

STANDARD OF CARE

Buprenorphine

2023

Northern Idaho

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PURPOSE

The **Buprenorphine Standard of Care** is a guide created for primary care providers in Northern Idaho who treat patients with opioid use disorder (OUD). The included information intends to support addressing addiction as a chronic, treatable illness in a clinical setting. The tools and resources inside can be personalized to your practice including:

- Best practices
- Medication information
- Special populations recommendations
- Risk Evaluation and Mitigation Strategy (REMS) Criteria
- Supporting resources

TECHNICAL ASSISTANCE CONTACT

Panhandle Health District
SUD Team at
208-415-5285.

We hope you find this document helpful as you grow services to meet the needs of your patients and our community. We aim to support your medication for opioid use disorder (MOUD) services. Should you have any questions, concerns, or feedback, please contact the Panhandle Health District at 208-415-5285.

INTRODUCTION

Section 1262 of the Consolidated Appropriations Act, 2023 (also known as Omnibus bill), removes the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications, like buprenorphine, for the treatment of opioid use disorder (OUD). It also removes other federal requirements associated with the waiver such as discipline restrictions, patient limits, and certification related to provision of counseling.

All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law (US Department of Justice, 2023).

PREVALENCE OF SUBSTANCE USE DISORDER IN IDAHO

In comparison to state and national rates, the five northern counties of Idaho (Benewah, Bonner, Boundary, Kootenai, and Shoshone) have elevated opioid prescribing rates with a limited treatment and recovery workforce providing services. Data prepared by the Board of Pharmacy and Prescription Monitoring Program report the average mean number of opioid prescriptions dispensed per 100 persons. In 2020, the opioid prescription rate in Northern Idaho was 84.3/100 compared to state of Idaho at 61.21/100 and the national rate of 43.3/100 (DOPL, 2023), (US CDC, 2021).

The Panhandle Health District rate per 100 persons exceeds the peak national prescribing rate of 81.3/100 in 2012. Shoshone County holds the highest rate in the target service area at 109.8/100 in 2020, down from 159.49/100 in 2016. This rate translates to enough opioids dispensed for every person in the county to have roughly 1 prescription where the average prescription length was written for two weeks (DOPL, 2023), (CDC, 2021).

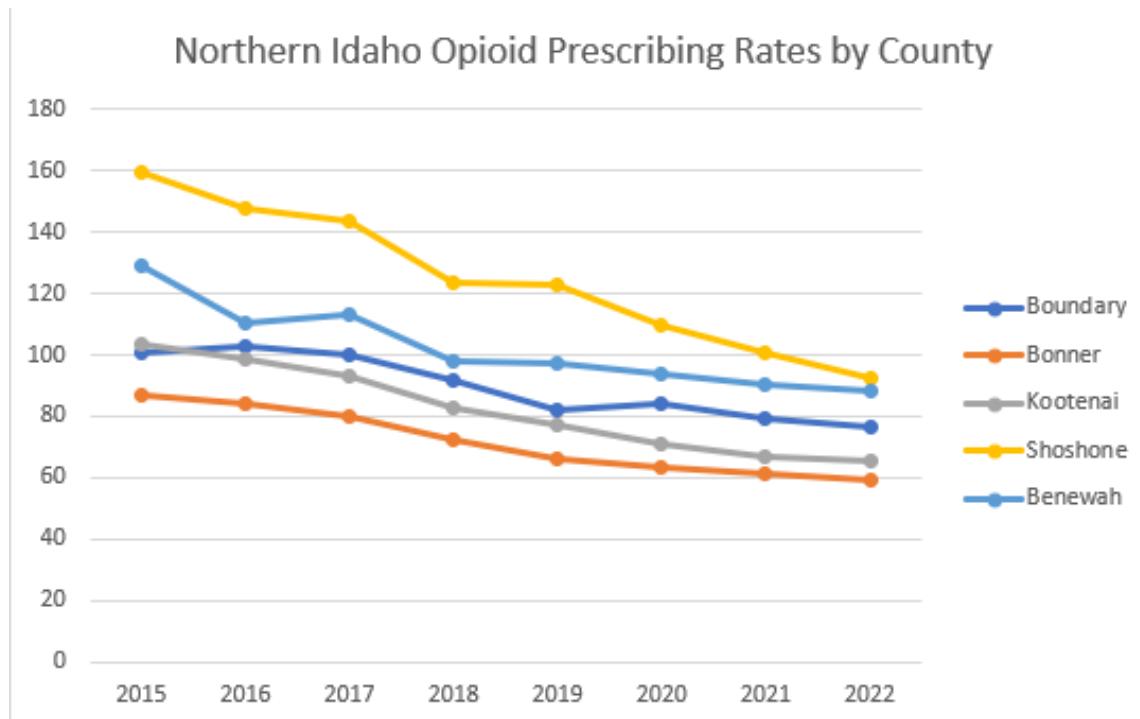


Figure 1. Rate of opioid prescriptions per 100 people by county in District 1.

Additional information from the Washington Post analyzed data from the Drug Enforcement Administration's Automation of Reports and Consolidated Orders System, known as ARCOS. Data from 2006 to 2012 revealed the following information regarding the number of prescription pain pills supplied to pharmacies in the district (Washington Post, 2020).

Benewah County

From 2006 to 2012, there were 3,372,120 prescription pain pills, enough for 51 pills per person per year, supplied to Benewah County, Idaho.

Bonner County

From 2006 to 2012, there were 12,246,020 prescription pain pills, enough for 43 pills per person per year, supplied to Bonner County, Idaho.

Boundary County

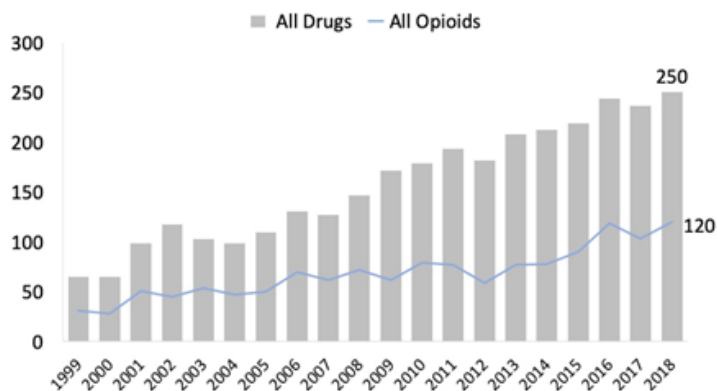
From 2006 to 2012, there were 3,607,840 prescription pain pills, enough for 47 pills per person per year, supplied to Boundary County, Idaho.

Kootenai County

From 2006 to 2012, there were 39,147,088 prescription pain pills, enough for 41 pills per person per year, supplied to Kootenai County, Idaho.

Shoshone County

From 2006 to 2012, there were 6,836,010 prescription pain pills, enough for 75 pills per person per year, supplied to Shoshone County, Idaho.



According to the Bureau of Vital Records and Health Statistics, between 2012 and 2018, 52% of drug-related deaths in District 1 were opioid-involved compared to the state of Idaho's rate of 45%. Furthermore, since 1999, approximately half of Idaho opioid overdose deaths have been caused by prescription opioids.

2.1 million people in the United States are estimated to have OUD (Dydyk et al., 2023).

Figure 2. The number of drug overdose deaths in Idaho. Drug categories presented are not mutually exclusive, and deaths may have involved more than one substance (CDC Wonder, 2021).

MEDICATION FOR OPIOID USE DISORDER (MOUD)

The goal of treatment for opioid addiction or opioid use disorder (OUD) is remission of the disorder leading to lasting recovery. Recovery is a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. This treatment approach has proved to be clinically effective and has been shown to:

- Improve patient survival
- Increase retention in treatment
- Decrease illicit opioid use and other criminal activity among people with substance use disorders
- Increase patients' ability to gain and maintain employment
- Improve birth outcomes among women who have substance use disorder and are pregnant
- Decrease HIV and hepatitis C contraction

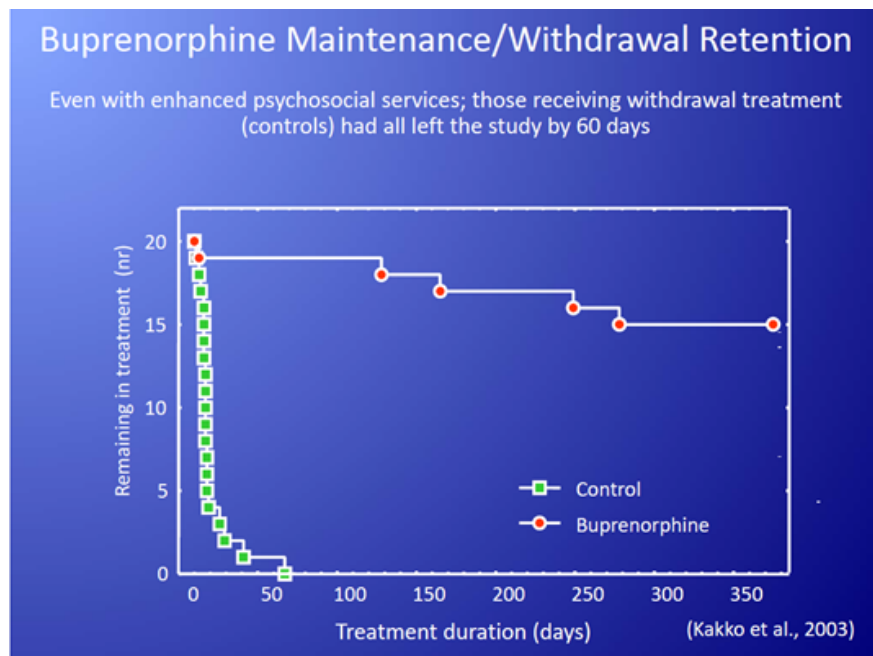


Figure 3. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomized, placebo-controlled trial (Kakko et al., 2003).

APPROVED MEDICATION

The Food and Drug Administration has three medications approved for OUD: methadone, naltrexone, and buprenorphine. This document is focused on clinical best practices for buprenorphine and suggests the combination with naloxone as the preferred clinical recommendation for MOUD to increase the protective factors for the patient.

FDA APPROVED MEDICATION FOR OUD

methadone
naltrexone
buprenorphine

MONO-PRODUCT (BUPRENORPHINE) FOR MOUD

Buprenorphine (mono-product)	
Pharmacology	Partial agonist
Regulations	Schedule III Visit SAMSHA for updated regulations:
Available Dosage Strengths of Buprenorphine (mono-products)	
Buprenorphine sublingual tablet (Subutex® available as generic)	2 mg, 8 mg
Buprenorphine long-acting subcutaneous injection (Sublocade®)	100 mg/0.5 mL, 300 mg/1.5 mL * Healthcare settings and pharmacies must be certified in the Sublocade® REMS program and only dispense the medication directly.

COMBINATION-PRODUCT (BUPRENORPHINE/ NALOXONE) FOR MOUD

COMBINATION-PRODUCT (BUPRENORPHINE/ NALOXONE)	
Pharmacology	Partial agonist and antagonist
Regulations	Schedule III Visit SAMSHA for updated regulations:

Corresponding Doses of Buprenorphine Products that Contain Naloxone

Buprenorphine/ naloxone sublingual tablet (available as generic)	Buprenorphine/ naloxone sublingual tablet with menthol flavor (Zubsolv®)	Buprenorphine/ naloxone buccal film (Bunavail®)
	0.7 mg/0.18 mg	
2 mg/0.5 mg	2 mg/0.5 mg	1.4 mg/0.36 mg
	4 mg/1 mg	2.9 mg/0.71 mg
8 mg/2 mg	8 mg/2 mg	2.1 mg/0.3 mg
	5.7 mg/1.4 mg	4.2 mg/0.7 mg
	12 mg/3 mg	8.6 mg/2.1 mg
	6.3 mg/1 mg	
	11.4 mg/2.9 mg	

WHY COMBINE BUPRENORPHINE WITH NALOXONE?

The combination product is a safer option with protective factors to reduce misuse, diversion, and overdose. Appropriate monotherapy use is limited to special populations discussed in further detail: Use of Buprenorphine/naloxone in Special Populations/situations.

The combination product is correctly administered sublingually or buccal. The response is that buprenorphine is highly bioavailable, and naloxone is minimally absorbed.

THE COMBINATION PRODUCT IS SAFER

Suboxone
Zubsolv
Bunavail
Sublocade

Incorrect Route of Administration	Protective Factor Response
Intravenous Injection	The combination product will have 100% naloxone bioavailability and will precipitate opioid withdrawal. Additionally, it will blunt or slow the early onset of buprenorphine.
Inhalation	The combination product will have a higher percentage of naloxone absorbed. This amount does not typically precipitate complete opioid withdrawal but has been demonstrated to elicit modest, disagreeable withdrawal-related effects and delay the early onset of buprenorphine (Yokell et al., 2011), (Walsh et al., 2016).

FIRST STEPS

Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder | Effective June 27th, 2023

On December 29, 2022, the Consolidated Appropriations Act of 2023 enacted a new one-time, eight-hour training requirement for all Drug Enforcement Administration (DEA)-registered practitioners on the treatment and management of patients with opioid or other substance use disorders. All DEA-registered practitioners, with the exception of practitioners that are solely veterinarians are responsible for satisfying this new training requirement.

Beginning on June 27, 2023, practitioners will be required to check a box on their online DEA registration form—regardless of whether a registrant is completing their initial registration application or renewing their registration—affirming that they have completed the new training requirement.

There are multiple ways that practitioners can satisfy this new training requirement.

First, the following groups of practitioners are deemed to have satisfied this training:

Group 1: All practitioners that are board certified in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, the American Board of Addiction Medicine, or the American Osteopathic Association.

Group 2: All practitioners that graduated in good standing from a medical (allopathic or osteopathic), dental, physician assistant, or advanced practice nursing school in the United States within five years of June 27, 2023, and successfully completed a comprehensive curriculum that included at least eight hours of training on:

- Treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or
- Safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

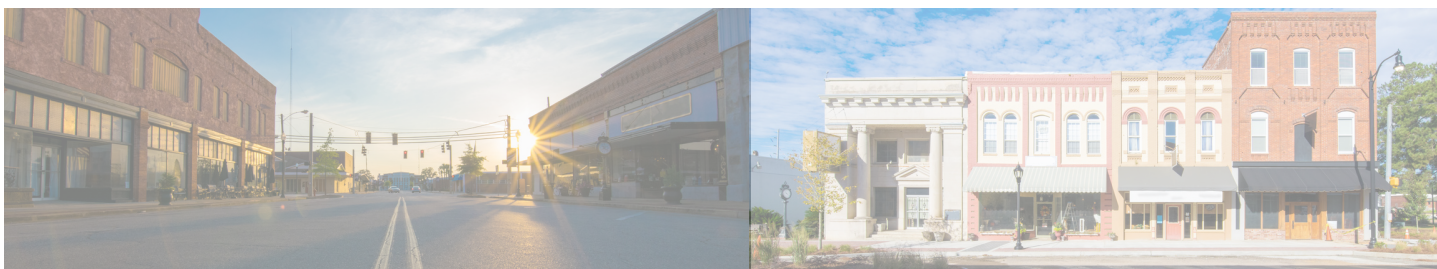
Second, practitioners can satisfy this training by engaging in a total of eight hours of training on treatment and management of patients with opioid or other substance use disorders from the groups listed below. A few key points related to this training:

- The training does not have to occur in one session. It can be cumulative across multiple sessions that equal eight hours of training.
- Past DATA-Waived trainings count towards a DEA registrant's 8-hour training requirement.
- Trainings can occur in a variety of formats, including classroom settings, seminars at professional society meetings, or virtual offerings (US Department of Justice, 2023).

- Past trainings on the treatment and management of patients with opioid or other substance use disorders can count towards a practitioner meeting this requirement. In other words, if you received a relevant training from one of the groups listed below— prior to the enactment of this new training obligation on December 29, 2022—that training counts towards the eight-hour requirement.

Accredited groups who may provide trainings that meet the new requirement:

- The American Society of Addiction Medicine (ASAM)
- The American Academy of Addiction Psychiatry (AAAP)
- American Medical Association (AMA)
- The American Osteopathic Association (AOA), or any organizations accredited by the AOA to provide continuing medical education
- The American Dental Association (ADA)
- The American Association of Oral and Maxillofacial Surgeons (AAOMS)
- The American Psychiatric Association (APA)
- The American Association of Nurse Practitioners (AANP)
- The American Association of Physician Associates (AAPA)
- The American Nurses Credentialing Center (ANCC)
- Any other organization accredited by the Accreditation Council for Continuing Medical Education (AACCME) or the Commission for Continuing Education Provider Recognition (CCEPR), whether directly or through an organization accredited by a State medical society that is recognized by the ACCME or CCEPR
- Any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR (DEA; Drug Enforcement Administration, 2023).



FIND A FREE MOUD TRAINING

- [SAMHSA](#)
- [PCSS](#)

REFERRALS

Check your agency listing on these commonly used referral sites. When someone is ready for treatment, ease of access is essential for the person, their support system, and minimizing appointment hesitation. New appointments can come from self-referrals, care teams, or social services. Maximizing community knowledge of MOUD providers through online databases reduces confusion for people and clinicians seeking services.

Please complete this application form to request that your facility be added to SAMHSA's Inventory of Treatment: [Findtreatment.gov](#)

MEDICATION OF OPIOID USE DISORDER (MOUD) PSYCHOSOCIAL SUPPORT

Be prepared to refer patients for psychosocial support by establishing a referral pipeline of cognitive behavioral therapy, individual and group counseling, or other forms of psychosocial treatment. These support services can increase engagement, MOUD retention rates, and the speed of recovery-supportive behaviors. A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay the pharmacological treatment of OUD.

“Once patients express interest in discontinuing or diminishing drug use, the core of care depends on the same kinds of cognitive behavioral approaches used for other chronic, relapsing conditions, such as hypertension and diabetes mellitus. These approaches include working with patients to encourage motivation to change, enhance adherence to medication through education, reward cooperation with treatment guidelines, keep motivation high, and teach ways to minimize relapses to drug use. Most of these elements are part of motivational interviewing.”
(Schuckit, 2016).

See the HHS recent evidence and current practice for psychosocial support in MOUD [here](#).

Create a relationship with a referring agency for smooth and timely warm handoffs. Support groups, peer supports, and counseling services can be found [here](#).

READINESS CHECKLIST

Tool Purpose: This tool is designed to be a helpful guide for leadership for any healthcare provider considering prescribing MOUD. The questions in this document can assist in determining organizational readiness to implement MAT. Please note that other tools may be more suitable depending on your practice's design and makeup.

The questions for this readiness checklist are organized into five key sections (National Council for Mental Wellbeing, 2020):

- Organizational readiness
- Economic and regulatory readiness
- Workforce readiness
- Community readiness
- Patient and caregiver readiness

PRINTABLE
VERSION OF THE
CHECKLIST

INTAKE APPOINTMENT PROCESS

If REMS is required, check *Appendix M: REMS for Buprenorphine Combination Product Prescribing*

BEST PRACTICE

Local Resource



ADOPTED FROM
KOOTENAI HEALTH
EMERGE PROGRAM

Welcome and clinic introductions

Medical History:

- Current and past medical problems.
- Current prescription medications.
- Does the patient have a primary care provider (PCP)?
- If yes, have the patient sign the release of information so notes can be sent.
- If there is no PCP, encourage getting established.
- Chemical Dependency History (when, duration, amount, route, last used).
- *Appendix D: MOUD Program Substance Use Intake Questionnaire*

Treatment history:

- Inpatient vs. outpatient?
 - If inpatient – detox or withdrawal?
- Was treatment completed?
- When?
- How many times?
- Meetings (Recovery group, AA, NA, church group, etc)?

Mental Health History:

- Screen for coexisting psychiatric illness (depression, anxiety, suicidality).
- Assess need for psych referral.

Social History:

- Housing
- Relationships
- Family
- Work
- Stressors

Substance Use History:

- Allow the patient to tell their story.
- Be a non-judgmental, quiet listener, and provide compassion. These strategies help build trust and a sense of safety.
- Guide with questions.
 - Tell me about your story.
 - Age when substance use started? Why? How has use progressed?
- Use the patient's completed pre-appointment worksheet for question guidance.

Formulate an Assessment and plan with the patient:

- Is medication for Opioid Use Disorder (MOUD) appropriate and desired for this patient?
- Which medication?
- Goals of treatment? Stabilize or taper off?
- Is inpatient or outpatient induction needed?
- Is Chemical Dependency Therapy recommended?
- Detox and treatment without medication assistance?
 - **Special circumstances only. Safety plan in place for overdose prevention.**

If appropriate for MOUD, review with the patient:

- Name and form of medication being prescribed.
- Use plain language (e.g., Suboxone, thin film).
- How to use and store selected medication.
- Potential Side Effects (not an exhaustive list).
 - Withdrawal if the patient stops taking or if taken with other opioids.
 - Danger when combined with alcohol or benzodiazepines.
 - Endocrine and metabolic effects may occur, such as adrenal insufficiency. Monitor patients with Addison disease, myxedema, or hypothyroidism.
 - Cardiovascular patients should avoid use with Class 1 (e.g., disopyramide) or Class 3 (e.g., amiodarone) antiarrhythmic medications or if they have a prolonged QT.
 - Falls, syncope, and orthostatic hypotension may occur with this medication.

Explain program expectations.

- Stolen or lost medications will not be replaced; the patient must keep them safe!
- Take medication as prescribed, never independently adjusting dose (amount and frequency).
- They may be asked to go to an inpatient chemical dependency program if they are not taking the prescription as prescribed.
- Use best practices to minimize diversion and medication misuse.
- Educate on never sharing medication with anyone for any reason—a negative urine screen for buprenorphine can cause dismissal from the program.

Random urine drug screens.

- Review expectations and policy. *Appendix L: MOUD Guidelines for Monitoring Urine Drug Test – Specimen Collection*

Safe keeping of opioid medications.

- Keep out of reach of children. Medications are safest up and away.
- If possible, do not let others (including youth family members) know where you keep your MOUD prescription.
- If you can, keep medications locked in a drawer, cupboard, or box.
- Free medication lock boxes for patients are available at Panhandle Health District.

Offer and strongly encourage counseling.

- Provide the patient with a referral to counseling and recovery groups.

FOR PREGNANT PATIENTS

Additional intake questions:

- OB History: (If establishing OB with your clinic, only brief history here, as this should be a separate in-depth appointment)
- Current OB provider?
- Brief OB history (G's/ P's, complications, risk factors)
- Current prenatal course thus far, any concerns/complications?
- Why we use medication, and how it can help reduce harm in pregnancy to mom and newborn.
- Withdrawal from Subutex can be very dangerous to pregnancy.
- Withdrawal in newborns, and potential for Neonatal Abstinence Syndrome (NAS).

Recommended consistent ongoing counseling and group therapy during pregnancy and after delivery:

- Motivational interviewing
 - We are here to help with a safe pregnancy for the woman and infant.
 - Our goal is to help keep moms and babies together and healthy after delivery.
 - Get connected with needed resources.
 - Be their relentless advocate in this new journey to sobriety and motherhood!

INDUCTION PROCESS AND PROTOCOL

Induction General Items

1. Set induction day and expectations.
2. Set up follow-up appointments:
 - a. 1 day
 - b. 2-4 days
 - c. 2 weeks after induction day
3. Provide prescriptions needed for induction day and any medications for symptomatic withdrawal (ondansetron, clonidine, loperamide, sleep aid, NSAID, etc.)
4. Make sure all contracts specific to MOUD care are signed (suggested at a minimum):
 - a. Appendix H: Consent for Treatment with Buprenorphine example
 - b. If applicable, Appendix I: Consent for Treatment with Buprenorphine During Pregnancy
 - c. Appendix J: Buprenorphine Program Treatment Agreement
5. Labs, if indicated (CMP, hepatitis B/C HIV, Pregnancy test)
6. EKG if indicated (Heart risks, antipsychotic meds <QT prolongation risk>)
7. Referrals set up if indicated (Chemical Dependency Treatment Inpatient or IOP (Intensive Outpatient Therapy), Psychiatrist, OB, other)
8. Release of information (OB, PCP, Chemical Dependency, Parole Officer, Child Protective Services)

INDUCTION

The induction or initiation of buprenorphine/naloxone therapy starts when the patient is experiencing moderate withdrawal symptoms from opioids (COWS >12) to avoid precipitated withdrawal. The time between the last dose of opioid and the first dose of buprenorphine/naloxone varies depending on if the opioid is short-acting (e.g., morphine, oxycodone, hydrocodone, heroin) or long-acting (e.g., methadone and controlled release formulations such as OxyContin®* or MS Contin®* or Duragesic patches).

INDUCTION IS TO BE PLANNED FOR 6 TO 12 HOURS AFTER THE LAST DOSE OF SHORT-ACTING OPIOIDS OR AT LEAST 24 HOURS AFTER THE LAST USAGE OF LONG-ACTING OPIOIDS.

Please note, if a patient is taking maintenance methadone, it is recommended that the prescribing methadone opioid treatment program (OTP) work with the patient for the switch from methadone to buprenorphine. The dose of methadone is to be tapered down to 30mg or less and is a carefully monitored process. Induction with buprenorphine/naloxone is planned for at least 72 hours after the last dose of methadone to decrease the risk of intense precipitated withdrawal symptoms.

See below for a guide on the induction process. In most patients, the buprenorphine/naloxone maintenance dose is achieved within a two-to-four-day period. The gradual increase in dosage is done according to each patient's individualized physical and psychological needs and should generally not exceed a maximum of 24mg of buprenorphine in one day. **Many patients respond to dosing between 8 and 12 mg daily** (National Alliance of Advocate for Buprenorphine Treatment, n.d.).

- Instruct patient on how to take their MOUD product (not limited to dosing, frequency, potential side-effects, when to call for assistance, follow up protocol, and pharmacy expectations) and provide the patient information about induction.
- Administer the patient's first dose (4 mg) of selected MOUD after moderate opioid withdrawal symptoms have developed.
- Consider using an opioid withdrawal scale for patient assessment: *Appendix F: Clinical Opioid Withdrawal Scale (COWS)* or *Appendix G: Subjective Opioid Withdrawal Scale (SOWS)* if starting induction at home.
- Remind the patient that opioid withdrawal symptoms usually alleviate in 20-40 minutes following the first dose of buprenorphine.
- If possible, observe the patient for 1-2 hours.
- Dispense or prescribe a second dose of 4 mg of selected MOUD if no precipitated withdrawal is observed.
- The usual first-day dose is 8 mg. Clinicians have reported prescribing a third dose (2-4 mg) to be taken later in the evening if needed for withdrawal symptoms.
- Assess patient response to the first day's dosing. If opioid withdrawal symptoms were entirely suppressed and the patient feels no withdrawal between doses, then keep the dose at the first day's total dose; otherwise, increase the dose by 2 or 4 mg on day 2.
- Assess patient response to the second day's dosing. If opioid withdrawal symptoms are fully suppressed, and the patient is feeling no withdrawal between doses, then keep the dose at the second day's dose; otherwise, increase the dose by 2 or 4 mg selected MOUD on day 3.
- After three days, once the patient is stable, or after a target dose of 16 mg selected MOUD or more is achieved, continue at that dose for 3-7 days until steady-state levels are achieved before increasing the dose further.
- Decrease doses by 2 mg at a time if the patient experiences intoxication (not withdrawal effects).

PRECIPITATED WITHDRAWAL

When a partial agonist (e.g., buprenorphine) or a full antagonist (e.g., naloxone) replaces an opioid receptor agonist (e.g., heroin, fentanyl, morphine), a precipitated opioid withdrawal can occur.

Symptoms of precipitated opioid withdrawal are severe and include increased heart rate, diaphoresis, agitation, diarrhea, tremor, irritability, anxiety, restlessness, tearing, rhinorrhea, vomiting, and piloerection (Haroz, Carroll, & Strayer, 2020).

Treatment:

1. Explain to the patient what has happened and how you can treat the symptoms.
2. Precipitated withdrawal is largely reversible with higher doses of buprenorphine.
3. Provide empathetic, compassionate, and apologetic support.
4. Manage symptoms with clonidine, loperamide, NSAIDs, or anti-emetics. Avoid benzodiazepines.
5. Encourage and motivate the patient to try again soon or continue if able.

TIPS TO AVOID

PRECIPITATED WITHDRAWAL:

- ENSURE THE PATIENT IS IN ADEQUATE WITHDRAWAL BEFORE STARTING INDUCTION.
- START AT A LOWER DOSE OF BUPRENORPHINE/NALOXONE.
- PROVIDE MORE FREQUENT ASSESSMENTS.

BEST PRACTICES

Understanding and overcoming common barriers to care for your patients and our Northern Idaho community is important for successful clinic-based MOUD services (Kelly, 2018).

USE INCLUSIVE LANGUAGE

- Use comparable medical terminology whenever possible.
- Use person-first language. For example, a person is not actively using drugs, versus their urine is clean.
- Avoid using stigmatizing terms. Stigmas are ever-changing but essential to keep all staff updated to provide an inclusive clinical setting. See Figure 4.
- Share solutions and options that locally exist.
- Provide details of those solutions.
- Humanize the condition.
- Use reliable sources.
- Communicate information about the many different pathways to recovery, including harm reduction and patient-centered successes.
- Given the big picture, SUD is a chronic disease, not an acute condition.
- Returning to use is normal and should be addressed but not penalized.

**USING INCLUSIVE LANGUAGE
CAN INCREASE SOMEONE'S
HOPE, CONFIDENCE, AND
WILLINGNESS TO SEEK
TREATMENT.**

Making the choice to avoid stigmatizing someone is more than being "kind" or "politically correct." Language can shape perceptions about someone's capacity to change.



Instead of:	Say:
Xdrug abuse	→ ✓ drug use
Xaddict, junkie Xdrug abuser	→ ✓ person who uses drugs
Xclean / dirty	→ ✓ not actively/ actively using drugs
Xcrazy, disturbed Xpsycho, schizo Xlunatic	→ ✓ person with a mental illness / condition
Xcommitted suicide	→ ✓ died by suicide / lost to suicide
Xhomeless person Xhobo, bum, transient	→ ✓ person who is homeless
Xthe homeless	→ ✓ person who is homeless/those that are homeless
Xfelon, convict	→ ✓ returning citizen

Figure 4. Stigma Reducing Language Guide (Recovery Research Institute, n.d.)

COORDINATE SUPPORT SERVICES

Provide a whole-patient approach by offering additional care coordination and support services for patients. Use a social needs screening tool to steer conversations about what services a patient may need. See Appendix A for a sample Social Determinants of Health Screening Tool.

Close loop referrals for food, housing, goods, transit, health, money, care, education, work, and legal services are available by zip code on Find Help Idaho: www.findhelpidaho.org

NALOXONE

Naloxone, an opioid antagonist, attaches to opioid receptors blocking the effects of opioids and reversing respiratory depression when administered for opioid overdose.

**BEST PRACTICE: LOCAL RESOURCE
ANTI-STIGMA CAMPAIGN
STORIESFROMNORTHIDAHO.ORG
REFERRALS
WWW.FINDHELPIDAHO.ORG
NALOXONE
WWW.NOTSCARYTOCARRY.ORG**

Idaho law permits providers, pharmacists, pharmacy technicians, and other healthcare professionals to prescribe and dispense naloxone to anyone at risk for an opioid-related overdose or to anyone who may encounter an at-risk individual. Every patient seen for MOUD should be offered a naloxone prescription (National Institute on Drug Abuse, 2023).

Free naloxone and other harm reduction services are available at NIAC (North Idaho Alliance of Care) and Heritage Health Recovery Services. Additional naloxone education and additional information can be found at www.notscarytocarry.org

NALOXONE HAS NO EFFECT IF ADMINISTERED TO A PERSON IN RESPIRATORY DEPRESSION FOR REASONS OTHER THAN AN OPIOID OVERDOSE. WHEN IN DOUBT, ADMINISTER NALOXONE.

	Brand	Strength
Naloxone Nasal Spray	Narcan® (OTC available)	4 mg/0.1 mL
	Kloxxado®	8mg/0.1mL
Naloxone Injection (Intramuscular)	Generic	0.4 mg/mL 4 mg/10 mL
Nalmefene Hydrochloride	Opvee	0..27 mg/mL 2.7 mg/10 mL

TELEHEALTH BENEFITS

Telehealth is a supported best practice for MOUD to minimize barriers to care. Specifically for people in rural settings, telehealth reduces transportation needs, fears of stigmatizing office visits, and allows for comprehensive care not limited to:

- Access providers and specialists, including mental and behavioral health, for chronic health conditions and medication management.
- Participate in supporting modalities as a hybrid approach to in-person care for optimal health.
- Monitor clinical signs of chronic medical conditions (e.g., blood pressure, blood glucose, and other remote assessments).
- Engage in case management for patients with difficulty accessing care (e.g., those living in rural settings, older adults, and those with limited mobility).
- Follow up with patients after hospitalization.
- Deliver advanced care planning and counseling to patients and caregivers to document preferences if a life-threatening event or medical crisis occurs.

To get started with telehealth and for further support services, visit: www.telehealth.hhs.gov/providers/getting-started/

For current regulations and suggestions visit ASAM (US Department of Health and Human Services, n.d.): www.asam.org/Quality-Science/covid-19-coronavirus/supporting-access-to-telehealth-for-addiction-services



LINK PATIENTS TO THE RECOVERY COMMUNITY

Recovery Services exist to remove barriers to recovery by providing free Peer-Based Recovery Support Services (P-BRSS) to individuals in our community through:

- Peer-Led Support Groups
- Recovery Support Services
- Advocacy in Our Community

What are Peer-Based recovery Support Services

(<https://store.samhsa.gov/sites/default/files/sma09-4454.pdf>)

Phoenix: Sober Active Communities. Offered virtually at www.thephoenix.org/find-a-class
Eligibility: 48 hours of continued sobriety, 18 years or older

INCREASE PROTECTIVE FACTORS FOR MEDICATION USE

Improving access to MOUD reduces the need and likeliness of medication diversion. The benefits of buprenorphine, specifically the combination product, greatly outweigh the risks.

Implement a structure that supports a safe prescribing environment:

- Prescribe sublingual films of MOUD combination products.
- Weekly office visits during the early treatment until the patient is deemed stable.
- Move visits to twice monthly as motivation to adhere to program requirements.
- Pill counts with patients.
- Offer harm reduction services such as medication lock boxes, co-prescription of naloxone, and syringe services (in person or by mail from NIAC).
- Urine Drugs Screens:
- Ensure the presence of treatment drugs.
- Follow up very soon with a repeat test if the absence is found or suspected.
- Allow return to use to be part of the patient's treatment journey.
- Minimal mandatory dismissals from treatment are not limited to breaking the patient code of ethics.
- See *Appendix L Sample MOUD Guidelines for Monitoring Urine Drug Test-Specimen Collection*

TAPERING OR DISCONTINUING BUPRENORPHINE/NALOXONE TREATMENT

Buprenorphine/naloxone is for long-term management of OUD; optimal duration is unknown.

OUD is a chronic condition; sometimes, treatment may be lifelong.

**RESEARCH SHOWS LONG-TERM
BUPRENORPHINE USE REDUCES THE RISKS
OF ILLICIT OPIOID USE AND OVERDOSE AND
RETAINS PATIENTS IN TREATMENT.**

When tapering buprenorphine/naloxone, a slow taper over several months is recommended.

- Reduce daily dose by 10% to 20% per month
- Goal is to avoid severe withdrawal symptoms

Inform the patient about the risk of resuming opioid use with the lowering dose of buprenorphine/naloxone and the loss of opioid tolerance with an increased risk of opioid overdose.

Should a patient discontinue buprenorphine and then be faced with the risk of returning to opioid use or is no longer in a controlled environment such as prison or treatment facility, pharmacotherapy for OUD should be offered (Pimlott, 2019).

USE OF BUPRENORPHINE IN SPECIAL POPULATIONS/ SITUATIONS

It is recommended to contact specialists and your network of providers, including the ECHO Idaho platform, for complex patient cases or prescribing to special populations and situations.

ACUTE PAIN

Management of acute pain for the patient currently being treated for OUD with buprenorphine/naloxone should be treated according to current acute pain recommendations.

Efforts should be made to treat pain with non-opioid analgesics such as NSAIDs and acetaminophen as tolerated.

If acute pain is moderate to severe and non-opioid analgesics are ineffective, the patient may benefit from additional doses of buprenorphine (ASAM, n.d.). Of note, the use of Suboxone and Subutex is FDA-approved for OUD. When used for pain, it is considered an off-label use (naabt.org).

The use of full agonist opioid medication in addition to buprenorphine/naloxone in the ambulatory setting is not recommended due to safety concerns (ASAM, n.d.).

ADOLESCENTS

Psychosocial, pharmacotherapy, and specialized treatment facilities are all treatments that should be considered for adolescents with OUD, with age considerations for pharmacotherapy.

Buprenorphine/naloxone is approved for ages 16 years and above.

ALLERGY TO NALOXONE

Careful assessment of a claimed naloxone allergy is warranted to avoid prescribing the mono-product. Naloxone hypersensitivity or allergy is infrequent; education may be necessary to distinguish between a true allergic reaction and symptoms of opioid withdrawal (US Department of Health and Human Services, 2021).

BEST PRACTICE

Local Resource



UNIVERSITY OF IDAHO ECHO
PHONE: 208-364-4698
FAX: 208-364-3178
ECHOIDAHO@UIDAHO.EDU
SCHEDULE

ECHO IDAHO

COMORBIDITIES IN OUD

It is not uncommon for many OUD patients to have other behavioral health conditions. Management of anxiety and depression often results in higher success of OUD treatment. Combining MOUD with counseling and behavioral therapies is strongly recommended (US Department of Health and Human Services, 2021).

Chronic pain in patients treated with buprenorphine/naloxone for OUD may be managed with split dosing of the daily buprenorphine/naloxone dose, for example, dosing every 6 to 8 hours. HIV-positive patients on highly active antiretroviral therapy (HAART) may also be treated for OUD with buprenorphine/naloxone without a change in the effectiveness of HAART (Kumar Viswanath & Saadabadi, 2023).

HEPATIC IMPAIRMENT

The liver metabolizes buprenorphine and naloxone, which can predispose those with hepatic impairment to the risk of buprenorphine toxicity and precipitated withdrawal. With moderate hepatic impairment, combination products are not recommended. **In severe hepatic impairment, do not use the combination product.**

POLYSUBSTANCE USE/ CO- OCCURING SUBSTANCE USE

OUD often accompanies the misuse of other substances. Research has shown that treatment of OUD with buprenorphine/naloxone should not be withheld due to polysubstance use unless pharmacologic contraindications exist or risks outweigh the benefits of treating OUD.

Serious risks are associated with the combined use of buprenorphine/naloxone and benzodiazepines, and other CNS depressants like alcohol. However, in 2017 the FDA advised against withholding opioid addiction treatment medications because untreated OUD has more significant risks. Patient education on the severe risks of overdose and death is integral.

Work with the patient to taper or discontinue benzodiazepines and CNS depressants while being treated for OUD with buprenorphine/naloxone.

In the presence of an alcohol use disorder, monitoring of liver function is recommended to ensure appropriate buprenorphine prescribing in the setting of hepatic impairment (US Department of Health and Human Services, 2023).

PREGNANCY AND BREASTFEEDING

The standard of care for OUD in pregnancy/breastfeeding is methadone. If methadone treatment is unavailable, maintenance treatment with buprenorphine is considered safe during pregnancy and breastfeeding and is preferred over not treating OUD in pregnancy.

CONTINUED RESEARCH HAS CONCLUDED THAT USE OF THE COMBINATION PRODUCT IN PREGNANCY IS SAFE AND PREFERRED (LAURA MCNICHOLAS, 2004).

The American College of Obstetricians and Gynecologists (ACOG) issued the ACOG Committee Opinion in August 2017 on Opioid Use and OUD in Pregnancy with the following highlights:

- Buprenorphine mono-product is recommended during pregnancy to avoid the risk of opioid withdrawal to fetus from naloxone, but the combination product use is becoming more widely used during pregnancy.
- Unlike methadone, the dosing of buprenorphine tends not to change significantly during and after pregnancy. Buprenorphine treatment should continue postpartum, as this is a high-risk period for the recurrence of opioid use.
- It is not recommended to transition from methadone to buprenorphine during pregnancy to avoid precipitated withdrawal.

SUSPECTED DIVERSION

Prevent diversion by performing thorough patient assessments and patient education, prescribing therapeutic dosages with limited quantity, checking the Prescription Drug Monitoring Program (PDMP) at every visit, performing urine drug testing, requesting patients bring wrappers for film products at each visit, and scheduling unannounced medication counts that require the patient to appear within 24 hours of the request.

**THE PREFERRED MEDICATION
FOR TREATING OUD IS THE
COMBINATION PRODUCT
BUPRENORPHINE/NALOXONE.**

Signs of possible diversion and misuse include:

- Missed appointments.
- Requests for early refills.
- Requests to replace lost or stolen prescriptions.
- Urine drug tests are negative for buprenorphine metabolites.
- Reports of allergies or intolerance of naloxone.
- Fresh injection marks.

Should diversion continue despite an increased intensity of services such as weekly visits and increased counseling, an alternative treatment plan like methadone may be warranted. Research shows most diverted buprenorphine is used to self-treat OUD and not taken for its euphoric effects (Providers Clinical Support System, 2021).

SWITCHING FROM METHADONE TO BUPRENORPHINE/NALOXONE

It is recommended a patient be converted from methadone to buprenorphine/naloxone by the methadone provider currently treating the patient. The daily dose of methadone must be tapered down to 30mg over a closely monitored period.

Once a patient is stable on a therapeutic dose of buprenorphine/naloxone, it is reasonable for a provider to assume prescriptive responsibilities at this time. The goal of buprenorphine/naloxone dosing is to ensure control of opioid cravings and prevent or reduce withdrawal symptoms. Start low and go slow. Buprenorphine has a long half-life.

DOSE ADJUSTMENTS

HEPATITIS

- **Severe hepatic impairment: Use is not recommended**
- Moderate hepatic impairment: Bunavail and Cassipa: Use may not be appropriate
- Moderate hepatic impairment: Suboxone SL film: Not recommended for induction therapy
- Moderate hepatic impairment: Suboxone SL tablets: May be used for maintenance therapy; dosage adjustments may be needed; monitor carefully and watch the patient for symptoms of precipitated opioid withdrawal.
- Moderate hepatic impairment: Zubsolv SL tablets: Use may not be appropriate but may be considered for maintenance treatment.

KIDNEY DISEASE

No dose adjustment necessary.

GERIATRIC

It may be necessary to start at the low end of the dosing range and titrate slowly.

PEDIATRIC (ADOLESCENTS) 16 AND OLDER

Limited data available—Suboxone Sublingual: Tablets or Film

- **Induction:** Note: Combination products should only be administered for induction in patients dependent on short-acting opioids (e.g., heroin, oxycodone) who have begun to show mild to moderate opioid withdrawal signs (to avoid precipitated withdrawal) and whose last dose of opioids was at least 6 to 12 hours before induction.
- **Initial:** 2 to 4 mg; if no signs of precipitated withdrawal after 60 to 90 minutes, it may increase in increments of 2 to 4 mg. Once the initial dose is tolerated, it may increase to a clinically effective dose that provides 24 hours of stabilization.
- After induction and titration, daily doses, usually ≥ 8 mg/day, are necessary. In patients continuing to use opioids, consider increasing the dose by 4 to 8 mg to a daily dose of 12 to 16 mg/day. Maximum daily dose: 24 mg/day.

Not approved for under 16 years of age (US Department of Health and Human Services, n.d.).

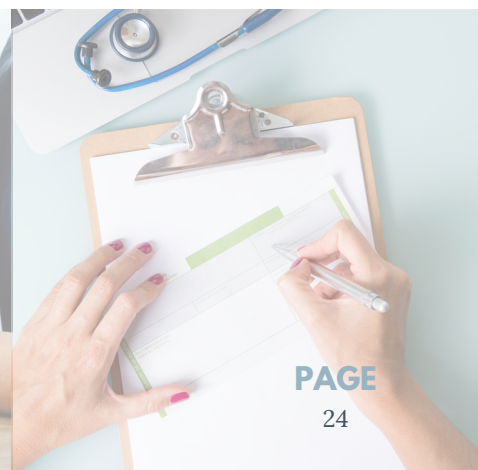
ADDITIONAL RESOURCES WITH LINKS

- [The American Society of Addiction Medicine \(ASAM\) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.](#)
- [Providers Clinical Support System](#)
- [SAMHSA TIP 63: Medications for Opioid Use Disorder](#)



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APPENDIX A: SOCIAL DETERMINANTS OF HEALTH SCREENING TOOL

We believe everyone should have the opportunity for health. Some things like not having enough food or reliable transportation or a safe place to live can make it hard to be healthy. Please answer the following questions to help us better understand you and your current situation. We will try as much as we can to set you up with the right resources.

	Yes	No
Within the past 12 months, did you worry that your food would run out before you got money to buy more?		
Within the past 12 months, did the food you bought just not last and you didn't have money to get more?		
Within the past 12 months, have you ever stayed: outside, in a car, in a tent, in an overnight shelter, or temporarily in someone else's home (i.e. couch-surfing)?		
Are you worried about losing your housing?		
Within the past 12 months, have you been unable to get utilities (heat, electricity) when it was really needed?		
Within the past 12 months, has a lack of transportation kept you from medical appointments or from doing things needed for daily living?		
Do you feel physically or emotionally unsafe where you currently live?		
Within the past 12 months, have you been hit, slapped, kicked or otherwise physically hurt by anyone?		
Within the past 12 months, have you been humiliated or emotionally abused by anyone?		
I really want to make changes in my drinking.		
I really want to make changes in my drug use.		
Do you need support for a loved one who is struggling with substance abuse?		
Are any of your needs urgent? For example, you don't have food for tonight, you don't have a place to sleep tonight, you are afraid you will get hurt if you go home today, you're scared you may overdose.		
Would you like help with any of the needs that you have identified?		

APPENDIX B: DRUG SCREENING QUESTIONNAIRE (DAST-10)

DRUG SCREENING QUESTIONNAIRE (DAST-10)

Using drugs can affect your health and some medications you may take. Please help us provide you with the best medical care by answering the questions below.

The various classes of drugs may include cannabis (marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD) or narcotics (e.g., heroin). The questions do not include alcoholic beverages.

Please answer every question. If you have difficulty with a statement, then choose the response that is mostly right.

Have you used drugs other than those required for medical reasons?	No	Yes
Do you abuse more than one drug at a time?	No	Yes
Are you always able to stop using drugs when you want to?	No	Yes
Have you ever had blackouts or flashbacks as a result of drug use?	No	Yes
Do you ever feel bad or guilty about your drug use?	No	Yes
Does your spouse (or parents) ever complain about your involvement with drugs?	No	Yes
Have you neglected your family because of your use of drugs?	No	Yes
Have you engaged in illegal activities in order to obtain drugs?	No	Yes
Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	No	Yes
Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)?	No	Yes

Please indicate what kind of drug (s) you use, how often you use them, and when your use started _____

Have you ever been in treatment for substance use? (circle one) Yes No

DAST-10 SCORES AND ZONES

Scoring: Score 1 point for each question answered “Yes,” except for question 3 for which a “No” receives 1 point

Score	Risk Level	Intervention
0	Zone 1: No risk	Simple advice: Congratulations this means you are abstaining from excessive use of prescribed or over-the counter medications, illegal or non-medical drugs.
1-2	Zone 2: Low Level of Risk	Brief Intervention (BI). You are at risk. Even though you may not be currently suffering or causing harm to yourself or others, you are at risk of chronic health or behavior problems because of using drugs or medications in excess.
3-5	Zone 3: Intermediate Level of Risk	Extended BI (EBI) and RT – your score indicates you are at an “intermediate level” of problem drug use. Talk with a professional and find out what services are available to help you to decide what approach is best to help you to effectively change this pattern of behavior.
6-10	Zone 4: Very High Risk, Probable Substance Use Disorder	EBI/RT- considered to be at a “substantial to severe level” of problem drug use. Refer to specialist for diagnostic evaluation and treatment.

Brief education: Inform patients about low-risk consumption levels and the risks of excessive alcohol use.

Brief intervention: Patient-centered discussion that employs Motivational Interviewing concepts to raise an patient’s awareness of their substance use and enhances their motivation to change their use. Brief interventions are typically performed in 3-15 minutes, and should occur in the same session as the initial screening. Repeated sessions are more effective than a one-time intervention.

If a patient is ready to accept treatment, a referral is a proactive process that facilitates access to specialized care for individuals likely experiencing a substance use disorder. These patients are referred to alcohol and drug treatment experts for more definitive, in-depth assessment and, if warranted, treatment. However, treatment also includes prescribing medications for substance use disorder as part of the patient’s normal primary care.

For additional screening tools visit [National Institute on Drug Abuse: Screening and Assessment Tools Chart](#)

(Office of Addiction Services and Supports, 2017)

APPENDIX C: STEPS TO BRIEF INTERVENTION

RAISE THE SUBJECT

- Thanks for filling out this form – is it okay if we briefly talk about your substance use?
- Just so you know, my role is to help you assess the risks so you can make your own decisions. I want to help you improve your quality of life on your own timeline.
- What can you tell me about your substance use? (OHSU Family Medicine, 2023)

SHARE INFORMATION

- Explain any association between the patient's use and their health complaint, then ask, "Do you think your use has anything to do with your [anxiety, insomnia, STD, etc,]?"
- Share information about general risks of use and/or low-risk limits of alcohol use.
- Ask the patient: "What do you think of this information?" (OHSU Family Medicine, 2023)

ENHANCE MOTIVATION

- Ask patient about perceived pros and cons of their use, then summarize what you heard.
- Where do you want to go from here in terms of your use? What's your goal, or vision?
- Gauge patient's readiness/confidence to reach their goal. If using Readiness Ruler: "Why do you pick that number on a scale of 0-10 instead of ____ [lower number]?" (OHSU Family Medicine, 2023).

READINESS RULER

The readiness ruler is a helpful tool to support the use of Motivational Interviewing (MI), the evidence based treatment, by services providers and is typically used in a conversational approach . An example of a readiness ruler can be accessed [here](#).

Questions that can be asked with the readiness ruler are:

- How confident are you about making this change?
- How important is this change to you right now? (CWRU, 2021).

IDENTIFY PLAN

- If patient is ready, ask: "What steps do you think you can take to reach your goal?"
- Affirm the patient's readiness/confidence to meet their goal and affirm their plan.
- "Can we schedule an appointment to check in and see how your plan is going? You may want to change it or make a new plan." (OHSU Family Medicine, 2023).

SUBSTANCE USE HISTORY

SMOKING

Have you ever smoked or chewed tobacco? _____
 If Yes: What age did you start? _____
 Do you currently smoke or chew? _____
 *** If YES, how much daily? _____
 Are you interested in quitting? _____
 ***If NO, when did you quit? _____
 How much did you smoke prior to quitting? _____

ALCOHOL

Do you drink any alcoholic beverages: beer, wine, liquor? _____
 If YES: What is the most you may drink in one setting? _____
 How many times a week? _____
(Male; >14/wk or >4 per sitting, Female >7/wk or >3 per sitting in the last 2 years: Do Audit C)
 If NO: Have you ever been a heavy drinker in the past? _____
 Any history of DUI's? _____

OTHER DRUGS

Do you now, or have you ever, used in excess any of the following recreational drugs or prescription medications not originally prescribed to you?
 Please indicate when, how long, and last use.

- | | |
|--|--|
| <input type="checkbox"/> Marijuana _____ | <input type="checkbox"/> Amphetamines (Adderall, Ritalin) _____ |
| <input type="checkbox"/> Cocaine _____ | <input type="checkbox"/> Opiates (Heroin, Hydrocodone, Oxycodone, Methadone, Fentanyl, Suboxone) _____ |
| <input type="checkbox"/> Heroin _____ | <input type="checkbox"/> Hallucinogens (PCP, Shrooms) _____ |
| <input type="checkbox"/> Ecstasy _____ | |
| <input type="checkbox"/> Methamphetamines _____ | |
| <input type="checkbox"/> Benzodiazepines (Ativan, Lorazepam, Valium) _____ | |

DRUG(S) OF CHOICE:

When did you start using?

When did you start using daily?

How much were/are you using?

How much money were/are you spending daily?

ADDICTION CRITERIA

- ☐ Have you noted TOLERANCE? (need for increase amounts to achieve intoxication or desired affects?
- ☐ Have you noted WITHDRAWAL? (physical symptoms (nausea, shakes, etc) when you don't have the drug?
- ☐ Have you taken the drug in larger amounts or over longer time than instructed?
- ☐ Have you had the persistent desire to cut down use but been unsuccessful?
- ☐ Have you spent a lot of time and effort trying to obtain the substance?
- ☐ Have you given up important social, work, leisure activities because of use?
- ☐ Has your use caused family, friendship, work, and financial stress?
- ☐ Have you continued drug use despite knowing it is harmful for your health?

How did you use your substance of choice? (IV, smoke, snort, chew, swallow)?

Have you been screened for HIV, Hepatitis, and STD's in the past 6 months?

Have you been involved in Rehabilitation Programs in the past? If yes, when and where?

APPENDIX E: DSM 5 OPIOID USE DISORDER CHECKLIST

DIAGNOSTIC CRITERIA (Opioid Use Disorder requires at least 2 criteria be met within a 12 month period)	Meets Criteria? (Yes or No)	Notes/Supporting Information
Opioids are often taken in larger amounts or over a longer period of time than intended.		
There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.		
Craving, or strong desire to use opioids.		
Recurrent opioid use resulting in failure to fulfil major role obligations at work, school, or home.		
Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.		
Important social, occupational, or recreational activities are given up or reduced because of opioid use.		
Recurrent opioid use in situations in which it is physically hazardous.		
Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused by or exacerbated by opioids.		

<p>Tolerance as defined by:</p> <p>(A) A need for markedly increased amounts of opioids to achieve intoxication or desired effect.</p> <p>(B) Markedly diminished effect with continued use of the same amount of a substance.</p>		
<p>Withdrawal as manifested by either of the following:</p> <p>(A) The characteristic opioid withdrawal symptoms.</p> <p>(B) The same, or closely related to, substance taken to relieve or avoid withdrawal symptoms.</p>		

Patient Name: _____ DOB: _____

Completed by/Witness: _____ Date: _____

APPENDIX F: CLINICAL OPIOID WITHDRAWAL SCALE (COWS)

For each item, circle the number that best describes the patient's signs or symptoms. Rate only on the apparent relationship to opioid withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

COWS SCREENING TOOL	
Patients Name: Date and Time: Reason for this assessment:	
Resting Pulse Rate: measured after patient is sitting or lying for one minute _____beats/minute 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	GI Upset: over last ½ hour 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
Sweating: over past ½ hour not accounted for by room temperature or patient activity. 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	Tremor: observation of outstretched hands 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness: observation during assessment 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds	Yawning: observation during assessment 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult

<p>Bone or Joint aches: if patient was having pain previously, only the additional component attributed to opioids withdrawal is scored</p> <p>0 not present</p> <p>1 mild diffuse discomfort</p> <p>2 patient reports severe diffuse aching of joints/ muscles</p> <p>4 patient is rubbing joints or muscles and is unable to sit still because of discomfort</p>	<p>Gooseflesh skin</p> <p>0 skin is smooth</p> <p>3 piloerection of skin can be felt or hairs standing up on arms</p> <p>5 prominent piloerection</p>
<p>Runny nose or tearing: not accounted for by cold symptoms or allergies</p> <p>0 not present</p> <p>1 nasal stuffiness or unusually moist eyes</p> <p>2 nose running or tearing</p> <p>4 nose constantly running or tears streaming down cheeks</p>	<p>Total Score _____</p> <p>The total score is the sum of all 11 items</p> <p>Initials of person completing assessment:_____</p> <p>Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36+ = severe withdrawal</p>

APPENDIX G: SUBJECTIVE OPIOID WITHDRAWAL SCALE (SOWS)

Instructions: We want to know how you are feeling. In the column below today's date and time, use the scale to write in a number from 0-4 about how you feel about each symptom right now.

Scale: 0 = not at all 1 = a little 2 = moderately 3 = quite a bit 4 = extremely

DATE						
TIME						
	SYMPTOM	SCORE	SCORE	SCORE	SCORE	SCORE
1	I feel anxious					
2	I feel like yawning					
3	I am perspiring					
4	My eyes are tearing					
5	My nose is running					
6	I have goosebumps					
7	I am shaking					
8	I have hot flushes					
9	I have cold flushes					
10	My bones and muscles ache					
11	I feel restless					
12	I feel nauseous					
13	I feel like vomiting					
14	My muscles twitch					
15	I have stomach cramps					
16	I feel like using now					
Total						

Mild Withdrawal = score of 1 – 0

Moderate withdrawal = 11 – 20

Severe withdrawal = 21 – 30

APPENDIX H: CONSENT FOR TREATMENT WITH BUPRENORPHINE EXAMPLE

Buprenorphine is a medication approved by the FDA for treating people with Opioid Dependence or Use Disorder. Buprenorphine is an opioid but not as potent an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence on the opioid type.

Buprenorphine withdrawal is generally less intense than heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opioid withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

If you are dependent on opioids, you should be in as much withdrawal as possible when you take your first dose of buprenorphine. If you are not in withdrawal, buprenorphine may cause significant opioid withdrawal. Therefore, you should take the first dose in the office and remain there for observation. Within a few days, you will have a prescription for buprenorphine filled at the pharmacy.

Some patients find that it takes several days to transition from the opioid they had been using to buprenorphine. During that time, any use of other opioids may cause an increase in symptoms. After you become stabilized on buprenorphine, expect other opioids to have less effect. Attempts to override the buprenorphine by taking more opioids could result in opioid overdose. You should not take any other medication without discussing it with your provider first.

Combining buprenorphine with alcohol or other medications can be very dangerous. Combining buprenorphine with other medications such as Valium, Ativan, or other benzodiazepines has significant consequences and can result in death.

The form of buprenorphine (Suboxone) you may be taking is a combination of buprenorphine with a short-acting opioid blocker called naloxone. If the Suboxone were dissolved and injected by someone taking heroin or another potent opioid, it could cause severe opioid withdrawal.

Buprenorphine must be held under the tongue until it dissolves completely. The body will then absorb it over the next 30-120 minutes. It will not be absorbed by the stomach if swallowed.

Alternatives to Buprenorphine

Some hospitals with specialized SUD treatment units can provide withdrawal management and intensive counseling. Some outpatient SUD treatment services also provide individual and group therapy, which may emphasize treatment that does not include maintenance on buprenorphine or other opioid-like medications.

Patient Signature _____

Date: _____

APPENDIX I: CONSENT FOR TREATMENT WITH BUPRENORPHINE DURING PREGNANCY

Patients Printed Name: _____

I consent to Kootenai Clinic Family Medicine Residency's specially licensed providers to treat me with buprenorphine during my pregnancy.

My provider has explained the following to me about the proposed treatment:

- What it involves
- The benefits, risks or side effects, including any problems that may occur
- The likelihood of achieving treatment goals
- Other treatment choices and their benefits, risks, and side effects

1. I have been diagnosed with an opioid use disorder and understand that it is far safer to treat this disorder during pregnancy than to continue to use other opioids or abruptly stop using opioids and experience withdrawal.

2. I understand that if I continue to get high during pregnancy or experience withdrawal, my baby might experience several complications, including being born too early, having trouble growing in my uterus, and might die.

3. I understand that methadone remains the standard of care for treating opioid disorders during pregnancy. Methadone has been available for over 40 years, so more is known about the short- and long-term impacts of using this medication during pregnancy. Buprenorphine is a newer medication than methadone. While preliminary evidence suggests that it is as safe as methadone for me and my baby, no long-term studies are currently available. I understand that using buprenorphine during pregnancy may have lasting effects on my baby as they grow.

4. I understand that a problem with taking any opioid during pregnancy (including methadone or buprenorphine) is that my baby may have a withdrawal syndrome called Neonatal Abstinence Syndrome (NAS) after birth. Babies with Neonatal Abstinence Syndrome may experience trouble sleeping or feeding, tremors, sneezing, irritability, vomiting, weight loss, and seizures. Neonatal Abstinence Syndrome can be safely treated with medications or other therapies.

5. I understand that my baby will be monitored for Neonatal Abstinence Syndrome in the hospital for at least five days after birth and may require treatment. If treatment is required, the hospitalization period may be extended.

6. I understand that if I use medications or other substances not prescribed to me, such as benzodiazepines, amphetamines, cocaine, or marijuana during pregnancy, it may affect my baby's health. I also understand that buprenorphine does not treat dependence on, or addiction to, any of these other substances.

I have discussed the benefits and risks of using buprenorphine during pregnancy, and I have decided to take buprenorphine rather than methadone. I understand that medical knowledge on the actual or potential risks of buprenorphine on pregnant women and unborn children is still uncertain.

My provider explained this treatment to me and answered all of my questions to my satisfaction.

After discussing that choice with my provider, I know I can change my mind and withdraw this consent.

Patient Signature

Date:

Provider Signature

Date:



APPENDIX J: BUPRENORPHINE PROGRAM TREATMENT AGREEMENT

Patient Name _____

DOB: _____

This agreement provides the patient and the buprenorphine provider with a written list of rules and expectations that must be followed to allow the patient to remain in the treatment program. It is based on the trust between the patient and the medical provider. You must be honest and cooperative with the providers and all staff members. Inform the providers of any drug or alcohol relapses or missteps before they come to light through other sources. Violating any part of this contract will provide sufficient grounds to terminate buprenorphine treatment. You will have no recourse or cause for appeal.

I am requesting that my provider provide buprenorphine treatment for Opioid Dependence for
(list drugs of choice): _____

I freely and voluntarily agree to accept this treatment agreement, as follows:

1. I agree to keep and be on time for all my appointments with the provider and their assistant. If you cannot make your appointment, you must contact the office and speak with someone to reschedule this appointment at least two days before your scheduled appointment. Failure to do so will be considered a no-show and is grounds for termination. It is your responsibility to ensure you are scheduled for an appointment before needing the following prescription of buprenorphine.
2. I agree to conduct myself courteously in the clinic. Disrespectful or inappropriate behavior toward staff or the other patients will not be tolerated and may be grounds for immediate expulsion from the program.
3. I understand and agree that any attempts to obtain or use any opioid medication or heroin must stop immediately.
4. I agree not to arrive at the office intoxicated or under the influence of drugs. If I do, the staff will not see me, and I will not be given any medication until my next appointment.
5. I agree not to sell, share, or give any of my medication to another person. Suboxone use by someone who is not addicted to opioids could cause them to experience severe withdrawal. I understand that mishandling my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.
6. I agree that my buprenorphine prescriptions can only be given to me at my regular appointments. You must pick up each prescription in person. No refills will be provided over the phone. Any missed office visits will result in my inability to get a prescription until my next visit.

7. I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place, inaccessible to children, guests, or household members. I agree that lost or stolen medication will not be replaced regardless of the reason for such loss. There are lock boxes available for this purpose. I agree that if anyone besides myself swallows any of my prescription MOUD, I will call 911 or the Poison Control Center immediately.
(phone # 1-800-222-1222)

8. I understand that medication alone is insufficient treatment for my disease. I agree to participate in the recommended patient education and relapse prevention programs to assist me in my treatment. Written proof of attendance may be required.

9. How well I am doing will determine Take-home doses and frequency of visits. Buprenorphine will be prescribed in quantities to last from visit to visit. You will be required to be seen at least once monthly once stabilized.

10. I agree to take buprenorphine as prescribed at the dose determined by my physician. Self-regulation of your dose is only allowed if you have specific instructions from your provider. If you feel you need a higher dose than prescribed, you must bring this to the physician's attention during an appointment.

11. It has been explained to me that buprenorphine itself is an opioid and can produce physical dependence that is similar to heroin.

12. If applicable, I agree to tell my provider if I become pregnant or ever think I may be pregnant.

13. I have been informed that suboxone is to be placed under the tongue for it to dissolve and be absorbed properly. It should never be injected or taken by IV. I have been informed that injecting my prescription MOUD or any other opioid regularly could lead to sudden and severe opioid withdrawal.

14. I agree to bring my remaining prescription MOUD to every appointment with my physician to count the remaining prescription.

15. I have been informed that it can be dangerous to mix buprenorphine with alcohol or another sedative drug such as Valium, Ativan, Xanax, Klonopin, or any other benzodiazepine drug-so dangerous that it could result in an accidental overdose, over-sedation, coma, or death. I agree not to use alcohol or any sedative drugs at any time while being treated with buprenorphine. I have been informed that violating this agreement may be grounds for termination from the program.

16. I agree that a network of support, and communication among persons in that support network, is an important part of my recovery. I will be asked for my authorization to allow telephone, written, or face-to-face communication, as appropriate, between staff from my treatment team and outside parties, including other providers, therapists, probation or parole officers, and other parties when staff has decided that open communication about my treatment, on my behalf, is necessary.

17. I agree that I will be open and honest with my counselors and providers. I will inform staff about my cravings, discuss my potential for relapse, and specifically about any relapse before a drug test result shows it.

18. Periodic urine drug tests and medication counts are done as a tool to support your treatment. Urine drug screening will be done randomly as well as at the discretion of your provider. You must bring your medication to be counted if called in for a random urine drug screen. You are expected to return a call and be scheduled for a nurse visit, urine drug screen, and medication count within 24 hours of the office contacting you. It is your responsibility to notify the office if you will be leaving town for any time; if you fail to do so and are called in for a random urine drug screen, you will be marked as a no-show for this visit.

19. As part of the program, we may inform Urgent Care facilities and the Emergency Department of your contract and treatment with buprenorphine.

20. I understand that there are alternatives to buprenorphine treatment for opioid addiction including:

- a. Medical withdrawal and drug-free treatment
- b. Naltrexone treatment
- c. Methadone treatment

21. In return of agreeing to, and complying to this contract, you may expect:

- To be treated with dignity just as any other person with a chronic medical condition.
- Regular office visits and continued prescriptions for buprenorphine.
- Phone calls or phone messages to be answered within a reasonable period of time. Because of limited office hours this may be up to 72 hours depending on the circumstance.
- We will always maintain confidentiality of information about your identity and condition. We release this information only with your written permission, except in situations that it is necessary to consult with your other medical providers, counselors, etc.; or when required by legal authorities. HIPAA regulations will be strictly applied.

Patient Signature _____

Date: _____

Witness/Staff Signature/Title: _____

Date: _____

Pharmacy at which you will be filling your prescription: _____

We reserve the right to contact your pharmacy and verify your prescription is being filled appropriately.

*If you change pharmacies, it is your responsibility to notify the office of those changes.

APPENDIX K: HERITAGE HEALTH STANDARD OF CARE WORKFLOW FOR MEDICATION FOR OPIOID USE DISORDER (MOUD)

HERITAGE HEALTH MEDICAL PROVIDERS/CLINIC:

Provider meets with patient for induction of buprenorphine:

This is a 40-minute new patient visit that includes a complete physical examination, review of the MOUD contract, the patient signs a release of information (ROI) for Heritage Health Recovery Services (Restored Paths, RP), the patient submits a urine sample for a urine drug screen (UDS), and medical staff runs an Idaho Board of Pharmacy (IBOP) prescription monitoring report.

Warm hand-off to behavioral health consultant (BHC) to liaison appointment to RP:

Depending on financial eligibility criteria, patient is scheduled for an evaluation or Global Appraisal of Individual Needs (GAIN) assessment at RP.

BHC sends patient case to the primary care provider (PCP) to inform the evaluation date/time. The patient is scheduled a follow-up visit with provider within two days unless previously prescribed and tolerated buprenorphine.

Follow-up visits are weekly until the patient has established outpatient treatment with a SUD program or Heritage Health Recovery Services; and, Urine Drug Screen (UDS) has been negative for any illicit substances and positive for buprenorphine.

Once patient is established with Heritage Health Recovery Services and UDS results are unremarkable, patient follow-up visits are once a month.

Once long-term sobriety established, the patient may be given refills and seen every month.

The MOUD treatment team (which consists of physicians, NPs, PAs, medical assistants, SUD clinicians, BHC) meet monthly to staff all shared patients on the MOUD program. Special attention is dedicated to patients not in compliance with MOUD contract or are struggling bio-psycho-socially.

Patients have access to other behavioral health services in this collaborative care model including psychiatry and mental health counseling.

HERITAGE HEALTH HERITAGE HEALTH RECOVERY SERVICES:

ROUTE #1

Client already met with provider for suboxone and RP received fax from provider as referral.

Schedule client for assessment (three hours) if BPA or Medicaid. Schedule one hour if cash or other insurance.

Assessment level determines how many groups patient should attend per week. Clients are assigned to groups, primary counselor who they see two times per month, and assigned a drug testing facility where testing takes place two times per week.

SUD program lasts 3-12 months depending on client assessment and progress.

The primary counselor meets with MOUD treatment team monthly to staff patients in program.

Providers are emailed with any significant issues in the interim (return to use, life changes, partner left, job lost, etc.).

ROUTE #2

Client presents to RP for an assessment by self-referral.

Schedule and complete assessment- assign groups, schedule individual session, and assign drug testing facility.

Let them know about MOUD services. Check with the provider's MA to see if that person is on the waiting list or needs to make an appointment.

The primary counselor meets with MOUD treatment team monthly to staff patients in program.

Email team with any significant issues.

APPENDIX L: MOUD GUIDELINES FOR MONITORING URINE DRUG TEST SPECIMEN COLLECTION

It is the policy of the [name of clinic or provider] to monitor the use of drugs by collecting random, observed, and temperature-monitored urine samples at a frequency determined by clinical staff per Federal and State regulations.

PURPOSE

Urine samples are collected and tested to assist in stabilizing a patient on the proper dosage of methadone or buprenorphine. Drug test results may suggest that a patient's dosage needs adjustment or that a more intensive level of care is needed. Positive drug tests alone do not confirm that a patient is not engaged in treatment or is not in compliance. The entire clinical picture must be considered. Drug tests are not used to punish patients or as the sole reason to discharge them from treatment. Patients must be assured that the results are confidential and will be released only with their permission or pursuant to a court order (21 CFR, Part 2).

GENERAL INFORMATION AND DESIRED OUTCOME

Under clinic policy and State and Federal regulations, each new patient provides one random urine sample per week for the first six months and samples less frequently after that, based on treatment progress. The medical staff monitors each patient no less than once a month. Urine samples are collected randomly. The patient is unaware of when they will be asked to provide a urine sample so that a more accurate assessment of drug abuse patterns is made. The urine is tested for several drugs of abuse and the presence of treatment medication. Patients may refuse to provide urine specimens for many reasons but are encouraged to provide them. If a patient refuses to provide a specimen, urine is collected at the next dosing appointment.

If a patient has a positive drug test or fails to provide a valid specimen at the next appointment or request, a review of progress in treatment and the number of days supplied (e.g., may decrease the number of days supplied per prescription to a week or less) and may result in more frequent required clinic and pharmacy visits. The counseling, nursing, and medical staff are notified and consulted when patients test positive or refuse to provide samples.

PROCEDURE

The following guidelines for observing or temperature-monitoring urine specimens help increase the validity of each sample.

- If a urine specimen is collected with a temperature higher than 99.8°F, the patient's temperature is taken (if the patient's temperature is elevated, the temperature of the urine specimen also may be elevated).
- Before a patient enters a bathroom stall, he or she is asked to leave coat, outer garments, purse, and bags outside the bathroom to prevent falsification of the sample. A patient is asked to wash and dry their hands before and after giving samples to prevent urine contamination. Bacterial overgrowth invalidates a urine specimen. To the extent possible, staff members ensure that patients do not conceal falsified urine specimens on their persons.

- If collection of a urine sample is observed directly (versus temperature monitored), the following steps are performed to ensure an accurate specimen:

1. The patient is observed to ensure that he or she does not add water to the urine from the toilet or sink to dilute it. (Where health department regulations permit, hot water in the bathroom should be turned off.)
 2. Female: A female observer accompanies a female patient into the restroom. The patient is asked to void into a urine container and not to flush the toilet. A wide-mouth collection container may be used and the contents then transferred to a smaller container. The staff member observes collection of the specimen directly. The collection site observer also flushes the toilet.
 3. Male: A male observer accompanies a male patient into the restroom. The client uses a urinal and is asked to void into a urine container. This is observed directly.
- The patient provides 50 cc of urine.
 - The sample is checked for color, temperature (90.5–99.8°F/32.5–37.7°C), and any contamination. The temperature is checked 30 seconds after the specimen is provided.
 - After a sample is obtained, a staff member verifies the urine temperature and checks the container for pinholes before placing it in a plastic envelope.
 - If the urine sample is not sent immediately to the laboratory, it is stored properly in a refrigerator that is used exclusively for laboratory samples.
 - Proper security of urine specimens is maintained to prevent loss or switching of urine. Specimens are placed in a locked refrigerator in a locked room.

If a patient is unable to provide a urine specimen, they are asked to drink plenty of water. Special considerations are given to patients with health problems that interfere with urination, including renal failure, neurological disorders, and paruresis. Any patient who is still unable to provide a urine sample must be prepared to give the sample on the following day. If a patient refuses to provide a sample, he or she must be referred to a counselor. After a clinical review, the treatment plan and the frequency of clinic visits may be modified (University of New Mexico, 2021).

APPENDIX M: REMS FOR BUPRENORPHINE COMBINATION PRODUCT PASSING

REMS GOALS

To reduce the risk of misuse, abuse, or accidental overdose and to inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine containing products.

REMS REQUIREMENTS

BTOD Applicants must ensure that prescribers and patients comply with the following requirements (U.S. Food and Drug Administration, 2022):

1. Prescribers who prescribe or dispense buprenorphine transmucosal products for opioid dependence (BTOD) must:	
Before treatment initiation (first dose)	<ol style="list-style-type: none"> 1. Assess the patient's condition to verify the patient meets the diagnostic criteria for opioid dependence. 2. Counsel the patient on the risks described in the Prescribing Information and Medication Guide. 3. Counsel the patient on safe storage of the medication.
During treatment; at the first visit following induction	<ol style="list-style-type: none"> 4. Prescribe a limited amount of medication.
During treatment; at visits scheduled at intervals commensurate with patient stability	<ol style="list-style-type: none"> 5. Assess the patient's compliance with the prescribed medication, appropriateness of the dosage prescribed, whether patient is receiving the necessary psychosocial support, and whether patient is making adequate progress towards treatment goals. 6. Counsel the patient about compliance with their medication. 7. Complete the Appropriate Use Checklist. Retain a completed copy in the patient's record or by using another method (e.g., electronic health record) specific to the prescriber's office practice.
2. Patients who are prescribed buprenorphine transmucosal products for opioid dependence:	
Before treatment initiation	<ol style="list-style-type: none"> 1. Receive counseling from the prescriber on the risks and safe storage of the medication.
During treatment; at time intervals determined by your prescriber	<ol style="list-style-type: none"> 2. Be monitored for compliance with the prescribed medication, appropriateness of the dosage prescribed, assessment of whether receiving the necessary psychosocial support, and whether making adequate progress towards treatment goals.

To inform healthcare providers about the REMS Program and the risks and safe use of buprenorphine transmucosal products for opioid dependence, BTOD Applicants must disseminate REMS communication materials according to the table below:

Prescribers certified to treat opioid dependence under the Consolidated Appropriations Act	REMS Letter: Dear Prescriber Letter with attachments Prescriber Brochure and Appropriate Use Checklist. 1. Mail within 60 days of approval of the BTOD REMS and annually thereafter.
All prescribers certified to treat opioid dependence under Consolidated Appropriations Act since the last dissemination	REMS Letter: Dear Prescriber Letter with attachments Prescriber Brochure and Appropriate Use Checklist 1. Mail monthly.
Retail pharmacies authorized by the DEA to handle schedule III controlled substances	REMS Letter: Dear Pharmacist Letter with attachment Pharmacist Brochure. 1. Mail within 60 days of approval of the BTOD REMS and annually thereafter.

TO SUPPORT REMS PROGRAM OPERATIONS, BTOD APPLICANTS MUST:

1. Establish and maintain a REMS Program website, www.btodrems.com. The REMS Program website must include the option to print the Prescribing Information, Medication Guides, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product websites.
2. Make the REMS Program website fully operational and all REMS materials available through the website, BTOD REMS specialists and call center within 60 calendar days of REMS modification.
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-223-3922.

TO ENSURE REMS PARTICIPANTS COMPLIANCE WITH REMS PROGRAM, BTOD APPLICANTS MUST:

4. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to, records of mailings and outbound calls. These records must be readily available for FDA inspections.
5. Establish a plan for addressing noncompliance with REMS Program requirements.
6. On a monthly basis, identify and attempt to contact all newly DATA 2000-certified prescribers and a random sample of existing DATA-2000 certified prescribers to create awareness of the program, confirm that REMS materials have been received, and confirm understanding of the BTOD REMS requirements.

- Mail a copy of the REMS materials to prescribers who request or did not receive the REMS materials.
- Provide additional follow-up information about the BTOD REMS program.
 1. Option I: a live online meeting to review BTOD REMS requirements
 2. Option II: a field visit to review BTOD REMS requirements

7. Monitor compliance with the prescriber requirements to document prescribing and dispensing with documentation of safe use conditions through surveys of patients and prescribers, evaluations of health care utilization databases, and ongoing surveillance (sources including, but not limited to, internet, national databases, and surveys conducted at substance abuse treatment programs).

8. Take reasonable steps to improve implementation of and compliance with the requirements in the BTOD REMS Program based on monitoring and evaluation of the BTOD REMS Program.

REMS ASSESSMENT TIMETABLE

BTOD NDA Applicants must submit REMS Assessments at 12 months from August 31, 2021, and annually after that. To facilitate the inclusion of as much information as possible while allowing a reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude at least 60 calendar days before the submission date for that assessment. BTOD NDA Applicants must submit each assessment so that the FDA will receive it on or before the due date.

REMS MATERIALS

The following materials are part of the BTOD REMS:

Training and Education Materials

Patient

1. Medication Guide (available at www.btodrems.com)

Patient Care Form

2. Appropriate Use Checklist

Communication Materials

3. Dear Prescriber Letter
4. Dear Pharmacist Letter
5. Prescriber Brochure: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers
6. Pharmacist Brochure: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists

Other Materials

7. BTOD REMS Website (www.btodrems.com)
8. USA Drug and Food Administration
(<https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>)

MOUD

Medication for opioid use disorder (MOUD) is offered to patients who have a current diagnosis of opioid use disorder (OUD), moderate to severe, and who meet predetermined criteria. The level of severity is determined by the number of diagnostic criteria an individual meets. Most prescriber visits for MOUD are coded as general medical (E/M) visits.

GENERAL DOCUMENTATION TIPS

- Document reasons for encounter and relevant history.
- Document assessment, clinical impression, and diagnosis.
- Document the patient's progress, response to changes in treatment, and diagnosis revision.
- Document plan of care.
- Document the rationale for order diagnostic and other ancillary services, or ensure it is easily inferred.
- Document the duration of the visit. E/M codes may be based on complexity or time.

Add-on codes:

- Prolonged visit codes: May also be added onto E/M codes for services that extend beyond the typical service. This includes with or without face-to-face patient contact. Time spent does not need to be continuous.
- SBIRT codes: May also be added onto E/M codes for screening and early intervention services by using modifier 25, "Significant, separately identifiable E/M service by the same physician or other qualified health care professional on the same day of the procedure or other service." Screening should occur with any routine wellness visit as standard of care. These may also apply in the acute visit for individuals who are still in the precontemplation or contemplation stage, and not yet ready to proceed with MOUD. SBIRT is commonly performed within a general medical visit. Thus, most prescriber visits should include an SBIRT code. (Please see SBIRT section for more detailed description).

Evaluation and Management Visit			
Category	Visit Length/Complexity	CPT Code	Description/Example
New patient	20-29 mins Straightforward: problem-focused	99202	Pre-induction or assessment visit: Comprehensive evaluation for appropriateness, such as during an Adult Wellness Visit or acute visit for OUD. Induction visit: MOUD medication induction.
	30-44 mins Low: expanded problem-focused	99203	
	45-59 mins Moderate: detailed	99204	
	≥ 60 mins High: comprehensive	99205	

Established patient	10-14 mins Straightforward: problem-focused	99212	<p>Pre-induction visit: Comprehensive evaluation for appropriateness, such as during an Adult Wellness Visit or acute visit for OUD.</p> <p>Induction visit: MOUD medication induction.</p> <p>Maintenance visit: MOUD medication, acute visit for OUD. Additionally, counseling codes are commonly added, since counseling and coordination of service with additional specialists comprise the majority of follow-up visits.</p>
	15-24 mins Low: expanded problem-focused	99213	
	25-39 mins Moderate: detailed	99214	
	≥ 40 mins High: comprehensive	99215	
Prolonged visits	30-74 mins	99354	<p>May also be added onto E/M codes for services that extend beyond the typical service time, with or without face-to-face patient contact. Time spent does not need to be continuous.</p> <p>Induction visit: MOUD medication induction</p>
	75-104 mins	99355	
	105+ mins	99354 + 99355x2	

SCREENING, BRIEF INTERVENTION, AND REFERRAL TO TREATMENT (SBIRT)

SBIRT is an early intervention for individuals with non-dependent substance use to help before the person needs more extensive or specialized treatment and is thus considered pre-induction or pre-treatment. This approach differs from the specialized treatment of individuals with more severe substance misuse or those who meet the criteria for a substance use disorder.

- **Screening:** Screen or assess a patient for risky substance use behaviors with standardized assessment tools to identify the appropriate level of care (in Medicare, known as Medicare Structured Assessment). Screening quickly assesses the severity of substance use and identifies the appropriate level of treatment. See Appendix B for a sample of a standardized assessment tool.
- **Brief Intervention:** Brief intervention focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change. In a short conversation, engage the patient showing risky substance use behaviors to increase awareness and give feedback, motivation, and advice. Medicare covers up to five counseling sessions. Each State determines the Medicaid amount, duration, and scope of services beneficiaries get. See Appendix C for sample steps of a brief intervention.
- **Referral to treatment:** Refer patients whose assessment or screening shows a need for additional services to brief therapy or additional treatment through specialty care.

SBIRT DOCUMENTATION TIPS

- Identify appropriate health risk factors.
- Document both the screening and any necessary intervention.
- Use a validated screening instrument (DAST). Not doing so may jeopardize payment.
- The Five A's model may be useful: Screening (Ask, Assess) and Brief Intervention (Advise, Assist, Arrange).
- Document the duration of the intervention. Brief interventions generally must last at least 15 minutes to be reimbursed. SBIRT codes are time-based.
- Add-on codes: Report CPT codes 99408, 99409, and H0049 with other evaluation and management (E/M) codes if appropriate by using modifier 25, "Significant, separately identifiable E/M service by the same physician or other qualified health care professional on the same day of the procedure or other service."

A NOTE ABOUT MEDICAID BILLING

- If a State chooses to cover SBIRT under its Medicaid Program, the State may choose which codes are preferred to bill brief intervention services. All codes have historically been accepted by Medicaid.
- Traditionally, reimbursement is greater for CPT (E/M) codes > HCPCS G codes > HCPCS H codes, and thus correspond to their preferred use (CPT more common, HCPCS H codes least common).

SBIRT			
Payor	Visit Length	Code	Description
Commercial insurance/Medicaid	15-30 mins	99408	Alcohol or substance (other than tobacco) misuse structured screening assessment and brief intervention services.
Commercial insurance/Medicaid	> 30 mins	99409	
Medicare/Medicaid	5-14 mins	G2011	
Medicare/Medicaid	15-30 mins	G0396	
Medicare/Medicaid	> 30 mins	G0397	
Medicaid	15-30 mins	H0049	
Medicaid	Per 15 mins > 30 mins	H0050	

MOUD BUNDLED SERVICES

In the CY 2020 Physician Fee Schedule final rule, CMS included new coding and payment for a monthly bundle of services for treating OUD furnished by practitioners in an office or outpatient setting. CMS hopes that adding a bundled payment program for OUD treatment services under the PFS will “incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care.”

At least one psychotherapy service must be furnished to bill for these codes.

Bundled payments may be submitted once the time threshold is met.

Practitioners reporting the OUD bundle must furnish a separately reportable initiating visit in association with the onset of OUD treatment. The initiating visit should establish the patient/doctor relationship, allow the practitioner to assess the patient to determine the clinical appropriateness of medication for opioid use disorder (MOUD), if applicable, and provide an opportunity to obtain the required patient consent to receive care management services.

OUD bundle payment for subsequent months may be billed following the initiating visit and month.

Monthly Bundled Services			
Visit Timing	Visit Length	Code	Description
First calendar month	15-30 mins	99408	Alcohol or substance (other than tobacco) misuse structured screening assessment and brief intervention services.
subsequent months	> 30 mins	99409	
Initial or subsequent months	5-14 mins	G2011	

MOUD ALGORITHMS

Were services pre-induction (Algorithm A) or active treatment (Algorithm B) for OUD?

Algorithm A: Pre-induction services

SBIRT CODES

Commercial insurance

- 99408: 15-30mins
- 99409: > 30 mins

Medicare

- G2011: 5-14mins
- G0396: 15-20mins
- G0397: > 30 mins

Medicaid

- Any of the above, or
- H0049: 15-30mins
- HH050: > 30mins

Medicaid note:

- * The State may choose which codes are preferred.
- * Traditionally, reimbursement is greater for E/M codes > G codes > H codes.

Was pre-induction performed as part of a larger visit?
(It is uncommon to provide SBIRT services alone)

Add E/M code with modifier 25:

New patient: complexity or time

- 99202: straightforward, 20-29mins
- 99203: low, 30-44mins
- 99204: medium, 45-59mins
- 99205: high, ≥ 60mins

Established patient: complexity or time

- 99212: straightforward, 10-14mins
- 99213: low, 15-24mins
- 99214: medium, 25-39mins
- 99215: high, ≥ 40mins

Algorithm B: Active MOUD services

ARE YOU USING FEE FOR SERVICE OR
BUNDLED PAYMENT BILLING?

Fee for Service E/M codes

New patient: complexity or time

- 99202: straightforward, 20-29mins
- 99203: low, 30-44mins
- 99204: medium, 45-59mins
- 99205: high, ≥ 60mins

Established patient: complexity or time

- 99212: straightforward, 10-14mins
- 99213: low, 15-24mins
- 99214: medium, 25-39mins
- 99215: high, ≥ 40mins

DID SERVICES EXTEND BEYOND TYPICAL
EXPECTED SERVICES OR TIME?

Add prolonged service code according to
time:

- 99354: 30-74 mins
- 99355: 74-104 mins
- 99354 + 99355 x2 :105 + mins

Bundled Payment Codes

- At least one psychotherapy service must be furnished to bill for these codes

First calendar month: G2086

- Require 70+ minutes in month

Subsequent month: G2087

- Requires 60+ minutes in month

DID SERVICE EXTEND BEYOND 120 MINS?

Add prolonged service code in addition to
primary visit code:

- G2088: for each additional 30 mins beyond initial 120 mins.

APPENDIX O: OUTPATIENT CLINIC INDUCTION PROTOCOL

<p>Day 1</p>	<p>Patient presents to clinic in withdrawal RN or physician assessment with COWS</p> <ul style="list-style-type: none"> • COWS needs to be at least 6 in order to proceed. If 5 or less, reschedule induction. <p>Assess starting point:</p> <ul style="list-style-type: none"> • For mild withdrawal symptoms (COWS 6-12), initiate with 2 mg buprenorphine • For moderate (≥ 13) or severe (≥ 25) withdrawal symptoms, initiate with 4 mg buprenorphine <p>Write prescription for buprenorphine/naloxone, film or tablets</p> <ul style="list-style-type: none"> • 2/0.5 mg #4-6 • 4/1 mg #2-3 • 8/2 mg #1-2 <p>Patient takes first dose under observation of RN, NP, or physician Observe patient in clinic for 1-2 hours</p> <ul style="list-style-type: none"> • If precipitated withdrawal symptoms occur, treat as appropriate or consider transfer to ED • If withdrawal symptoms relieved, patient discharged • If withdrawal symptoms persist after 60-90 minutes (COWS ≥ 6) then a second dose of buprenorphine is given under observation of RN, NP, or physician <p>If second dose is given, observe patient for an additional 1-2 hours</p> <ul style="list-style-type: none"> • If withdrawal symptoms relieved, patient discharged • If withdrawal symptoms persist, give symptomatic treatment (clonidine, NSAIDs, anti-emetics, etc.) and discharge patient <p>Maximum Day 1 dose: 8-12 mg *</p>
<p>Day 2</p>	<p>Patient returns to clinic Patient takes total dose received on Day 1 under observation of RN, NP, or physician Patient observed in clinic for 1-2 hours If withdrawal symptoms relieved, patient discharged If withdrawal symptoms persist after 60-90 minutes (COWS ≥ 6) then a second dose of buprenorphine is given under observation of RN, NP, or physician Patient observed additional 1-2 hours If withdrawal symptoms relieved, patient discharged If withdrawal symptoms persist, give symptomatic treatment (clonidine, NSAIDs, anti-emetics, etc.) and discharge patient Maximum Day 2 dose: 12-16 mg</p>
<p>Day 3</p>	<p>MD writes prescription if necessary Patient takes total dose received on Day 2 under observation of RN, NP, or physician Patient observed in clinic for 1-2 hours If withdrawal symptoms relieved, patient discharged with prescription for days 4-7 If withdrawal symptoms persist after 60-90 minutes (COWS ≥ 6) then a second dose of buprenorphine is given under observation of RN, NP, or physician Patient observed additional 1-2 hours If withdrawal symptoms relieved, patient discharged with prescription for days 4-7 If withdrawal symptoms persist, give symptomatic treatment (clonidine, NSAIDs, anti-emetics, etc.) and discharge patient with instructions to return the following day Maximum Day 3 dose: 16 mg Maximum Day 1 dose: 8-12mg (Caddy, 2017)</p>

APPENDIX P: HOME INDUCTION PROTOCOL

Home induction is the preferred method, if an option

DAY 1

Before taking your first dose of medication:

You should stop taking all opioids for 12-24 hours. Wait at least:

- 12 hours since last heroin
- 12 hours since last pain pill
- 24 hours since last methadone

Wait as long as you can. If you do not wait long enough, the buprenorphine can cause you to go into immediate withdrawal, which is extremely uncomfortable.

You should feel pretty lousy, like you're getting the flu, with at least 3 of the following symptoms:

<ul style="list-style-type: none"> • Very restless, can't sit still • Twitching, tremors, or shaking • Enlarged pupils • Bad chills or sweating • Heavy yawning 	<ul style="list-style-type: none"> • Joint and bone aches • Runny nose or tears in your eyes • Goose bumps/goose flesh • Cramps, nausea, vomiting, or diarrhea • Anxious or irritable – easily overwhelmed or irritated
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First dose:

- 4 mg film under tongue
- Two 2 mg tablets under tongue
- Half 8 mg tablet under tongue

Do not swallow buprenorphine – it only works when allowed to dissolve under your tongue or inside your cheek. **These symptoms are normal and you will feel better soon.**

Call your provider or office staff to check in.

Dose #	Amount	Time	Time to next dose
1st dose	4 mg		Wait 1-2 hours between each dose. If you feel fine, do not take anymore unless you start to feel withdrawal again.
2nd dose (if needed)			
3rd dose (if needed)			
Total on Day 1 (max: 12 mg)			

DAY 2

What was the total amount of buprenorphine you took yesterday?

4 mg

- Feel fine? Take 4 mg this morning
- If you feel some withdrawal symptoms, start with 8 mg

8 mg

- Feel fine? Take 8 mg this morning
- If you feel some withdrawal symptoms, start with 12 mg

12 mg

- Feel fine? Take 12 mg this morning
- If you feel some withdrawal symptoms, start with 16 mg

Dose #	Amount	Time	Time to next dose
1st dose			Later in the day, see how you feel. If you feel okay, do not take more. If you still feel withdrawal, take another 4 mg dose.
2nd dose (if needed)			
Total on Day 1 (max: 16 mg)			

DAY 3

Follow up visit

Date:

Time:



DEFINITIONS/GLOSSARY

Diversion: Unauthorized rerouting or misappropriate use of prescription medicine to someone other than for whom it was intended (including sharing or selling a prescribed medication) (PCSS)

Misuse: Taking medication in a manner by route or by dose, other than prescribed (PCSS)

MOUD: Medication for Opioid Use Disorder

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

OUD: Opioid Use Disorder: Per DSM-5, a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what the DSM-IV termed “opioid abuse” and “opioid dependence”. An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period. (SAMHSA)

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

SUD: Substance Use Disorder

Suboxone: buprenorphine HCl/naloxone HCl dihydrate

Subutex: buprenorphine HCl

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. (SAMHSA)

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

Relapse: A process in which a person with OUD who has been in remission experiences a return of symptoms or loss of remission. A relapse is different from a return to opioid use in that it involves more than a single incident of use. Relapses occur over a period and can be interrupted. Relapse need not be long-lasting. (SAMHSA)

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

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