock, DBH Deputy Director of Adult Community Treatment
Connie Cahalan, DBH Director of Children’s Services

RE: Assessment Billing – No Recoupment after Eligibility Determination

AFFECTED PROGRAMS: SOR, CPR, CSTAR, JRI

There are no CIMOR business rules tied to the comprehensive assessment and billing of other services. The diagnosis and functional assessment score are required to be in CIMOR.

If an individual’s Eligibility Determination has been completed and s/he receives services, but then discontinues services prior to the completion of the comprehensive assessment (within the first 30 days), the services billed and paid for will not be recouped. Providers should bill for all services rendered.

If you have any questions, you may email the CIMOR DBH Support Center by logging in and selecting the Help Ticket option found on the left side menu of the portal, https://portal.dmh.mo.gov

NKB: Idn

ec: Laurie Epple
    Jennifer Johnson
    Rhonda Turner
    Gail Erke

Angela Plunkett
    Tim Rudder
    DBH Regional Staff
    Brent McGinty

An Equal Opportunity Employer; services provided on a nondiscriminatory basis.
Appendix M.

Transportation Services

Transportation - Mileage. (A0080, $0.37/mile) Transportation assists consumers in achieving and sustaining recovery goals when they do not have the means to provide personal transportation.

1. Transportation shall be limited to specific destinations and/or appointments as defined by the department. Allowable transportation services shall include:

   a. To and from certified alcohol or drug treatment and rehabilitation programs;
   b. To and from recovery support services;
   c. To and from doctor’s appointments, dental appointments, or appointments with other healthcare providers;
   d. To and from probation and parole, court or other criminal justice agencies; and
   e. To and from employment-seeking activities and/or active employment.

2. Staff or volunteers who provide transportation services shall meet the background screening requirements in 9 CSR 10-5.190 and hold a class E chauffeur’s license, or if transporting more than fifteen (15) passengers, a CDL license.

3. The vehicle used for transportation shall be currently licensed, properly insured and provide safe and reliable transportation for consumers.

4. Transportation – Mileage is limited to 100 miles per consumer per day.

   Documentation; includes the consumer name, the date of transportation, the originating location name and address, the destination name and address, miles traveled, the purpose of the travel, the rendering practitioner (Driver). Each consumer being transported shall sign a transportation log. The provider shall maintain transportation logs with original consumer signatures.

   ***For confidentiality concerns, actual home address of consumer does not need to be recorded on the log, and may be recorded as “consumer’s residence.” Transportation-Public (T2004, unit actual cost of buss pass) Consumers must be actively engaged in treatment services to be eligible for transportation services. Eligible transportation services include; to and from treatment, recovery support services, physician visits, dental appointments, probation and parole, court, employment seeking, and employment. The contractor may distribute bus passes daily, weekly, or monthly.

   Documentation includes; public transportation system name, serial number of the bus pass, purchase price of the bus pass, length of bus pass (Daily, weekly, monthly), date pass was issued and staff member issuing the bus pass.
Appendix N.

Outreach Service Codes

H0023 AH Behavioral health outreach 15 Minute(s) Psychologist
H0023 HM Behavioral health outreach 15 Minute(s) Peer Specialist
H0023 HN Behavioral health outreach 15 Minute(s) Bachelor
H0023 HO Behavioral health outreach 15 Minute(s) QMHP
H0023 SA Behavioral health outreach 15 Minute(s) APN
Appendix O. Sample brochure outlining buprenorphine clinic protocols (to adapt based on agency needs)

A quick guide to your buprenorphine program

NP drugs include all non-prescribed drugs and alcohol

Starting
How often do I need to come to the clinic?
We will give you enough medication for 3-4 days at each visit with your doctor or care manager.
When can I move to the next phase?
When your lab is:
   - heroin and painkillers
   + buprenorphine
What if this phase isn’t working?
If your lab is:
   - buprenorphine
and you don’t have your unused medication, we will prescribe you daily buprenorphine to take with us at the clinic.

Getting stable
How often do I need to come to the clinic?
We will give you enough medication for 1 week at each visit with your doctor or care manager.
When can I move to the next phase?
When you have 4 weekly labs that are:
   - all NP drugs except marijuana
   + buprenorphine
This phase takes at least 8 weeks.
When would I enter Starting again?
If your lab is:
   + heroin, painkillers OR
   - buprenorphine

Taking strides
How often do I need to come to the clinic?
We will give you two weeks of medication at each visit with your doctor or care manager.
When can I move to the next phase?
When you have 4 labs that are:
   - all NP drugs except marijuana
   + buprenorphine
This phase takes at least 8 weeks.
When would I enter Getting Stable again?
If your lab is:
   + any NP drug except marijuana
   + buprenorphine
When would I enter Starting again?
If your lab is:
   + any NP drugs except marijuana
   - buprenorphine

Maintaining
How often do I need to come to the clinic?
We will give you enough medication for 4 weeks at each visit with your doctor or care manager.
When would I enter Getting Stable again?
If your lab is:
   + any NP drugs except marijuana
   + buprenorphine
When would I enter Starting again?
If your lab is:
   + any NP drugs except marijuana
   - buprenorphine

These guidelines should help you know what to expect. Your physician may make different decisions based on clinical information not considered here.

For 24-hour support, call
###-####-####
Tools of the Trade

Resources for the Use of Methadone and Naltrexone

Compiled by clinical consultants and project staff of Missouri’s State Opioid Response Grant
September, 2019

The information presented in this handbook was retrieved and consolidated from the following resources:

- Alkermes, Inc. Human Prescription Drug Label
  https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cd11c435-b0f0-4bb9-ae78-60f101f3703f

- American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use TREATMENT IMPROVEMENT PROTOCOL --Tip 43
  https://www.asam.org/docs/advocacy/samhsa_tip43_matforopioidaddiction.pdf?sfvrsn=0

- American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use TREATMENT IMPROVEMENT PROTOCOL --Tip 63

- The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use (PCSS MAT Training: Providers’ Clinical Support System for Medicated Assisted Treatment

- The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use (PCSS MAT Training: Providers’ Clinical Support System for Medicated Assisted Treatment Module

- Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders
Resources for Use of Methadone and Naltrexone Table of Contents

Identifying Patients who may be Appropriate for Methadone Treatment ........................................ 53
Considerations Prior to Induction on Methadone .................................................................................. 53
Types of Settings for the Prescription of Methadone ........................................................................ 54
Methadone Induction ............................................................................................................................... 54
Dosing and Maintenance ........................................................................................................................... 55
Potential Adverse Effects and Changes in Dosage .............................................................................. 56
Drug Interactions ..................................................................................................................................... 57
Potential Triggered Withdrawal .............................................................................................................. 58
Take Home Doses and Contingency Contracting .................................................................................. 58
Switching from Methadone to Buprenorphine or Naltrexone and Tapering ........................................ 58
Identifying Patients who may be Appropriate for Naltrexone Treatment ............................................. 60
Types of Settings for the Prescription of Naltrexone .......................................................................... 61
Important Note on Naltrexone Induction .............................................................................................. 62
Dosing and Maintenance ......................................................................................................................... 63
Potential Adverse Effects ....................................................................................................................... 65
How to Address Request to Discontinue Naltrexone .......................................................................... 66
Appendix: Federal guidelines .................................................................................................................. 68
Identifying Patients who may be Appropriate for Methadone Treatment

Methadone is recommended for patients who may benefit from daily dosing and supervision in an Opioid Treatment Program (OTP), or for patients for whom buprenorphine for the treatment of Opioid Use Disorder (OUD) has been used unsuccessfully in an OTP or Office-Based Opioid Treatment (OBOT) setting.

Methadone is a treatment option recommended for patients who are physiologically dependent on opioids, able to give informed consent, and who have no specific contraindications for agonist treatment when it is prescribed in the context of an appropriate plan that includes psychosocial intervention.

Methadone is contraindicated for the following conditions:

● Patients with known hypersensitivity to methadone hydrochloride.

● Patients experiencing respiratory depression (in the absence of resuscitative equipment or in unmonitored settings).

● Patients with acute bronchial asthma or hypercapnia (also known as hypercarbia).

● Patients with known or suspected paralytic ileus.

Methadone should be used with caution for the following conditions:

● Patients with decompensated liver disease (eg, jaundice, ascites) due to increased risk of hepatic encephalopathy.

● Patients with respiratory insufficiency.

● Patients with concomitant substance use disorders, particularly patients with sedative, hypnotic, or anxiolytic use disorders. Interactions between methadone and hypnotics, sedatives, or anxiolytics may be life-threatening.

● Patients with regular or risky alcohol use.

● Patients with concomitant psychiatric diagnoses that impair their ability to maintain daily attendance at an OTP.

● Patients with low levels of physical dependence to opioids should be started with low doses of methadone.

Considerations Prior to Induction on Methadone

When considering a patient’s eligibility for methadone treatment, consider the following:

● Obtain a thorough drug and medication history, including results of drug and other laboratory tests. When adding any drugs to a therapeutic regimen, start with low doses, increase slowly, and monitor patient reactions closely.
- Educate patient about the risks of drug interactions, potentially lethal drugs or medications during agonist-based pharmacotherapy, possible cardiovascular risks, and possible effects of deviating from dosage schedules and amounts.

- Substitute alternative medications that do not interact with opioid treatment medications or have the least potential for interaction.

- Consider whether administering other medications with or without food or altering dosing schedules might reduce the risk of drug interactions.

- Simplify the medication regimen to make it easier for the patient to adhere to it.

- Adjust opioid medication dosage based on patient response to avoid drug interaction, but be vigilant for signs of withdrawal or sedation.

- Increase drug testing and monitoring of drug serum levels. Advise patient of the physical signs of adverse interactions, and explain what to do if these occur.

- Be aware of concomitant diseases (e.g., liver disease) that might influence the potential for adverse drug interactions.

**Types of Settings for the Prescription of Methadone**

The choice of available treatment options for addiction involving opioid use should be a shared decision between clinician and patient. Clinicians should consider the patient’s preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction involving opioid use.

The venue in which treatment is provided is as important as the specific medication selected. OTPs offer daily supervised dosing of methadone, and increasingly of buprenorphine. In accordance with the Federal law (21 CFR §1306.07), office-based opioid treatment (OBOT), which provides medication on a prescribed weekly or monthly basis, is limited to buprenorphine.

Federal and state-approved OTPs dispense methadone and supervise medication administration. Treatment should include relapse monitoring with frequent testing for alcohol and other relevant psychoactive substances. Testing for methadone and buprenorphine is recommended to ensure adherence and detect possible diversion.

**Methadone Induction**

The first methadone 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 continue the
dose induction process. If sedation or intoxication occurs after 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.

If the patient shows neither sedation nor reduction of objective signs of opioid 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 over-sedation.

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. For some patients, the lower range of initial doses is best. Dose with 10 mg to 20 mg in patients who:

- Are age 60 and older.
- May have lower levels of opioid tolerance based on their recent history.
- Use sedating medications, such as benzodiazepines, antipsychotics, or antidepressants.
- Engage in problematic or risky drinking or have alcohol use disorder.
- Take medications that can increase methadone serum levels or are stopping medications that
decrease methadone serum levels.
- Have medical disorders that may cause hypoxia, hypercapnia, or cardiac arrhythmias. These
  include:
  - Asthma, chronic obstructive pulmonary disease, and kyphoscoliosis.
  - Obesity.
  - Sleep apnea.
  - QTc prolongation.
  - Cor pulmonale.
  - Electrolyte abnormalities, such as hypokalemia or hypomagnesemia
  - A family history of cardiac arrhythmias, fainting or dizziness, or sudden death

**Dosing and Maintenance**

Methadone has a long half-life and care must be taken to avoid too rapid dose increases during the first
1–3 weeks of treatment, so as to avoid increasing the dose before the full effect of the last dose has been
realized. Dosing should be based on patients achieving goals of treatment, can vary widely between
patients, and doses do not correlate well with blood levels.

Trough and peak plasma levels of methadone (or methadone blood levels) may be used in addition to
clinical evaluation to assess the safety and adequacy of a patient’s dose, particularly in patients who seem
to be rapid metabolizers and may need a split dose. A relatively low dose of methadone (i.e., <30mg a
day) can lessen acute withdrawal, but it is often not effective in suppressing cravings and blocking the
effects of other opioids.
Though a few patients respond to a maintenance dose of 30–60 mg per day, most patients fare better if their initial 30–40 mg per day dose is gradually raised to a maintenance level of 60–120 mg per day, which typically creates sufficient tolerance to minimize a euphoric response if patients self-administer additional opioids. Multiple randomized trials have found that patients have better outcomes, including retention in treatment, with higher doses (80–100 mg per day) than lower doses.\(^1,2\) Though not well studied, doses above 120 mg per day are being used with some patients as blockade of opioid effects is becoming increasingly more difficult due to the increased purity of heroin and strength of prescription opioids.

The optimal duration of treatment with methadone has not been established; however, it is known that relapse rates are high for most patients who drop out; thus long-term treatment is often needed. Treatment duration depends on the response of the individual patient and is best determined by collaborative decisions between the clinician and the patient. Treatment should be reinstituted immediately for most patients who were previously taking methadone and have relapsed or are at risk for relapse.\(^3\)

**Potential Adverse Effects and Changes in Dosage**

Possible side effects of methadone include the following\(^4\):

- Constipation
- Nausea
- Sweating
- Sexual dysfunction or decreased libido
- Drowsiness
- Amenorrhea
- Weight gain
- Edema

Higher methadone doses may be associated with increased risk of adverse effects, including prolongation of the QT interval and other arrhythmias, which in some cases have been fatal (the QT interval is the interval between the beginning of the Q deflection to the end of the T wave. Certain medications increase the QT interval which in turn can increase their chance of a patient to develop lethal arrhythmias). The US FDA issued a safety alert for methadone regarding these cardiac events. Clinicians, in consultation with patients, may need to consider the relative risk of adverse events due to QT prolongation with methadone as compared to the risk of morbidity and mortality of an untreated OUD. Changing to buprenorphine or naltrexone maintenance should be considered when risks of QT prolongation are high as they do not seem to significantly prolong the QT.

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Certain medical factors may cause a patient's dosage requirements to change, including (but not limited to) starting, stopping, or changing the dosage of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; significant increase or decrease in weight; or aging (elderly patients are sometimes more sensitive to drugs such as opioids). Patient complaints of opioid craving, withdrawal symptoms, medication side effects, or intoxication always should be investigated and never should be dismissed. Mildly to moderately overmedicated patients might show “nodding” and closing of the eyes or might fall asleep at inappropriate times.

Patients might scratch their faces continuously, especially their noses. In some cases, sedation might occur but be unapparent, and some overmedicated patients might feel mildly stimulated. Nausea also can occur, particularly in newer patients. Patients should be told when overmedication is suspected, and their dosage should be reduced. Patients also might report feeling high or loaded and ask for a reduced dosage. Such a reduction can be helpful for patients committed to abstinence rather than ongoing medication maintenance because they may find physical reminders of intoxication discouraging, frightening, or relapse triggering.

Patients who report that they have vomited their medication pose special problems. The American Society of Addiction Medicine consensus panel recommends that only doses lost to witnessed emesis be replaced. Emesis 30 minutes after dosing can be handled by reassuring patients that the full dose has been absorbed. Emesis at 15 to 30 minutes after dosing can be handled by replacing half the dose, and the whole dose should be replaced if emesis occurs within 15 minutes of dosing.

If vomiting persists, it is important to remember that only a portion of the gut is emptied with forceful emesis; therefore, the risk of accumulated toxicity increases with repeated dose replacements. Causes of emesis including pregnancy should be explored. Ingestion of smaller amounts of medication over a few minutes can be helpful and prudent, as can the occasional use of antiemetic medicines.

**Drug Interactions**

Significant medication interactions to consider before starting methadone are as follows:

- Methadone may prolong the QT interval and should be used in caution with other agents that may also prolong the QT interval. These include class I or class III antiarrhythmic drugs, calcium channel blockers, some antipsychotics, and some antidepressants.

- Methadone is metabolized through the cytochrome P450 enzyme pathway. Many agents interact with this pathway including alcohol, anticonvulsants, antiretrovirals, and macrolide antibiotics.

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Potential Triggered Withdrawal
Environmental cues, including people, places, things, and feelings associated with drug taking, can be associated strongly with opioid craving and withdrawal. Such reactions may be identical to opioid withdrawal symptoms and can stimulate drug craving and relapse long after opioid use has stopped and physical dependence has been controlled. Environmental changes and other stressors can cause patients to perceive that a dose on which they were stabilized is no longer adequate and to experience increased drug craving. Events that increase the availability of substances of abuse, such as another person who uses drugs moving into a patient’s home or new sources of illicit drugs, can intensify craving.

When their discomfort resumes after a period of abstinence, patients might feel that they are weak willed. They need reassurance that this reaction is a condition of their brain chemistry, not a weakness of will. In animal models, withdrawal symptoms have been conditioned to appear with environmental cues after months of abstinence from opioids. (Self and Nester, 1998.) Increased medication dosages are appropriate in such cases, although efforts also should focus on resolving the troublesome situations such as developing ways to avoid people, places, and things that trigger opioid craving or relapse. Conversely, diminished triggers and reduced drug availability can diminish drug craving and might indicate the possibility of decreasing medication dosage if a patient prefers.

Take Home Doses and Contingency Contracting
The American Society of Addiction Medicine consensus panel believes that any manipulation of dosage as either a positive or a negative consequence of behavior is inappropriate and has no place in OUD treatment. The only type of contingency contracting related to medication that should be supported in medical OUD treatment is that associated with take-home medication. Take-home medication is controlled by Federal regulations, and access is based on several factors, including drug abstinence, OTP attendance, length of time in treatment, and overall functioning. An increase in medication dosage should not be a reward for positive behavior change, although not everyone in the field shares this viewpoint. (However, providing extra take-home doses as an incentive to decrease substance misuse and increase treatment program participation has been found effective and is a medically ethical practice.) Although the consensus panel acknowledges important behavioral aspects of addiction and the value of contingency management as an aid to behavioral change, using medication dosage as a reward or punishment is considered inappropriate.7

Switching from Methadone to Buprenorphine or Naltrexone and Tapering
Switching from methadone to another medication for the treatment of OUD may be appropriate if the patient experiences intolerable side effects or is not successful in attaining or maintaining treatment goals through the use of methadone.

Patients switching from methadone to buprenorphine in the treatment of OUD should be on low doses of

methadone before switching medications. Patients on low doses of methadone (30–40 mg per day or less) generally tolerate transition to buprenorphine with minimal discomfort, whereas patients on higher doses of methadone may experience significant discomfort in switching medications.

Patients switching from methadone to oral naltrexone or extended-release injectable naltrexone must be completely withdrawn from methadone and other opioids before they can receive naltrexone. The only exception would apply when an experienced clinician receives consent from the patient to embark on a plan of naltrexone facilitated opioid withdrawal management.

Patients who discontinue agonist therapy with methadone or buprenorphine and then resume opioid use should be made aware of the risks associated with opioid overdose, and especially the increased risk of death.8

**Work with methadone clinic staff to coordinate the methadone taper and with the transition to buprenorphine/naloxone:**

1. Establish with both patient and methadone clinic that, if the transition to buprenorphine/naloxone is unsuccessful (e.g., patient begins to experience withdrawal that interferes with functioning or leads to return to use, or patient does not tolerate the medication), the patient may return to methadone treatment without a gap in treatment.

2. Educate patients regarding appropriate methadone dose levels for transferring to buprenorphine/naloxone. To decrease the level of physical opioid dependence and minimize the chance for precipitated withdrawal, most patients will need to have their dose tapered to 30mg before beginning buprenorphine/naloxone treatment. Inform patient that the tapering and transitioning period may include discomfort and increased risk for relapse.

**Choose approach:**

Provide target methadone dose: 20–30 mg daily for one to two weeks prior to transition is optimal, but not always necessary.

Alternate approach: taper methadone dose to the point of patient experiencing moderate opioid withdrawal, with objective withdrawal symptom documentation via COWS, then initiate buprenorphine/naloxone. Inpatient detoxification is another option to assist a patient in the transition from methadone to buprenorphine/naloxone. Advise patient to arrange for time off from work and family support with childcare and other responsibilities during the transition, as discomfort may last 1–2 weeks. Timing for last methadone dose/first buprenorphine/naloxone dose is difficult to predict: Generally, at least 36–96 hours after the last methadone dose, but utilizing clinical assessment and judgment is essential.

Long half-life of methadone (storage in body tissues, especially liver) causes unpredictable clearance.

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Initiation of buprenorphine/naloxone should be guided by withdrawal symptoms objectively documented with a COWS score of 13–15, rather than by time since last methadone dose. Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and be continued during induction if prescribed by provider. More intensive stabilization support may be needed (e.g., telephone contact up to 3 times daily, until maintenance dosing is attained). Frequent visits, adequate supports, and a supportive environment to assist in the transition are important.

Providers should be experienced in induction prior to transitioning a patient from methadone maintenance to buprenorphine/naloxone.

Having the patient go to an inpatient detoxification clinic to make this transition can be a safer, more effective way to get the patient from methadone maintenance to buprenorphine/naloxone.

**Induction recommendations:**

Once a COWS score of 13–15 is documented, start buprenorphine/naloxone at 2mg/0.5mg sublingually, as prescribed.

Continue to dose patient as prescribed until physical withdrawal symptoms have been reduced to manageable levels or are absent. Patients transitioning from methadone may require higher dosing initially and then a taper down over time.

Continue induction according to patient’s prescription order, assessing symptoms of withdrawal and cravings. Manage symptoms with adjunctive comfort medications, as appropriate, with provider input. Comfort medications include agents to minimize nausea, vomiting, and diarrhea. Also, encourage copious oral hydration prior to induction.

Support and access to providers are critical components to assist patients make this transition and not jeopardize their recovery. ⁹

**Identifying Patients who may be Appropriate for Naltrexone Treatment**

**Oral Naltrexone**

Because oral naltrexone has high rates of non-adherence and the potential for overdose upon relapse, this treatment is best for candidates who can be closely supervised and who are highly motivated. There is a risk of opioid overdose if the patient ceases naltrexone and then uses opioids. Groups that may benefit from oral naltrexone include steadily-employed patients, those who have been using drugs for only a short time (e.g., younger patients), those with high levels of motivation and social support, and those under threat of legal sanctions.

Extended-Release Injectable Naltrexone (XR-NTX)

Regarding opioid use, extended-release injectable naltrexone is FDA approved for relapse prevention, not OUD. This is because it cannot be taken when opioids are still in one’s system/a patient is physically dependent. XR-NTX may be especially useful for patients who have contraindications to buprenorphine and methadone; patients confined to drug-free environments such as prison or inpatient rehabilitation; patients living in areas where agonist treatment is not available; or individuals who are highly motivated and desire to taper off their current agonist therapy. Because it is an FDA-approved for the treatment of alcohol use disorder, it may be well suited for patients with co-occurring opioid and alcohol use disorders.

Considerations before Prescribing Naltrexone

The effectiveness of oral naltrexone is limited, given poor adherence and the requirement of 7 to 14 days of opioid abstinence before initiation. During this waiting period, patients may drop out of care. One study found significantly lower patient retention in treatment after incarceration for patients treated with oral naltrexone compared with methadone.10

Data is not available at present on the recommended length of treatment with oral naltrexone or XR-NTX. Duration of treatment depends on the response of the individual patient, the patient’s individual circumstances, and clinical judgment.

Special consideration should be made in naltrexone dosing for incarcerated groups. Reentry into the community after imprisonment is a high-risk period for relapse to opioid misuse and overdose. Therefore, extended-release injectable naltrexone dosing before re-entry may serve to prevent relapse and overdose in the immediate period following release (though long-term follow up care is essential otherwise overdose risk returns to high levels).

Types of Settings for the Prescription of Naltrexone

Patients with OUD need to discontinue opioids and wait 7 to 14 days after the last opioid use (including any given for withdrawal treatment) before receiving oral naltrexone or XR-NTX. They can do so through medically supervised withdrawal in a controlled environment, such as an inpatient unit, residential addiction treatment program, correctional facility, or hospital, or on an outpatient basis. Financial issues and managed care constraints may influence patients’ access to controlled treatment environments.

Various approaches to rapid naltrexone induction have been developed and more recently refined 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 care.

Important Note on Naltrexone Induction

Before administering naltrexone, it is important that the patient has been adequately detoxified from opioids. Naltrexone can precipitate severe withdrawal symptoms in patients who have opioids in their systems. As a general rule, patients should be free from short-acting opioids for about 6 days before starting naltrexone, and free from long-acting opioids such as methadone and buprenorphine for 7–10 days. A naloxone challenge can be used if it is uncertain whether the patient is no longer physically dependent on opioids. In the naloxone challenge, naloxone hydrochloride (a shorter-acting injectable opioid antagonist) is administered and the patient is monitored for signs and symptoms of withdrawal. A low-dose oral naltrexone challenge has been used as an alternative.

Patients should be seen frequently at the beginning of their treatment. Weekly or more frequent visits/communications are recommended until patients are determined to be stable. The stability of a patient is determined by an individual clinician based on a number of indicators which may include abstinence from illicit drugs, participation in psychosocial treatment and other recovery-based activities, and good occupational and social functioning. Stable patients can be seen less frequently, but should be seen at least monthly. ¹¹

Oral Naltrexone

Use in limited circumstances after discussing risks and benefits, as well as alternative treatment options, with the patient. Do the naloxone challenge. The first oral naltrexone dose should be 25 mg. The dose can be increased on the second day to 50 mg daily if necessary. If desired, switch patients who tolerate a daily dose of 50 mg to a 3-day-per-week regimen for a total weekly dose of 350 mg.

Extended-Release Injectable Naltrexone (XR-NTX)

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.

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 the status of referrals to counseling or other services.

**Dosing and Maintenance**

**Oral Naltrexone**

The optimal length of treatment with oral naltrexone is not known. In general, the longer patients take an effective medication, the better their outcomes.

Oral naltrexone may be taken daily in 50 mg doses or 3x weekly in two 100 mg doses, followed by one 150 mg dose.

Oral formula naltrexone may be considered for patients where adherence can be supervised or enforced.¹²

**Extended-Release Injectable Naltrexone (XR-NTX)**

XR-NTX must be suspended only in the diluent supplied in the carton and must be administered only with one of the administration needles supplied in the carton. The microspheres, diluent, preparation needle, and an administration needle with needle protection device are required for preparation and administration. Two thin-walled 1 1/2-inch needles with needle protection device and two 2-inch thin-walled needles with needle protection device have been provided to accommodate varying patient body habitus. For patients with a larger amount of subcutaneous tissue overlying the gluteal muscle, the administering healthcare provider may utilize the supplied 2-inch needle with needle protection device to help ensure that the injectate reaches the intramuscular mass. For very lean patients, the 1 1/2-inch needle may be appropriate to prevent the needle contacting the periosteum. Either needle may be used for patients with average body habitus. A spare administration needle of each size is provided in case of clogging. Do not substitute any other components for the components of the carton.

Prior to preparation, allow the drug to reach room temperature (approximately 45 minutes).

Parenteral products should be visually inspected for particulate matter and discoloration prior to administration whenever solution and container permit. A properly mixed suspension will be milky white, will not contain clumps, and will move freely down the wall of the vial.

The product should be prepared and administered by a healthcare provider.

The carton should not be exposed to temperatures exceeding 25°C (77°F). 7°F). The entire carton should be stored in the refrigerator (2 to 8°C, 36 to 46°F). Unrefrigerated, XR-NTX microspheres can be stored at temperatures not exceeding 25°C (77°F) for no more than 7 days prior to administration. Do not expose unrefrigerated product to temperatures above 25°C (77°F). XR-NTX should not be frozen.

Prepare and administer the XR-NTX suspension using aseptic technique.

1. Remove the carton from refrigeration. Prior to preparation, allow drug to reach room temperature (approximately 45 minutes).
2. To ease mixing, firmly tap the XR-NTX microspheres vial on a hard surface, ensuring the powder moves freely.
3. Remove flip-off caps from both vials.
4. Wipe the vial tops with an alcohol swab.
5. Place the 1-inch preparation needle on the syringe and withdraw 3.4 mL of the diluent from the diluent vial. Some diluent will remain in the diluent vial.
6. Inject the 3.4 mL of diluent into the XR-NTX microsphere vial.
7. Mix the powder and diluent by vigorously shaking the vial for approximately 1 minute. Ensure that the dose is thoroughly suspended prior to proceeding to Step E.
   A properly mixed suspension will be milky white, will not contain clumps, and will move freely down the walls of the vial.
8. Immediately after suspension, withdraw 4.2 mL of the suspension into the syringe using the same preparation needle.
9. Select the appropriate needle for an intramuscular injection based on patient's body habitus:
   - 1 1/2-inch syringe
   - 2-inch syringe
10. Remove the preparation needle and replace with appropriately selected administration needle for immediate use.
11. Peel the blister pouch of the selected administration needle open halfway. Grip the base of the needle, not the safety sheath. Attach the luer connection to the syringe with an easy clockwise twisting motion.
12. Seat the needle firmly on the needle protection device with a push and clockwise twist.
13. Move the safety sheath away from the needle and toward the syringe barrel. Pull the sheath away from the needle - do not twist the sheath because it could result in loosening the needle.
14. Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until 4 mL of the suspension remains in the syringe. (The suspension is now ready for immediate administration.)
15. Using a circular motion, clean the injection site with the alcohol swab. Let the site dry before injecting. Do not touch the site again before giving injections.
16. Administer the suspension by deep intramuscular (IM) injection into a gluteal muscle, alternating buttocks per monthly injection. Remember to aspirate for blood before injection.
17. If blood aspirates or the needle clogs, do not inject. Change to the spare needle provided in the carton and administer into an adjacent site in the same gluteal region, again aspirating for blood before injection.
18. Inject the suspension in a smooth and continuous motion. (XR-NTX must not be given intravenously or subcutaneously.)
19. After the injection is administered, cover the needle by pressing the needle protection device against a flat surface using a one-handed technique to activate the safety mechanism away from self and others.
20. Visually confirm needle is fully engaged into the needle protection device. Dispose of used and unused items in appropriate waste containers (See nih.gov.)
**Blockade testing:** It is expected that approximately 50% of patients will ‘test’ blockade often same day as discharge. Make sure sufficient levels of naltrexone are present on discharge (oral supplementation if NTX-XR is given on the day of discharge.) Most commonly patients will test 1-3 times with low doses of opioid during the first few days after discharge, after which they are reassured blockade works and do not return to use. Some patients will use large amounts, for 1-3 weeks, trying to get high. Very few patients will continue using, often IV, even though they are blocked, but are interested in staying on naltrexone.

**Additional concerns**
Rarely, NTX is quickly metabolized, blood levels are low and patients may become re-dependent while receiving NTX as recommended.

**Some patients have increased craving and may use in weeks 3-4. This is a high risk time when the blockade is wearing off. In these patients, more frequent injection or oral supplementation is needed.** Most commonly, the first sign of relapse is missing doses/injections. The blockade fully wears off 2-3 days after oral and 5-6 weeks after injectable doses.

Risk of overdose is significant if patient decides to stop taking naltrexone, stop attending treatment and resumes opiate use. Consider transition onto an agonist medication to decrease the risk of overdose if unable to comply with NTX.\(^\text{13}\)

Additional supports and involving network members may be useful to improve adherence, as well as:
- Inpatient stabilization and another attempt at antagonist treatment
- Residential treatment/supportive Recovery Home
- Transition onto agonist medication

**Potential Adverse Effects**

**Both Formulations**
Naltrexone, both oral and extended-release injectable, is generally well tolerated. Apart from opioids, it does not typically interact with other medications. Most common side effects can include (in random order): insomnia, lack of energy/ sedation, anxiety, nausea, vomiting, abdominal pain/cramps, headache, cold symptoms, joint and muscle pain. For XR-NTX, to reduce injection site reactions in obese patients, a longer needle size may be used.

Discuss the risks and benefits of continuing naltrexone with patients who become pregnant while receiving naltrexone treatment and whose OUD is in remission. Unlike methadone and buprenorphine, naltrexone has not been extensively researched in pregnant populations and is not recommended for use.

Precipitated opioid withdrawal can occur in patients who used illicit opioids recently or switched from an opioid agonist medication. Symptoms may be severe enough for hospitalization. To avoid precipitated withdrawal from either formulation, patients should typically stop use of short-acting opioid agonists for 7 to 10 days and long acting agonists for 10 to 14 days.\(^\text{14}\)


Extended-Release Injectable Naltrexone (XR-NTX)

Possible side effects of XR-NTX include:
- Insomnia.
- Injection site pain.
- Hepatic enzyme abnormalities.
- Nasopharyngitis.

With XR-NTX, severe injection site reactions may occur (e.g., cellulitis, hematoma, abscess, sterile abscess, necrosis). Some cases may require surgical intervention and may result in significant scarring.

Patients are vulnerable to opioid overdose death after completing the every-4-weeks or once-monthly dosing period, missing a dose, or stopping treatment. Additionally, trying to override the opioid blockade with high opioid doses may cause overdose.

As with any IM injection, use caution in patients with thrombocytopenia or a coagulation disorder. Hepatitis has been associated with XR-NTX, often in the presence of other potential causes of hepatic toxicity (e.g., alcohol liver disease, viral hepatitis). Monitor liver function tests during treatment. Stop naltrexone in the presence of acute hepatitis and severe liver disease. Initiate or refer patients to treatment for hepatitis.

Use cautiously in patients with moderate to-severe renal impairment, because the medication is eliminated primarily through the kidneys.

Hypersensitivity reactions can occur, including rash, urticaria, angioedema, and anaphylaxis.

Monitor patients with OUD for depression and suicidal ideation. Naltrexone use has been occasionally associated with dysphoria, although it’s unclear whether this is a side effect of the medication or a manifestation of underlying depression or depressed mood related to OUD. Monitor patients for depression, which is common with OUD.

**How to Address Request to Discontinue Naltrexone**

Like buprenorphine and methadone, barring contraindications, patients should continue taking naltrexone as long as they benefit from it and want to continue. Published data on the long-term effectiveness of naltrexone compared to methadone or buprenorphine does not yet exist.

- 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 of switching buprenorphine or methadone treatment.
Discourage discontinuation in patients who are not yet stable, 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 cautiously explore the option of medication discontinuation 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.\(^\text{15}\)

Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal.

Patients being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or buprenorphine used should be low.

Patients should not be switched until a significant amount of naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended release injectable naltrexone.

Patients who discontinue antagonist therapy and resume opioid use should be made aware of the increased risks associated with opioid overdose, and especially the increased risk of death.\(^\text{16}\)

Any patients who want to transition from an antagonist to an agonist, or who wants to discontinue treatment, should be provided with overdose education and rescue naloxone (Narcan).

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Appendix: Federal guidelines on mandating counseling services, negative drugs screens, etc. to receive medication and rules about involuntary withdrawal

Relevant Selections from Federal OTP Guidelines – Code of Federal Regulations (SAMHSA, 2001)


https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines

(f) Required services—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(j) Interim maintenance treatment. **I.e., only providing medication while patients wait for a "spot" to get more comprehensive care
(1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment.

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

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.
Involuntary Withdrawal from Treatment (i.e., "administrative withdrawal")

A major goal of an OTP is to retain patients for as long as they can benefit from and express a desire to continue treatment. Programs should make every effort to intervene productively in a patient’s situation before resorting to administrative withdrawal. For example, patients with disruptive behavior should be screened and, if needed, referred for a full psychiatric evaluation. The type and quantity of behavioral services as well as the medical supervision for patients at risk for administrative withdrawal should be matched to address the degree of risk behavior. Involuntary "administrative withdrawal" requires OTPs to define and follow due process. The underlying goal is for involuntary medically supervised withdrawal to reflect a humane partnership between the patient and the treatment program. The program policies and procedures must take into consideration, on a case-by-case basis, all factors affecting the patient and all the steps involved in the process must be documented. Because of the risk of fatal overdose if relapse occurs, medically supervised withdrawal services should be accompanied by relapse prevention counseling, overdose prevention education as well as a naloxone prescription. The treatment and aftercare plans should always include a strategy to transition to medication assisted treatment including antagonist pharmacotherapy if needed.

42 CFR § 8.12 does not specify under what conditions administrative withdrawal is considered appropriate.

Standard practice regarding involuntary discharge among OTPs provide for the following situations:

- **Nonpayment of fees.** Remedies may include referral to a more affordable OTP or other forms of medication-assisted treatment.

- **Disruptive conduct or behavior.** Disruptive behaviors include dealing drugs, repeated loitering, or violation of treatment program rules resulting in documented observable, negative effect on the individual, program, staff, and/or other patients not successfully addressed by more conservative means. Clinical interventions should be aimed at retaining these patients in treatment and may include, as appropriate, intensified counseling opportunities, special treatment plans addressing the behavior, and/or referrals for mental health evaluation.

- **Violent conduct or threatening behaviors.** Violent conduct or threatening behaviors include assaults or attempted assaults and direct and credible threats of violence towards other patients, program staff members, or visitors. If practical under the circumstances and with due regard for patient and OTP staff safety, before administrative discharge, it is recommended that the OTP conduct a crisis assessment to address suicide risk, danger to self or others, urgent or critical medical conditions, and immediate threats. Please refer to SAMHSA’s Suicide Prevention App for Behavioral Health and Primary Care Providers (http://store.samhsa.gov/apps/suicidesafe/)

- **Incarceration or other confinement** that does not permit medically supervised withdrawal for patients receiving maintenance therapy with an opioid agonist.

**NO MENTION OF MISSING COUNSELING OR CONTINUED DRUG USE AS GROUNDS FOR INVOLUNTARY WITHDRAWAL**

When a patient is administratively discharged from an OTP, the program must employ the same principles as those used for voluntary medically supervised withdrawal from medication. The goal is to follow a withdrawal schedule that is based on sound clinical judgment and close patient monitoring. A schedule for medically supervised withdrawal for administrative withdrawal from treatment is generally a minimum of 21 days, but the physician may adjust this timeframe depending on clinical factors. The patient’s condition during this medically supervised withdrawal and all steps to address it should be documented in the patient’s record.
Administrative withdrawal is usually involuntary and used only when all therapeutic options have been exhausted. Given the short timeframe in which administrative withdrawal occurs and the poor prognosis of patients who are involuntarily discharged, the preferred approach is for OTPs to refer or transfer patients to a suitable alternative treatment program. Because of the risks of relapse following detoxification, patients should be offered a relapse prevention program that includes counseling, naloxone and opioid antagonist therapy.

**Substance Abuse Counseling**

Appropriately trained, experienced, and certified or licensed substance abuse counselors should provide services at the intensity and for the duration required to meet each patient’s needs as referenced in the individualized treatment plan. While there are no set patient-to-staff ratios specified in the federal regulations, states have set patient-to-staff ratios as high as 75:1 and as low as 30:1. States allow for an increase in the ratio under certain circumstances. Staff ratios should be sufficient to ensure that patients have reasonable and prompt access to counselors and receive counseling services at the required levels of frequency and intensity. An OTP’s staffing of counselors is based on the characteristics and needs of particular patient populations and state requirements.

Relevant FAQ:

*When a person in treatment for opioid addiction is abstinent from illicit opioids but tests positive for another drug, can we keep him or her in treatment?*

Yes, a person who tests positive for drugs other than opioids may be kept in treatment. SAMHA encourages OTPs to ensure that the abuse of drugs other than opioids is addressed in treatment. The OTP should provide appropriate counseling and other treatment if it identifies abuse of other drugs or alcohol as a problem. When necessary, the OTP may refer the patient to another program for additional treatment services. For further information, please refer to TIP 43.
Appendix Q.
GPRA Information

The Substance Abuse and Mental Health Services Administration (SAMHSA) has released the approved Government Performance and Results Act (GPRA) tool that is a requirement of the SOR grant.

Please note the following important points pertaining to the GPRA requirement:

- The SOR-approved GPRA tool is the original GPRA tool with which many providers are already familiar.
- Data collection points are at **INTAKE** and at **6 MONTHs** post GPRA intake.
- The window to collect the follow-up GPRA opens at five months after the intake GPRA date and closes after eight months. It is recommended agencies collect follow-ups as close to the 5-month mark as possible as it often takes considerable time to locate some consumers.
- Follow-up GPRAs may be collected via telephone interview.
- Our expected Intake GPRA rate is **100%**
- Our expected GPRA follow-up rate is **80%**.
- Providers will utilize CIMOR to enter GPRA data.
- IT staff is adding three additional questions that were not in the prior GPRA version in CIMOR. This is expected to be completed by the end of October.
- Please collect GPRAs in the interim using paper documentation or your local electronic medical record (EMR) until such time they may be entered into CIMOR.
- The DMH will batch upload GPRA data into the SAMHSA Performance Accountability and Reporting System (SPARS) system.
- After completion of the **GPRA follow-up** at the required intervals, providers should bill: **GPRA Follow-up/DCI Reassessment - H0001 TS - $61.81**
- There are no special requirements associated with staff that collect GPRAs. The Division recommends that agencies designate one or two staff members to focus on GPRA tracking and collection, especially the follow-up GPRAs.
Accessing GPRA in CIMOR Instructions

**Step 1:** Select “GPRA” under the Consumer tab. Select “Assessment GPRA-SOR”.

**Step 2:** Select “Add Intake SOR”.

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*Image of the CIMOR interface with highlighted steps.*
**Step 3:** Enter the client intake interview date in the “Interview Date” section.

**Step 4:** Once GPRA tool is completed, click “Save” and submit the survey.
GPRA Requirement for ALL Opioid SOR Consumers

On March 5, 2020, the Department of Mental Health (DMH) will deploy the updated State Opioid Response (SOR) Government Performance and Results Act (GPRA) into CIMOR. The following business rules will be relaxed until September 30, 2020, (which is the duration of the Opioid SOR Grant YEAR 2):

Providers can only add a GPRA within the last thirty days.

Providers can only bill a service with a current (initial or follow-up) GPRA on file for the consumer.

Effective October 1, 2020, the relaxed rules will revert back to the original rules. Providers will only be able to add a GPRA interview date within the last 30 days from the current date for a consumer. For example, if the current date is 10/01/2020, CIMOR will only allow a GPRA interview date from 09/01/2020 to 10/01/2020. The provider will not be able to add an encounter for ADA Opioid SOR Grant program without a current GPRA.

In order to add a SOR GPRA, please add the following roles to your profile:

GPRA-DCI-Update
GPRA-DCI-View

Step by Step GPRA Roles Instructions

1. Go to https://portal.dmh.mo.gov
2. Click the Please log in link, left-hand side of the screen
3. Enter your credentials
4. Click the Apps-Docs-Videos link, left-hand side of the screen
5. Click the Access Request Application (ARA)

6. Click New Request
7. Read and Accept Terms of Agreement
8. Click ADA and CPS checkbox
9. Select your employer using the dropdown menu
10. Select your Supervisor from the Dropdown menu
11. Locate the Role Name GPRA-DCI-Update and GPRA-DCI-View
12. Click Add for both roles
13. Go back to the top of the screen and click Next
14. User is directed to Confirmation page
15. Review the roles select
16. Click Submit Request