Opioid Use Disorder Guidance

Federal Bureau of Prisons

About This Document

This document contains 8 separate MODULES. For details on what a particular module covers, see the short **TABLE OF CONTENTS** at the beginning of that module.

PRINTING: Most likely, you are viewing this document in PDF format. Note that each module starts on its own page 1. To print an individual topic without printing the entire document, use the page numbers listed below.

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- **MODULE 6. PHARMACY LOGISTICS** and **MODULE 8. CONTINUOUS QUALITY IMPROVEMENT** are deleted and the remaining modules renumbered.

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A. OPIOID USE DISORDER

BACKGROUND

Opioids are natural or synthetic chemicals that interact with opioid receptors on the nerve cells in the body and in the brain to reduce feelings of pain. Historically, ***opiates*** referred to drugs derived from the opium poppy (e.g., oxycodone, hydrocodone, codeine, morphine), while ***opioids*** referred to synthetic drugs active at the mu receptor and designed to mimic naturally occurring opiates (e.g., tramadol, fentanyl, methadone). There are also semi-synthetic opioids, such as heroin, which is made by processing morphine. Today, the term opioid is used to refer to the entire class of mu opioid receptor agonist drugs, regardless of origin (natural, synthetic, or semi-synthetic; legal or illegal).

Opioid use disorder (OUD) is a chronic relapsing disease with significant economic, personal, and public health consequences. Approximately 3 million people in the United States have had or currently have OUD (Azadfard et al. 2023). Opioid-related overdoses and deaths are a national crisis. The number of overdose deaths increased by over 30% from 2019 to 2020 and by another 15% in 2021. In 2020, opioids were involved in over 74% of drug overdose deaths (CDC 2022). In addition to the toll of OUD on our patient population, many Federal Bureau of Prisons (FBOP) employees have friends or family who are battling this disorder or who have died from overdose.

For every drug overdose resulting in death, there are many more nonfatal overdoses, and each one carries an economic and emotional toll. In 2018, opioid overdose, misuse, and dependence accounted for over $786 billion in total costs and $89 billion in health care costs. The mean health care cost savings of averting OUD is estimated at $244,030 per person (Murphy 2020).

OUD in the Prison Population: A study by Bronson et al. (2017) showed approximately 63% of incarcerated individuals meet the criteria for substance use disorder (SUD) and up to one-quarter of these individuals with SUD have OUD. Another study found within the first two weeks after release from prison, individuals have a significantly higher relative risk of death from drug overdose compared to the general population (Hartung et al. 2023; Shabbar et al. 2018). Research also suggests access to health care coverage and continuity of care following incarceration reduce the potential for re-arrest, particularly among individuals with SUD (Bird 2015; Gordon 2014; Green 2018; Kinlock 2007; Westerberg 2016). Treatment of OUD in incarcerated individuals has the added benefit of reducing violence and disciplinary issues related to opioids and drug debts within our prisons.

MEDICATION FOR OUD

The FBOP has a longstanding commitment to ensuring the medical care provided to our patients is safe, effective, and comparable to community standards. **Medication for OUD is a lifesaving, appropriate, first-line treatment for many patients, especially those with moderate-to-severe OUD.** Current evidence-based trends in the treatment of OUD recognize medication has a primary role and benefit independent of behavioral therapy. As an example, one large study found treatment with methadone or buprenorphine following a non-fatal opioid overdose was associated with a 59% reduction in opioid-related mortality (Larochelle 2018).

Benefits of medication for OUD include the following:

- Reduced risk of overdose-related death
- Reduced risk of HIV, viral hepatitis, and cellulitis infection in injection drug users
- Reduced criminal behavior
- Reduced rates of psychiatric complications
- Increased retention in treatment programs

FDA-approved medication for OUD are methadone (a full opioid agonist), buprenorphine (a partial opioid agonist), and naltrexone (an opioid antagonist). When taken as directed, both methadone and buprenorphine can reduce cravings and the symptoms of withdrawal without producing euphoria. Naltrexone blocks the effects of opioids and has demonstrated efficacy in reducing opioid misuse.

Extended-release naltrexone initiated prior to release from controlled environments may be useful in preventing return to opioid use and has been shown in short-term pilot studies (Friedmann et al. 2018) to increase treatment engagement after release. The oral formulation of naltrexone is not widely used to treat OUD because of low rates of patient acceptance and high rates of non-adherence leading to lack of efficacy. However, consideration should be given to its use in situations where adherence can be ensured, as with observed daily dosing. Naltrexone is also FDA-approved for the treatment of alcohol use disorder (AUD) and therefore may be useful for patients with both OUD and AUD.

Terminology: Medication for OUD is sometimes referred to as MOUD. Medication-assisted treatment, or MAT, describes the use of medication in combination with counseling and/or behavioral therapy. The preferred terms for treatment of OUD continue to evolve; to avoid confusion, this document refers to either medication for OUD or treatment for OUD rather than MOUD or MAT.

BEHAVIORAL THERAPY FOR OUD

Behavioral therapy refers to psychosocial treatment or other non-medication treatment provided by persons trained in behavioral and psychosocial therapies (e.g., psychologists, drug treatment specialists, licensed clinical social workers, etc.) Treatment may include motivational interviewing, cognitive behavioral therapy, family therapy, 12-step programs, addiction counseling, or group therapy. Behavioral therapy can be an effective treatment for OUD whether or not it is used in combination with medication.

Studies in the community have shown treatment with medication alone, as compared to treatment with behavioral therapy alone, produces a lower risk of overdose (Wakeman et al. 2020). Studies examining outcomes of combined behavioral and medication treatment modalities have, in general, also demonstrated superiority to behavioral health therapy alone (Dugosh 2016; Zhang et al. 2022). American Society of Addiction Medicine (ASAM) guidelines for OUD state that while further research is needed to determine the most effective behavioral therapies, psychosocial treatment is an important part of the treatment of OUD and should be offered to all patients receiving medication for OUD (ASAM 2020). The FBOP recommends individualized treatment plans for patients receiving medication for OUD; however, declination or unavailability of behavioral therapy does not hinder or prevent treatment with medication. **As a stand-alone treatment, behavioral therapy may be most appropriate for individuals with mild OUD, a history of successful behavioral therapy, and/or ineligibility for, or a strong preference against, medication for OUD.**

REDUCING STIGMA

Stigma remains one of the biggest barriers to treatment for persons with OUD, and the terminology surrounding OUD has contributed to a stigmatizing culture that may discourage people from seeking help.

Using language that acknowledges OUD as a brain disorder helps to reduce stigma and improve treatment outcomes. When talking to patients with OUD, clinicians are encouraged to use objective, descriptive, and respectful language, as demonstrated in **TABLE 1**.

TABLE 1. PREFERRED TERMINOLOGY VS. STIGMATIZING TERMINOLOGY

STIGMATIZING LANGUAGE	PREFERRED LANGUAGE	REASONING
Abuse, addiction, habit, problem	Substance use disorder, substance misuse	Avoids perpetuating negative/punitive attitudes, even among treatment professionals. Habit inaccurately implies a person is choosing to use substances and can simply stop whenever.
Addict, alcoholic, crackhead, junkie, abuser, user	Person with substance use disorder	Avoids demeaning language that labels a person by their illness
Dirty drug test, clean drug test	Drug monitoring, drug screen, drug test, positive/negative drug test	More neutral, professional, and accurate
Dirty, clean, sober	Actively using, in recovery, not actively using	More neutral, professional, and accurate
Drug replacement, substitution therapy	Medication for opioid use disorder, methadone, buprenorphine, naltrexone	Medication for OUD is life-saving and effective treatment yet is frequently referred to as **replacement**. This language contributes to the mistaken notion that medication is a means of substituting a legal opioid for an illegal opioid, as opposed to being a legitimate medical treatment.

B. DEFINITIONS

ADDICTION MEDICINE SPECIALIST: an FBOP employee with specialized training to treat opioid use disorder and includes the FBOP Chief of Addiction Medicine, Addiction Medicine Advanced Practice Provider, and Substance Use Disorder Clinical Pharmacy Consultants.

DRUG ENFORCEMENT ADMINISTRATION (DEA): the federal agency responsible for enforcing the controlled substance laws of the United States.

C. REGULATORY AUTHORITY

FIRST STEP ACT

The First Step Act of 2018 (FSA) requires federal criminal justice reforms meant to reduce recidivism risk and improve correctional outcomes. Under Title VI of the FSA, FBOP is required to provide a plan for expanding access to evidence-based treatment—including medication, as appropriate—for adults in custody with OUD. After submitting the plan, FBOP is required to execute this plan and provide regular status updates. As such, **the goal is to provide all treatment services onsite at each FBOP institution without relying on community providers**. This will result in lower costs (e.g., fewer custody officers needed for escorted trips, less overtime pay, reduced contract costs), lower public safety risks (by reducing escorted trips offsite), improved standardization of care, and less potential for medication diversion.

CODE OF FEDERAL REGULATIONS

Effective April 2, 2024, the Code of Federal Regulations, *eCFR :: 42 CFR Part 8 Subpart C -- Certification and Treatment Standards for Opioid Treatment Programs*, was updated to state the following:

- ***8.11(h)(3) - Medication units, long-term care facilities and hospitals.***

  Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.

All FBOP facilities will continue to maintain DEA Hospital/Clinic Registration as directed in Program Statement 6360.02 Pharmacy Services.

AMERICANS WITH DISABILITIES ACT

The Americans with Disabilities Act (ADA) prohibits discrimination against persons in recovery from OUD who are not engaging in illegal drug use, including those who are taking legally prescribed medication for OUD. Discriminatory practices in correctional facilities include blanket policies of discontinuing medication for OUD on intake and *administrative* decisions to refuse access to medication for OUD. The ADA has determined financial and employment constraints are not reasonable defenses for withholding treatment.

➔ *Additional information can be found in The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery (U.S. Department of Justice, Civil Rights Division).*

D. FBOP OPIOID USE DISORDER GUIDANCE

This *FBOP Opioid Use Disorder Guidance* replaces the previous *Clinical Guidance for Opioid Use Disorder* and *Technical Guidance for Medication Treatment for Opioid Use Disorder* in all locations. This document is not a legal document. It is a guidance document providing a review and summary of statutory and regulatory requirements in addition to clinical guidance and recommended best practices in its application to a carceral environment. References to statutory or regulatory requirements use language such as "must," "shall," or "required" and will include citations. Recommended practices in this plan are voluntary and are identified with language such as "should," "may consider," or "recommend." Readers are strongly encouraged to become familiar with the resources for management of OUD provided in Section E. Additional Resources of this module.

The *FBOP Opioid Use Disorder Guidance* is divided into 8 modules. These modules are reviewed and approved at least annually under the direction of the FBOP medical director and are available through Sallyport for all FBOP employees:

- Module 1. Mission and Overview
- Module 2. Administrative Requirements for Treatment of Opioid Use Disorder
- Module 3. Evaluation and Treatment Initiation
- Module 4. Review of Medication for Opioid Use Disorder
- Module 5. Monitoring and Follow-Up
- Module 6. Medication Administration and Diversion Control
- Module 7. Special Populations
- Module 8. Transitions of Care

E. ADDITIONAL RESOURCES

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION / DEPARTMENT OF HEALTH AND HUMAN SERVICES

- **Medication for Substance Use Disorder (SUD):** https://www.samhsa.gov/medications-substance-use-disorders
- **Naltrexone:** https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naltrexone
- **Buprenorphine:** https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine
- **Buprenorphine Quick Start Guide:** https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf
- **Methadone:** https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone
- **Practitioner and Treatment Program Locator:** https://findtreatment.gov/
- **Center for Substance Abuse Treatment (CSAT):** https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat
- **Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder:** https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf

- **Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings:** https://store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf
- **The Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide:** includes a summary of the key differences between extended-release injectable naltrexone, methadone, and buprenorphine and covers key information on assessing a patient's need for treatment, initiating treatment, monitoring patient progress, adjusting the treatment plan, and deciding whether and when to end medications for OUD. https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4892r.pdf

OTHER ORGANIZATIONS

- **American Academy of Addiction Psychiatry (AAAP):** http://www.aaap.org
- **American Society of Addiction Medicine (ASAM):** http://www.asam.org
- **Association for Addiction Professionals (NAADC; formerly National Association for Alcoholism and Drug Abuse Counselors):** http://naadac.org
- **California Society of Addiction Medicine (CSAM):** https://csam-asam.org/
- **College on Problems of Drug Dependence (CPDD):** https://cpdd.org/
- **National Clinical Consultation Center (NCCC) Substance Use Management:** https://nccc.ucsf.edu/clinician-consultation/substance-use-management/ Providers may email or call NCCC directly to obtain patient-specific guidance on all aspects of substance use management. If NCCC is consulted, providers must ensure all patient information is de-identified.
- **Providers Clinical Support System (PCSS) Mentoring Program:** Federally funded through SAMHSA, offers 3 levels of mentoring. Including an online discussion forum, emailing to ask a question and one-on-one mentoring. One-on-One mentoring can be requested: Mentor Request Form - PCSS (pcssnow.org)
- **National Institute on Alcohol Abuse and Alcoholism (NIAAA):** http://www.niaaa.nih.gov/
- **National Institute on Drug Abuse (NIDA):** http://www.nida.nih.gov/
- **Office of National Drug Control Policy (ONDCP):** http://www.whitehousedrugpolicy.gov
- **Food and Drug Administration (FDA) Sublocade Risk Evaluation and Mitigation Strategy (REMS):** https://www.sublocaderems.com/
- **Food and Drug Administration (FDA) Brixadi Risk Evaluation and Mitigation Strategy (REMS):** https://brixadirems.com/

F. REFERENCES

American Society of Addiction Medicine (ASAM). *Appropriate Use of Drug Testing in Clinical Addiction Medicine.* 2017. https://www.asam.org/quality-care/clinical-guidelines/drug-testing.

American Society of Addiction Medicine (ASAM). *The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update*. 2020. https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery. U.S. Department of Justice, Civil Rights Division. April 5, 2022. https://archive.ada.gov/opioid_guidance.pdf.

Aslim EG, Mungan MC, Navarro CI, Yu H. The effect of public health insurance on criminal recidivism. *J Pol Anal Manage*. 2022;41(1):45-91. https://doi.org/10.1002/pam.22345.

Azadfard M, Huecker MR, Leaming JM. *Opioid Addiction*. Treasure Island, FL: StatPearls Publishing; 2023. https://www.ncbi.nlm.nih.gov/books/NBK448203/.

Bird SM, Fischbacher CM, Graham L, Fraser A. Impact of opioid substitution therapy for Scotland's prisoners on drug-related deaths soon after prisoner release. *Addiction*. 2015;110(10):1617-1624. doi:10.1111/add.12969.

Bronson J, Stroop J, Zimmer S, Berzofsky M. (2017). Drug use, dependence, and abuse among state prisoners and jail inmates, 2007–2009. NCJ 250546. Special Report of the United States Department of Justice, Office of Juvenile Justice and Delinquency Prevention, Bureau of Justice Statistics. https://bjs.ojp.gov/library/publications/drug-use-dependence-and-abuse-among-state-prisoners-and-jail-inmates-2007-2009.

Bruneau J, Ahamad K, Goyer ME, et al. Management of opioid use disorders: A national clinical practice guideline. *CMAJ.* 2018;190(9):E247-E257. http://www.cmaj.ca/content/190/9/E247.

Buprenorphine: Drug Safety Communication – FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain. Food and Drug Administration. January 12, 2022. https://www.fda.gov/safety/medical-product-safety-information/buprenorphine-drug-safety-communication-fda-warns-about-dental-problems-buprenorphine-medicines?utm_medium=email&utm_source=govdelivery.

Chang G. Substance use during pregnancy: Overview of selected drugs. In: Post TW, ed. *UpToDate*. Waltham, MA: UpToDate. Updated 2020. Accessed January 24, 2023. http://www.uptodate.com.

Committee on Obstetric Practice, American Society of Addiction Medicine. (2017; reaffirmed 2021). Opioid use and opioid use disorder in pregnancy. Committee Opinion 711. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.

Death Rate Maps & Graphs. Centers for Disease Control and Prevention. Updated June 2, 2022. https://www.cdc.gov/drugoverdose/deaths/index.html.

Dugosh K, Abraham A, Seymour B, McLoyd K, Chalk M, Festinger D. A systematic review on the use of psychosocial interventions in conjunction With medications for the treatment of opioid addiction. *J Addict Med.* 2016 Mar-Apr;10(2):93-103. https://doi.org/10.1097/ADM.0000000000000193

Evans EA, Pivovarova E, Stopka TJ, Santelices C, Ferguson WJ, Friedmann PD. Uncommon and preventable: Perceptions of diversion of medication for opioid use disorder in jail. *J Subst Abuse Treat.* 2022 Jul;138:108746. https://doi.org/10.1016/j.jsat.2022.108746.

Friedmann PD, Wilson D, Hoskinson R Jr, Poshkus M, Clarke JG. Initiation of extended release naltrexone (XR-NTX) for opioid use disorder prior to release from prison. J Subst Abuse Treat. 2018 Feb;85:45-48. https://doi.org/10.1016/j.jsat.2017.04.010.

Ghosh SM, Klaire S, Tanguay R, Manek M, Azar P. A review of novel methods to support the transition from methadone and other full agonist opioids to buprenorphine/naloxone sublingual in both community and acute care settings. *Can J Addict*. 2019;10(4):41-50. http://doi.org/10.1097/CXA.0000000000000072.

Gordon MS, Kinlock TW, Schwartz RP, Fitzgerald TT, O'Grady KE, Vocci FJ. A randomized controlled trial of prison-initiated buprenorphine: Prison outcomes and community treatment entry. *Drug Alcohol Depend*. 2014;142:33-40. https://doi.org/10.1016/j.drugalcdep.2014.05.011.

Green TC, Clarke J, Brinkley-Rubinstein L, et al. Postincarceration fatal overdoses after implementing medications for addiction treatment in a statewide correctional system. *JAMA Psychiatry*. 2018;75(4):405-407. https://doi.org/10.1001%2Fjamapsychiatry.2017.4614.

Hartung, D. M., McCracken, C. M., Nguyen, T., Kempany, K., & Waddell, E. N. (2023). Fatal and nonfatal opioid overdose risk following release from prison: A retrospective cohort study using linked Administrative Data. *J. Subst. Use*, *147*, 208971. https://doi.org/10.1016/j.josat.2023.208971.

Hegmann K., Weiss M., Bowden, K., et al. ACOEM practice guidelines: Opioids and safety-sensitive work. *J Occu Environ Med*. 2014;56(7):e46-e53. 10.1097/JOM.0000000000000237.

Howell BA, Hawks L, Wang EA, Winkelman TNA. Evaluation of changes in US health insurance coverage for individuals with criminal legal involvement in Medicaid expansion and nonexpansion states, 2010 to 2017. *JAMA Health Forum*. 2022;3(4):e220493. https://doi.org/10.1001/jamahealthforum.2022.0493.

Hser, Y. I., Saxon, A. J., Huang, D., Hasson, A., Thomas, C., Hillhouse, M., Jacobs, P., Teruya, C., McLaughlin, P., Wiest, K., Cohen, A., & Ling, W. (2014). Treatment retention among patients randomized to buprenorphine/naloxone compared to methadone in a multi-site trial. *Addiction (Abingdon, England)*, *109*(1), 79–87. https://doi.org/10.1111/add.12333

Jarvis M, Williams J, Hurford M, Lindsay D, Lincoln P, Giles L, Luongo P, Safarian T. Appropriate Use of Drug Testing in Clinical Addiction Medicine. J Addict Med. 2017 May/Jun;11(3):163-173. https://pubmed.ncbi.nlm.nih.gov/28557958/

Kinlock TW, Gordon MS, Schwartz RP, O'Grady K, Fitzgerald TT, Wilson, M. A randomized clinical trial of methadone maintenance for prisoners: Results at 1-month post-release. *Drug Alcohol Depend*. 2007;91(2-3):220-227. https://doi.org/10.1016/j.drugalcdep.2007.05.022.

Larochelle MR, Bernson D, Land T, Stopka T, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study. *Ann Intern Med*. 2018;169(3)137-145. https://doi.org/10.7326/m17-3107.

Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev*. 2014 Feb 6;(2):CD002207.doi: https://doi.org/10.1002/14651858.CD002207.pub4.

Mattick RP, Breen C, Kimber J, Davoli M. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database Syst Rev*. 2009 Jul 8;(3):CD002209. doi: 10.1002/14651858.CD002209.pub2.

Medication-Assisted Treatment (MAT) in the Criminal Justice System: Brief Guidance to the States. Substance Abuse and Mental Health Services Administration (SAMHSA). 2019. https://store.samhsa.gov/product/Medication-Assisted-Treatment-MAT-in-the-Criminal-Justice-System-Brief-Guidance-to-the-States/PEP19-MATBRIEFCJS.

Murphy SM. The cost of opioid use disorder and the value of aversion. *Drug Alcohol Depend*. 2020 Dec 1;217:108382. doi: 10.1016/j.drugalcdep.2020.108382.

Schulze H, Schumacher M, Urmeew R, et al. (2012). Driving under the influence of drugs, alcohol and medicines in Europe – Findings from the DRUID project. European Monitoring Centre for Drugs and Drug Addiction. Druid Thematic Papers. https://orbit.dtu.dk/en/publications/driving-under-the-influence-of-drugs-alcohol-and-medicines-in-eur.

Seligman NS, Rosenthal E, Berghella V. (2023). Overview of management of opioid use disorder during pregnancy. In: Post TW, ed. *UpToDate*. Waltham, MA: UpToDate. Accessed January 24, 2023. http://www.uptodate.com.

Ranapurwala, S. I., Shanahan, M. E., Alexandridis, A. A., Proescholdbell, S. K., Naumann, R. B., Edwards, D., & Marshall, S. W. (2018). Opioid overdose mortality among former North Carolina inmates: 2000–2015. *Am. J. Public Health 108*(9), 1207–1213. https://doi.org/10.2105/ajph.2018.304514

Rudolph, K. E., Williams, N. T., Goodwin, A. T., Shulman, M., Fishman, M., Díaz, I., Luo, S., Rotrosen, J., & Nunes, E. V. (2022). Buprenorphine & methadone dosing strategies to reduce risk of relapse in the treatment of opioid use disorder. *Drug and Alcohol Dependence*, *239*, 109609. https://doi.org/10.1016/j.drugalcdep.2022.109609

Silverstein SM, Daniulaityte R, Martins SS, Miller SC, Carlson RG. "Everything is not right anymore": Buprenorphine experiences in an era of illicit fentanyl. *Int J Drug Policy*. 2019 Dec;74:76-83. doi: 10.1016/j.drugpo.2019.09.003.

Synthetic Opioid Overdose Data. Centers for Disease Control and Prevention. Updated June 6, 2022. https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html.

Tran TH, Griffin BL, Stone RH, Vest KM, Todd TJ. Methadone, buprenorphine, and naltrexone for the treatment of opioid use disorder in pregnant women. *Pharmacotherapy*. 2017;37(7):824-839. doi: 10.1002/phar.1958.

Treating Opioid Addiction in Criminal Justice Settings. National Institute on Drug Abuse. Updated December 14, 2007. https://nida.nih.gov/publications/treating-opioid-addiction-in-criminal-justice-settings.

Wakeman, S. E., Larochelle, M. R., Ameli, O., Chaisson, C. E., McPheeters, J. T., Crown, W. H., Azocar, F., & Sanghavi, D. M. (2020). Comparative effectiveness of different treatment pathways for opioid use disorder. *JAMA Netw Open*. 2020;*3*(2). https://doi.org/10.1001/jamanetworkopen.2019.20622

White, W. L., Campbell, M. D., Spencer, R. D., Hoffman, H. A., Crissman, B., & DuPont, R. L. (2014). Patterns of abstinence or continued drug use among methadone maintenance patients and their relation to treatment retention. *Journal of psychoactive drugs*, *46*(2), 114–122. https://doi.org/10.1080/02791072.2014.901587

Wilson N, Kariisa M, Seth P, Smith 4th H, Davis NL. Drug and opioid-involved overdose deaths – United States, 2017-2018. *MMWR Morb Mortal Wkly Rep*. 2020;69(11):290-297. doi: 10.15585/mmwr.mm6911a4.

Westerberg VS, McCrady BS, Owens M, Guerin P. Community-based methadone maintenance in a large detention center is associated with decreases in inmate recidivism. *J Subst Abuse Treat*. 2016 Nov;70:1-6. doi: 10.1016/j.jsat.2016.07.007.

Zhang, P., Tossone, K., Ashmead, R., Bickert, T., Bailey, E., Doogan, N. J., Mack, A., Schmidt, S., & Bonny, A. E. Examining differences in retention on medication for opioid use disorder: An analysis of Ohio Medicaid data. *J. Subst. Abuse Treat.* 2022;136:108686. https://doi.org/10.1016/j.jsat.2021.108686

MODULE 2. ADMINISTRATIVE REQUIREMENTS FOR TREATMENT OF OPIOID USE DISORDER

WHAT'S NEW

- *Section C. Continuous Quality Improvement* has been added and replaces **MODULE 8. CONTINUOUS QUALITY IMPROVEMENT**.
- *Section D. OTP Meeting and Reports* relettered and renamed to *Section B. OUD Meetings.*
  - References to OTP meeting requirements have been removed and recommended meetings and reporting elements have been clarified.

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A. MODULE OVERVIEW

As the provision of opioid use disorder (OUD) treatment services expands to meet the requirements of the First Step Act (FSA), continued reliance on community treatment providers outside of the Federal Bureau of Prisons (FBOP) Health System has the potential to overwhelm custody officers—who must escort prisoners during offsite medical trips—as well as local clinics and other community providers. As such, **the goal is to provide all treatment services onsite at each FBOP institution**. This will result in lower costs (e.g., fewer custody officers needed for escorted trips, less overtime pay, reduced contract costs), lower public safety risks (by reducing escorted trips offsite), improved standardization of care, and less potential for medication diversion. Additionally, embedding OUD treatment into the primary care model, improves accessibility, reduces stigma, and offers an integrated, patient-centered approach to care. Shifting treatment from a specialized community OTP to primary care settings can streamline access for patients, normalize the process, and address challenges such as stigma and reluctance to seek treatment.

B. OUD MEETINGS

Implementation and management of OUD treatment is more effective with a multidisciplinary approach. To aid in effective communication, monthly (or more frequently, if needed) OUD staff meetings are recommended. The purpose of this multidisciplinary meeting is to foster communication between departments and keep everyone informed about individual patient progress.

- Attendance should include the institution Clinical Director, primary care provider(s), social workers, nurses, psychologists, pharmacists, a unit team representative, and Captain, or respective actings.
- Suggested topics for discussion include, but are not limited to, the following:
  - Aftercare plans for patients who are transferring out of FBOP custody.
  - Treatment plans for complex patient cases.
  - Current metrics such as rates of suspected overdose, frequency and results of urine drug screens, diversion attempts, rates of illicit drug introduction on the compound, etc.
  - Plans to manage current wait lists for treatment evaluation and initiation.

C. CONTINUOUS QUALITY IMPROVEMENT

A robust approach to patient monitoring and continuous quality improvement is essential to ensure safety and maximize clinical outcomes for patients with OUD. The local Quality Improvement Committee (QIC) already established under **Program Statement 6013.01 Health Services Quality Improvement,** Section 5, will be responsible for surveillance, and when applicable, quality improvement studies to improve aspects of care for patients receiving medications for OUD. The FBOP utilizes the PDCA (Plan, Do, Check, Act) model in developing and implementing quality improvement studies and outcome-based monitoring initiatives. If studies related to patients receiving medications for OUD or processes for OUD management are undertaken, they should be approved in the local Governing Body meeting with progress thereafter recorded in the QIC quarterly meeting minutes as part of the facility-wide Quality Improvement Program activities.

Ongoing surveillance of patients and processes is essential to inform administrators and clinicians of trends so necessary interventions can be initiated at the earliest possible time. Statistical reporting should, at a minimum, occur quarterly and include the following elements:

1. The number of patients with screening indicated (OUD Administrative Code "OUD Tx Screening Indicated (OUDSI))
2. The number of patients receiving medications for OUD (OUD Administrative Code "OUD Tx On Medication (OUDPA))
3. Adverse health events or deaths for patients receiving medications for OUD
4. Surveillance of naloxone administration, to include the number of patients who received naloxone and the number of patients where naloxone was indicated but not administered (i.e., missed opportunities)
5. Other issues or trends of interest or identified by the facility

The above data elements should be recorded in QIC meeting minutes with appropriate actions and responsibility assigned. The current QIC Meeting Minute template, which includes these elements, is located on the Population and Correctional Health page on the FBOP intranet. In addition to the quarterly reporting requirement, each facility should report the above metrics as annual values at the end of each fiscal year. A facility may include additional temporary or ongoing statistical metrics as it deems necessary to support local processes or quality improvement studies. These ad hoc metrics can be initiated and/or discontinued at the recommendation of the QIC when studies resulting from them are concluded.

The FBOP has implemented reporting systems for healthcare employees to voluntarily report, in a nonpunitive environment, adverse and near-miss events affecting patient safety. The facility HSA and CD will ensure institution employees report adverse and near-miss events, when indicated. This component is addressed in **Program Statement 6013.01 Health Services Quality Improvement,** Section 10 - Risk Management, Error Reduction, and Patient Safety and in **Program Statement 6360.02 Pharmacy Services,** Section 8.c - Patient Safety and Section 12 - Medication Errors.

Identified patient safety concerns, adverse events and near-misses will be monitored by the QIC and Institution Chief Pharmacist and serve as the basis for root cause analysis, quality improvement studies, and reformative or therapeutic actions to promote the habitual practice of safety creating an evolving culture that is both non-punitive and transparent.

D. TRAINING REQUIREMENTS

The FBOP Medical Director establishes required training for providers who prescribe medication for OUD. The required training and process to obtain prescribing access in BEMR is described on the following page.

BUPRENORPHINE

The following training is required for *all* Clinical Directors and all other providers prescribing buprenorphine:

- Physicians are required to complete 8 hours of training, available here: 8 Hour MOUD Training (sudtraining.org)
- Nurse practitioners are required to complete 8 hours of training, available here: APNA eLearning Center: MSUD: Medications for Substance and Opioid Use Disorders - 2023
- Physician assistants are required to complete 8 hours of training, available here: 8 Hour MOUD Training (sudtraining.org)
- Pharmacists are required to complete 8 hours of training available here: 8 Hour MOUD Training (sudtraining.org)

Documentation of training certification will be maintained in the provider credential file. Upon completion of the required training, follow the Guidance for Obtaining BEMR Prescribing Rights.

METHADONE

BOP-approved training is required for *all* Clinical Directors and all other providers prescribing methadone and can be found on Health Services Division's Continuing Professional Education page on Sallyport. Completing this training will provide 6.0 hours of accredited Continuing Education for physicians, advanced-practice providers (APPs), nurses, and pharmacists. Documentation of training certification will be maintained in the provider credential file. Upon completion of the required training, follow the Guidance for Obtaining BEMR Prescribing Rights.

NALTREXONE

All privileged employees or employees working under a practice agreement may prescribe naltrexone.

AUTHORITY TO PRESCRIBE

Only providers with evidence of completion of the required training are authorized to prescribe medications for OUD (i.e., copy of certification of completion in the provider credential file).

GUIDANCE FOR OBTAINING BEMR PRESCRIBING RIGHTS

To obtain rights to orders medications for OUD, a request will be sent via a Help Desk ticket to the BEMR Health Informatics Team. A copy of the completion certificate for the required training must be attached to the request. The BEMR Health Informatics Team will update the provider permissions to allow the ordering of methadone, buprenorphine, or both for OUD without verbal order.

MODULE 3. EVALUATION AND TREATMENT INITIATION

WHAT'S NEW

- Edits have been made throughout the module for formatting and clarity.
- References to the long-acting buprenorphine injection, Brixadi®, have been added.
- SENTRY MAT codes are no longer used and all references to these SMD codes have been updated to BEMR OUD Administrative Codes throughout this module. *Appendix 1* has been updated to reflect the same.
- *Section A. Regulatory Requirements* has been deleted and remaining sections relettered.
- *Prioritization for Evaluation* has been updated to clarify that patients with suspected overdose within the past two years, regardless of time until release, are higher priority than those without suspected overdose and releasing in 90 days or less.
- The following significant updates have been made to *Section D. Initial Medical Evaluation*:
  - Medical urine drug screens should be completed ideally, within 7 days to help reduce precipitated withdrawal but no more than 14 days prior to initiating medication.
  - Even if a qualified behavioral health provider has already documented an DSM-V diagnosis of OUD, a medical provider must still enter an appropriate ICD-10 diagnosis upon evaluation and prior to treatment initiation.
  - Clarification to state that patient evaluation by a qualified behavioral health provider is recommended prior to initiating medication for OUD but should not delay initiation of treatment if relapse or severe withdrawal is a concern.
- The following significant updates have been made to *Section E. Diagnosis*
  - Health care providers must enter an appropriate ICD-10 diagnostic code when ordering medications for OUD.
  - *Table 1. DSM-V Common Diagnostic Codes for Opioid Use Disorder* added.
- Clarifications have been made to *Section F. Treatment Selection – Documentation of Treatment Refusals*.

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A. SCREENING AND ASSESSMENT FOR OPIOID USE DISORDER

It is recommended all patients, upon entry into a FBOP facility, be screened and scheduled for opt-out urine drug screening for opioids, to include fentanyl. Urine drug screening should be prioritized, and testing performed for any patient who reports opioid use disorder (OUD) or recent opioid usage at intake. In addition to urine drug screening, all patients, regardless of risk factors, should also be asked about unhealthy drug use and if they have any history of receiving treatment for OUD.

Patients should continue to be screened for OUD throughout their incarceration, as clinically appropriate. Indications a patient may require assessment for OUD include one or more of the following:

- Non-health services employee referral
- Patient requests evaluation
- Opioid positive urine drug screen
- Observed signs of opioid withdrawal
- Naloxone administration for opioid overdose reversal
- Any opioid-related misconduct, to include protective custody for opioid debt
- Pregnancy and any opioid use history
- Review of the OUD dashboard shows that screening is indicated

Patients with OUD and clinical indications for treatment are offered treatment regardless of disciplinary status, placement in restrictive housing, or other coexisting mental or medical health conditions.

B. CONTINUING MEDICATION FOR OPIOID USE DISORDER ON INTAKE

When a patient enters FBOP custody on a prescribed medication for OUD, they **will be continued** on that same medication pending further evaluation unless its use is clearly medically contraindicated. Intake evaluation should include:

- The patient's history of OUD
- Previous medication(s) used
- Medical records from previous community-based treatment programs to confirm current or past treatment for OUD. If outside records are not available at intake, they should always be requested. Scan any received documents or failure to receive them into the electronic health record (EHR).
  - *For best patient outcomes, all efforts should be made to confirm previous medication and dosage used by obtaining outside medical records or contacting the previous provider and/or dispensing pharmacy.*
- Current medication name(s), dosage(s), administration frequency, and expiration(s) of the prescription(s) (scan all relevant paperwork into document manager)
- Signed consent form for the specific OUD medication utilized and the OUD Treatment Agreement scanned into the EHR as soon as possible. OUD medication should not be withheld pending signatures.

For patients entering FBOP custody taking medication for OUD, an initial medical evaluation and full medical exam will be conducted within 30 days of intake per **Program Statement 6031.05 Patient Care** and the patient will be enrolled in the Substance Use Disorder chronic care clinic. This initial exam will generally be conducted by providers authorized to complete these visits within the institution. Refer to *Section D* for required components of the initial medical evaluation.

- If the institution does not have a provider authorized to provide methadone in-house, the medication will be continued, and the patient will be referred to a FBOP telehealth provider or community OTP. If neither option is available or feasible, the patient may be referred to the Regional Medical Director or Chief of Addiction Medicine for alternative options.

Upon initial exam, a health services employee will enter the OUD Administrative Code "OUDPA" (OUD Tx on Medication) in the EHR.

- Refer to Appendix 1 for additional information on OUD Administrative codes.

C. EVALUATION FOR TREATMENT-NAÏVE PATIENTS

Patients within the FBOP requesting treatment for OUD will be evaluated on a case-by-case basis and prioritized according to medical necessity (see below).

Management of OUD is not a one-size-fits-all approach, and many factors are involved in determining the most effective treatment plan for a patient. Health Services and Psychology employees at the local level must collaborate to determine the most effective treatment plan.

PRIORITIZATION FOR EVALUATION

When there is a significant number of patients pending screening or evaluation, provider vacancies, and/or limited employee resources, patients will be prioritized based on medical necessity. **The below prioritization list is intended to be flexible and followed with consideration of the entire clinical picture.** It is not to be used to restrict access for those who appropriately meet clinical criteria for treatment of OUD. Recommended prioritization for evaluation is as follows, with criteria listed in order of priority:

1. Patients who arrive to an institution on medications for OUD treatment.
2. Patients who are pregnant ***and***:
    a. Currently positive for illicit opioid use ***or***
    b. Have a history of OUD treatment ***or***
    c. Have an OUD diagnosis on record ***or***
    d. Have been otherwise identified for OUD evaluation
3. Patients with any use of naloxone in an FBOP institution at any time in the last two years.
    a. Higher prioritization given to those with two or more uses of naloxone within two years.
4. Patients with evidence of active illicit opioid use confirmed by urine drug screen *or* are releasing within the next 90 days with any of the following:
    a. An ICD-10 diagnosis of Opioid Dependence or DSM-V diagnosis of OUD.
    b. Current OUDMSC (OUD Tx Medical Screen Complete), OUDPSC (OUD Tx Psych Screen Complete), or OUDSI (OUD Tx Screening Indicated) administrative code.

(list continues on the next page)

5. Referrals (from employees or patients) reporting increased mental health symptoms resulting from imminent, current, or elevated risk for opioid use while incarcerated.
6. Referrals (from employees or patients) indicating prior treatment for OUD or other opioid-specific risk factors not listed above.
7. Referrals (from employees or patients), not meeting any of the above criteria and in order of receipt.

In addition to the above, it is strongly recommended institutions maintain a prioritized roster of patients who are pending evaluation. This list should be reviewed, at a minimum, at each facility's monthly OUD staff meeting (refer to **MODULE 2. ADMINISTRATIVE REQUIREMENTS FOR TREATMENT OF OPIOID USE DISORDER**). The goal of this roster is to encourage collaboration between the treatment teams (psychology services, medical services, and correctional services) to ensure those patients at highest risk for adverse health outcomes are evaluated and treated in a timely manner.

D. INITIAL MEDICAL EVALUATION

The initial medical evaluation may be completed by a physician, nurse practitioner, physician assistant, or pharmacist with a collaborative practice agreement. Previously completed assessments from other, appropriate sources (e.g., intakes completed by community providers or FBOP encounters that remain clinically relevant) can be utilized to support or supplement the initial medical evaluation.

- *While pharmacists are not authorized to diagnose a medical condition, they may still complete the initial evaluation if the patient has already been diagnosed with Opioid Dependence by a provider authorized to diagnose.*

The initial medical evaluation should document the following elements:

- **Opioids and all other substance use history**, to include drug(s) of choice and/or alcohol, last use, frequency, amount, route of administration, age of onset, periods of abstinence, other drugs used together or separately, withdrawal symptoms experienced, accidental overdoses, and interactions with medical providers related to substance use to include any history of treatment.
  - Consider obtaining incident reports, correctional urine drug screen results, and review presentence investigation reports for any criminal history involving opioid drug use.
  - If currently taking medication for OUD, include details of current benefits and/or side effects of the medication, contraindications (if any) for current medication, and past use of any other medication for OUD.
- **History of current (prescribed and over the counter (OTC)) medication use**, including side effects, potential drug-drug interactions, and outcomes.
- **Behavioral health history**, to include any current or past diagnoses, treatment, and stability (if any) for the following: depression, anxiety, personality disorders, post-traumatic stress disorder, bipolar disorder, and psychotic disorders. Consider obtaining a history of self-harm behaviors.
- **Symptoms of withdrawal** using the Clinical Opiate Withdrawal Scale (COWS), when appropriate (refer to Section H. Opioid Withdrawal) to help establish whether the patient is opioid tolerant or naïve at presentation. (Opioid tolerance is discussed in detail in **MODULE 4. REVIEW OF MEDICATIONS FOR OPIOID USE DISORDER**).

- **Baseline tests:**
  - **Medical urine drug screen (UDS)** completed ideally, within 7 days to help reduce precipitated withdrawal but no more than 14 days prior to initiating medication.
    - *Refer to Urine Drug Screening During Initial Diagnostic Evaluation, below, and **MODULE 5. MONITORING AND FOLLOW-UP** for information regarding UDS.*
  - **Female patients only:** Administer a pregnancy test ideally, within 7 days but no more than 14 days prior to initiating medication. This can be a point-of-care urine pregnancy test documented in the EHR flowsheets.
  - **Comprehensive metabolic panel** no more than 14 days prior to initiating medication.
  - *These tests are required prior to initiating treatment for OUD. If a patient refuses any of the above tests, a signed refusal form will be obtained, scanned in the EHR, and the OUD Administrative code will be changed to OUD Tx Declined (OUDDE).*
- **Testing at baseline or no more than 6 months after OUD treatment initiation:**
  - Complete blood count, thyroid-stimulating hormone test, urinalysis, screening for viral hepatitis, HIV and any clinically relevant STIs.
  - *These tests should be offered but are not required to initiate or continue treatment for OUD.*
- **Cardiac risk assessment** if considering methadone (refer to Appendix 2. Cardiac Risk Assessment for Methadone).
- **Assessment of education, motivation, and community access**, to include level of education, short- and long-term goals of treatment for OUD, and consideration of future community access to treatment services. The patient should also be educated on OUD diagnosis, the respective risks and benefits of treatment options, and how medications work to treat OUD.
  - *Initiation of medication for OUD prior to release should be conducted with enough time to establish an effective maintenance dose (refer to **MODULE 4. MEDICATION FOR OPIOID USE DISORDER**), evaluate tolerability and compliance with treatment, and arrange transition of care to the community. Typically, this requires 30 to 90 days. In instances where there is insufficient time to establish treatment, the institution social worker (if available) or Transitional Care team (at sites without an institution social worker) should be notified via referral form to arrange evaluation for treatment and/or follow-up upon release. Refer to **MODULE 8. TRANSITIONS OF CARE** for additional information.*
- **Appropriate ICD-10 diagnosis (if applicable).** Refer to Section E. Diagnosis .
  - *If a qualified behavioral health provider has already documented a DSM-V diagnosis of OUD, a medical provider must still enter an appropriate ICD-10 diagnosis upon evaluation and prior to treatment initiation.*
- **Behavioral health evaluation referral**, if indicated. Co-management with a qualified behavioral health provider is ideal, especially if the patient's mental health history is significant or the patient is expected to require long-acting naltrexone (Vivitrol ®).
  - *Patient evaluation by a qualified behavioral health provider is recommended prior to initiating medication for OUD but should not delay initiation of treatment if relapse or severe withdrawal is a concern.*

If, after initial medical evaluation, it is determined a patient meets the clinical criteria for OUD and medication is clinically indicated, the institution should then complete the following steps:

1. Notify the local DAP-C/Psychology or other identified qualified behavioral health provider(s) of plans to initiate medication for OUD so they may complete a behavioral health treatment plan and enroll them in the appropriate form of therapy.
2. Initiate treatment at the same time as the initial evaluation or notify other applicable health services employees to proceed with treatment initiation.
3. Add the patient to the Substance Use Disorder Chronic Care Clinic in the EHR.
4. Update the OUD Administrative code to OUD Tx Medical Screen Complete (OUDMSC).

INTERMITTENT USE

Patients reporting **intermittent use** (e.g., recreational use without a pattern of significant impairment or distress) of opioids may not meet criteria for OUD diagnosis. Treatment is not indicated for patients who do not meet criteria for diagnosis.

➔ *Refer to Section E. Diagnosis for criteria. Note, diagnostic consideration for OUD includes a review of the patient's remote history.*

All patients with an active diagnosis of OUD or history of OUD who refuse treatment offered at time of evaluation or have a risk of OUD (including those reporting intermittent use) should continue to be evaluated for harm reduction strategies, especially prior to release, and given nasal naloxone upon release from custody.

➔ *Refer to **MODULE 8. TRANSITIONS OF CARE** for additional guidance on harm reduction strategies.*

URINE DRUG SCREENING DURING INITIAL DIAGNOSTIC EVALUATION

A urine drug screen (UDS) performed during initial evaluation of a patient for treatment of OUD can be used as a component of assessment and treatment planning. The UDS can provide baseline, objective information to compare with the patient's self-report. For example, when there is a discrepancy between a subjective patient report and objective drug testing, the inconsistency provides an opportunity for dialogue between the provider and patient to discuss the discrepancy. This dialogue will enhance diagnostic accuracy and appropriateness of the treatment plan. A UDS can also serve as a tool for estimating the risk of acute withdrawal and help guide the treatment of opioid withdrawal.

The UDS is only a snapshot of a specific time frame with definitive cutoff values. Urine drug screening alone is not a diagnostic test for OUD diagnosis nor a determinant of the severity of OUD and should be used only with other pertinent clinical information in generating a treatment plan for a patient. The presence or absence of opioids in a UDS does not, by itself, qualify or disqualify a patient for OUD treatment.

Prior to the initial medical evaluation, **consider obtaining multiple random drug tests over a 2-week period** to assist in determining whether the patient is actively using opioid substances and to what degree or frequency. A positive UDS for illicit opioids (including buprenorphine) or other illicit substances, such as methamphetamine, should alert a provider that further follow-up for this patient is needed.

E. DIAGNOSIS

Diagnoses that define a patient's exact opioid use history can be given by medical staff (nurse practitioners, physician assistants, & physicians) via the use of an appropriate ICD-10 code (as listed below) or by mental health professionals via use of an appropriate DSM-V diagnosis (as listed below).

- DSM-V diagnosis of Opioid Use Disorder (OUD – mild, moderate, or severe) is equivalent to ICD-10 diagnosis of Opioid Dependence (mild, moderate, or severe).
- Health care providers must enter an appropriate ICD-10 diagnostic code when ordering medications for OUD.

DSM-V CODES FOR OUD

TABLE 1. DSM-V COMMON DIAGNOSTIC CODES FOR OPIOID USE DISORDER

DSM-V CODE	DSM-V DESCRIPTOR	COMMENTS
F1110	Opioid Use Disorder – MILD	Mild OUD (2–3 symptoms)
F1120a	Opioid Use Disorder – MODERATE	Moderate OUD (4–5 symptoms)
F1120b	Opioid Use Disorder – SEVERE	Severe OUD (6 or more symptoms)
F11.99	Unspecified Opioid Related Disorder	Category of presentation of some symptoms of opioid related disorder but does not meet full criteria for any specific opioid related disorder.
F11.23	Opioid Withdrawal	Symptoms of opioid withdrawal after stop of opioid use OR after use of opioid antagonist medication.

The DSM-V criteria for OUD diagnosis requires the presence of at least 2 out of 11 manifestations of "clinically significant impairment or distress" occurring "within a 12-month period," meaning the symptoms persisted for at least any 12-month period and not necessarily within the previous 12 months. The DSM-V also addresses severity of the condition (mild, moderate, or severe) and status of treatment (early remission, sustained remission, and/or ongoing maintenance therapy).

➔ *Refer to the American Psychiatric Association Opioid Use Disorder Diagnostic Criteria for specific DSM-V criteria.*

Determining severity: Severity of OUD is based on the number of symptoms present according to the DSM-V criteria provided in the link above:

- **Mild**: presence of 2 to 3 symptoms
- **Moderate**: presence of 4 to 5 symptoms
- **Severe**: presence of 6 or more symptoms

For example, a patient who has been incarcerated for 8 years and who has been completely abstinent from opioid use but reports a history of 8 out of the 11 criteria listed in the DSM-5 ten years ago for 2 years, could be diagnosed as ***severe opioid use disorder in sustained remission in a controlled environment.*** Following this example, if the patient were to be initiated on the long-acting injectable naltrexone, the patient's new diagnosis would be ***severe opioid use disorder in sustained remission on maintenance therapy in a controlled environment***.

ICD-10 CODES FOR OUD

Opioid Dependence diagnoses are given based on presence of the same criteria utilized for DSM-V codes for Opioid Use Disorder noted above. Diagnosis requires the presence of at least 2 out of 11 manifestations of "clinically significant impairment or distress" occurring "within a 12-month period," meaning the symptoms persisted for at least any 12-month period but not necessarily within the previous 12 months.

TABLE 2. ICD-10 DIAGNOSTIC CODES FOR OUD

ICD-10 CODE	QUALIFIER	ICD-10 DESCRIPTOR	COMMENTS
F1110	**-**	Opioid dependence - MILD	Mild OUD (2–3 symptoms)
F1120	***a**	Opioid dependence - MODERATE	Moderate OUD (4–5 symptoms)
F1120	***b**	Opioid dependence - SEVERE	Severe OUD (6 or more symptoms)
F1110	**R**	Opioid Dependence, MILD, in Remission in a controlled setting	Mild OUD, in remission in a controlled environment
F1120	**a-R**	Opioid Dependence, MODERATE, in remission	Moderate OUD, in remission in a controlled environment
F1120	**b-R**	Opioid Dependence – SEVERE, in Remission	Severe OUD, in remission in a controlled environment
F119	**-**	Opioid Use, Unspecified	Does not meet criteria for OUD, but confirmed intermittent use
T402X1A	**-**	Poisoning by other opioids, accidental (unintentional), initial encounter	
Z79891	**-**	History of Narcan use	

The diagnostic specifier "in remission, in a controlled environment" may be appropriately added for certain patients within our custody. For example, a patient that meets criteria for opioid dependence in the past but has not met any criteria of opioid dependence (except for opioid cravings) in >1 year (due to circumstances unique to the carceral setting including limited access to opioids or an inability to pay for them) may be considered "in remission, in a controlled environment." **It is important to note that such a specifier should not be confused with any form of resolution of this illness**. As such, these patients can rapidly return to use at any time (even while incarcerated) and remain at the same risk of accidental overdose and death as others without this specifier both before and after release. Given this, patients with this specifier should always be considered for medication evaluation and possible treatment as appropriate, especially as they get closer to release.

F. TREATMENT SELECTION

Treatment selection is guided by the findings of the initial medical evaluation. **There is no "one-size-fits-all" approach to OUD treatment, and it is challenging to predict whether a patient will respond best to methadone, buprenorphine, or naltrexone.** The goals of treatment for OUD, regardless of the medication selected, include the following:

- Minimizing harm from ongoing illicit opioid use.
- Sustained recovery with abstinence from other illicit substances.
- Reduced cravings or urges for illicit opioids.
- Engagement in recovery-oriented activities.

Decisions as to which OUD medication is prescribed are individualized for each patient based on severity of symptoms, treatment goals, access to and availability of treatment after release (including aftercare planning, see **MODULE 8. TRANSITIONS OF CARE**), and the patient's willingness to comply with the expectations of treatment with medication.

Table 3 and Table 4 may be used as a guide when considering what medication is best to accomplish treatment goals for a patient with OUD. Providers should also consider the following questions:

- Is the patient open to pharmacotherapy?
- What treatment resources for OUD are local to where they will release to in the future?
- Does the patient understand the pros and cons of each treatment option?
- What type of treatment setting does the patient prefer?
- What is the patient's medical history and contraindications?
- Is there adequate time to initiate and evaluate response to treatment prior to release or transfer?

Although each of the medications listed in Table 3 and Table 4 are FDA approved for the treatment of OUD, these medications vary in their FBOP national drug formulary status, prescribing criteria, dosage, forms of administration, and mechanisms of action. As with any drug treatment, the most up-to-date clinical resources should be referenced when considering side effects, drug interactions, and contraindications.

➔ *Refer to **MODULE 4. MEDICATION FOR OPIOID USE DISORDER** for an in-depth review of each treatment option, including guidance on dosing during initiation, maintenance, escalation, discontinuation, and conversion between medications.*

(Table 3 begins on the following page)

TABLE 3. COMPARISON OF MEDICATIONS FOR OUD

	Naltrexone	Buprenorphine	Buprenorphine/ Naloxone	Methadone
FORMULATIONS[1]	Long-acting injection (*Vivitrol*®) Tablet (*various generics*)	Long-acting injection (*Sublocade*® *or Brixadi* ®) Sublingual tablet (*various generics*)	Sublingual film (*Suboxone*®)	Tablet
MECHANISM OF ACTION	Opioid receptor antagonist	Partial opioid receptor agonist	Partial opioid receptor agonist / opioid receptor antagonist	Full opioid receptor agonist
ORDERING RESTRICTIONS	No restrictions	REMS registration required for *Sublocade*® and *Brixadi* ®	No restrictions	Can only be administered for treatment of OUD in an OTP or under hospital/clinic DEA registration within a correctional system.
SPECIAL CONSIDERATIONS	• Also indicated for alcohol dependence. • No misuse potential. • Opioid withdrawal may occur if started soon after last opioid use.	• Less potential for respiratory depression or overdose than methadone if taken at doses greater than prescribed. • Buprenorphine can precipitate opioid withdrawal in opioid-dependent patients (including patients on methadone). • The tablet formulation of this medication has higher risk of misuse as snorting or injecting can result in euphoria.	• Naloxone in this formulation has little effect if taken orally. However, if the medication is snorted or injected, it will blunt the agonist effects of buprenorphine.	• Blunts or blocks effects of other illicit opioid substances. • Has many contraindications. • If administered under hospital/clinic DEA registration within a correctional system, patient must have primary diagnosis *other than* OUD.

[1] Several of these medications are available but are non-formulary. Refer to the "FBOP National Formulary" for guidance.

TABLE 4. TREATMENT SELECTION CONSIDERATIONS

Patient Characteristics	Recommended Treatment	Additional CONSIDERATIONS
Currently prescribed medication for OUD	Continue current medication if patient is stable and there are no contraindications.	• When clinically appropriate or when diversion may be a concern, consider conversion from oral to long-acting injectable buprenorphine when patient is stable in shared decision-making with the patient.[1]
Mild OUD	Long-acting injectable naltrexone[2]	• If naltrexone fails due to lack of efficacy (e.g., no reduction of cravings) or leads to unacceptable side effects, consider buprenorphine as next option. • If buprenorphine fails due to lack of efficacy or leads to unacceptable side effects, consider methadone.[3]
Moderate-to-severe OUD, *post-withdrawal / in remission, not currently using opioids*	Long-acting injectable naltrexone[2] If previously treated successfully, consider restarting the same medication at a lower dose.	• If naltrexone fails due to lack of efficacy (e.g., no reduction of cravings) or leads to unacceptable side effects, consider buprenorphine as next option. • If buprenorphine fails due to lack of efficacy or leads to unacceptable side effects, consider methadone.[3]
Moderate-to-severe OUD, *currently using illicit opioids*	Buprenorphine-containing products.	• If naltrexone or buprenorphine fails due to lack of efficacy (e.g., no reduction of cravings) or leads to unacceptable side effects, consider methadone.[3] • When clinically appropriate, consider conversion from oral to long-acting injectable buprenorphine when patient is stable.[1]
Pregnant with OUD	Buprenorphine-containing products OR methadone.	See MODULE 7. SPECIAL POPULATIONS for information regarding treatment for pregnant patients with OUD.

[1] Refer to MODULE 4. REVIEW OF MEDICATION FOR OPIOID USE DISORDER for guidance on converting patients to long-acting injectable buprenorphine.

[2] Supervised (directly observed therapy) daily oral naltrexone is a reasonable alternative to long-acting injectable naltrexone in highly motivated patients who do not wish to receive injections.

[3] Refer to MODULE 4. REVIEW OF MEDICATION FOR OPIOID USE DISORDER for additional methadone use criteria.

DOCUMENTATION OF TREATMENT REFUSAL

REFUSAL DURING INTAKE OR INITIAL SCREENING: In some instances, an employee other than a provider authorized to order OUD medications may perform the initial screening to determine patient interest in proceeding with diagnosis and treatment evaluation. If, upon screening, the patient is uninterested in further evaluation, the employee will complete the following:

- **Document in the EHR**
  - The reason (if any) the patient was identified for evaluation.
  - Education provided to the patient (e.g., review of diagnosis, risks and benefits of treatment, risks of treatment refusal, etc.).
  - The reason (if any) the patient is refusing further evaluation. Consider quoting the patient's exact response for this refusal.
  - *Refer the patient to a provider if the patient is unable to make an informed refusal.*
- **Obtain medical treatment refusal** that indicates why the patient was identified for screening (i.e., dashboard, diagnosis on record, report of opioid use at intake, etc.) and the patient's reason(s) for refusing evaluation (consider quoting). The medical treatment refusal form is signed and scanned into the document manager.
  - *Since the patient may not yet have a diagnosis of OUD and/or the most clinically appropriate treatment has not yet been determined, only a provider authorized to prescribe medications for OUD may obtain a treatment refusal for specific medications.*
- **Update the OUD Administrative Code** to OUD: OUDDE (OUD TX Declined)

REFUSAL OF MEDICATIONS: The selection of treatment should be made through shared decision-making between the patient and provider. Shared decision-making results in superior outcomes including treatment adherence, retention, and positive health outcomes.

Some patients may be uninterested in medications for OUD, even when clinically indicated and recommended by a provider. In these instances, an authorized health service provider (as previously described) will meet with the patient to explore the patient's rationale for not wanting treatment. In any situation where the patient chooses to not start or continue pharmacotherapy, the authorized provider will complete the following:

- **Document in the EHR**
  - Education provided to the patient (e.g., review of diagnosis, risks and benefits of treatment, risks of treatment refusal, etc.).
  - The specific treatment options discussed and offered.
  - The reason (if any) the patient is refusing to initiate or continue treatment. Consider quoting the patient's exact response for this refusal.
- **The medical treatment refusal form is signed and scanned** into the document manager.
- **Update the OUD Administrative Code**
  - If the patient is refusing to initiate medications for OUD: OUDDE (OUD TX Declined)
  - If the patient started medications for OUD and then refused: OUDDC (OUD Tx Discharged)

G. TREATMENT INITIATION

As with any chronic disease state, treatment may be initiated at the initial medical evaluation or the patient may be referred to another authorized provider (e.g. APP, a pharmacist with a collaborative practice agreement) to review the initial diagnostic evaluation findings and work with the patient to develop an individualized treatment plan. When the patient starts OUD medication, a health services employee will update the OUD Administrative Code to OUDPA (OUD Tx on Medication). If the plan is to transition to long-acting injections, ensure injections are properly scheduled in the EHR to allow monitoring by the transitional care team for release planning purposes.

The following components of OUD treatment initiation are recommended:

- A treatment plan is established and reviewed with the patient. The treatment plan is an individualized series of written statements specifying a patient's particular course of therapy and includes, at a minimum:
  - Treatment objectives and long-term goals
  - Frequency of follow-up
  - Type and frequency of diagnostic testing to include urine drug screens, EKG, CMP, and other laboratory tests as appropriate.
  - Additional referrals as needed (e.g., educational, vocational, and/or residential programs)
- Information on prevention of HIV and viral hepatitis exposure and treatment options for those infected is provided to each patient.
- Informed consent is obtained for the specific medication utilized. Blank OUD treatment consent forms are available in the EHR and once signed, will be uploaded into the patient's record.
- A signed OUD Treatment Agreement is obtained. The agreement form is available in the EHR and once signed, will be uploaded into the patient's record.

➔ *If the patient will receive methadone through a community OTP, refer to Appendix 3. Procedures for Documenting Community OTP Services for guidance to document methadone services provided through a community OTP in the electronic health record.*

H. OPIOID WITHDRAWAL

Patients taking opioids, either illicit or prescribed, may experience symptoms of opioid withdrawal, regardless of the medication utilized, indication, and/or compliance with its use. Symptoms of opioid withdrawal can include:

- Restlessness, irritability, anxiety
- Increased tearing
- Insomnia
- Muscle aches and muscle twitching
- Yawning
- Runny nose
- Abdominal cramps, nausea, diarrhea, vomiting
- Dilated pupils
- Sweating
- Piloerection
- Mild hypertension and/or tachycardia

TABLE 5. AVERAGE TIME TO ONSET OF OPIOID WITHDRAWAL SYMPTOMS

	EARLY WITHDRAWAL	FULLY DEVELOPED WITHDRAWAL	TOTAL DURATION OF WITHDRAWAL
SHORT-ACTING OPIOIDS	8 to 24 hours	1 to 3 days	7 to 10 days
LONG-ACTING OPIOIDS	Up to 36 hours	72 to 96 hours	14 days or more

DETERMINING SEVERITY OF WITHDRAWAL

The **Clinical Opiate Withdrawal Scale (COWS)** is an 11-item scale t used by clinicians in both inpatient and outpatient settings to reproducibly rate common signs and symptoms of opioid withdrawal and monitor these symptoms over time. The summed score for the complete scale can be used to help determine the stage or severity of opioid withdrawal and assess the patient's level of physical dependence on opioids.

➔ *Refer to Clinical Opiate Withdrawal Scale (COWS) available in the flowsheets section of the EHR.*

Practitioners may express concern about the subjective nature of patient-reported symptoms on the COWS and the specificity of the scale. However, the symptoms of opioid withdrawal (e.g., nausea, vomiting, sweating, joint aches, agitation, tremor) have been likened to a severe influenza infection and patients should not exceed the lowest score in most categories without exhibiting clinician-observable signs or symptoms of withdrawal. It is unlikely a patient will score moderate-to-severe without exhibiting objective signs and symptoms of withdrawal.

Throughout initiation of medication for OUD, clinicians should assess for signs and symptoms of withdrawal using the COWS. The COWS score is totaled to determine the severity of opioid withdrawal and the plan of action for treatment:

- **5–12:** mild opioid withdrawal
- **13–24:** moderate opioid withdrawal
- **25–36:** moderately severe opioid withdrawal
- **>36:** severe opioid withdrawal

SUPPORTIVE THERAPY DURING WITHDRAWAL

Patients experiencing symptoms of withdrawal may require short-term supportive therapy, including non-opioid medication, to manage their symptoms.

➔ *Refer to the FBOP Clinical Guidance for Medically Supervised Withdrawal for Inmates with Substance Use Disorders for additional guidance on managing withdrawal.*

APPENDIX 1. OUD ADMINISTRATIVE CODES

Administrative Code	Plain Language Definition
OUD Tx Screening Indicated (OUDSI)	Patient has been identified (e.g., patient self-request, employee request, dashboard identification, history of overdose, etc.) for evaluation and possible initiation of OUD treatment. *Patients with this administrative code should be screened to ensure those at highest risk for overdose are prioritized to be evaluated for diagnosis and treatment.*
OUD Tx Medical Screen Complete (OUDMSC)	Evaluation for OUD has been completed by an authorized provider, including diagnostic assessment for ICD-10 code for Opioid Dependence and determination of appropriateness for OUD treatment.
OUD Tx Psychology Screen Complete (OUDPSC)	OUD Tx screening has been completed by Psychology. *Completion of psychology screening is not required prior to treatment initiation.*
OUD Tx on Medication (OUDPA)	Patient is currently receiving medications for OUD.
OUD Tx Declined (OUDDE)	Patient has *never* started OUD medications in the FBOP and declines initiation of treatment.
OUD Tx Discharged (OUDDC)	Patient *started* on OUD medication in the FBOP then stopped treatment.
OUD Tx Medically Not Indicated (OUDMNI)	Patient either does not currently meet criteria for ICD-10 code of Opioid Dependence or is *currently* ineligible for medications for OUD (e.g., mental health issues, cannot give informed consent for treatment, has medical contraindications to treatment, etc.) *If the status of the above changes, the patient may be reconsidered for treatment initiation.*

Refer to Health Service Division's Health Technology page on Sallyport for additional ADMIN code information.

APPENDIX 2. CARDIAC RISK ASSESSMENT FOR METHADONE

Methadone treatment has been associated with QTc prolongation and includes an FDA black box warning on Torsades de Pointes. The prevalence of QTc prolongation resulting from methadone treatment is unknown, but the condition has been estimated to occur in up to 2% of patients. SAMHSA recommends all sites providing methadone for OUD develop a strategy to reduce the risk of cardiac complications associated with methadone. For this reason, institutions should conduct and document the following for all patients being considered for treatment with methadone as part of a cardiac risk management plan adapted from SAMSHA's SAMHSA's Treatment Improvement Protocol TIP 63:

1. **Assess cardiac risk factors, including, at a minimum:**
    a. Any family history of sudden cardiac death, arrhythmia, myocardial infarction, heart failure, prolonged QTc interval, or unexplained syncope.
    b. Any patient cardiac pathology (e.g., history of arrhythmia, myocardial infarction, heart failure, prolonged QTc interval, unexplained syncope, palpitations, seizures, etc.).
    c. Current use of medications that may increase QTc interval.
    d. Patient history or current use of cocaine and/or methamphetamines.
    e. Electrolyte assessment for hypokalemia or hypomagnesemia.
2. **Develop a risk stratification plan, to include:**
    a. An ECG at baseline, 30 days after initiating methadone, and annually thereafter while on methadone.
    b. Discussion of risks, benefits, and alternative treatment options to methadone for patients with QTc intervals between 450 and 500 milliseconds at baseline. Address modifiable risk factors to reduce risk, if indicated.
    c. Do not initiate methadone treatment for patients with QTc intervals above 500 milliseconds at baseline.
    d. For patients with prolonged QTc intervals (> 500 milliseconds) discovered during treatment, consider lowering the methadone dose, discuss risks and benefits to treatment with methadone, change concurrent medication(s) that prolong the QTc interval if indicated, and consider alternatives. Include follow-up ECG monitoring after any intervention.
    e. Continue to monitor for cardiac issues over time, particularly with advancement of patient age due to increased risk of sedation and/or QTc prolongation leading to torsade's de pointes.

APPENDIX 3. PROCEDURES FOR DOCUMENTING COMMUNITY OTP SERVICES

1. Document External Encounter and Plan of Care:

An FBOP provider will generate an Administrative Note in the EHR that includes pertinent information relative to the treatment plan as described in the example below. Copy and paste the example text below and save as a local text string and modify to actual patient situation.

Treatment for OUD Consultation Follow-up *[insert date of clinic visit]*

Patient Engle, Zelda X, Reg # 12345-678 was seen today in [*Insert Full Name and Address of Community Clinic*] clinic by Dr. [*insert provider's name*] with DEA license # [*insert number to include letters if appropriate*] waiver and the plan of care is [*insert medication name*].

The plan of care states:

[*Insert drug name, strength, directions*]. Plan of care is from [*insert dates of beginning and ending of plan of care*]. Provider is Dr. [*insert provider name*] with address of [*insert address*] and phone number [*insert phone number*].

The documentation from Dr. [*insert name*] has been scanned into document manager. The original documentation has been forwarded to the pharmacy for processing.

Will need a follow up consultation in one (1) week.

- Notify Pharmacy staff of this prescription.
- Do not taper the patient's medication dose without consulting the OTP.
- Verify any/all information presented by the patient with the OTP whenever possible.

2. Obtain Medication

- The medication will be sent back with the patient as "take home doses." Take home doses are provided at the discretion of the OTP and may be requested to avoid daily medical trips.
- Methadone brought back to the institution will be logged into the main stock controlled substance inventory and accounted for as any other controlled substance with the following specific guidance:

  1) Create a new sub-stock location using the name of the OTP or community pharmacy as the sub-stock location name.
  2) Document the medication as received from the sub-stock location to the institution main stock narcotic inventory.
  3) Move the medication to the appropriate sub-stock location for administration.

3. Add the External Medication Order to the Patient Profile

In addition to the EHR Administrative Note completed by an FBOP provider (see #1 above), in order to properly document administration on eMAR, a medication order will be entered into the EHR. Pharmacy will enter the order via the "New Rx" function on the patient profile using the information from the non-FBOP provider. The "Provider" used will be the community OTP provider that supplied the plan of care.

- If the community provider is not already in the EHR, contact the health informatics team at *BOP-HSD-HealthInformatics-S@bop.gov* to have the provider added. Specify the provider's name, address, phone number, DEA number and name of OTP.
- Include all information regarding community provider and OTP in the directions of the RX entry to indicate where the order came from.
- Instructions must clearly denote which doses are expected to be administered in OTP clinic (if any) or during institution pill line.
- Pharmacy will verify the provider's DEA number at this DEA website: *https://apps.deadiversion.usdoj.gov/webforms2/spring/validationLogin?execution=e1s1.* No other credentialing is necessary.

5. Scan Documentation

- After entering the New RX and printing the label, attach the Rx order label to the documentation provided by the OTP and scan in all supporting documentation from the outside provider into the document manager.

6. Document Medication Administration

- **Administered at the institution:** Document methadone administered during pill line on eMAR as any other pill line medication. Refer to **MODULE 6. MEDICATION ADMINISTRATION AND DIVERSION CONTROL** for additional guidance.
- **Administered at an OTP:** Document methadone administered at an OTP on eMAR as "other" and add "admin at OTP" in free text field. Request copies, preferably weekly, of the administration record from the community OTP to scan in to the EHR.

MODULE 4. REVIEW OF MEDICATION FOR OPIOID USE DISORDER

WHAT'S NEW

- Edits have been made throughout the module for formatting and clarity.
- *Opioid Tolerant vs Opioid Naïve* section has been added to define opioid "tolerant" and "naïve" and distinguish how this distinction may affect treatment decisions. Additionally, headings and figures throughout this module have been updated from "Opioid Dependent" to "Opioid Tolerant" and "Opioid Abstinent" to "Opioid Naive".
- *Opioid Toxicity* section has been added to define signs and symptoms of toxicity and recommended education for both patient and providers on identifying and treating toxicity.
- References to the long-acting buprenorphine injection, Brixadi®, have been added throughout the module to include new sections on *Initiation of Long-Acting Buprenorphine (Brixadi®)* and *Switching to Long-Acting Injections – Brixadi®*.
- *Table 1. Sublocade® Dosing Recommendations* *and* *Table 2. Brixadi® Dosing Recommendations.* have been added.
- Criteria for the use of long-acting buprenorphine have been updated to reflect clinical review elements established via Medical Director's memo issued November 26, 2024.
- New section *Switching from Long-Acting Injections to Daily Oral Buprenorphine*, *Table 3. Dosing Recommendations for Conversion from Sublocade® to Oral Buprenorphine* and *Table 4. Dosing Recommendations for Conversion from Brixadi® to Oral Buprenorphine* have been added.
- New section *Switching from Buprenorphine to Methadone*, *Table 5. Dosing Recommendations for Conversion from Sublocade® to Methadone* and *Table 6. Dosing Recommendations for Conversion from Brixadi® to Methadone* have been added.
- New section *Switching Between Long-Acting Injections* and *Table 7. Dosing Recommendations for Conversion Between Buprenorphine Long-Acting Injections* have been added.
- Guidance on conversion between long-acting buprenorphine to long-acting naltrexone has been updated to state the following: *although conversion is not generally recommended, if a patient is currently receiving long-acting buprenorphine injections and conversion to long-acting naltrexone injections is necessary, the LAI should be stopped, and naltrexone test doses should not be initiated until 1 to 2 weeks after the next scheduled LAI dose.*
- Frequency of follow-up for both buprenorphine and methadone have been updated to state *once stabilization has been maintained >1 year, patients should be seen at least quarterly thereafter.*
- The section *Dental Considerations for Sublingual Buprenorphine* has been updated to clarify that while a consultation request should be entered prior to initiation; completion of a dental evaluation is NOT required prior to treatment initiation.
- Criteria for the use of methadone have been updated to reflect clinical review elements established at the Winter 2024 National Pharmacy and Therapeutics meeting.
- Guidance on injectable naloxone challenge dose prior to initiating long-acting naltrexone has been removed.

TABLE OF CONTENTS

A. CLINICAL CONSIDERATIONS FOR TREATMENT OF OPIOID USE DISORDER

There is no "one size fits all" approach to treatment of Opioid Use Disorder (OUD). Decisions about which medication for OUD to prescribe are individualized for each patient based on symptoms, treatment goals, aftercare planning (refer to **MODULE 8. TRANSITIONS OF CARE**), and the patient's willingness to comply with the expectations of treatment with medication for OUD.

➔ *Refer to **MODULE 3. EVALUATION AND TREATMENT INITIATION** for a review of goals of treatment and considerations when developing a treatment plan.*

Although all the below-listed medications are FDA approved for the treatment of OUD, these medications vary in their prescribing criteria, dosage forms, and mechanism of action. As with any drug treatment, the most up-to-date clinical resources should be referenced when considering side effects, drug interactions, and contraindications to therapy. Determination of which medication to use is a shared decision-making process based on treatment history, current state of illness, and a discussion of risks versus benefits between the clinician and the patient.

OPIOID TOLERANT VS OPIOID NAÏVE

When determining the most clinically appropriate medication for treatment of OUD, the provider should always first clearly identify if the patient is **OPIOID TOLERANT** (typically associated with regular use of opioid(s) daily over an extended period) or **OPIOID NAÏVE** (typically associated with minimal, intermittent, or distant past use of opioids) prior to treatment initiation. Distinguishing between opioid tolerant and opioid naïve is necessary to determine the most clinically appropriate and effective dose of medication and ensure the safety of selected medications offered to the patient. For example, patients who are opioid naïve could develop symptoms of opioid toxicity that could escalate to death if they are too rapidly titrated with buprenorphine.

- **OPIOID TOLERANCE** is defined using both subjective and objective findings:
  - Subjective patient report of a clear and current need for increased opioid usage to obtain a similar desired effect overtime (typically to pursue euphoria or resolve opioid withdrawal symptoms).
  - Objective symptoms of opioid withdrawal identified by elevated Clinical Opiate Withdrawal Scale (COWS) score of at least 11 or greater.
  - Other objective factors that could be associated with opioid tolerant status may include one or more of the following:
    - Recent intake from the community
    - History of extensive drug debt while in custody
    - Frequent incident reports for opioid use
    - Recent medical or correctional UDS positive for opioid(s)
    - Current prescription opioids prescribed for chronic pain.

- **OPIOID NAÏVE** is defined using both subjective and objective findings:
  - There is no evidence of opioid tolerance (no clear and current need for increased opioid usage to obtain a similar desired effect over time).
  - Objective symptoms of opioid withdrawal are little to none (COWS score of less than 11.
  - Other objective factors that could be associated with opioid naïve status may include one or more of the following:
    - extended length of time in custody
    - recent medical or correctional UDS have been negative for opioids.

Many patients in the FBOP are opioid naïve based on their minimal or infrequent misuse of opioids or complete abstinence from opioids. However, it is critical to remember that presence or absence of opioids in one or even multiple UDS does not, by itself, indicate opioid tolerant OR opioid naïve status, respectively. For example, due to price and availability, patients in FBOP custody who misuse opioids are often doing so in subtherapeutic or micro doses and often infrequently. Therefore, a positive test(s) indicating illicit opioid use, including buprenorphine, does not immediately indicate opioid tolerance.

For example:

- If a patient is opioid tolerant at time of initiation of naltrexone, an opioid antagonist, treatment will result in precipitated withdrawal (more rapid/severe form of opioid withdrawal), whereas if the patient is opioid naïve at time of naltrexone initiation there is no such risk of precipitated or any other form of opioid withdrawal.
- If a patient is opioid tolerant at time of initiation of buprenorphine or methadone, opioid agonists, the dosage of these medications can typically be higher and advanced more rapidly upon initiation of treatment. Whereas, if the patient is opioid naïve at time of initiation of an opioid agonist, they are at much higher risk of opioid toxicity and accidental overdose (with risk of death) if the starting dose is too high, or the dose is advanced too rapidly.

OPIOID TOXICITY

Symptoms of opioid toxicity include sedation, lethargy, shallow breathing, respiratory distress/hypoxia, hypotension, nausea/vomiting, miosis, or altered mental status. Signs and symptoms of opioid toxicity can occur for a variety of reasons at any time during use of any opioid including opioids used illicitly or appropriately prescribed (including buprenorphine and methadone). Given the risk of respiratory depression and possible death, it is critical that all employees and patients are educated on the signs and symptoms of opioid toxicity, how to respond appropriately should opioid toxicity be suspected, and the importance of appropriate medical follow up when adding or augmenting opioids.

- **At baseline**, educate all patients receiving medication for OUD on signs and symptoms of opioid toxicity and instruct them to present to sick call immediately if they experience any of them.
- **In mild cases of opioid toxicity (symptoms of mild to moderate sedation)** – immediately reduce the dose of opioid agonist medication and follow up with the patient again within 24 hours.
- **In more severe cases (severe sedation and/or additional symptoms of toxicity)** – immediately administer naloxone and refer patient to the outside hospital for further stabilization efforts.

B. BUPRENORPHINE AND BUPRENORPHINE/NALOXONE

Use and formulation: Buprenorphine is a partial opioid agonist, available with and without naloxone, in the following formulations in the FBOP:

- **Buprenorphine/naloxone sublingual films (Suboxone ®)**
  - Naloxone is given in combination with buprenorphine to reduce the potential for misuse, as it decreases the euphoria and risk of accidental overdose of this opioid if injected.
- **Buprenorphine-only long-acting injection (Sublocade ® or Brixadi ®)**
  - Buprenorphine long-acting injections are not on FBOP formulary and are recommended only for patients meeting the following conditions:
    - Institution has an active REMS enrollment, and documentation is clearly provided that demonstrates patient meets any of the following criteria:
      - Failure to meet treatment goals (continued opioid cravings, continued illicit opioid use, and/or presence of physical opioid withdrawal symptoms) on sublingual buprenorphine/naloxone despite an appropriate dosage (at least 16 mg daily), evidence of compliance, AND for a duration of at least 3 months. See OUD Modules for guidance on treatment goals.
      - Two or more separate, documented, cases of sublingual buprenorphine/naloxone diversion AND treatment with buprenorphine remains the best treatment option for the patient.
      - Patient has significant, documented neurological or psychiatric comorbidities which preclude successful administration of formulary options on directly observed therapy (pill line).
- **Buprenorphine-only sublingual tablet (Subutex®)**
  - The buprenorphine-only sublingual tablet is not on FBOP formulary and is recommended only for patients meeting the following conditions:
    - Documented or observed allergic reaction to naloxone (rare)
    - Moderate to severe hepatic impairment
    - Confirmed pregnancy

INITIATION PHASE

The goal of the initiation phase is to **determine the minimum dose of buprenorphine** at which the patient markedly diminishes or discontinues use of other opioids, experiences minimal withdrawal symptoms, minimal or no side effects, and reduced cravings.

Precipitated withdrawal: Buprenorphine has a high affinity for opioid receptors and can displace full agonists, causing an acute, and potentially severe, precipitated opioid withdrawal in patients who are opioid tolerant. The likelihood of precipitating withdrawal upon starting buprenorphine is reduced as the interval increases between the last dose of the opioid and the first dose of buprenorphine.

Reducing the risk of precipitated withdrawal: As a condition of initiating buprenorphine (with or without naloxone), patients with established opioid tolerance who are actively or have recently used opioids should be exhibiting symptoms of mild to moderate opioid withdrawal. The American Society of

Addiction Medicine (ASAM) recommends a COWS score of ≥ 11 as an appropriate level of withdrawal for starting buprenorphine in patients who are currently misusing opioids. (Refer to **MODULE 3. EVALUATION AND TREATMENT INITIATION** for additional information on COWS assessments and scores.) Depending on the duration of action of the opioid, patients are likely to achieve this level of withdrawal after the following period of time has elapsed since the last opioid dose:

- 6 - 12 hours for short-acting opioids (e.g., immediate-release morphine, heroin)
- 24 hours for sustained-release opioid medications
- 24 - 72 hours for methadone (for methadone doses ≥ 30 mg, more time may be required before buprenorphine can be initiated)

- *For patients with recent or suspected fentanyl use, consider initiating buprenorphine (with or without naloxone) with COWS score ≥ 13.*
- *For patients that are opioid naive, precipitated withdrawal is not a risk. Instead, these patients are at risk for opioid toxicity and possible overdose. Therefore, the initial dose should be lower and increased slower than in opioid tolerant patients. See **INITIATION FOR OPIOID NAÏVE PATIENTS** below.*
- *Refer to Figures 1, 2 and 3 for treatment algorithms for dose initiation.*

INITIATION OF ORAL BUPRENORPHINE FOR OPIOID TOLERANT PATIENTS - DAY 1

STEP 1. Ensure COWS score is ≥ 11 prior to initiating treatment.

- If a patient never experiences a COWS score ≥ 11, consider delaying induction by 1 to 2 days or reconsider if the patient is opioid tolerant and, if so, proceed with **INITIATION FOR THOSE WITH MINIMAL TOLERANCE (OPIOID NAÏVE)** instead.

STEP 2. Administer initial dose of 4 mg of oral buprenorphine/naloxone.

- Relief of withdrawal symptoms should begin 30–45 minutes after the first dose.
- If symptoms of precipitated withdrawal occur, treat symptoms, and attempt initiation again in 24 hours.
- If patient is methadone or fentanyl-dependent, administer an initial dose of 2 mg.

STEP 3. Two hours after administering the first dose of buprenorphine/naloxone, assess the patient for signs and symptoms of withdrawal using COWS.

- If withdrawal symptoms are mild or relieved (COWS score ≤ 8), skip additional dose (Step 4) and proceed to Initiation Day 2 (All Patients).

STEP 4. If withdrawal symptoms persist or return (COWS score >8), administer an additional 2 to 4 mg of buprenorphine/naloxone.

- Additional doses are dependent on severity of withdrawal symptoms (e.g., a patient with moderate symptoms may only require an additional 2 mg rather than 4 mg).
- Repeat dose as needed for continuing withdrawal every 2 hours up to 8 mg **total** on Day 1. Do **not** exceed a total dose of 8 mg of buprenorphine on Day 1.

INITIATION OF ORAL BUPRENORPHINE FOR OPIOID NAÏVE PATIENTS – DAY 1

STEP 1. Administer initial dose of 2 mg of oral buprenorphine/naloxone.

- A lower dose of 1 mg may be used; additional accountability and documentation of the unused portion is required.

STEP 2. Two hours after administering the first dose of buprenorphine/naloxone, assess the patient for signs and symptoms of sedation and precipitated withdrawal. If the patient tolerates the dose well (no signs of sedation or precipitated withdrawal), proceed to Initiation Day 2 (All Patients).

- If the patient shows signs of sedation, do not proceed with initiation phase. Reassess the patient's indications for treatment or consider naltrexone.
- If the patient shows signs of precipitated withdrawal, treat symptoms according to *FBOP Medically Supervised Withdrawal for Inmates with Substance Use Disorder Clinical Guidance* and assess whether conditions for starting buprenorphine, as stated under "Reducing the risk of precipitated withdrawal," have been met. Attempt Initiation Day 1 again at least 24 hours later, if indicated.

INITIATION OF ORAL BUPRENORPHINE DAY 2 (ALL PATIENTS)

STEP 1. Administer the previous day's total dose as one dose in the morning.

STEP 2. Two hours after administering the dose of buprenorphine/naloxone, assess the patient for signs and symptoms of withdrawal using COWS.

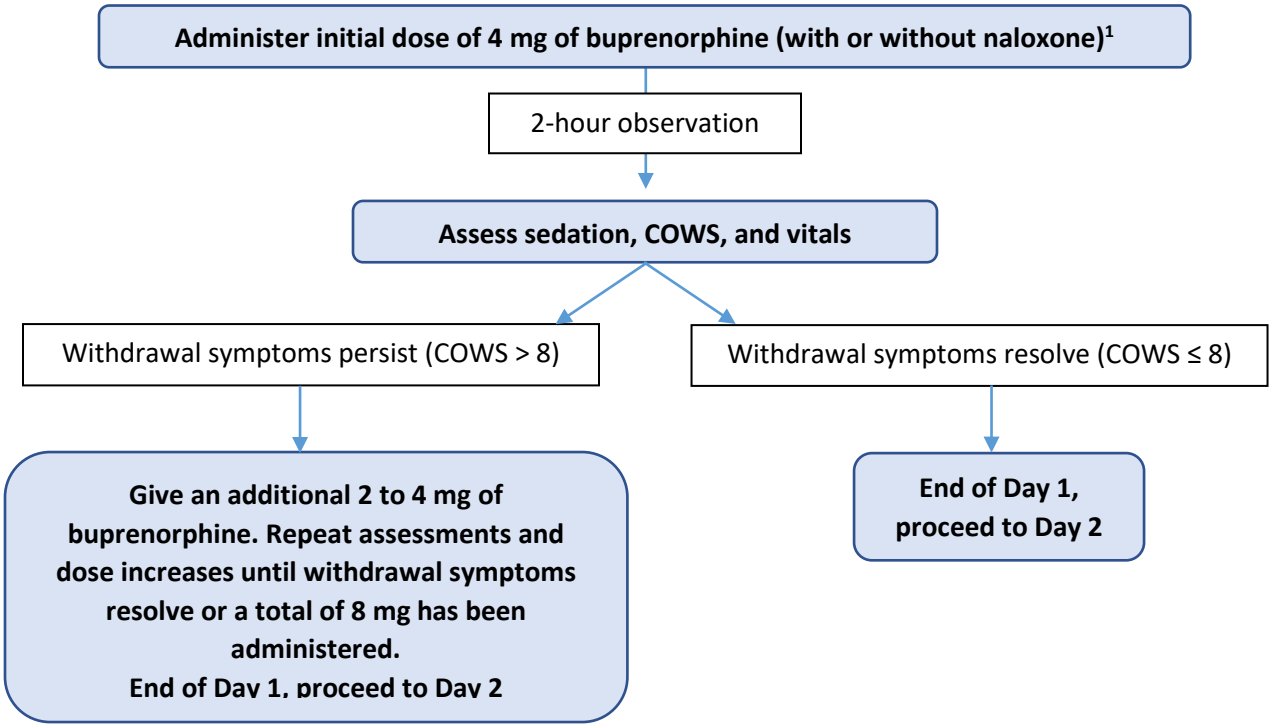
- If withdrawal symptoms were relieved or never occurred, skip additional doses (Step 3) and proceed to Stabilization Phase. The patient's total dose received on Day 2 is the starting dose for the patient's Stabilization Phase.

STEP 3. If withdrawal symptoms persist or return (COWS score >8), administer an additional 2 mg of buprenorphine/naloxone and repeat Step 2.

- Repeat dose as needed for continuing withdrawal every 2 hours up to 16 mg on Day 2.
- Do **not** exceed a total daily dose of 16 mg of buprenorphine.
- To avoid over-sedation in opioid-naïve patients, it is recommended to increase the dose more slowly, up to once weekly.

(Treatment algorithms begin on the following page)

FIGURE 1. INITIATION OF ORAL BUPRENORPHINE FOR OPIOID TOLERANT PATIENTS – DAY 1:



[1] For patients withdrawing from methadone or fentanyl, an initial dose of 2 mg is recommended.

FIGURE 2. INITIATION OF ORAL BUPRENORPHINE FOR OPIOID NAÏVE PATIENTS – DAY 1:

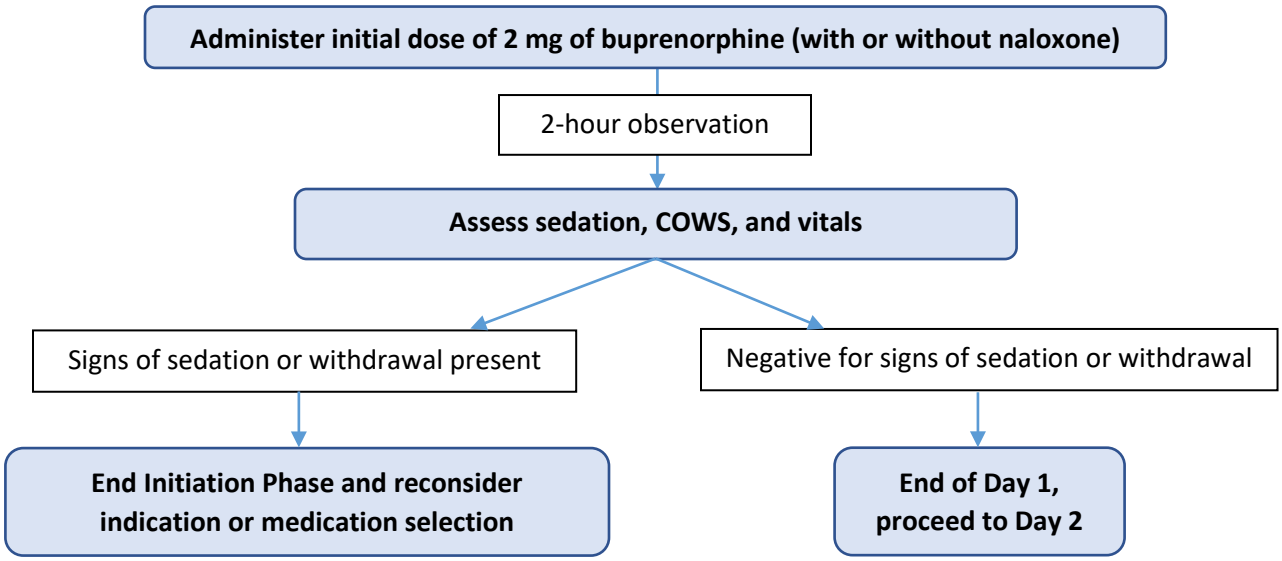
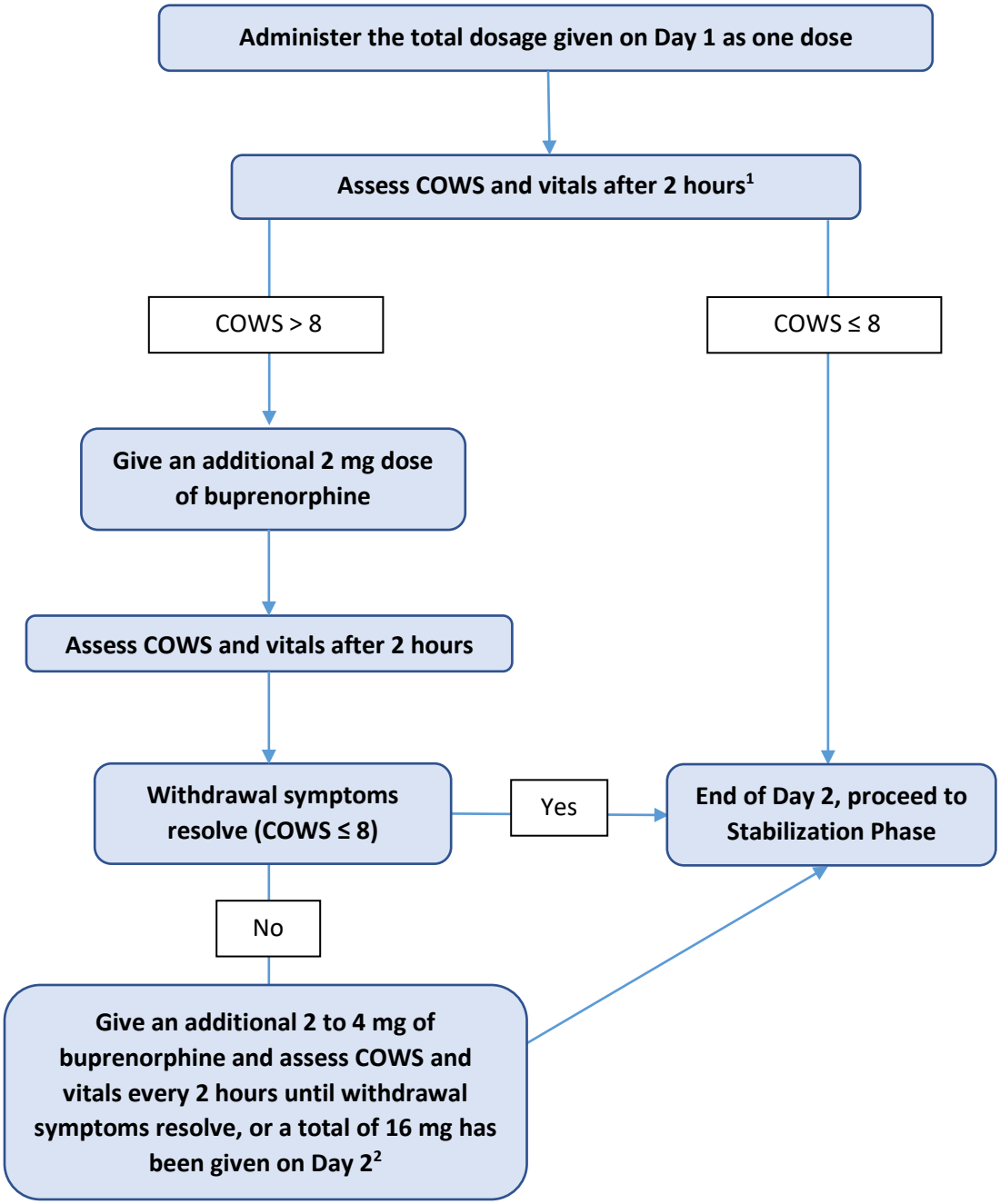


FIGURE 3. INITIATION OF ORAL BUPRENORPHINE DAY 2 (ALL PATIENTS)



[1] *Discontinue dose titration if patient exhibits signs of sedation.*
[2] *To avoid over- sedation in opioid-naive patients, it is recommended to increase the dose slowly, up to once weekly.*

INITIATION OF LONG-ACTING BUPRENORPHINE (BRIXADI ®)

For patients who are opioid naïve and inducted on buprenorphine, a sublingual equivalent dose should be tolerated as a maintenance dose before considering conversion to an equivalent Brixadi® dose as described in *Table 2* below.

For patients who are opioid tolerant but not currently taking buprenorphine, the following dose strategy may be used to induct patients on Brixadi®:

STEP 1. Ensure COWS score is ≥ 11 prior to initiating treatment.

- If a patient never experiences a COWS score ≥ 11, consider delaying induction by 1 to 2 days OR reconsider if patient is opioid tolerant and, if so, proceed with **INITIATION FOR THOSE WITH MINIMAL TOLERANCE (OPIOID NAÏVE)** instead.

STEP 2. Administer a 4mg sublingual buprenorphine/naloxone test dose.

STEP 3. Two hours after administering the test dose of buprenorphine/naloxone, assess the patient for signs and symptoms of withdrawal using COWS.

STEP 4. If withdrawal improves without precipitation, administer a 16mg weekly Brixadi® dose.

- If the patient tolerates the initial 16mg weekly dose well but is not achieving treatment goals consider an additional 8mg weekly dose 3 days after the 16mg weekly dose

STEP 5. Administer a follow-up dose in one week after the initial 16mg weekly dose.

- If the additional 8mg weekly dose was administered, administer a 24mg weekly dose one week after the initial 16mg weekly dose.
- If the additional 8mg weekly dose was not considered, continue with a 16mg weekly dose one week after the initial 16mg weekly dose.

STEP 6. Increase or decrease dose as needed and/or convert to the dose equivalent monthly dose at the next available dose interval as indicated.

For patient currently on oral buprenorphine who meet FBOP non-formulary use criteria to switch to Brixadi ®, see subsection *SWITCHING FROM ORAL BUPRENORPHINE TO LONG-ACTING INJECTIONS - BRIXADI®*

STABILIZATION PHASE

STABILIZATION is achieved when the patient experiences mild or no withdrawal symptoms, has minimal or no side effects, and has reduced cravings for opioid agonists. During the stabilization phase, providers can continue to adjust the daily dose if the patient experiences continued symptoms of withdrawal and cravings and continues to tolerate their current dose. Occasionally, dosing more frequently than once daily may be indicated in consultation with an FBOP addiction medicine specialist. Potential indications for increased dosing frequency include the following:

- Treatment goals are not met using once daily (QD) dosing at appropriate doses (16-24 mg). E.g., uncontrolled cravings and/or misuse of opioids and/or objective symptoms of withdrawal within a 24-hour period while on daily dosing.
- Drug interactions exist that may increase the metabolism of buprenorphine and interacting medications cannot be discontinued. See *TIP 63 Exhibit 3D.3* for a partial list of medications that may decrease buprenorphine serum levels. Medications include anticonvulsants, dexamethasone, and rifampin.

- Co-diagnosis of pain, which may require more than one daily dose when buprenorphine is the only prescribed opioid.

STABILIZATION PHASE FOR OPIOID TOLERANT PATIENTS:

- During stabilization, providers can continue to make dose adjustments of 2 mg to 4 mg of buprenorphine every 3 days based on continued symptoms of withdrawal and/or cravings for illicit substances. The recommended target dosage for buprenorphine is 12 to 16 mg per day. Nearly all patients stabilize on daily doses of 4 to 24 mg buprenorphine per day.
- When a total daily dose of 16 mg buprenorphine is achieved, no further dose increases are recommended for several (4-7) days to allow the medication to have maximum effect. Additional dose increases may be needed occasionally, up to 24 mg/day.
- There is limited data showing benefits of doses higher than the FDA label's recommended maximum dose of 24 mg of buprenorphine per day.
- Stabilization for patients who were opioid tolerant prior to initiation typically occurs within 3 to 7 days after the initiation phase. However, depending on the individual characteristics of the patient, more time may be required to achieve a maintenance dose.

STABILIZATION PHASE FOR OPIOID NAÏVE PATIENTS:

- During stabilization, providers can continue to make dose adjustments of up to 2mg of buprenorphine every 7 days. When a total daily dose of 8mg is achieved, no further dose increases are recommended unless objective findings for withdrawal symptoms or illicit substance use are confirmed.
- Stabilization doses are expected to be lower in individuals who were not opioid tolerant prior to initiation. Although there is no established recommended maintenance dose for previously opioid naive patients, the FBOP recommends the lowest possible tolerated dose where no signs of sedation, withdrawal, or cravings for illicit substances are present.

After stabilization has been achieved, patients can proceed with one of the following treatment choices if appropriate:

- **Continue with oral buprenorphine (with or without naloxone):** When stabilized on a daily dose of oral therapy, proceed to **MAINTENANCE PHASE**.

  OR
- **Convert to long-acting injectable buprenorphine (Sublocade® or Brixadi ®)** if FBOP non-formulary use criteria are met.

  ➔ *Refer to Switching Medications for guidance on converting the patient to monthly subcutaneous injections.*

  ➔ *Ordering and administering Sublocade® or Brixadi ® requires the institution to enroll in the respective REMS program. Instructions on how to enroll can be found at the following links:*

  - ***Sublocade:*** *https://www.sublocaderems.com/#Main*
  - ***Brixadi:*** *https://brixadirems.com/*

MAINTENANCE PHASE

When the minimum effective dose of buprenorphine (monotherapy or combined with naloxone) has been established, the dose should be continued based on the agreed upon patient and provider goals. The length of the maintenance phase is a collaborative decision between the patient and provider and depends on the patient adhering to the expectations of their treatment plan.

SWITCHING MEDICATIONS

Buprenorphine and buprenorphine/naloxone are generally well-tolerated. However, switching to other OUD medication may be appropriate in the following cases:

- Patient experiences intolerable side effects.
- Patient has not attained or maintained goals through the initially chosen medication.
- Patient requests a change and is a candidate for an alternative treatment.

See Appendix 1. Converting Between Medications for OUD

SWITCHING FROM ORAL BUPRENORPHINE TO LONG-ACTING INJECTIONS - SUBLOCADE®

Sublocade® should NOT be used until patients have completed the stabilization phase with dosages of at least 8 mg of buprenorphine daily for a minimum of 7 days.

The recommended dosing schedule is to initiate at 300 mg subcutaneous abdominal injection monthly for the first 1-2 months, followed by 100 mg every 28 days thereafter. Refer to **TABLE 1** for a summary of dosing recommendations. Per FDA labeling, Sublocade® may be administered early as 26 days apart.

TABLE 1. DOSING RECOMMENDATIONS FOR CONVERSION FROM ORAL BUPRENORPHINE TO SUBLOCADE®

Sublingual Buprenorphine Daily Maintenance Dose	Injection 1	Injection 2	Maintenance Dose
8-16mg/day	300mg	100mg*	100mg**
20-24mg/day	300mg	300mg	100mg**
*For patients still experiencing cravings or withdrawal symptoms after the initial 300mg dose, considering giving 300mg as the second month dose.			

After steady state (4-6 injections) has been achieved, if the patient is tolerating the 100 mg dose but does not demonstrate satisfactory response (e.g., continued reports of cravings, illicit substance use, or positive urine drug screens (UDS)), the dose may be increased back to 300 mg monthly.

- If utilizing 300mg as a maintenance dose, recommend increased follow up to assess tolerability including signs of oversedation, opioid induced constipation, and hepatic profile.

SWITCHING FROM ORAL BUPRENORPHINE TO LONG-ACTING INJECTIONS - BRIXADI®

For patients currently taking buprenorphine and FBOP non-formulary use criteria are met, Brixadi® may be considered if based on the following dose equivalents in TABLE 2.

TABLE 2. DOSING RECOMMENDATIONS FOR CONVERSION FROM ORAL BUPRENORPHINE TO BRIXADI®

Sublingual Buprenorphine Daily Maintenance Dose	Brixadi® Weekly	Brixadi® Monthly
<6mg	8mg	--
8-10mg	16mg	64mg
12-16mg	24mg	96mg
18-24mg	32mg	128mg

SWITCHING FROM LONG-ACTING INJECTIONS TO DAILY ORAL BUPRENORPHINE

Initiate oral buprenorphine on the next scheduled injection day instead of the buprenorphine injection. It is recommended to start at a more conservative dose (8 to 16 mg daily) and then titrate accordingly based on tolerance and achieving treatment goals.

TABLE 3. DOSING RECOMMENDATIONS FOR CONVERSION FROM SUBLOCADE® TO ORAL BUPRENORPHINE

Sublocade Dose	Daily Sublingual Buprenorphine Dose*
100mg maintenance dose	8-16mg
300mg maintenance dose	16-24mg
*based on average buprenorphine serum concentrations achieved at steady state for each dosage form	

TABLE 4. DOSING RECOMMENDATIONS FOR CONVERSION FROM BRIXADI® TO ORAL BUPRENORPHINE

Brixadi Monthly	Brixadi Weekly	Daily Sublingual Buprenorphine Dose*
	8mg	4mg
64mg	16mg	8-10mg
96mg	24mg	12-16mg
128mg	32mg	18-24mg
*based on average buprenorphine serum concentrations achieved at steady state for each dosage form		

SWITCHING TO NALTREXONE

From oral buprenorphine (monotherapy or with naloxone): Due to its long half-life, 10–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure the patient is not physically dependent on opioids before starting naltrexone.

From long-acting injectable (LAI) buprenorphine: Due to its long-acting formulation and variable half-life, conversion to naltrexone is difficult and not typically recommended If conversion is necessary, the LAI should be stopped, and naltrexone test doses should not be initiated until 1 to 2 weeks *after the next scheduled LAI dose.*

SWITCHING FROM BUPRENORPHINE TO METHADONE

When considering methadone, approval criteria must first be met prior to initiation. Transitioning from oral buprenorphine (monotherapy or with naloxone) to methadone does not typically result in adverse reactions. There is no time delay required in transitioning a patient from oral buprenorphine to methadone. For patients taking long-acting injectable buprenorphine, initiate methadone on the next scheduled injection day instead of the buprenorphine injection. It is recommended to start at a more conservative dose and then titrate accordingly based on tolerance and achieving treatment goals. Refer to *Section C. Methadone* for additional guidance on methadone initiation.

TABLE 5. DOSING RECOMMENDATIONS FOR CONVERSION FROM SUBLOCADE ® TO METHADONE

Sublocade Dose	Daily Methadone Dose*
100mg maintenance dose	5mg
300mg maintenance dose	10mg
*based on conservative dosing of buprenorphine to methadone morphine milligram equivalence (MME)	

TABLE 6. DOSING RECOMMENDATIONS FOR CONVERSION FROM BRIXADI ® TO METHADONE

Brixadi Monthly	Brixadi Weekly	Daily Methadone Dose*
	8mg	5mg
64mg	16mg	5mg
96mg	24mg	10mg
128mg	32mg	10mg
*based on conservative dosing of buprenorphine to methadone morphine milligram equivalence (MME)		

SWITCHING BETWEEN LONG-ACTING INJECTIONS

Switching between buprenorphine long-acting injections should be a clinical decision, and not based on logistical availability. There are no currently published data, studies, or recommendations on converting between buprenorphine LAIs. However, using studied buprenorphine serum concentrations found at steady state at each dose in separate studies of each LAI independently, **TABLE 7** on the following page may be used for guidance on converting between LAIs.

TABLE 7. DOSING RECOMMENDATIONS FOR CONVERSION BETWEEN BUPRENORPHINE LONG-ACTING INJECTIONS

Daily Sublingual Buprenorphine Dose	Brixadi® Weekly	Brixadi® Monthly	Sublocade®
<6mg	8mg	--	--
8-10mg	16mg	64mg	100mg*
12-16mg	24mg	96mg	300mg*
18-24mg	32mg	128mg	
For patients stable on 100 mg of Sublocade®, a 64 mg or 96 mg monthly (or weekly equivalent) Brixadi® injection may be considered. Similarly, for patients on 300 mg of Sublocade®, a 96 mg or 128 mg monthly (or weekly equivalent) Brixadi® injection may be considered. Dose selection should be made based on how well the patient is tolerating the current Sublocade® dose, taking a more conservative approach if tolerability or side effects are present at the current Sublocade® dose.			

MISSED BUPRENORPHINE DOSES

- **Fewer than 5 days since last oral dose:** Continue with next scheduled maintenance dose.
- **6 to 14 days since last oral dose:** restart at half the maintenance dose for 7 days, then return to previous maintenance dose.
- **15 or more days since last oral dose:** Repeat initiation phase.
- **Missed dose of long-acting buprenorphine injection:**
  - Missed dose should be given as soon as possible. Dosing delays of up to 2 weeks after due date are not expected to impact treatment.
  - If delays in injection are expected to exceed two weeks, administer the patient's last stabilization phase dose of oral buprenorphine daily until able to administer the previous maintenance dose injection.
  - If there is a significant gap in administration (> two weeks after due date), the patient may possibly require reassessment and restarting at the initiation phase of oral treatment prior to restarting the long-acting buprenorphine injection (especially in cases where the delay occurs prior to reaching steady state with use of long-acting injection).

FREQUENCY OF FOLLOW-UP

After a patient has completed the stabilization phase for buprenorphine, it is recommended they are seen at least once weekly for one month or until adherence to medication has been established, medication effectiveness has been documented, and there are negligible to no medication side effects.

Monthly visits may be reasonable once a patient has demonstrated abstinence from opioids, compliance with medication, absence of medication side effects, and stable mental health. **Once stabilization has been maintained >1 year, patients on buprenorphine should be seen at least quarterly thereafter.**

DENTAL CONSIDERATIONS FOR SUBLINGUAL BUPRENORPHINE

Dental officers should work with the treating providers when developing plans for managing oral pain in patients treated with opioid antagonists. Refer to **Module 7. Special Populations** for pain management guidance.

FDA Drug Safety Communications report an increased risk of dental problems, including tooth decay, tooth loss, and oral infection, with the use of intraoral buprenorphine-containing tablets and films. These side effects can be serious and occur in patients without a history of dental issues. Recommendations for managing these risks include:

- Prior to initiation of oral buprenorphine treatment plans, a medical-to-dental consultation request should be generated by the OUD-treating provider to request dental evaluation.
  - ➔ ***While a consultation request should be entered prior to initiation; completion of a dental evaluation is not required prior to treatment initiation.***
- Dental evaluation should include but not be limited to:
  - Comprehensive treatment planning examination
  - Caries risk assessment
  - Development of a dental caries preventive plan
    - ➔ *Refer to Preventive Dentistry: Oral Disease Risk Management Protocols*
  - Tracking to include full oral health reassessment at the end of buprenorphine therapy.
- Patients should be educated on the following:
  - The potential for dental problems with oral buprenorphine therapy
  - Gently rinsing teeth and gums with water and swallowing after buprenorphine administration
  - Avoiding tooth brushing for an hour after each oral buprenorphine dose

C. METHADONE

Formulation: Methadone is a full opioid agonist available as a tablet or orally disintegrating wafer.

Use of methadone as part of treatment for OUD is a clinical decision made through shared decision-making. Patient preference alone is not adequate justification for initiation. Methadone may be considered for patients who meet the following clinical review elements:

- **Intake to FBOP already on methadone:** Receipt of methadone for treatment of OUD is confirmed by the prior Opioid Treatment Program (OTP) through outside medical records or contact with the OTP.
  - Ordering provider must have prescribing rights for methadone or a TO/VO has been obtained by provider with prescribing rights for methadone.
  - For continuation upon intake, request will be approved by Regional Chief Pharmacist for 30 days pending initial evaluation.
- **For methadone initiation:**
  - Patient has documented diagnosis of OUD and/or Opioid Dependence.

- Ordering provider must have prescribing rights for methadone.
- Documentation in the Bureau Electronic Medical Record (BEMR) of plans for continuity of care after release.
- Must also meet at least one of following –
  - Patient is pregnant and prefers use of methadone over buprenorphine.
  - Patient has clearly documented serious allergy and/or side effect to buprenorphine in the FBOP.
  - Patient has clearly documented failure (e.g., severe opioid cravings, objective signs of opioid withdrawal, and/or continued use of illicit opioid use to supplement treatment, etc.) in the FBOP with consistent compliance with
    - Buprenorphine sublingual up to 24 mg daily > 2 months.
    - Appropriate dosing of long-acting buprenorphine injection > 4 months.

If, after intake, a patient continues to receive methadone through a community OTP, refer to Appendix 1 in **MODULE 3. EVALUATION AND TREATMENT INITIATION** for procedures for documenting the methadone order in the electronic health record.

INITIATION PHASE

Prior to beginning treatment, all new methadone initiations must be approved by the FBOP Chief of Addiction Medicine, or designee.

STEP 1. Administer an initial dose of methadone.

- Initiate low initial doses between 2.5 and 10 mg and slow dose titration for patients with low tolerance at initiation (e.g., opioid abstinence > 5 days, non-daily opioid use) or in other clinical situations where higher doses of methadone may be contraindicated (e.g., age > 60, history of QTc prolongation, respiratory disease, hepatic impairment, drug-drug interactions, etc.)
- Initial doses of 10 to 20 mg may be indicated for some patients. Refer to *SAMHSA TIP 63* for guidance on initial dose considerations.
- A maximum initial dose of 30 mg may be considered after consultation with an addiction medicine specialist for patients with no signs or symptoms of sedation or intoxication but with symptoms of withdrawal.

STEP 2. Two to four hours after initiating the dose of methadone, assess patient for signs of sedation or relief of withdrawal symptoms.

- If sedation occurs, the patient should stay under observation at the clinic until symptoms resolve. The patient should be reassessed the following day, and the dose should be reduced.
- If withdrawal symptoms have not been suppressed or if symptoms reappear after 2–4 hours, an additional 5 to 10 mg of methadone may be administered.

The maximum initial dose of methadone is 30 mg. The total dose on the first day may not exceed 40 mg without clear documentation in the medical chart to justify exceeding 30 mg.

STEP 3. If withdrawal symptoms decrease and do not return after 2 to 4 hours and there are no signs of sedation after the initial or additional dose, proceed to the **TITRATION AND MAINTENANCE PHASE** the following day.

TITRATION AND MAINTENANCE PHASE

Titrate to a dose that minimizes or prevents opioid withdrawal symptoms and prevents cravings for 24 hours—without excessive sedation or intoxication.

- *Dose increases should **not** be done daily because methadone levels do not reach steady state for approximately 7-10 days. Even when holding the methadone dose constant over several days, the methadone level will rise each day. There is high variation in how patients absorb, metabolize, and tolerate this medication.*

  - **Weeks 1-2:** Dose should be increased by 5 mg or less every 7 or more days.
  - **Weeks 3-4:** Dose can be increased in 5 mg increments every 5 days, based on the patient's symptoms of opioid withdrawal or sedation.
  - **Week 5 and beyond:** When an adequate dose is achieved, continue with the same treatment goals of avoiding sedation, eliminating withdrawal and cravings, and blocking the euphoric effects of illicit opioids.
  - The usual **MAINTENANCE DOSE RANGE** is 60 to 120 mg/day in a single dose. The Institution Clinical Director should be consulted prior to initiation of doses greater than 120 mg/day.

SWITCHING MEDICATIONS

Switching from methadone to another medication for OUD may be appropriate in the following cases:

- The patient experiences intolerable methadone side effects.
- The patient has not experienced a successful course of treatment on methadone.
- The patient wants to change and is a candidate for an alternative treatment.
- The FBOP Transitional Care Team and/or social worker has determined the patient will be unable to access methadone upon release.

- *See Appendix 1 for additional guidance regarding switching medications.*

SWITCHING TO BUPRENORPHINE

- Taper down to a target dose of 30 mg of methadone and remain on a 30 mg dose for ≥ 7 days, then discontinue methadone.
- Symptoms of mild to moderate withdrawal (COWS score ≥ 11) should be present before initiating buprenorphine (usually 24 to 72 hours after the last dose of methadone).
- To minimize the risk of precipitated withdrawal when switching to buprenorphine, use careful initial dosing of buprenorphine (recommended initial dose of 2 mg buprenorphine), followed by titration to an appropriate maintenance dose.

- *Refer to the buprenorphine discussion in this module for more information on* avoiding *precipitated withdrawal.*

SWITCHING TO NALTREXONE

Patients switching from methadone to naltrexone should be completely withdrawn from methadone before initiating naltrexone, which can usually be achieved within 7 days but may require as long as 14 days. A naloxone challenge may be used to confirm withdrawal is complete.

MISSED METHADONE DOSES

- **Fewer than 3 days missed:** Resume regular scheduled dose.
- **3 days missed:** Restart at 75% of the patient's confirmed maintenance dose. The dose should be increased by 5 mg per day until reaching the previous maintenance dose.
- **4 days missed:** Restart at 50% of the patient's confirmed maintenance dose. The dose should be increased by 5 mg per day until reaching the previous maintenance dose.
- **5 or more days missed:** Restart treatment per dosing guidance for the **INITIATION PHASE**.

FREQUENCY OF FOLLOW-UP

After a patient has been stabilized on methadone, it is recommended they are seen **at least once weekly for at least the first 2 months after initiation** or until adherence to medication has been established, medication effectiveness has been documented, and there are negligible-to-no medication side effects.

When a patient has demonstrated compliance and is on a therapeutic dose, less frequent visits may be needed. Monthly visits may be reasonable once a patient has demonstrated abstinence from opioids, compliance with medication, absence of medication side effects, and stable mental health**. Once stabilization has been maintained >1 year, patients on methadone should be seen at least quarterly thereafter.**

D. NALTREXONE

Use and formulation: Naltrexone, an opioid antagonist, has demonstrated efficacy in reducing return to illicit opioid use, increasing treatment retention, reducing opioid craving, and blocking euphoric effects of opioid use. Naltrexone may be particularly useful in patients with both alcohol and opioid use disorders. Naltrexone is available in the following formulations:

- **Long-acting injectable naltrexone (Vivitrol®)**
  - Preferred over oral naltrexone; however, oral naltrexone may still be considered in highly motivated patients.
  - Administered every 28 days by a health care provider as a 380 mg gluteal intramuscular injection. Alternate buttocks for each subsequent injection.
  - The patient should be issued an identification (ID) card stating they are taking long-acting naltrexone. The purpose of the ID card is to alert healthcare providers in the event of an emergency requiring treatment of pain with opioids. **The ID card and a copy of the FDA Medication Guide should be given to the patient by a healthcare provider at the institution.**
    - A copy of the Vivitrol® ID card can be obtained at: *https://www.vivitrol.com/content/pdfs/emergency-pain-management-card.pdf*
    - The FDA Medication Guide is available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s005s010MedGuide.pdf*

- Because of the risk of severe injection site reactions, refer to the Vivitrol® REMS website for patient counseling tools, and visual aids to reinforce proper injection technique: https://www.vivitrolrems.com/

- **Oral naltrexone**
  - Administered daily as a 50 mg dose.
  - Can precipitate opioid withdrawal syndrome; ensure patient is opioid- free for at least 7-10 days from last use of short-acting opioids and 10-14 days from last use of long-acting opioids prior to first dose (confirm with UDS).
  - Data shows oral naltrexone to be no more effective than placebo except in the following situations:
    - Highly motivated and compliant patients
    - Individuals with high levels of monitoring and/or negative consequences for non-adherence
    - Patients who wish to take antagonist treatment but cannot or will not take the long-acting injection

Prescribing restrictions: Naltrexone does **NOT** have any prescribing restrictions and can be prescribed by any provider licensed to prescribe medications.

INITIATION OF LONG-ACTING INJECTABLE NALTREXONE (VIVITROL®)

To reduce the risk of precipitated withdrawal, providers should confirm by UDS that the patient has **not** taken a short-acting opioid (including tramadol) for at least 6 to 10 days **OR** a long-acting opioid (including buprenorphine or methadone) for at least 7 to 14 days prior to the first injection. Providers should also conduct a **NALTREXONE OR NALOXONE CHALLENGE DOSE** as described below:

- **NALTREXONE CHALLENGE DOSE:** To reduce the risk of precipitated withdrawal and rule out hypersensitivity to naltrexone, an **ORAL CHALLENGE DOSE** of 50 mg naltrexone is administered 1 day prior to the first injection.
  - Prior to administering the naltrexone challenge dose, confirm there are no signs or symptoms of opioid withdrawal and check baseline vital signs.
  - After the oral challenge dose is administered, the patient is observed for 60-90 minutes for signs of withdrawal, and a COWS assessment is conducted.
  - After a successful challenge dose, the long-acting injectable naltrexone may be administered the following day and monthly thereafter.

LOOK-ALIKE/SOUND-ALIKE ALERT: *Naloxone is a subcutaneous challenge dose and naltrexone is an oral challenge dose.*

Naltrexone is not recommended for pregnant patients*. Pregnancy testing should be conducted prior to naltrexone initiation. Refer to* ***MODULE 7. SPECIAL POPULATIONS*** *for additional information.*

SWITCHING MEDICATIONS

Naltrexone is generally well-tolerated. However, switching to another medication for OUD may be appropriate in the following cases:

- Patient experiences intolerable side effects.
- Patient has not successfully attained or maintained treatment goals through the initially chosen pharmacotherapy option.
- Patient requests a change and is a candidate for an alternative treatment.

See Appendix 1. Converting Between Medications for OUD

SWITCHING TO BUPRENORPHINE OR METHADONE

- Wait 1 day before starting buprenorphine or methadone after stopping oral naltrexone tablets
- Wait 28 days from last long-acting injection before starting buprenorphine or methadone.
- Initial doses of methadone or buprenorphine should be low, and doses should be titrated slowly since the patient will not have physical dependence on opioids.

FREQUENCY OF FOLLOW-UP

After a patient has been initiated on naltrexone, it is recommended they are **seen at least once weekly** for at least a month or until adherence to medication has been established, medication effectiveness has been documented, and there are negligible- to- no medication side effects.

When a patient has demonstrated compliance and is on a therapeutic dose, less frequent visits may be needed. Monthly visits may be reasonable once a patient has been abstinent from opioids for several weeks and demonstrated compliance with medication, absence of medication side effects, and stable mental health. **Patients on naltrexone should be seen at least yearly, once stable.**

E. MANAGEMENT OF CONSTIPATION

Opioids, including buprenorphine and methadone, and naltrexone may affect gastrointestinal motility, often resulting in constipation. Concurrent use of constipating medications, advanced age, dehydration, and sedentary lifestyle may compound this side effect. Patients should be counseled on the risk of constipation and those patients with higher risk due to predisposing factors may be considered for prophylactic medication to prevent complications. Recommended FBOP formulary options include polyethylene glycol, senna, and lactulose. For hard or dry stools, docusate may also be added. Patients prescribed medication for OUD should be encouraged to increase their physical activity and fluid intake. Increased fiber intake may also help to avoid constipation. Patients who report constipation should be managed using publicly available guidelines.

F. CONSIDERATIONS FOR SAFETY-SENSITIVE WORK ASSIGNMENTS AND MEDICATION FOR OUD

Patients receiving medication for OUD may be required to work in safety-sensitive positions (SSPs) which may include tasks involving high levels of cognitive function such as usage of heavy machinery or driving. Medication used to treat OUD may lead to significant cognitive impairment, especially upon treatment initiation and dosage adjustment. As such, it is the employer's responsibility to monitor such individuals to ensure workplace safety, which is encapsulated in *OSHA's General Duty Clause, 29 USC 541(a)(1) of the Occupational Safety and Health Act of 1970*.

Studies evaluating the cognitive function of persons receiving medication for OUD have indicated that after an adjustment period, these side effects wane and functional impairment becomes negligible (*SAMHSA Tip 63*). In the absence of a specific standard, the American College of Occupational and Environmental Medicine recommends using vehicle driving as a surrogate measure for fitness to work in SSPs (Hegman 2014).

Experts (Schulze 2012) have recommended that individuals on medication for OUD be considered unfit to drive during the initiation and significant adjustment of their dosing treatment (approximately 3 weeks). Additionally, given the nature of substance use disorder and the risk of relapse into illegal drug use, it is important to ensure workers taking medication for OUD remain otherwise drug-free.

Given this evidence, it is recommended workers receiving medication for OUD:

- Be assigned to a Temporary Job modification that would enable them to avoid safety-sensitive work for a period of 1 month following treatment initiation/significant regimen modification.
- Be regularly screened for illicit drug use.

APPENDIX 1. CONVERTING BETWEEN MEDICATIONS FOR OUD

From ↓ To →	Methadone	Buprenorphine SL tabs or film	Buprenorphine long-acting injection	Naltrexone tablets	Naltrexone long-acting injection
Methadone		Taper down to a target dose of 30 mg of methadone over ≥7 days then discontinue. Start buprenorphine when COWS score ≥ 11.	Not recommended. Should be stabilized on oral buprenorphine before initiation of long-acting injection.	Should be completely withdrawn from methadone before starting naltrexone. This may take up to 14 days.	Should be completely withdrawn from methadone before starting naltrexone. This may take up to 14 days.
Buprenorphine SL tablets or film	There is no time-delay required when switching from buprenorphine to methadone		Start long-acting injection once the patient is stabilized on dose of 8 to 24 mg daily for a minimum of 7 days	Should be completely withdrawn from buprenorphine before starting naltrexone. This may take up to 14 days.	Should be completely withdrawn from buprenorphine before starting naltrexone. This may take up to 14 days.
Buprenorphine long-acting injection	Wait at least 28 days after last injection given before initiating methadone	Wait at least 28 days after last injection given before converting to oral buprenorphine		Not recommended. If necessary, discontinue LAI and initiate challenge dosing 1-2 weeks after next injection due date.	Not recommended. Should convert back to oral buprenorphine prior to converting to naltrexone.
Naltrexone tablets	Wait one day after taking naltrexone before initiating methadone	Wait one day after taking naltrexone before initiating buprenorphine	Not recommended. Should be stable on oral buprenorphine before initiation of long-acting injection.		Can start injection the next day after tolerating naltrexone tablet.
Naltrexone long-acting injection	Wait 28 days after receiving naltrexone long-acting injection before initiating methadone	Wait 28 days after receiving naltrexone long-acting injection before initiating buprenorphine	Not recommended. Should be stable on oral buprenorphine before initiation of long-acting injection.	Start oral tablets 28 days after the last injection	

MODULE 5. MONITORING AND FOLLOW-UP

WHAT'S NEW

- Edits have been made throughout the module for formatting and clarity.
- *Table 1* title changed to "Comparison of Presumptive and Definitive Urine Drug Screening"
- *Section B. Urine Drug Screening* updated considerably to include the following changes:
    - Additional comparison between presumptive and definitive tests added
    - Recommendations for situations when presumptive or definitive tests may be preferred
    - Section on *Presumptive Point-of-Care drug screens* added.
    - *Frequency of Urine Drug Screening* has been updated to remove the requirement for eight UDS per year and updated to recommended monthly UDS (POC acceptable) for patients on agonist medications, particularly early in their treatment. At a minimum, quarterly UDS are recommended for patients who are stable on either agonist medications or naltrexone.
    - Clarification that results of drug testing, when ordered by a medical provider, are protected medical information and not shared with a third party without the written consent of the patient.
- *Section C. Discontinuation of Medication for Opioid Use Disorder* updated to clarify recommended elements for documentation in the EHR when treatment is discontinued.
- SENTRY MAT codes are no longer used and all references to these SMD codes have been updated to BEMR OUD Administrative Codes throughout this module.

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A. FOLLOW-UP ASSESSMENTS

Follow-up is necessary during stabilization to assess response to treatment and make dose adjustments. Regular follow-up also increases the likelihood of adherence to medications and programming. Follow-up assessments should continue to cover the relevant topics covered in the initial assessment including treatment goals, craving management, progress with behavioral health counseling (as appropriate), and review of laboratory findings.

Because opioid use disorder (OUD) is a chronic, relapsing disease, the duration of treatment is individualized. Some patients may choose or require treatment for a few months to a few years, and some may require lifelong treatment. In general, medication for OUD should be continued for as long as the patient is willing to consent fully to their treatment plan and the patient continues to derive benefit from the medication. Assessments of patient response and adherence to their treatment plan should be conducted as outlined for each medication in **MODULE 4. REVIEW OF MEDICATION FOR OPIOID USE DISORDER**.

B. URINE DRUG SCREENING

Drug monitoring is used as a therapeutic tool to improve care. Urine drug screening (UDS) detects the presence or absence of specific drug and drug metabolites in a urine sample within a specific timeframe. Providers can use drug monitoring to provide motivation and reinforcement for abstinence, as well as to confirm adherence to medication for OUD. Patients should be educated on the therapeutic purpose of drug screening. All FBOP treatment agreements include the expectation that patients will comply with drug screening. Patients who will not comply with this expectation should be considered for alternative treatment modalities, or discontinuation of medication for OUD (For further guidance on discontinuation, see *Section C. Discontinuation of Medication for Opioid Use Disorder*.)

TYPES OF URINE DRUG SCREENING

There are two types of UDS, **presumptive screening** by immunoassay and **definitive screening** by gas chromatography-mass spectrometry/liquid chromatography-mass spectrometry (GC-MS/LC-MS). Presumptive screening serves as an initial screening tool only. Definitive screening is a confirmatory test that can identify and quantify specific drugs and/or drug metabolites. The FBOP has both presumptive and definitive tests available for drug monitoring. Comparison of these two types of tests is summarized in **TABLE 1**.

TABLE 1. COMPARISON OF PRESUMPTIVE AND DEFINITIVE URINE DRUG SCREENING

PRESUMPTIVE	DEFINITIVE
Preliminary	Confirmatory
Qualitative (positive or negative) results only	Quantitative results
Immunoassay	GC-MS/LC-MS

Table continues on next page

TABLE 1. COMPARISON OF PRESUMPTIVE AND DEFINITIVE URINE DRUG SCREENING (CONT.)

PRESUMPTIVE	DEFINITIVE
Results indicate a class or category and do not include drug metabolites	Results identify specific drugs and drug metabolites and substance levels if above detectable threshold for the substance and given test.
Can be completed in the clinic and do not require sending out to an external lab	Samples must be sent to an outside lab for advanced testing.
Minimal costs	Often cost significantly more than presumptive tests
Results are available immediately	Results may take several days
Decreased sensitivity and specificity compared to definitive testing, which may lead to false-negative (some data suggests this occurs ~10 to 15% of the time of all immunoassay tests) or false positive results (some data suggests this occurs ~5-10% of the time of all immunoassay tests)	Higher sensitivity and specificity than presumptive UDS, reducing the risk of false-negative or false-positive results.

Refer to *Appendix 1. Example Urine Drug Screen Laboratory Results* for an example of a positive presumptive test with reflex to a definitive test and an example of a negative presumptive test.

Presumptive UDS are recommended to be completed in the following instances:

- Intake to FBOP
- Initial evaluation for OUD
- Ongoing monitoring for patients receiving medications for OUD
- Any time a patient is presenting with altered mental status and/or suspected drug intoxication

Quantitative UDS are recommended to be completed in the following instances:

- Results of presumptive UDS yield unexpected positive or negative results
- Patient reports even mild symptoms of opioid toxicity
- Patient reports new side effects with current OUD medication
- Diversion of OUD medication is a concern
- Dosage or frequency of current treatment is changed or other medication changes that may interact with medications for OUD have occurred while on OUD treatment

TABLE 2, on the following page, lists the current tests available, whether they are presumptive or definitive, and the drugs included in the test.

TABLE 2. URINE DRUG SCREENING OPTIONS IN THE FBOP

BEMR TEST NAME	DRUGS SCREENED	PRESUMPTIVE AND/OR DEFINITIVE
Drug Monitoring Oxycodone Screen, Urine	Oxycodone, noroxycodone, oxymorphone	Presumptive Only
Point of Care (POC) Urine Drug Screen Cups[1]	Amphetamine, benzodiazepine, buprenorphine, cocaine, ethyl glucunoride, fentanyl, heroin, K2, methadone, methamphetamine, methylenedioxymethamphetamine, opiate, oxycodone, marijuana, tramadol	Presumptive Only
Drug Monitoring Panel 5 w/Conf, Urine[2,4]	Amphetamines, barbiturates, benzodiazepines, marijuana, cocaine, methadone metabolite, opiates, oxycodone	Presumptive with reflex to definitive test
Drug Monitoring Panel 8 w/Conf, Urine[3,4]	6-acetylmorphine, alcohol, amphetamines, benzodiazepines, buprenorphine, marijuana, cocaine, MDMA, opiates, oxycodone	
Drug Monitoring, Opioids Panel, with confirmation, Urine[4]	Buprenorphine and metabolites, fentanyl and metabolite, heroin metabolite, methadone and EDDP, methorphan and metabolite, mitragynine, opiates (codeine, hydrocodone, hydromorphone, norhydrocodone, morphine, oxycodone, oxymorphone, noroxycodone), tapentadol and metabolite, tramadol and metabolite	Presumptive with reflex to definitive test
Drug Monitoring Buprenorphine & Naloxone Qnt	Buprenorphine, naloxone, norbuprenorphine	Definitive
Drug Monitoring Fentanyl w/Conf, Urine	Fentanyl, norfentanyl	Definitive
Drug Monitoring Heroin Metab w/Conf, Urine	6-acetylmorphine	Definitive
Drug Monitoring MDMA/MDA w/Conf, Urine	MDMA, MDA	Definitive
Drug Monitoring, Methadone Metabolite, Urine	EDDP and Methadone	Definitive
Drug Monitoring Methylphenidate, Urine	Ritalinic acid	Definitive

[1] Require user training and competency prior to use. See additional information below.

[2] Does not test for buprenorphine or ethanol

[3] Does not test for methadone or barbiturates. If positive for buprenorphine, naloxone quantification will be available

[4]These drug monitoring panels DO NOT include fentanyl, and fentanyl testing must be ordered separately when screening for substance use disorders

PRESUMPTIVE POINT-OF-CARE URINE DRUG SCREENS

The **Abbott iCup Point of Care (POC) UDS cups** can be completed in-house by any appropriately-trained healthcare provider.

- *Further general information on the Abbott iCup POC UDS cup test can be found here –* Abbott Rapid Dx North America LLC I-DPG-1157-011 - McKesson Medical-Surgical
- *Further details on performing & interpreting the Abbott iCup Point of Care (POC) UDS cup tests can be found on the OUD Resources page on Sallyport.*
- *Lab professionals in medical centers with CAP accredited laboratories should NOT be involved in use of POC UDS cups as they are NOT CLIA waived tests.*

Results of all presumptive UDS will be recorded in the electronic health record (EHR) flow sheet. For further details on documentation of all Abbott iCup Point of Care (POC) UDS cup test results, please refer to the **POINT OF CARE TESTING MANUAL** available on FBOP intranet.

FREQUENCY OF URINE DRUG SCREENING

The frequency of UDS testing is a provider clinical decision made on a case-by-case basis. Patients will often require frequent drug testing early in treatment or during periods of return to use. More frequent testing may also be indicated when there is suspicion of illicit substance use, when there is non-adherence to prescribed medication for OUD, or for patients with a high vulnerability to return to use.

In order to help ensure the safety of patients receiving medications for OUD, there are two main reasons for continued drug screening throughout the course of treatment: 1) to confirm the presence of prescribed methadone or buprenorphine, and 2) to screen for misuse of other drugs not prescribed to the patient that could affect safety while on OUD agonist treatment (especially presence of alcohol, barbiturates, or benzodiazepines).

POC UDS tests are recommended because they provide rapid results and are easy to use. Completion of a POC UDS test is recommended monthly for patients on agonist/partial-agonist medications, particularly early in their treatment. Quarterly tests are recommended for all patients who are stable on their OUD medications, to include naltrexone.

FOLLOW-UP AFTER AN UNEXPECTED URINE DRUG SCREEN RESULT

After an instance of unexpected positive or negative UDS, follow-up with the patient is necessary. Elements of the follow-up encounter may include review of the results, discussion of risks of continued unexpected results, and review of the treatment plan and adjustments as necessary. Adjustments may include increasing the frequency of UDS, referral to psychology, adjustment of medication doses, etc.

FOLLOW-UP AFTER AN UNEXPECTED POSITIVE URINE DRUG SCREEN RESULT

Providers should foster an open and transparent dialogue with patients to create an environment where patients are willing to acknowledge continued illicit drug use. Unexpected positive test results are not uncommon, especially early in treatment. Several studies demonstrate that as many as 30% of patients taking medications for OUD tested positive for illicit substances (White 2014, Hser 2013). Unexpected

positive results alone are not cause for treatment discontinuation. Clinicians must weigh the risks of treatment discontinuation, to include increased comorbidity risk (skin infections, Hep C, HIV, STDs), recidivism, and serious injury or death from overdose.

At the same time, ignoring positive test results undermines treatment goals, and patients testing positive for illicit substances while on OUD treatment should be evaluated for treatment adjustments (Rudolph 2022), educated on expectations of treatment, and referred for increased behavioral health services as needed. Interventions made after a positive result should be clearly documented in the EHR.

FOLLOW-UP AFTER AN UNEXPECTED NEGATIVE URINE DRUG SCREEN RESULT

Unexpected negative results may indicate non-adherence to treatment and indicate possible diversion. Repeated unexplained negative test results for prescribed medication may justify discontinuing treatment. (Refer to *Section C. Discontinuation of Medication for Opioid Use Disorder*.)

Before a negative result is attributed to non-adherence, consideration should be given to the time when the UDS was collected, the half-life of the drug, and the timing of the last dose prior to collection. Providers may consult with an FBOP pharmacist for interpretation of a negative test result, if needed.

COMPARISON OF MEDICAL AND CORRECTIONAL URINE DRUG SCREENING

Patients may receive drug screening for medical reasons or for correctional reasons. These two programs are managed independently of one another. UDS conducted by correctional services should not be relied upon to meet the clinical need for monitoring patients on medication for OUD. However, if available, the data from UDS completed by correctional services can be reviewed by a medical provider and used to guide additional evaluation and treatment. See *Table 3* for a comparison of medical and correctional UDSs. Results of drug testing, when ordered by a medical provider, are protected medical information and not shared with a third party without the written consent of the patient.

TABLE 3. COMPARISON OF MEDICAL & CORRECTIONAL URINE DRUG SCREENING

	MEDICAL URINE DRUG SCREENING	CORRECTIONAL URINE DRUG SCREENING
Scheduled[1]	As clinically indicated	As determined by correctional services policies and procedures
Random	As indicated for suspicion	As indicated for suspicion
Employee Completing	Medical Employee	Custody Employee
Follow-up for Positive Findings	Documentation of finding and patient follow-up in the electronic health record. ***Cannot be used for the disciplinary process***	A positive result may only be confirmed by a clinician, qualified within their scope of practice, to review UDS laboratory results. May be used for disciplinary action if positive for anything other than prescribed medication(s).

[1]**SCHEDULED** UDSs should not be conducted on a regular basis (i.e., at the same time each month)

C. DISCONTINUATION OF MEDICATION FOR OPIOID USE DISORDER

OUD is a chronic, relapsing disease. **As with other chronic conditions, such as diabetes or hypertension, failure to maintain adherence to all requirements of treatment is not normally an adequate reason for discontinuation.** Throughout treatment, patients should be encouraged to engage in behavioral therapy and maintain adherence to medication for OUD.

When patients are less adherent to the treatment plan, the primary goals should be to keep the patient on medication and work toward greater adherence. If a patient refuses or fails to show for 3 or more doses within a 7-day period, a health services employee should follow-up with the patient to explore reasons for missed or refused doses, including assessment for signs of withdrawal. At times, a patient's failure to meet treatment expectations may warrant a pause or decrease in medication or conversion to a different formulation to encourage greater compliance. Discontinuation of medication should only be considered after collaborative discussion with the patient, the behavioral health team, and the medical team. Discontinuation of OUD medication without a patient evaluation is not an acceptable practice. Monthly OUD staff meetings can be a setting to discuss the potential for intensifying or discontinuing medication for OUD. Discussions with the patient regarding discontinuation of medication will be documented in the EHR. If, after discussion, the patient chooses to discontinue the medication for OUD, a medical treatment refusal will be signed and scanned into the EHR. Refer to **MODULE 3. EVALUATION AND TREATMENT INITIATION** for additional guidance regarding treatment refusals. If possible, the medication should be tapered to avoid withdrawal symptoms.

➔ *Refer to Table 4 and the FBOP Clinical Guidance Medically Supervised Withdrawal for Inmates with Substance Use Disorder for guidance on tapering a patient off medication for OUD.*

If medication for treatment of OUD is being discontinued (voluntarily or involuntarily), patients should be encouraged to seek and engage with behavioral health counseling and/or health care providers. These providers should use motivational interviewing strategies to address stages of change or barriers to adherence. Patients should continue to be monitored for indications to restart treatment during incarceration or in preparation for release. If the medication was discontinued due to diversion, strong consideration should be given to reinitiating medication prior to release.

The following instances may warrant discontinuation of medication for OUD:

- Patient desires to discontinue or reduce medication for OUD
- Repeated attempts at diversion of medication in violation of treatment agreement, placing the patient and other AICs in danger
- Repeated non-compliance with adherence to directly observed therapy despite best efforts to educate the patient
- Disruptive, violent, or threatening conduct
- Repeated failures to report for behavioral health or medical appointments
- Failure to adhere to treatment agreements outlined in Informed Consent and/or Treatment Agreement

If the patient is voluntarily choosing to discontinue treatment the reason the patient is asking for discontinuation of OUD medication, the plan for tapering off current OUD treatment (if appropriate), and other forms OUD medications (if any) were offered during discussion of discontinuation must be

documented in the EHR. Additionally, a signed detailed treatment refusal form will be completed and uploaded in the EHR for all patients who refuse treatment with medication for OUD. The OUD Administrative Code will be updated to OUD Tx Discharged (OUDDC).

If the OUD medication is being involuntarily discontinued, the reason for discontinuation, the plan for tapering off current OUD treatment, and other forms OUD medications (if any) were offered at time discussion of discontinuation will be documented in the EHR. The OUD Administrative Code will be updated to OUD Tx Discharged (OUDDC).

TABLE 4. TAPERING RECOMMENDATIONS FOR DISCONTINUATION OF MEDICATION FOR OUD

DRUG NAME	DISCONTINUATION[1,2]
Methadone	• Abrupt discontinuation should be avoided unless clinically necessary. • Decrease dose by 5-10% of the maintenance dose every 1 to 2 weeks.[1, 2]
Buprenorphine oral[3]	• Abrupt discontinuation should be avoided unless clinically necessary. • Daily doses >8mg, reduce dose by 4 mg every 2 weeks • Daily dose <8mg, reduce dose by 2 mg every 2 weeks.
Buprenorphine long-acting injection	• Due to the long-acting formulation, tapering is not required for long-acting injectable buprenorphine.
Naltrexone oral	• Discontinuation can occur anytime without any risk of patient developing physical withdrawal symptoms.
Naltrexone long-acting injection	• Discontinuation can occur at any time without any risk of patient developing physical withdrawal symptoms; however, it may take 28 days after receiving the last injection for the effects to wear off.

[1] Even with a slow taper, physical withdrawal symptoms may still occur. The patient may be prescribed medications for short-term use to reduce withdrawal symptoms (see the *FBOP Clinical Guidance on Medically Supervised Withdrawal of Inmates with Substance Use Disorders*).

[2] Consider naltrexone after discontinuation (tablets or long-acting injection) to aid in the reduction of cravings and to help avoid any positive reinforcement (or euphoria) if a relapse should occur.

[3] The discontinuation schedule should be individualized to the patient and will also depend on length of treatment, genetic factors, metabolism, and other rationale in the electronic medical record.

MONITORING THE PATIENT DURING DISCONTINUATION

In addition to addressing the physical symptoms of withdrawal that may emerge during discontinuation, medical and behavioral health employees should continue to monitor and educate the patient on the following issues:

- Psychiatric comorbidities, especially anxiety and depression.
- Return and/or worsening of chronic physical pain.
- Somatic consequences of drug use including the risk of overdose death.
- Risk of acquiring infectious diseases (HIV/hepatitis) from illicit IV drug use.
- The importance of family education and support.
- Structuring time in pro-social activities and alternative adaptive coping mechanisms.

APPENDIX 1. EXAMPLE URINE DRUG SCREEN RESULTS

Quest Diagnostics™

Report Status: Final

[redacted]

Patient Information	Specimen Information	Client Information
[redacted]	[redacted]	[redacted]

Drug Monitoring Report

Test Ordered	Result	Cutoff	Lab
DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE			Z99
Alcohol Metabolites	NEGATIVE	500 ng/mL	
Amphetamines	NEGATIVE	500 ng/mL	
Benzodiazepines	NEGATIVE	100 ng/mL	
Buprenorphine	POSITIVE	5 ng/mL	
Buprenorphine	257	2 ng/mL	
Norbuprenorphine	221	2 ng/mL	
Naloxone	17	2 ng/mL	
Buprenorphine Comments: *See Buprenorphine Notes, LDT Notes*			
Cocaine Metabolite	NEGATIVE	150 ng/mL	
6 Acetylmorphine	NEGATIVE	10 ng/mL	
Marijuana Metabolite	NEGATIVE	20 ng/mL	
MDMA	NEGATIVE	500 ng/mL	
Opiates	NEGATIVE	100 ng/mL	
Oxycodone	NEGATIVE	100 ng/mL	

Test Ordered	Result	Reference Range	Lab
SPECIMEN VALIDITY TEST			Z99
Creatinine	101.4	> or = 20.0 mg/dL	
pH	6.2	4.5-9.0	
Oxidant	NEGATIVE	<200 mcg/mL	

NOTES AND COMMENTS

This drug testing is for medical treatment only. Analysis was performed as non-forensic testing and these results should be used only by healthcare providers to render diagnosis or treatment, or to monitor progress of medical conditions.

Buprenorphine Notes:
Buprenorphine, Norbuprenorphine detected is consistent with the use of the drug(s) Buprenorphine or Buprenorphine with Naloxone. Naloxone may be negative due to poor oral bioavailability and/or short half-life.
Buprenorphine, Norbuprenorphine, Naloxone detected is consistent with the use of the drug Buprenorphine and Naloxone.

LDT Notes:
Confirmation tests were developed and their analytical performance characteristics have been determined by Quest Diagnostics. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Healthcare Providers needing Interpretation assistance, please contact us at 1.877.40.RXTOX (1.877.407.9869) M-F, 8am to 10pm EST

Quest Diagnostics

Report Status: Final

[redacted]

Patient Information	Specimen Information	Client Information
[redacted]	[redacted]	[redacted]

Drug Monitoring Report

Test Ordered	Result	Cutoff	Lab
DRUG MONITOR, PANEL 5, SCREEN, URINE			AT
Amphetamines	NEGATIVE See Note A	500 ng/mL	
Barbiturates	NEGATIVE See Note A	300 ng/mL	
Benzodiazepines	NEGATIVE See Note A	100 ng/mL	
Cocaine Metabolite	NEGATIVE See Note A	150 ng/mL	
Marijuana Metabolite	NEGATIVE See Note A	20 ng/mL	
Methadone Metabolite	NEGATIVE See Note A	100 ng/mL	
Opiates	NEGATIVE See Note A	100 ng/mL	
Oxycodone	NEGATIVE See Note A	100 ng/mL	

Test Ordered	Result	Reference Range	Lab
SPECIMEN VALIDITY TEST			AT
Creatinine	204.5	> or = 20.0 mg/dL	
pH	5.9	4.5-9.0	
Oxidant	NEGATIVE	<200 mcg/mL	

NOTES AND COMMENTS

This drug testing is for medical treatment only. Analysis was performed as non-forensic testing and these results should be used only by healthcare providers to render diagnosis or treatment, or to monitor progress of medical conditions.

Note A:
The results are presumptive; based only on screening methods, and they have not been confirmed by a definitive method.

Healthcare Providers needing Interpretation assistance, please contact us at 1.877.40.RXTOX (1.877.407.9869) M-F, 8am to 10pm EST

MODULE 6. MEDICATION ADMINISTRATION AND DIVERSION CONTROL

WHAT'S NEW

- This Module has been renumbered to Module 6.
- Edits have been made throughout the module for formatting and clarity.
- The recommended observation time after oral buprenorphine film administration has been updated in the *Procedures for Administration of Oral Medication* section.
- *Procedures for Administration of Long-Acting Buprenorphine Injections* section updated to include Brixadi® information and best practices to reduce attempts to divert the injection.
- Section D. Substock Inventory removed. Facilities should refer to Program Statement 6360.02 Pharmacy Services for policies regarding controlled substance inventories.

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A. OVERVIEW

In addition to following the procedures for medication administration in **Program Statement 6360.02 Pharmacy Services,** this module reviews additional measures to reduce the risk of diversion of medication for opioid use disorder (OUD). Institutions may choose to implement additional procedures to reduce diversion risk.

Receiving medication for OUD does not exclude patients from the disciplinary process. If diversion is identified, incident reports and other disciplinary measures may be imposed, as appropriate and in accordance with **Program Statement 5270.09, CN-1 Inmate Discipline Program**, while the patient continues to receive treatment. All instances of diversion or attempts at diversion should be documented in the medical record along with counseling and corrective action taken.

- ***If a patient is caught diverting OUD medication, it is not grounds for immediate discontinuation of treatment.*** *A patient evaluation is necessary, and the multidisciplinary team should meet to discuss whether treatment should be continued, intensified, or modified as clinically indicated. All efforts should be focused on allowing the patient to continue in treatment. The team should also discuss procedures that can be put in place to prevent future diversion, such as increased vigilance in directly observed therapy procedures, or a change in medication or formulation.*

B. MEDICATION ADMINISTRATION

Reducing the risk of diversion begins with effective medication administration technique. Medication will be administered in accordance with **Program Statement 6360.02 Pharmacy Services** and the FBOP National Formulary. The following measures in this section may also be considered to help prevent diversion.

PROCEDURES FOR ADMINISTRATION OF ORAL MEDICATION

Institution decisions regarding pill line operations should include considerations for how procedures to reduce diversion will be implemented. Suggested methods to reduce diversion are described below.

- Conduct an initial mouth check prior to administration to ensure the oral cavity is cleared of any potential tools for diversion (such as dentures or peanut butter on the roof of the mouth).
- Remove the medication from the automated medication dispensing cabinet (AMDC) under the patient's profile and immediately administer to the patient.
  - The preferred method of methadone administration is orally (in a non-extended-release oral wafer or tablet) that is *crushed and floated in water*.
  - Buprenorphine-containing sublingual (SL) films or tablets should not be crushed or dissolved in water.
  - *To avoid excess medication, do not cut films or split dose formulations (e.g., for a 20 mg dose, use two 10 mg tablets instead of splitting a 40 mg tablet in half).*

(list continues on the next page)

- Because buprenorphine and methadone are both controlled substances, direct supervision is required for the duration of medication administration.
- Immediately following the administration of methadone, it is recommended the patient be instructed to drink water and/or eat crackers.
- **For buprenorphine-containing SL films:**
  - To aid dissolution and absorption, UpToDate recommends instructing patients to wet their palate by swishing and swallowing water prior to strip placement.
  - Per the manufacturer drug package insert, instruct patients to place one film under the tongue close to the base on the left or right side. If more than one film is needed, place the additional film under the tongue on the opposite side from the first film. Place the films in a manner to minimize overlapping as much as possible. Do not move film after placement. If a third film is necessary to achieve the prescribed dose, place it under the tongue on the left or right side after the first two films have dissolved.
  - Once the film is administered, employees will ensure initiation of the dissolution process. The local Pharmacy and Therapeutics (P&T) committee will determine whether to implement an observation time. If implementing an observation time, a 30-second window is typically sufficient to confirm the strip has begun to dissolve. There is no clinical evidence that longer observation periods either improve patient outcomes or reduce diversion.
  - After administration, conduct a second mouth-check to ensure the film is properly placed under the tongue and has begun to dissolve. Once placement has been confirmed, the patient may be excused from pill line.

PROCEDURES FOR ADMINISTRATION OF LONG-ACTING BUPRENORPHINE INJECTIONS

- Injectable buprenorphine is approved for subcutaneous injection and administered by healthcare employees properly trained in the applicable long-acting injection's REMS requirements for administration. Refer to the manufacturer package insert for approved sites for injection. Proper injection techniques should be utilized to decrease the possibility of injection site leakage and mitigate the potential for misuse.
- If refrigeration is required, remove the injection from the refrigerator under the patient's profile at least 15 minutes prior to administration to allow the dose to come to room temperature.
  - If the injection is refrigerated prior to administration, the best way to avoid injection site pain is to allow the medication to come to room temperature prior to injection.
- Following the injection, a small amount of blood and/or fluid at the injection site is typical and should be wiped away. A larger amount of leakage could indicate inappropriate injection technique. The following injection techniques should be utilized to prevent leakage
  - The patient should discard any gauze used, and it is recommended that a bandage *not* be applied to injection site.
  - Once the entire contents of the syringe have been injected, release the pinched skin but do not remove the needle/syringe.
  - Wait 3-5 seconds to ensure any medication in the bevel of the needle itself has been fully administered.

- Slowly remove the needle at the same angle as the injection.

- The patient may be tempted to manipulate the injection site in an attempt to extract medication. It is recommended the patient be instructed to not touch the injection site and sit/lay in the clinic setting under observation for 5-10 minutes post injection.

➔ *Refer to the* package inserts *for Sublocade® and Brixadi ®for additional guidance on administration of injectable long-acting buprenorphine.*

PROCEDURES FOR ADMINISTRATION OF LONG-ACTING NALTREXONE INJECTIONS

- Injectable naltrexone is approved for deep intramuscular injection into a gluteal muscle only.
- The medication should be removed from the refrigerator at least 45 minutes prior to administration to allow the dose to come to room temperature.

➔ *Refer to the package insert for additional guidance on administration of long-acting injectable naltrexone.*

PROCEDURES FOR DIVERSION ATTEMPTS

Patients may divert medications for different reasons – they may be coerced to divert, or the dose may not be adequate to control symptoms and the patient is attempting to hoard or adjust doses to desired effect. After a diversion attempt is reported, it is important for a provider to follow-up with the patient to evaluate reasons for diversion and adjust the treatment plan, such as provide tailored patient education, adjust the dose to better manage symptoms, change medication formulation, increase behavioral or counseling therapy services, or re-evaluate accuracy of diagnosis. Discerning why a patient is attempting to divert will improve outcomes of tailored interventions. Patients receiving long-acting buprenorphine injections should be counseled that any attempt to manipulate the injection site is viewed as a diversion attempt. If an attempt to divert medication is observed, the observing employee will:

- If applicable, complete an Incident Report in accordance with **Program Statement 5270.09 CN-1 Inmate Discipline Program.**
- Discuss instances of suspected or confirmed diversion with the institution Clinical Director and/or at the monthly OUD Staff meeting.
- Refer to **MODULE 5** for detailed guidance regarding medication discontinuation.

ADMINISTRATION RECORDS

Per *21 CFR 1304.22(c)*, federal regulations require dispensers maintain complete and accurate records of all medication administration activities. Upon completion of medication administration and the observation period (if required), medication administration will be documented in the electronic (eMAR) or paper medication administration record according to Program Statements **6360.02 Pharmacy Services** and **6031.05 Patient Care.**

C. RECORD AUDITING

In accordance with **Program Statement 6360.02 Pharmacy Services**, the Institution Chief Pharmacist or designee will review all controlled substance discrepancy reports daily, ensuring documentation on the eMAR matches removal from the AMDC. If discrepancies cannot be resolved, institutions should follow procedures in PS 6360.02.

MODULE 7. SPECIAL POPULATIONS

WHAT'S NEW

- Minor revisions to grammar and formatting have been made throughout the module.
- This Module has been renumbered to Module 7.

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A. PREGNANCY

For pregnant patients, both the American Society of Addiction Medicine (ASAM) and the American College of Obstetrics and Gynecology (ACOG) recommend continuing medication for opioid use disorder (OUD) over initiating medically-supervised opioid withdrawal because of the high rate of relapse among those not on medication for OUD. All pregnant patients with recent opioid use and who are at risk for withdrawal, including pregnant patients entering custody already on medication for OUD, should receive a **prompt referral** to a provider authorized to provide medication for OUD as well as referral to an obstetrician.

For all pregnant patients who have active OUD, treatment with either buprenorphine or methadone is indicated as a component of comprehensive prenatal care. Opioid agonist and partial agonist therapies reduce the maternal-fetal risks of untreated OUD, including the risk of death by overdose and blood-borne infectious diseases. Additional risks associated with opioid misuse during pregnancy include preeclampsia, placental abruption, placental insufficiency, fetal growth retardation, miscarriage, and fetal death. Neonatal abstinence syndrome (NAS), also called opioid withdrawal syndrome, can occur with active opioid use, to include with agonist or partial agonist opioids used to treat OUD, during pregnancy.

Treatment with medication for OUD has been shown to improve maternal and neonatal outcomes by reducing maternal mortality and severe morbidity, improving the infant's birth weight, and reducing the overall frequency of obstetrical complications.

- *All women of childbearing age should receive information on the risk of NAS prior to starting any medication for OUD, including the Substance Abuse and Mental Health Services Administration (SAMHSA) documents on this subject: Healthy Pregnancy Healthy Baby Fact Sheets | SAMHSA Publications and Digital Products*

Monitoring of medication for OUD during pregnancy is the same as for the non-pregnant patient, including regular follow-up evaluations and urine drug testing. Refer to **MODULE 5. MONITORING AND FOLLOW-UP** for additional guidance.

Buprenorphine has several advantages over methadone for pregnant patients:

- Buprenorphine does not require dose adjustments during pregnancy (whereas methadone typically requires higher doses during the second or third trimester due to changing maternal metabolism).
- NAS is typically less severe with buprenorphine than with methadone.

Per the ACOG committee opinion reaffirmed in 2021 **–** *The buprenorphine monoproduct (without naloxone) had been recommended during pregnancy to avoid any potential prenatal exposure to naloxone, especially if injected. However, recent studies evaluating the use of the combination product buprenorphine with naloxone found no adverse effects, and outcomes were similar when compared with buprenorphine alone*. The use of buprenorphine monoproduct (without naloxone) is approved for pregnant patients in the FBOP. Long-acting buprenorphine products are not typically recommended for pregnant patients. Providers are encouraged to consult with an addiction medicine specialist if long-acting buprenorphine is considered.

Methadone is also a viable choice for treatment of OUD and may be considered for all pregnant patients, but especially in the following circumstances:

- Patient is already stable on methadone and continuing medication for OUD during pregnancy.
- Patient cannot tolerate buprenorphine.
- Patient expresses preference for methadone after adequate counseling on treatment options.

Due to increased metabolism and circulating blood volume in the second and third trimester of pregnancy, **methadone dose may need to be increased** or switched to twice daily if symptoms of withdrawal or cravings are reported by the patient. During the postpartum period, titration to lower doses of methadone may be needed to avoid sedation.

It is not recommended to start naltrexone during pregnancy, owing to insufficient evidence on the safety and efficacy of use during pregnancy. Patients already taking naltrexone may continue naltrexone during pregnancy; however, it may also be appropriate to transition to methadone or buprenorphine. If the patient's risk for relapse is low, it may be appropriate to discontinue OUD treatment if the patient and provider agree. Of note, a pregnant patient maintained on naltrexone will be refractory to narcotic analgesics in postpartum recovery.

- *A naltrexone or naloxone challenge dose is contraindicated in pregnancy because of the risk of precipitating opioid withdrawal.*

B. PAIN MANAGEMENT

It is likely that patients with OUD will at some point experience acute and/or chronic pain. It is important to properly identify the etiology of pain to treat the patient safely and effectively.

Non-pharmacologic treatments should be considered when available and appropriate for treatment of pain, to include dental pain. If pharmacologic treatment is indicated, non-narcotic medications such as acetaminophen and NSAIDs should be tried first, if appropriate. Adjunctive medications including anticonvulsants, tricyclic antidepressants, topical analgesics, and norepinephrine-serotonin reuptake inhibitors may also be used.

- *See the FBOP Clinical Guidance on Pain Management of Inmates for more information for both pharmacologic and non-pharmacologic treatment options.*
- *Providers may consult with OUD Clinical Pharmacy Consultants for further guidance on pain management for patients prescribed medication for OUD.*

CO-OCCURRING CHRONIC PAIN AND OPIOID USE DISORDER

Per the National Institute on Drug Abuse Common Comorbidities with Substance Use Disorders Research Report, *chronic pain is a physical problem that has a complex relationship with substance use disorders, particularly opioid misuse and addiction.* *Chronic pain and associated emotional distress are thought to dysregulate the brain's stress and reward circuitry, increasing the risk for opioid use disorder.* Patients who are being treated for chronic pain should be routinely evaluated for OUD.

It is not uncommon for a patient to have both chronic pain and opioid use disorder. If a patient is being treated for chronic pain with an FDA-approved medication for OUD (i.e., methadone or buprenorphine) and has a co-occurring opioid use disorder/opioid dependence diagnosis, the patient should be offered/referred for additional behavioral support and services.

ACUTE AND/OR CHRONIC PAIN MANAGEMENT

- **Naltrexone:** Patients on naltrexone will not respond to opioid analgesics due to its blockade effect on the opioid receptor. Mild acute pain may be treated with non-opioid analgesics and moderate to severe pain may be treated with high-potency NSAIDs (e.g., ketorolac). If opioids are indicated, discontinuation of naltrexone is required prior to initiation of opioid therapy.
- **Buprenorphine:** Temporarily increasing buprenorphine dose and/or dividing doses may be effective for acute pain not controlled with non-opioid analgesics. Analgesic effects of buprenorphine typically last 6 to 8 hours, while the effect on cravings lasts up to 24 hours. For severe acute pain, discontinuing buprenorphine and initiating a high-potency opioid may be necessary. Patients should be monitored closely and interventions such as regional anesthesia and/or non-opioid therapy should be considered.
- **Methadone:** For severe acute pain, temporarily increasing the methadone dose or dosing frequency may be effective in patients where pain is not controlled with non-opioid analgesics. Similar to buprenorphine, the analgesic effects of methadone typically last 6 to 8 hours, while the effect on cravings may last 24 to 36 hours. For severe acute pain not responding to an increase in dose or dosing frequency, administration of short-acting opioids in addition to methadone may be considered. Use of non-opioid therapies is recommended to manage chronic pain when possible.

PERI-OPERATIVE PAIN MANAGEMENT

Whenever possible, prior to surgical intervention, institutions must notify the community surgical team of the patient's current OUD treatment plan and coordinate plans for perioperative pain management.

- **Naltrexone**: Oral naltrexone should be discontinued 72 hours before surgery and extended-release injectable naltrexone should be discontinued 30 days before an anticipated surgery. When restarting naltrexone postoperatively, a three-to-seven-day period of abstinence from opioids is recommended.
- **Buprenorphine:** Discontinuation of buprenorphine before surgery is not required; however, if the decision to discontinue buprenorphine before an elective surgery is made, it should be done in consultation with the attending surgeon, the anesthesiologist, and the addiction treatment provider. If buprenorphine is discontinued before surgery, this should occur about 24 hours in advance of the surgery, and buprenorphine should be restarted postoperatively when the need for intravenous full opioid agonist analgesia has passed.
- **Methadone:** Discontinuation of methadone before surgery is not necessary. Patients on methadone for the treatment of OUD and admitted for surgery may require short-acting opioid pain relievers in addition to methadone. The prescribed dose of opioid analgesics may need to be increased due to tolerance.

C. CO-OCCURRING PSYCHIATRIC DISORDERS

It is common for individuals with OUD to have a concurrent psychiatric disorder. Studies have shown a higher prevalence of substance use in people with psychiatric disorders compared to the general population. However, co-occurring psychiatric disorders should not prevent patients from being considered for medication for OUD.

In addition to psychiatric disorders, active substance use, as well as withdrawal, are independent risk factors for suicide. It is important to screen all patients being considered for treatment with medication for OUD for any co-occurring psychiatric disorders and suicide risk.

Due to their higher risk, patients with psychiatric disorders on medication for OUD should be closely monitored for suicidal ideation and actively engaged in treatment with a mental health professional. In addition, prior to initiation, patients should be negative for suicidal and homicidal ideation and stable on current psychiatric therapy. Throughout stabilization and maintenance phases, patients should be closely monitored for any acute changes in their mental health.

Forensic restoration or "study" patients with a co-occurring OUD diagnosis may be eligible for treatment of OUD. There are no absolute contraindications to the concurrent use of psychiatric medications and medications for OUD. Side effects may be mitigated by slow dosing of agonist medications and close monitoring for signs of sedation, intoxication, or other side effects. Providers are encouraged to consult with an addiction medicine specialist in cases where significant mental health disorders may co-exist with OUD prior to determining treatment options.

D. AGING AND ELDERLY PATIENTS

Like managing other chronic disease states, special care should be given to aging and elderly patients with respect to identifying OUD and considering and implementing treatment. For the purposes of this document and pursuant to **PS 5241.01 Management of Aging Offenders**, the term "aging" refers to individuals who are 50 to 64 years old and "elderly" refers to individuals who are 65 years or older.

DIAGNOSIS AND ASSESSMENT

Aging and elderly patients with OUD may be difficult to identify due to several factors, including:

- OUD is more often associated with younger age groups.
- Aging and elderly patients may be in denial as to the impact of OUD on their social environment.
- Age-related changes and/or comorbid medical conditions can mask signs of OUD.

It is critical to understand that OUD can impact individuals of all ages and in all stages of life. With the aging of the Baby Boomer population (those born between 1946 and 1964), the healthcare system can expect an increased prevalence of aging and elderly patients with chronic conditions, including OUD.

Strategies to overcome barriers to identifying OUD in aging and elderly patients include the following:

- Educate all patients on OUD, including risk factors, symptoms, and available treatment.
- Educate providers and other members of the healthcare team on how to screen, diagnose, refer, and/or treat a diverse range of patients with OUD.
- Reduce stigma or hesitation associated with seeking OUD treatment by using destigmatizing language and using patient-centered approaches to therapy.

The diagnostic criteria in **MODULE 3. EVALUATION AND TREATMENT INITIATION** are used to diagnose all patients, *regardless of age*. However, several specific signs and symptoms can help providers recognize possible OUD in aging and elderly patients:

- History of falls: conduct risk assessments and ask about falls regularly
- Presence of GI conditions, especially constipation, which is a common adverse effect of opioid use
- Presence of co-existing or worsening cognitive impairment or psychiatric conditions, which can be exacerbated by opioid use.
- Irregular sleep; insomnia or somnolence may be a side effect of chronic opioid use
- Change in mental status, which can be caused by opioid misuse

In addition to the above symptoms, the Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP) is a validated screening tool for use in elderly patients to determine the risk of adverse drug events and the potential for inappropriate prescribing or misuse of opioids.

TREATMENT CONSIDERATIONS

When a patient has been diagnosed with OUD, all treatment options should be considered. However, there are age-specific factors to account for when selecting and initiating treatment for OUD. For example, aging and elderly patients may have difficulty understanding the medical system or treatment directions, whether due to natural aging or neurocognitive impairment (e.g., dementia).

Older patients also have higher rates of:

- Pain
- Psychiatric disorders
- Renal and hepatic dysfunction due to chronic disease and/or aging
- Polypharmacy and/or multiple prescribers/specialists providing care leading to drug-drug or drug-disease interactions

➔ *Refer to **MODULE 4. MEDICATION FOR OPIOID USE DISORDER** for medication considerations as well as related FBOP clinical guidance documents to manage aging and elderly patients with characteristics that may complicate OUD treatment.*

While no FDA-approved medication for OUD is contraindicated in aging and elderly patients, providers should consider the following in addition to other unique patient factors and medication information covered in previous sections:

BUPRENORPHINE

- Therapy should be initiated with a lower dose compared to the general population and titrated even more cautiously; "start low and go slow."

- Half-life is more predictable compared to methadone and less influenced by renal and hepatic impairment.
- Therapeutic effects can be prolonged in older adults, potentially allowing for oral dosing every other day.

METHADONE

- Aging and elderly patients receiving methadone maintenance treatment have similar outcomes compared to younger patients with regard to treatment success and reduced relapse.
- Therapy should be initiated with a lower dose compared to the general population and titrated even more cautiously; "start low and go slow".
- There is an increased risk in elderly patients for sedation and QTc prolongation leading to torsade de pointes. Refer to **MODULE 3. EVALUATION AND TREATMENT INITIATION** for discussion of cardiac risk evaluation.

NALTREXONE

- As in other patient populations who meet criteria for naltrexone, the long-acting injection is preferred. The oral formulation is recommended only if the patient is highly motivated and cognitively able to adhere to daily dosing.

*Refer to **PS 5241.01 Management of Aging Offenders** for additional FBOP procedures for managing aging and elderly patients.*

MODULE 8. TRANSITIONS OF CARE

WHAT'S NEW

- Minor revisions to grammar and formatting have been made throughout the module.
- *Section A. Aftercare Planning* has been updated considerably.
- Information has been added throughout the module on the Harm Reduction and Reentry Toolkit.
- *Section D. Procedures for Providing Release or Transfer Medication* and *Table 1. Summary of Days Supply* have been updated to clarify procedures for methadone take home doses.
- *Appendix 1. OUD Aftercare for Full-term Release Without Onsite Social Work* added.
- *Appendix 2. OUD Aftercare for Full-term Release With Onsite Social Work* added.

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A. AFTERCARE PLANNING

Providing quality care and treatment includes planning for what will happen when a patient leaves the institution. As the selection of a particular medication for Opioid Use Disorder (OUD) may be influenced by future community access, **aftercare planning must begin with the patient during the initial evaluation and continue throughout treatment via regular multidisciplinary team meetings.** If future community resources are unknown, medication should be selected based on other confirmed patient factors and preferences as discussed in **MODULE 3. EVALUATION AND TREATMENT INITIATION**. Providers should coordinate aftercare planning with the Transitional Care Team (TCT) and/or Social Work as recommended in the following situations.

FULL-TERM RELEASE AT AN INSTITUTION WITHOUT A SOCIAL WORKER

For patients who are full-term release and will not be going to an RRC or HC, and in a screening status (BEMR Admin codes: OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete) or actively receiving medications for OUD prior to release must receive an aftercare plan or aftercare resources. It is the institution's responsibility to ensure continuity of care is addressed. Guidance for institutions without a social work onsite is provided below.

→ *Refer to Appendix 1. OUD Aftercare for Full-term Release Without Onsite Social Work for a summary of the following guidance.*

PATIENTS ON ACTIVE TREATMENT

An aftercare plan is required for all patients who are actively receiving treatment at release. Transitional Care Social Work (TCSW) will develop comprehensive aftercare plans for these patients. To initiate this process, the institution must complete the *MAT Aftercare Social Work Referral Form* and *MAT Release of Information* (ROI), available on the Health Services Division – Transitional Care page on Sallyport, and send to *BOP-HSD-MATSocialWork-S@bop.gov*. These forms should be sent as close to 90 days prior to release as possible, but no later than 14 days prior to release to ensure sufficient time to complete a comprehensive plan. Both forms are located on the FBOP intranet on the Health Services Division OUD Resources page on Sallyport. The referral form should be completed as much as possible, but at an absolute minimum, the referring institution must provide a confirmed release address and release date, as well as name and contact information for the assigned FBOP case manager. Upon receipt of the referral form and ROI, TCSW will complete a comprehensive, individualized aftercare plan for each patient. This aftercare plan will include the following information:

- Community provider contact information and an intake appointment **or** instructions for completing a same day access/walk-in intake, as determined by receiving clinic procedure.
- Medicaid/healthcare application and/or instructions for alternative funding sources.
- Contact information for accessible primary care and behavioral health treatment.
- Appropriate crisis lines, hotlines and information for the 2-1-1 locator service.
- Local Narcotics Anonymous contact information and additional recovery and community resources as available and appropriate.
- Contact information for assigned probation office, as appropriate.
- Documentation of release medication, including number of doses provided at release and due

date of next injection (if applicable).

The completed plan and additional reentry resources will be sent via email to the appropriate probation office (when applicable), the institution point of contact and/or the referring provider. These documents should be printed onsite and provided to the patient once received. Additional resources will be provided via link or attachment, to include the following:

- *Harm Reduction and Reentry Toolkit* available on the Health Services Division – Transitional Care page on Sallyport
- Local state Medicaid application (located on Tab 1 of the *OUD Reentry Guide* available on the Health Services Division – Transitional Care page on Sallyport)
- Other documents as appropriate to individual needs (e.g., community resource guide, clinic admission documents, local harm reduction information, etc.)

TCSW will complete a BEMR MAT Aftercare Plan note documenting the plan and resources sent to the institution. A BEMR note indicating that these items have been received by the patient should be completed by the employee who directly provided these documents to the patient.

PATIENTS IN AN OUD SCREENING STATUS

All patients releasing in a screening status (BEMR Admin codes: OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete) should receive aftercare and reentry resources prior to release. A referral is not needed for these patients. TCSW will notify probation of the release as appropriate and send reentry resources to the institution via link and/or attachment, to include the following:

- *Harm Reduction and Reentry Toolkit* available on the Health Services Division – Transitional Care page on Sallyport
- Releasing state page from the *OUD Reentry Guide* available on the Health Services Division – Transitional Care page on Sallyport
- Local state Medicaid application (located on Tab 1 of the *OUD Reentry Guide*)

TCSW will complete a BEMR MAT Aftercare Plan note documenting the resources sent to the institution. The institution must ensure that all resources are printed and provided to the patient prior to release. A BEMR note indicating that these items have been received by the patient should be completed by the employee who directly provided these documents to the patient.

FULL-TERM RELEASE AT AN INSTITUTION WITH SOCIAL WORKER ONSITE

→ Refer to Appendix 2. OUD Aftercare for Full-term Release With Onsite Social Work for a summary of the following guidance.

For patients who are full-term release and will not be going to an RRC or HC, the institution social worker will facilitate aftercare for all patients receiving medications for OUD, as well as those releasing in a screening status (BEMR Admin codes: OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete) at their respective institutions. TCSW is available to advise on aftercare plans and the aftercare process, as needed. Email *BOP-HSD-MATSocialWork-S@bop.gov* to request a consultation.

PATIENTS ON ACTIVE TREATMENT

The institution social worker will complete a comprehensive, individualized aftercare plan for each patient actively receiving medications for OUD at release. Aftercare related calls and any collateral or patient contacts should be documented as they occur using the BEMR MAT Aftercare Plan note.

This aftercare plan will include the following information:

- Community provider clinic contact information and an intake appointment **or** instructions for completing a same day access/walk-in intake, as determined by receiving clinic procedure.
- Medicaid/healthcare application and/or instructions for alternative funding sources.
- Contact information for accessible primary care and behavioral health treatment.
- Appropriate crisis lines, hotlines and information for the 2-1-1 locator service.
- Local Narcotics Anonymous contact information and additional recovery and community resources as available and appropriate.
- Contact information for assigned probation office, as appropriate.
- Documentation of release medication, including number of bridge doses provided at release and due date of next injection (if applicable).

In addition to the aftercare plan, the resources listed below must also be provided to the patient:

- *Harm Reduction and Reentry Toolkit* available on the Health Services Division – Transitional Care page on Sallyport
- Local state Medicaid application (located on Tab 1 of the *OUD Reentry Guide* available on the Health Services Division – Transitional Care page on Sallyport)
- Additional local resources as appropriate to individual needs (other healthcare or recovery resources, housing resources, reentry programs, etc.)

Efforts leading up to the completed aftercare plan should be consistently documented in BEMR using the MAT Aftercare Plan note. The aftercare plan should be provided to the patient and documented in BEMR using the MAT Aftercare Plan note no less than one week prior to release or transfer. If the patient has additional release planning needs related to their medical or mental health care level, this note type must still be used for the specific OUD aftercare plans.

PATIENTS IN AN OUD SCREENING STATUS

All patients releasing in a screening status (BEMR Admin codes: OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete) must receive aftercare and reentry resources prior to release. The institution social worker should monitor all upcoming releases and ensure that the following resources are provided, at a minimum:

- *Harm Reduction and Reentry Toolkit*
- Releasing state page from the *OUD Reentry Guide*
- Local state Medicaid application (located on Tab 1 of the *OUD Reentry Guide*)
- Additional local resources as appropriate to individual needs (other healthcare or recovery resources, housing resources, reentry programs, etc.)

The institution social worker will complete a BEMR note using the MAT Aftercare Plan note documenting the resources provided to the patient.

RELEASE TO RESIDENTIAL REENTRY CENTER OR HOME CONFINEMENT TRANSFERS

Aftercare planning for patients transferring to Residential Reentry Center (RRC) or home confinement (HC) for less than 14 days should be completed by TCSW or onsite social work, using the appropriate process for full term releases, either active on treatment or in a screening status, as described above.

Evaluation and treatment of patients who remain in a screening status at the time of their transfer and have more than 14 days at an RRC or HC will be managed by Community Treatment Services (CTS). No further action will need to be taken by the institution.

Aftercare planning for patients active on treatment and transferring to RRC or HC for more than 14 days will be addressed by the TCT and CTS. TCSW referral and onsite social work aftercare planning are not required for these patients. Aftercare coordination between the TCT and CTS is as follows:

- TCT will notify CTS of all patients who are actively receiving medication for OUD with a scheduled RRC or HC transfer date once they begin medication **or** receive transfer dates.
- TCT will notify the institution of any potential concerns with medication supply, ensuring that each patient has a minimum of 14 days of medication coverage after transfer.
- TCT will notify CTS when a patient has transferred to RRC/HC.
- TCT notifications will include the type of medication prescribed and injection dates/days of coverage (if applicable).
- TCT will coordinate with CTS and institutions regarding any questions about medication supply after transfer.

B. HARM REDUCTION

Harm reduction focuses on meeting patients where they are in their recovery process while keeping them engaged in strategies to reduce the likelihood of negative consequences for them and their communities, such as overdose, infectious disease, relapse, and recidivism. Quality care and treatment includes incorporating various harm reduction strategies with aftercare planning to appropriately address patient needs as they transition from the institution back to the community.

HARM REDUCTION AND REENTRY TOOLKIT

Regardless of method of release, all patients at risk for overdose, including those with any BEMR admin code for OUD, should be provided with the *FBOP Harm Reduction and Reentry Toolkit*. This toolkit provides necessary information and resources for patients to continue or seek treatment and to reduce the risk of adverse events after release. All previous FBOP Harm Reduction psychoeducational handouts are included in the Toolkit, along with additional Harm Reduction information, recovery guides and reentry resources.

NASAL NALOXONE (NARCAN®)

Nasal naloxone is recommended for all patients identified with OUD or otherwise at risk for opioid overdose upon release or transfer to an RRC or HC, regardless of whether they are actively receiving medication for OUD while in custody. These patients should be prescribed nasal naloxone prior to release or transfer to RRC or HC. The provider should ensure that the patient is educated to recognize

the signs of opioid overdose and how to administer naloxone. It should also be stressed that patients should inform others of where they keep their naloxone as they will not be able to self-administer in the event of an overdose.

- *Refer to BEMR and the Harm Reduction and Reentry Toolkit for a patient handout on nasal naloxone administration.*

HIV PRE-EXPOSURE PROPHYLAXIS

Approximately 36,000 people in the United States are infected with HIV each year. A key strategy for ending the HIV epidemic is the use of pre-exposure prophylaxis (PrEP), a prevention method in which people who are not infected with HIV, but who may be at risk of exposure, take preventative medication to reduce their risk of acquiring the virus. Studies show that when taken daily, PrEP can reduce a person's risk of acquiring HIV from intravenous (IV) drug use by at least 74% and from sex by up to 99%. IV drug use is a major risk factor for acquiring HIV, and all patients with a history of IV drug use should be educated on and offered PrEP prior to release from custody.

- *For additional information regarding PrEP, refer to the FBOP Clinical Guidance for HIV Management.*

FENTANYL TEST STRIPS

Fentanyl is a synthetic opioid 50 to 100 times more potent than morphine. Over 82% of all opioid overdose-related deaths are caused by fentanyl and other synthetic opioids. Test strips can be used to identify the presence of fentanyl in a substance. Patients should be educated about fentanyl test strips and referred to the State Opioid Treatment Authority (SOTA) *i*n their release state for further information about availability and legality of fentanyl test strips in their area.

- *Refer to the Harm Reduction and Reentry Toolkit for a patient handout on fentanyl test strips.*

NEEDLE EXCHANGE PROGRAMS

Needle exchange programs (NEPs), also known as syringe service programs (SSP), provide access to clean and sterile needles/syringes for people who use IV drugs. NEPs also facilitate the safe disposal of used needles. NEPs often provide access to other services such as to medical care, infectious disease screening, substance use treatment, and community resources. NEPs are not currently legal in all states.

- *A directory of available NEPs can be located here*: *NASEN | North America Syringe Exchange Network: NASEN Directory*.

C. MEDICATION CONSIDERATIONS PRIOR TO RELEASE

For patients who declined medication for OUD or were unable to comply with their treatment plan resulting in discontinuation of treatment during incarceration, initiation of treatment in preparation for release should be considered. The selection of medication for OUD prior to release should be based on factors described in **MODULE 4. MEDICATION FOR OPIOID USE DISORDER** and should involve a full evaluation as described in **MODULE 3. EVALUATION AND TREATMENT INITIATION.**

- *Initiation of medication for OUD prior to release should be conducted with enough time to establish an effective maintenance dose (refer to **MODULE 4. MEDICATION FOR OPIOID USE DISORDER**), evaluate tolerability and compliance with treatment, and arrange transition of care to the community. Typically, this will take 30 to 90 days. In instances where there is insufficient time to establish treatment, TCT should be notified to arrange evaluation for treatment and/or follow-up upon release.*

CONVERSION OF MEDICATION FOR OUD PRIOR TO RELEASE

A patient may have limited ability to continue certain medications for OUD upon release. There may be health insurance considerations or a lack of OTP access in geographic proximity to the releasing community. In these situations, it is important to discuss alternative treatment options to provide the highest likelihood of continuity of care. The choice to convert to a different treatment should be based on a combination of clinical factors and patient preference. Conversion prior to release should be conducted as described in **MODULE 4. MEDICATION FOR OPIOID USE DISORDER** and with enough time to confirm tolerability of effective maintenance dosing.

D. PROCEDURES FOR PROVIDING RELEASE OR TRANSFER MEDICATION

Except for long-acting injectable medications (i.e., Vivitrol ®, Sublocade®, or Brixadi®), patients receiving medication for OUD who are transferring to RRC, HC, or full-term release should be provided with the maximum supply of OUD medication allowed by policy and DEA regulations. Refer to *Table 1* for a summary of day supply considerations for release or transfer medications. The following bullets summarize procedural considerations for providing release medications:

- Prior to release, facilities should document in the medical record that the patient has been clearly informed of the responsibility they have to maintain security of medication for OUD.
- Per BOP Program Statement 5800.18 Receiving and Discharge Manual, *R&D staff ensure the inmate receives medication before leaving the institution.*
- Some facilities may choose to give a small quantity of medication to the patient and ship the remaining days supply to the RRC with signature required upon delivery.
  - Per *21 CFR 1301.74*: *When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.* Only FBOP-contracted carriers may be utilized. The United States Postal Service cannot be used to ship controlled substances. **FedEx and UPS are both authorized to ship controlled substances.**
- Once medications have been received by the RRC, unless the patient is returning to a facility, any unused medications should not be returned to the facility and the RRC should dispose of it per their procedures for destruction of controlled substances.

(Table 1 begins on the following page)

TABLE 1. SUMMARY OF DAYS SUPPLY FOR RELEASE OR TRANSFER

	Oral buprenorphine-containing medications (Suboxone©, Subutex©)	Methadone (FBOP)[1]	Methadone (Community OTP)[1]
RRC **Home Confinement** **Full Term Release**	Up to 30 days supply[2]	**First 14 days of treatment:** up to 7 days supply **15 to 30 days of treatment:** up to 14 days supply **31 days of treatment:** up to 28 days supply *Lock box recommended*	Coordinate take-home dose quantities with community OTP. *Lock box required*
FBOP to FBOP Transfer	7 days supply	7 days supply *Tamper-evident sealed bag recommended*	Coordinate take-home dose quantities with community OTP. *Tamper-evident sealed bag required*

[1] It remains within the FBOP provider's discretion to determine the number of take-home doses within each category of 'stable' or 'less stable'.
[2] Some facilities may choose to give a small quantity (e.g., 7 days supply) of medication to the patient and ship the remaining days supply to the RRC with signature required upon delivery.
[3] Refer to TCT for further guidance

BUPRENORPHINE CONSIDERATIONS

Oral buprenorphine-containing medication may be prescribed similarly to other controlled substances within regulations. A maximum of 30 days supply may either be given to the patient, mailed to the final destination, or a combination thereof. Arrangements for access to long-acting injectable buprenorphine will be coordinated by the FBOP institution social worker or TCT. ***No injectable medications will be sent with the patient.***

METHADONE CONSIDERATIONS

RECOMMENDED QUANTITY OF TAKE-HOME DOSES

A "take home" dose refers to any methadone dose given outside of the confines of the prescribing institution, to include medication sent with a patient upon release to home confinement, release on good conduct time, or transfer to RRC. The FBOP recommendations for methadone take-home doses is consistent with *Title 42 Part 8.12 of the Code of Federal Regulations Opioid Treatment Program*:

> *In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the*

therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

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

It remains within the FBOP provider's discretion to determine the number of take-home doses to be sent with the patient. However, the following restrictions for days supply limits must be followed and the rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record:

- If a patient has been on methadone 14 days or less, the take-home supply should not exceed 7 days.
- If the patient has been on methadone 15 to 30 days, the take-home supply should not exceed 14 days.
- If the patient has been on methadone 31 days or greater, the take-home supply should not exceed 28 days.

If methadone is provided through a community OTP, the local OTP may have additional restrictions regarding procedures for take-home doses and institutions should ensure the OTP is notified of impending release as early as possible.

SECURITY OF TAKE-HOME DOSES

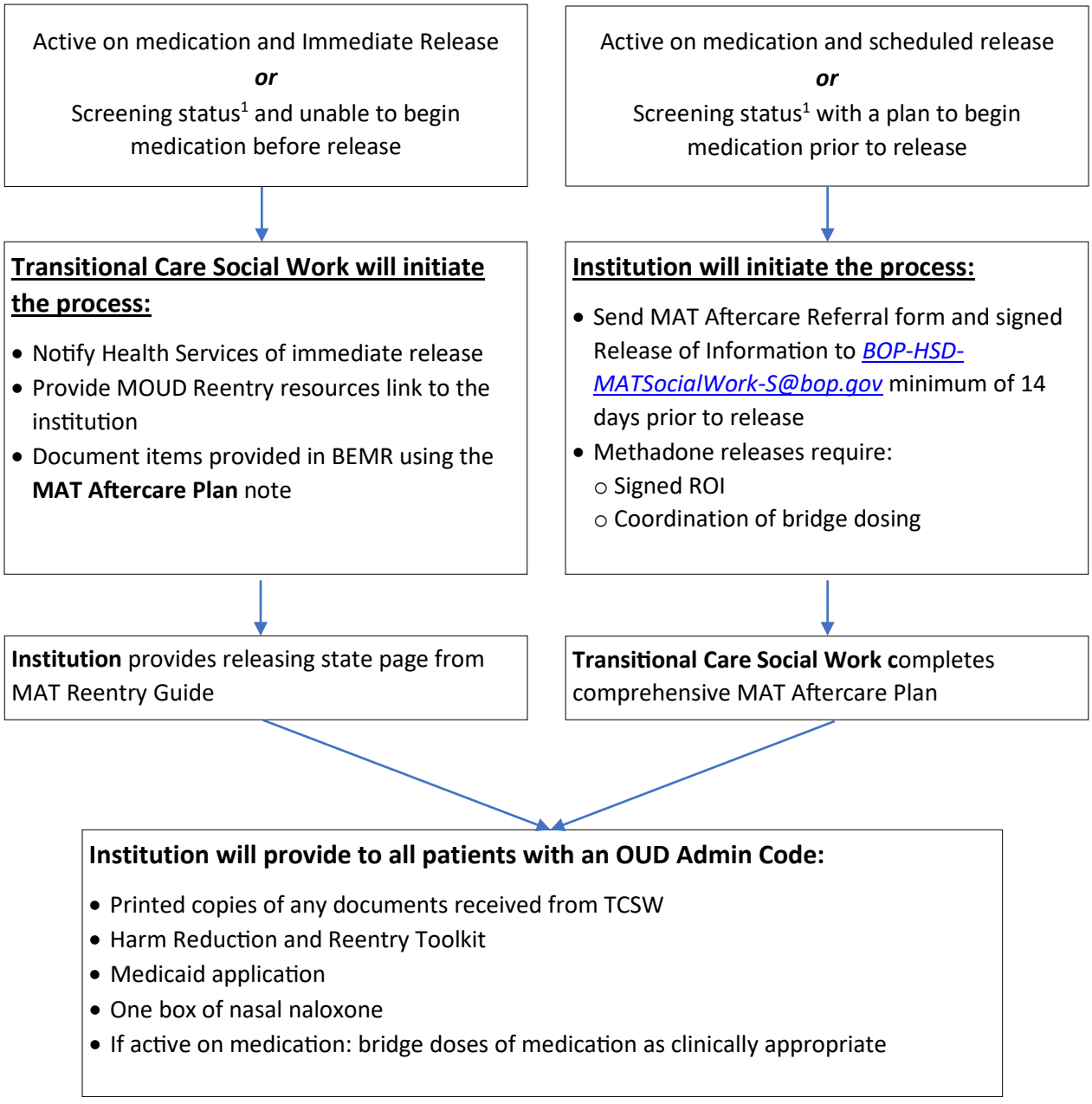
FBOP recommendations for security of methadone take-home doses are consistent with *SAMSHA Federal Guidelines for Opioid Treatment Programs*, **Guidelines for Security of Take-Home Medication:** *Patients receiving unsupervised (take-home) medication* [i.e., methadone] *should use a locked container to inconspicuously and safely transport take-home medication packaged in individual bottles that are labeled in accordance with the regulations and store the medication at home. The regulations do not mandate that patients use a specific type of locking container.*

An Example of an appropriate lock box is below:

https://www.medline.com/product/Medication-Lock-Box/Pill-Reminders/Z05-PF19247?question=box

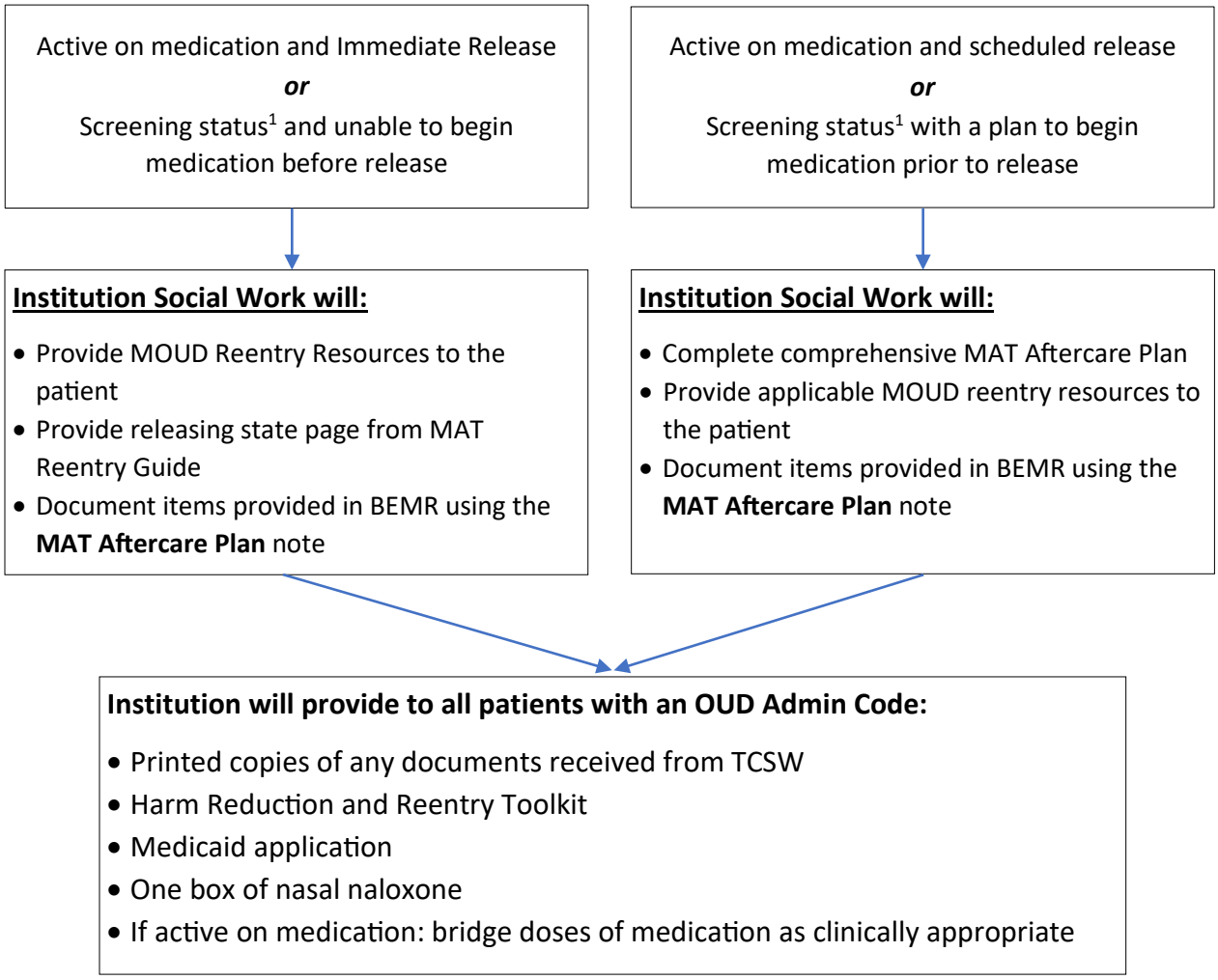
If the patient is transferring from one FBOP location to another, a tamper-evident sealed bag is sufficient for transport.

APPENDIX 1. OUD AFTERCARE FOR FULL-TERM RELEASE WITHOUT ONSITE SOCIAL WORK



[1] Screen status includes any patient with a BEMR Administrative Code of OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete

APPENDIX 2. OUD AFTERCARE FOR FULL TERM RELEASE WITH ONSITE SOCIAL WORK



[1] Screen status includes any patient with a BEMR Administrative Code of OUD TX Screening Indicated, OUD TX Psych Screen Complete, OUD TX Medical Screen Complete