Office-based Opioid Treatment after the X-Waiver

Treating Opioid Use Disorder in the Ambulatory Setting

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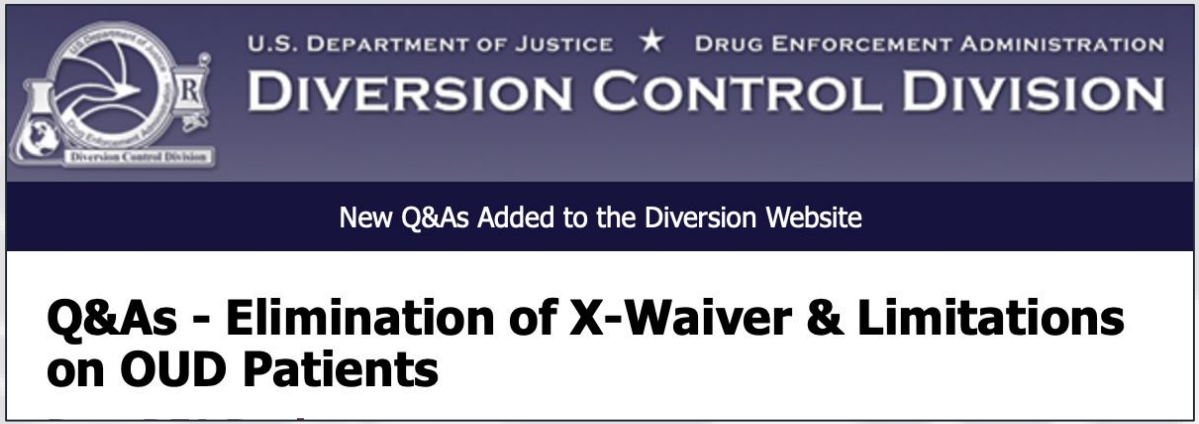
EXPLORE
HEALTHCARE SUMMIT

Consolidated Appropriations Act of 2023 Eliminates the X-waiver

Waiver Elimination (MAT Act)

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). With this provision, and effective immediately, SAMHSA will no longer be accepting NOIs (waiver applications).

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



Question: In light of the elimination of the DATA-Waiver (X-waiver) requirement, do I need to take any action to get an updated DEA registration certificate?

Answer: No action is needed on the part of registrants, as a result of the statutory repeal of 21 U.S.C. 823(h)(2). On December 29, 2022, with the signing of the CAA[i], Congress eliminated the DATA-Waiver requirement. Specifically, Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022) removed the federal requirement for practitioners to apply for a special waiver prior to prescribing buprenorphine for the treatment of Opioid Use Disorder (OUD). It also removed the requirement for the assignment of an identification number (i.e., X-waiver number) associated with being a DATA-waived provider, for inclusion with the registration issued to the practitioner. 21 U.S.C. 823(h)(2)(D)(ii). **EO-DEA260, DEA-DC-067, March 22, 2023.**

[i] Pub. L. No. 117-328, 136 Stat. 4459 (2022).

Question: Are there any limitations on the number of patients with OUD that a practitioner may treat with buprenorphine after the passage of the Consolidated Appropriations Act of 2023 (CAA)?

Answer: After enactment of the CAA,[ii] there are no longer limitations, under federal law, on the number of patients with OUD that a practitioner may treat with buprenorphine. On December 29, 2022, President Biden signed into law the CAA which expanded patient access to medications for OUD. Specifically, Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022) amended the Controlled Substances Act by repealing the "DATA-Waiver" requirement codified in 21 U.S.C. 823(g)(2), which had previously imposed limits or patient caps on the number of OUD patients a prescriber may treat with buprenorphine. These limits were previously outlined at 21 U.S.C. 823(g)(2)(B)(iii), and allowed qualified practitioners to treat up to 30, 100, or 275 patients at one time. **EO-DEA263, DEA-DC-066, March 21, 2023.**

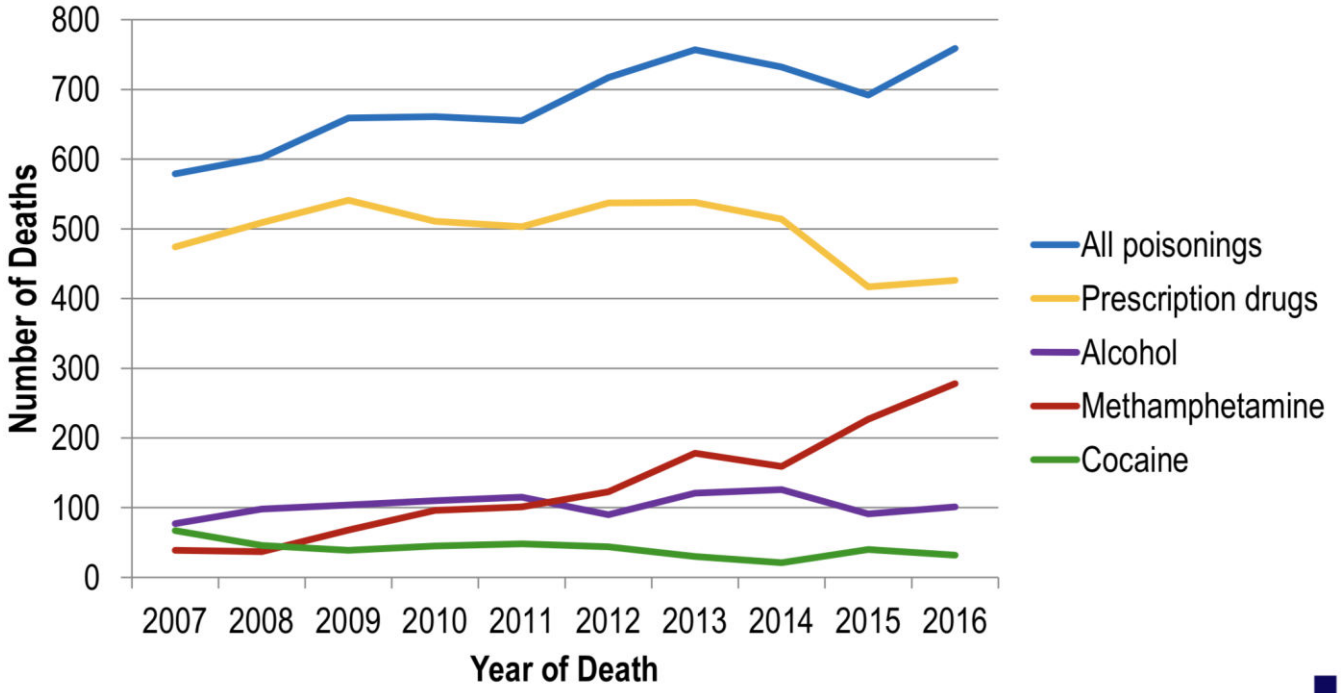
[ii] Pub. L. No. 117-328, 136 Stat. 4459 (2022).

Consolidated Appropriations Act of 2023 SUD CME Requirements

- Requires new or renewing Drug Enforcement Administration (DEA) registrants, as of June 27, 2023, to have completed at least 8 hours of training on opioid or other substance use disorders, as well as the safe pharmacological management of dental pain.
- Practitioners can meet this requirement in one of three ways:
    1. A total of 8 hours of training from various training entities on opioid or other substance use disorders.
    2. Board certification in addiction medicine or addiction psychiatry.
    3. Graduation within 5 years and in good standing from a medical, advanced practice nursing, or physician assistant school in the United States that included successful completion of an opioid or other substance use disorder curriculum of at least 8 hours.

SAMHSA. Recommendations for Curricular Elements in Substance Use Disorders Training. Retrieved from https://www.samhsa.gov/medications-substance-use-disorders/provider-support-services/recommendations-curricular-elements-substance-use-disorders-training.

Deaths Involving Prescription Drugs, Illicit Drugs, or Alcohol by Year of Death, Unintentional Poisoning, Oklahoma, 2007-2016



Source: OSDH, Injury Prevention Service, Fatal Unintentional Poisoning Surveillance System (Abstracted from Medical Examiner reports)

Oklahoma State Department of Health

AMA
AMERICAN MEDICAL ASSOCIATION

2022 OVERDOSE EPIDEMIC REPORT

"2022 Overdose Epidemic Report." AMA End the Epidemic. American Medical Association, September 8, 2022. https://end-overdose-epidemic.org/highlights/ama-reports/2022-report/.

Reductions in opioid prescribing have not led to reductions in drug-related mortality

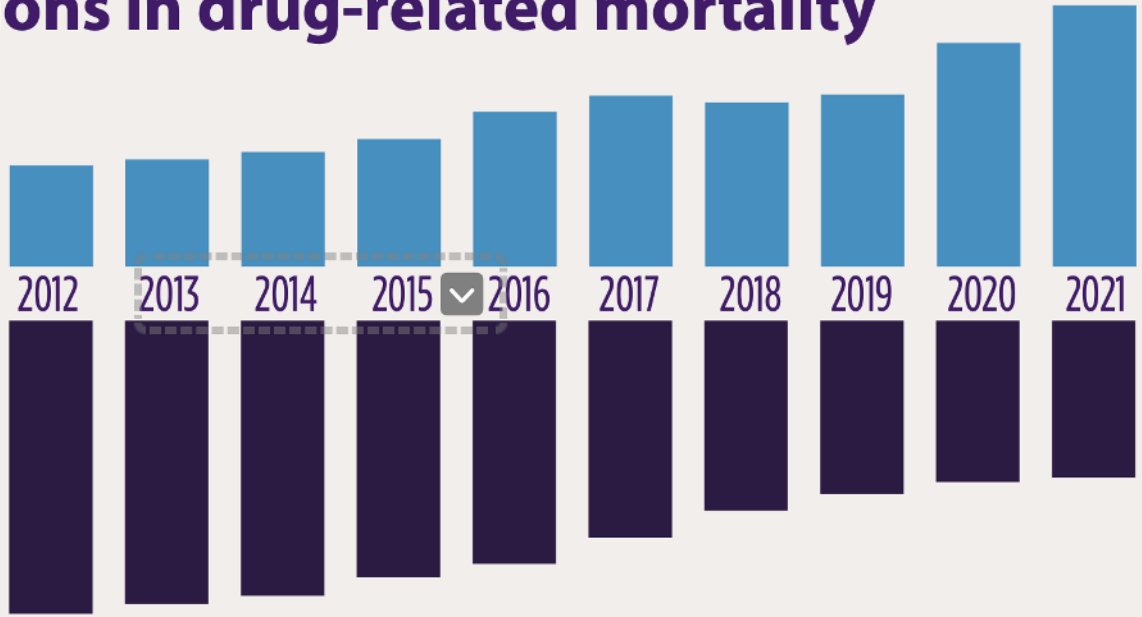
2021 overdose deaths:

107,521*

2021 opioid prescriptions:

139,617,469[1]

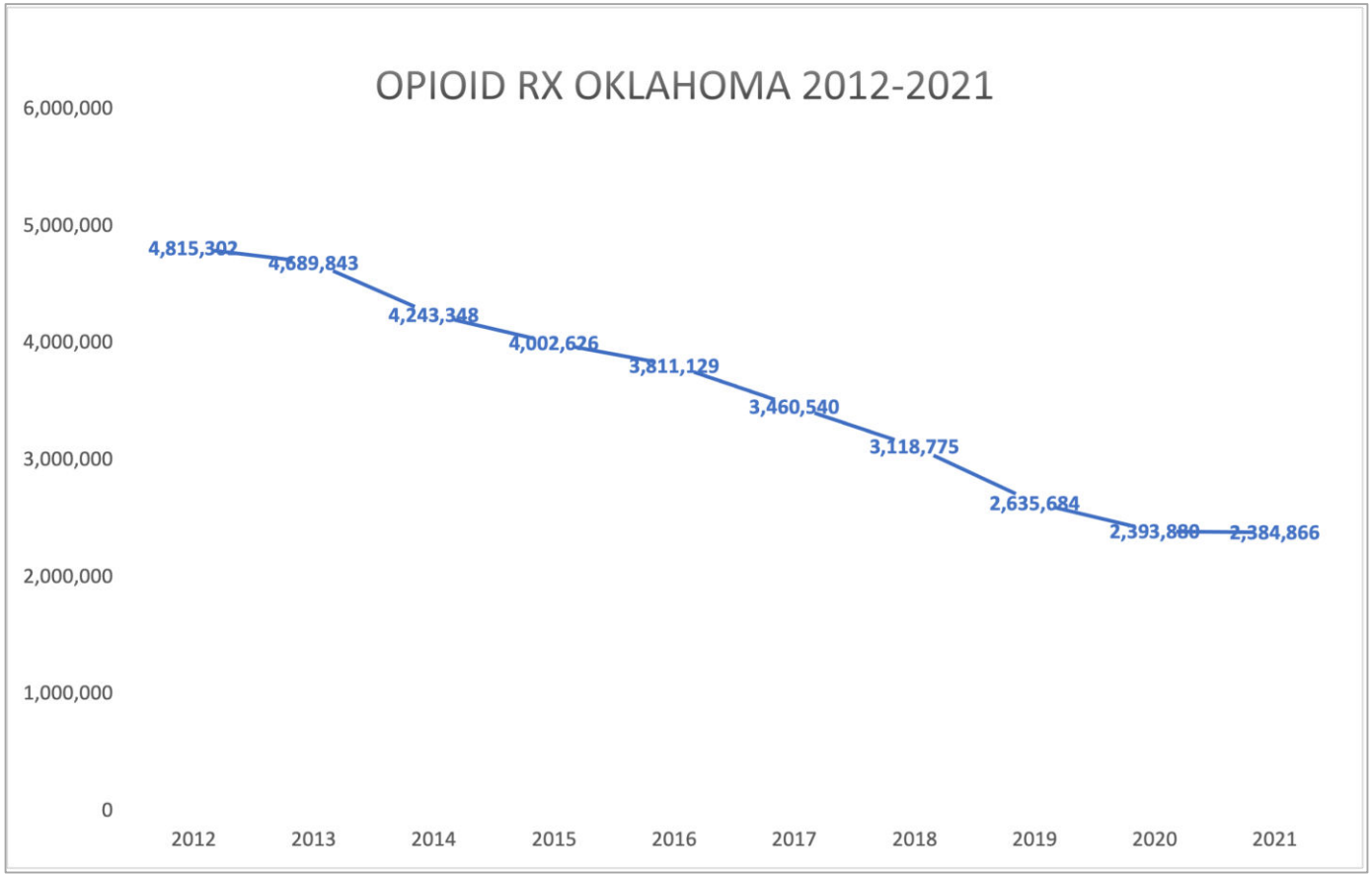
(46.4% decrease since 2012)



*Provisional data for the 12-month period Jan. 2021–Dec. 2021

https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

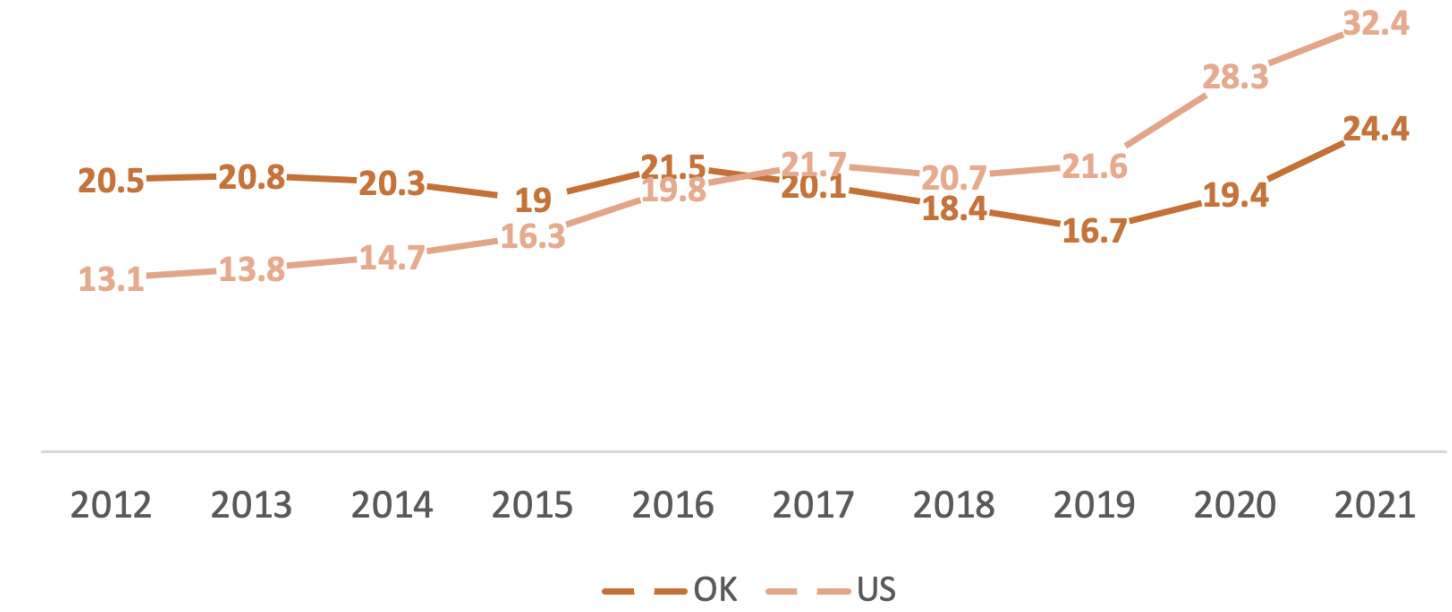
"2022 Overdose Epidemic Report." AMA End the Epidemic. American Medical Association, September 8, 2022. https://end-overdose-epidemic.org/highlights/ama-reports/2022-report/.



53% Reduction

"2022 Overdose Epidemic Report." AMA End the Epidemic. American Medical Association, September 8, 2022. https://end-overdose-epidemic.org/highlights/ama-reports/2022-report/.

ALL DRUG OVERDOSE DEATH RATES PER 100,000 (AGE ADJUSTED)

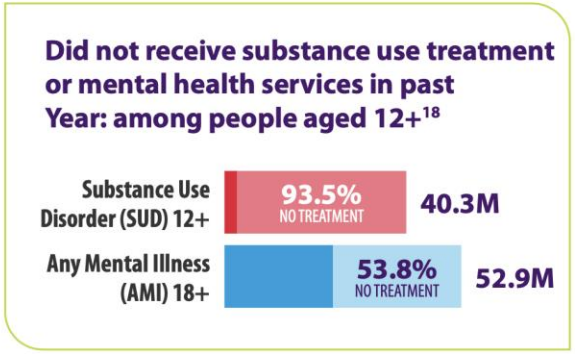


https://www.kff.org/other/state-indicator/opioid-overdose-death-rates. Accessed 4-14-23.

Ending the nation's drug-related overdose and death epidemic means increasing access to medications to treat opioid use disorder and evidence-based harm reduction initiatives.

Increasing access to syringe services programs is essential to limiting the spread of blood-borne infectious disease.

Medications to treat opioid use disorder are the gold standard,[17] but too few individuals receive it.



Year	Buprenorphine prescriptions dispensed from retail pharmacy[1]
2017	14,115,168
2018	15,617,470
2019	16,808,528
2020	17,461,686
2021	17,738,055

"2022 Overdose Epidemic Report." AMA End the Epidemic. American Medical Association, September 8, 2022. https://end-overdose-epidemic.org/highlights/ama-reports/2022-report/.

Lecture Overview

- Diagnosing Opioid Use Disorder
- Treating Opioid Use Disorder
- Recovery and Medications

Diagnosing Opioid Use Disorder

Patterns Suggestive of Addiction (4 C's)

- Preoccupation with use because of **C**raving
- Impaired **C**ontrol
- **C**ompulsive use
- Continued use in spite of adverse **C**onsequences

Prescription Opioid Misuse

- Prescription misuse is usually the first sign of pathology.
- 40% incidence when non-cancer pain is treated with opioids.

Ives T.J., Chelminski P.R., Hammett-Stabler C.A., et al: **Predictors of opioid misuse in patients with chronic pain: a prospective cohort study.** BMC Health Serv Res 2006; 6: pp. 46

Risk Factors for Prescription Misuse

- Current misuse predicts future misuse.
- Past or current history of an addiction disorder to any substance.
- Negative affective disorders.
  - Major Depression, Anxiety, Personality Disorders.
- Previous or current history of sexual or physical abuse.
- Family history of substance use disorders.
- History of illegal activities.

Becker, W. C., Sullivan, L. E., Tetrault, J. M., Desai, R. A., & Fiellin, D. A. (2008). Non-medical use, abuse, and dependence on prescription opioids among U.S. adults: psychiatric, medical, and substance use correlates. **Drug and Alcohol Dependence**, 94(1-3), 38-47.

Aberrant Drug Related Behaviors

- **Aberrant Behavior** is a patient behavior that breaches of mutually established medical boundaries.
- Categories:
  - Loss of control/compulsive use.
  - Violations of social norms.
  - Continued use despite harm.

Portenoy, Russell K, **Opioid therapy for chronic nonmalignant pain: a review of the critical issues.** Journal of Pain and Symptom Management , Volume 11 , Issue 4 , 203 – 217 doi: 10.1016/0885-3924(95)00187-5

ADRB Less Predictive of Addiction

- Aggressive complaining about the need for more drug.
- Drug hoarding during periods of reduced symptoms.
- **Requesting specific drugs.**
- Openly acquiring similar drugs from other medical sources.
- Unsanctioned dose escalation or other noncompliance on one or two occasions.
- Unapproved use of the drug to treat another symptom.
- Reporting psychic effects not intended by the clinician.
- **Resistance to changes in therapy.**

Portenoy, Russell K, **Opioid therapy for chronic nonmalignant pain: a review of the critical issues.** Journal of Pain and Symptom Management , Volume 11 , Issue 4 , 203 – 217 doi: 10.1016/0885-3924(95)00187-5

Elderly man misses random pill count...

ASSESSMENT AND PLAN:

1. Congestive heart failure exacerbation. The patient has markedly improved with Lasix. We will check 2D echo. Meanwhile, continue Lasix, aspirin, Plavix, beta blockers. No ACE given. The patient's renal function, current creatinine of 2.01. May recommend low-dose statin despite LDL being 34.
2. Elevated troponins/non ST elevation myocardial infarction. Scheduled for MPS. Meanwhile, continue aspirin, Plavix and beta-blockers.
3. Chronic pain syndrome. We will resume the patient's medication, has been on oxycodone. Unfortunately, was cut off by his pain physician for nonadherence to his contract. He has been off his medications, will resume 50 mg of oxycodone 4-6 times daily.
4. Acute kidney injury. We will continue supportive management. We will check his renal function in a.m.

Discussed my _____.

Incomplete dictation BF 7/8

ADRBs More Predictive of Addiction

- Prescription forgery.
- Stealing or “borrowing” drugs from others.
- Injecting oral formulations.
- Obtaining prescription drugs from nonmedical sources.
- **Concurrent abuse of alcohol or illicit drugs.**
- **Multiple dose escalations or other noncompliance despite warnings.**
- **Multiple episodes of prescription “loss”.**
- Repeatedly seeking prescriptions from other clinicians or from emergency departments (EDs) without informing the prescriber or after a warning to desist.
- **Evidence of deterioration in the ability to function at work, in the family, or socially that appears to be related to use of the drug.**
- Repeated resistance to changes in therapy despite clear evidence of adverse physical or psychological effects from the drug.
- Selling prescription drugs.

Portenoy, Russell K, **Opioid therapy for chronic nonmalignant pain: a review of the critical issues.** Journal of Pain and Symptom Management , Volume 11 , Issue 4 , 203 – 217 doi: 10.1016/0885-3924(95)00187-5

Established patient, unexpected UDS…

I have been treating [redacted] for the past eight months for her chronic pain since my partner, Dr. [redacted], left the practice. Unfortunately, on her most recent urine drug screen, she tested positive for street methamphetamines. Due to this, we are going to be releasing her from [redacted].

Attenuation and Addiction

- With continued opioid use, the dopaminergic effect decreases and increased consumption is needed to maintain “normal” levels of pleasure.

- Recreational users are motivated by positive reinforcement.
  - Excess dopamine activity.
- Addicted users are motivated by negative reinforcement.
  - Deficient dopamine activity.

Screening/Risk Tools for OUD

- Opioid Risk Tool (ORT): Categorizes patient risk for aberrancy.
  - Low (score of 3 or lower)
  - Moderate (score of 4 to 7)
  - High (score of 8 or higher)
- Current Opioid Misuse Measure (COMM): Can identify aberrant drug-related behavior in patients who are currently taking opioids.

Social History:	ORT	Note space:	D3 47.8 FM
Do you have a Family History of Alcohol abuse?	Yes No		1 3
Do you have a Family History of Street drug abuse?	Yes No		2 3
Do you have a Family History of Prescription drug abuse?	Yes No		4 4
Do you have a Personal History of Alcohol abuse?	Yes No		3 3
Do you have a Personal History of Street drug abuse?	Yes No		4 4
Do you have a Personal History of Prescription drug abuse?	Yes No		5 5
Is your age between 16 and 45 years old?	Yes No		1 1
Do you have a Personal History of Preadolescent Sexual Abuse?	Yes No		3 0
Do you have a History of ADD, OCD, Bipolar or Schizophrenia?	Yes No		2 2
Do you have a Personal History of Depression?	Yes No		1 1

Review of Body Systems: Circle your symptoms. Write in any others. Circle "OK" if no symptoms present.

Constitution	OK Fever Chills Fatigue Weight loss Weight gain of: pounds in: weeks.
Ears/Throat	OK Sore throat Ear pain Congestion Drainage Sinus pain Hearing Loss
Heart	OK Chest pain Chest pressure Forceful beats Irregular beat High blood pressure
Lungs	OK Cough Cough up blood Cough up mucus Short of Breath Wheezing Asthma
Digestive	OK Heartburn Nausea Vomiting Diarrhea Constipation Blood in stool Dark stools
Genital-Urinary	OK Burning Frequency Blood in urine Nocturnal urination Pregnancy Erectile problem
Blood & Glands	OK Anemia Easy bruising Easy bleeding Lymph node enlargement
Eyes	OK Double vision Mattering Itchiness Blurring Loss of vision
Hormones	OK Excess thirst Excess urination Cold or heat intolerance Menstrual problems
Bones & Muscle	OK Joint pain Joint stiffness Joint swelling Muscle aches Gout Back pain Ankle swelling
Nerves	OK Headache Dizziness Numbness Weakness Fainting Seizures Tremors
Allergies	OK Medicine allergy Dye allergy Seasonal allergy Food allergy Latex allergy
Skin	OK Rashes Lumps Dryness Change in moles Change in pigment or color
Emotions	OK Depression Poor sleep Anxiety Stress Memory disturbance Suicidal thinking

Opioid Use Disorder (DSM-V)

- The opioid is often taken in larger amounts or over a longer period than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control use.
- A great deal of time is spent on activities necessary to obtain, use, or recover from the effects of the opioid.
- Recurrent use results in failure to fulfill major role obligations.
- Use is continued despite persistent, or recurrent social or interpersonal problems caused or exacerbated by the substance.
- Important social, occupational, or recreational activities are reduced because of use.
- Use occurs in situations in which it is physically hazardous.
- Use is continued despite knowledge of a persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the opioid.
- Tolerance is present (not counted for those taking medications under medical supervision).
- Withdrawal occurs (not counted for those taking medications under medical supervision).
- There is craving or a strong desire or urge to use the opioid.

Opioid Use Disorder (DSM-V) Severity

- Mild: Presence of 2–3 symptoms. F11.10
- Moderate: Presence of 4–5 symptoms. F11.20
- Severe: Presence of 6 or more symptoms. F11.20

Tips for Detecting Opioid Use Disorder

- Physical dependence occurs when opioid use is prolonged.
- Opioid misuse is usually the first sign of pathology.
- Failing social obligations suggests addiction.
- Craving is the hallmark of addiction.
- Look for use motivated by negative reinforcement.

Diagnosing Opioid Use Disorder

MAT Defined

- Medication-assisted treatment (MAT) is the use of medications for opioid use disorder (MOUDs) with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.

"Medication and Counseling Treatment." SAMHSA - Substance Abuse and Mental Health Services Administration. September 28, 2015. Accessed July 21, 2018. https://www.samhsa.gov/medication-assisted-treatment/treatment.

MOUD vs Tapering & Withdrawal

- Majority of patients relapse with withdrawal management alone
  - Including with tapering
  - Including residential detoxification
    - One 2010 prospective cohort study of 109 patients
    - 91% of patients relapsed
    - 59% relapsing in the first week

Smyth BP. Barry J, Keenan E. Ducray K. Lapse and relapse following inpatient treatment of opiate dependence. IrMedJ. 2010;103(6):176-179.

SAMHSA
Substance Abuse and Mental Health Services Administration

BUPRENORPHINE QUICK START GUIDE

Important Points to Review With the Patient

Specifically discuss safety concerns:

- **Understand that discontinuing buprenorphine increases risk of overdose death upon return to illicit opioid use.**
- **Know that use of alcohol or**

Facts About Buprenorphine

- FDA approved for Opioid Use Disorder treatment in an office-based setting.
- For those with tolerance to opioids as a result of OUD, buprenorphine is often a safe choice.
- Buprenorphine acts as a partial mixed opioid agonist at the μ-receptor and as an antagonist at the κ-receptor. It has a higher affinity for the μ-receptor than other opioids, and it can precipitate withdrawal symptoms in those actively using other opioids.
- It is dosed daily, has a long half-life, and prevents withdrawal in opioid dependent patients.
- Can be in tablet, sublingual film, or injectable formulations

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- Buprenorphine acts as a partial mixed opioid agonist at the μ- receptor and as an antagonist at the κ-receptor. It has a higher affinity for the μ-receptor than other opioids, and it can precipitate withdrawal symptoms in those actively using other opioids.
- It is dosed daily, has a long half-life, and prevents withdrawal in opioid dependent patients.
- Many formulations contain naloxone to prevent injection diversion. This formulation is the preferred treatment medication.
- There is a “ceiling effect” in which further increases above 24mg in dosage does not increase the effects on respiratory or cardiovascular function.
- Buprenorphine should be part of a comprehensive management program that includes psychosocial support. Treatment should not be withheld in the absence of psychosocial support.
- Overdose with buprenorphine in adults is less common, and most likely occurs in individuals without tolerance, or who are using co-occurring substances like alcohol or benzodiazepines.

1. Assess the need for treatment

- For persons diagnosed with an opioid use disorder,* first determine the severity of the patient's substance use disorder. Then, identify any underlying or co-occurring diseases or conditions, the effect of opioid use on the patient's physical and psychological functioning, and the outcomes of past treatment episodes.
- A patient's history includes a medical and psychiatric history, substance use history, and family and psychosocial support evaluation.
- Access the patient's prescription drug use history through the state's Prescription Drug Monitoring Program (PDMP), to detect unreported use of other medications, such as sedative-hypnotics or alcohol, that may interact adversely with the treatment medications.
- A physical examination that focuses on physical findings related to addiction and its complications.
- Laboratory testing to assess recent opioid use and screen for other drugs. Useful tests include a urine drug screen or other toxicology screen, urine test for alcohol (ethyl glucuronide), liver enzymes, serum bilirubin, serum creatinine, and tests for hepatitis B and C and HIV. Providers should not delay treatment initiation while awaiting lab results.

2. Educate the patient

- **Educate the patient about how the medication works and the associated risks and benefits; obtain informed consent; and educate on overdose prevention.**
- There is potential for relapse & overdose on discontinuation of the medication. Patients should be educated about the effects of using opioids and other drugs while taking the prescribed medication and the potential for overdose if opioid use is resumed after tolerance is lost.

3. Evaluate the need for medically managed withdrawal from opioids

- Those starting buprenorphine must be in a state of withdrawal.

4. Address co-occurring disorders

- Have an integrated treatment approach to meet a patient's substance use, medical and mental health, and social needs.

5. Integrate pharmacologic and nonpharmacologic therapies

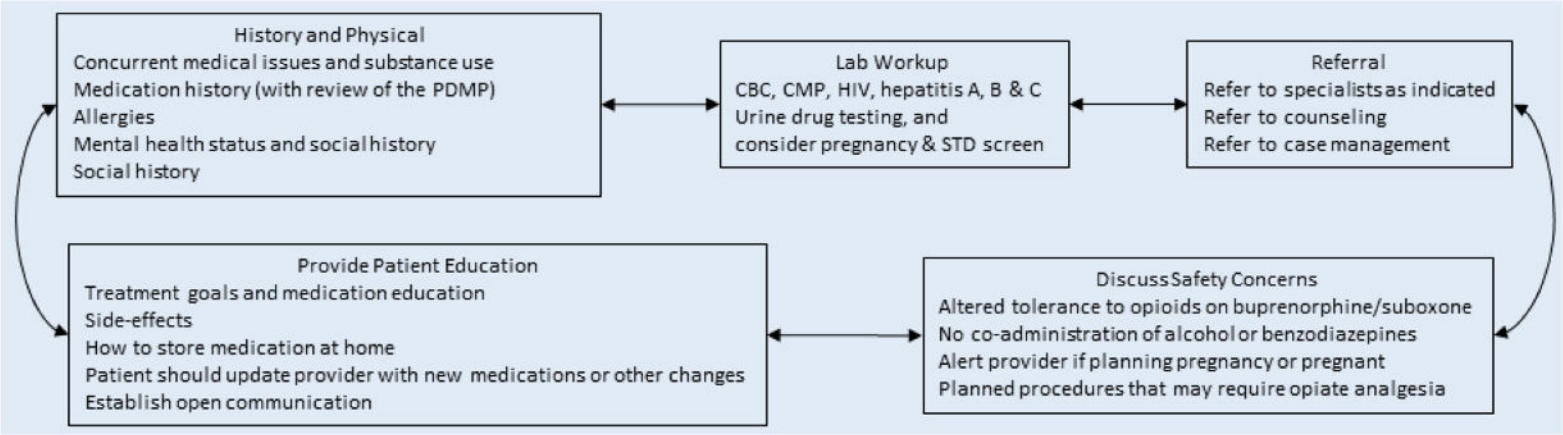
- All medications for treating the opioid use disorder are prescribed as part of a comprehensive individualized treatment plan that includes counseling, other psychosocial therapies, and social support through participation in mutual-help programs.

6. Refer patients for higher levels of care, if necessary

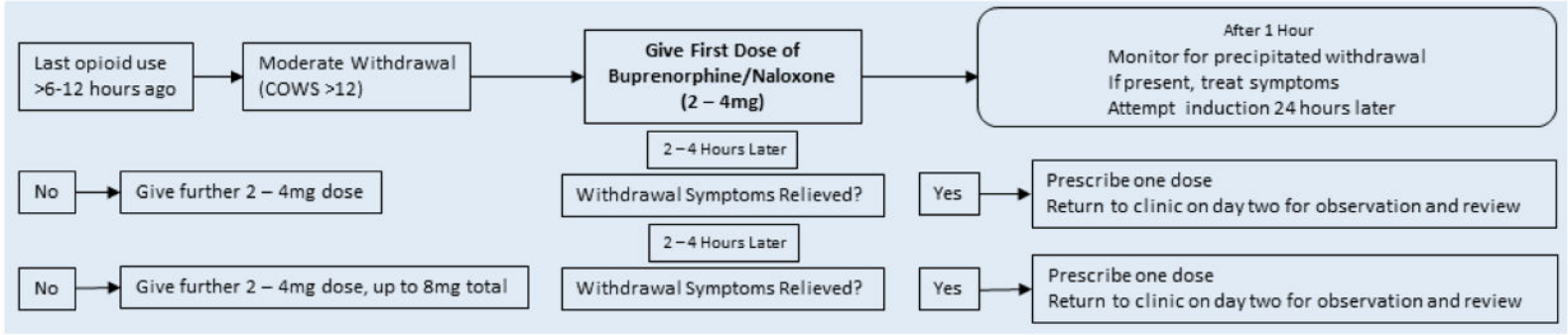
- **Refer patients for higher levels of care, if necessary**
- Refer the patient for more intensive or specialized services if office-based treatment with buprenorphine or naltrexone is ineffective, or the clinician does not have the resources to meet a particular patient's needs.
- Providers can find programs in their areas or throughout the United States by using SAMHSA's Behavioral Health Treatment Services Locator at www.findtreatment.samhsa.gov.

Algorithm for In-Office Induction (for home induction prescriptions may be given)

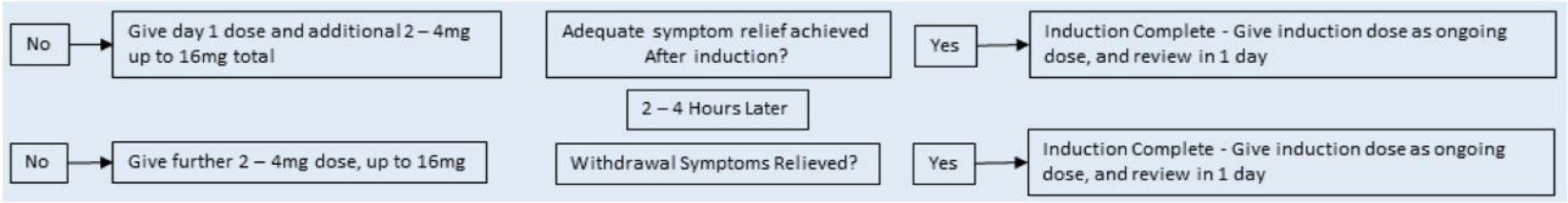
Initial Assessment



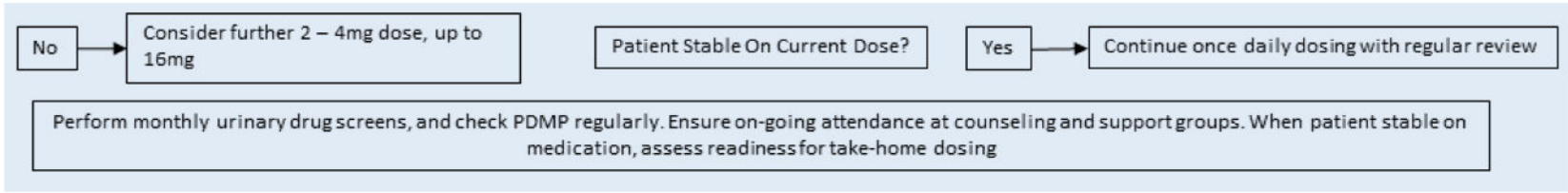
Day One (Induction)



Day Two



Maintenance



Skiatook Family Clinic
201 East 2nd
Skiatook, OK 74070
Tel. 918/396-1262 Fax. 918/396-4598

OPIOID WITHDRAWAL RECORD (Induction Form)

(Adapted from Clinical Opioid Withdrawal Scale)

Patient Name [redacted] **Treatment Start Date** 7/24/18

Circle the number/description which best corresponds to your patient's present symptoms

Parameter	Baseline Observation Time: 2/0.5 4/1 08:30	1st Dose Observation Time: 09:30	1st Dose, 2nd Observation (if needed) Time: 10:30	2nd dose (if needed) Time: 2/0.5 4/1 11:30	2nd Dose Observation Time:
Resting pulse rate _____beats/min *Measure after patient is sitting lying for 1 minute* **0** pulse rate 80 or below **1** pulse rate 81-100 **2** pulse rate 101-120 **4** pulse rate greater than 120	0 1 2 4 — 77	0 1 2 4 — 86	0 1 2 4 — 97	0 1 2 4 — 85	0 1 2 4
Sweating *Over past 30 minutes: 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	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
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	0 1 3 5	0 1 3 5	0 1 3 5	0 1 3 5	0 1 3 5
Tremors *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	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
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	0 1 2 5	0 1 2 5	0 1 2 5	0 1 2 5	0 1 2 5

	Baseline Observation	1st Dose Observation	1st Dose, 2nd Observation	2nd dose	2nd Dose Observation
GI upset *Over last 30 minutes* **0** no GI symptoms **1** stomach cramps **2** nausea or loose stool **3** vomiting or diarrhea **5** multiple episodes of diarrhea or vomiting	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5
Anxiety or irritability **0** none **1** patient reports increasing irritability or anxiousness **2** patient obviously irritable/anxious **4** patient so irritable/anxious that participation in assessment is difficult	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Bone or joint aches *If patient was having pain previously, gauge the additional component attributed to opioid withdrawal only* **0** not present **1** mild diffuse discomfort **2** patient reports severe diffuse aching of joints/ muscles **4** patient is rubbing joints or muscles and is unable to sit still because of discomfort	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
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	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Runny nose or tearing *Not accounted for by cold symptoms or allergies* **0** not present **1** nasal stuffiness or unusually moist eyes **2** nose running or tearing **4** nose constantly running or tears streaming down cheeks	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Gooseflesh skin **0** skin is smooth **3** skin piloerection can be felt or hairs standing up on arms **5** prominent piloerection	0 3 5	0 3 5	0 3 5	0 3 5	0 3 5
Total Score _____ Total score is the sum of all 11 items • 5-12 = mild • 13-24 = moderate • 25-36 = moderately severe • >36 = severe withdrawal	19	9	6	3	

Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Journal of Psychoactive Drugs, 35*(2), 253-259.

Find Services Near You

Opioid Addiction

Urgent Recovery and Crisis Center

Support Groups

And More

https://oklahoma.gov/odmhsas.html

What should I do if a patient diverts or miss use his medication?

1. Misuse or diversion doesn't mean automatic discharge from the practice.
2. Document and describe the misuse and diversion incident. Also, document the clinical thinking that supports the clinical response, which should be aimed at minimizing future risk of diversion while still supporting the use of MAT.
3. Strongly consider smaller supplies of medication and supervised dosing.
4. Treatment structure may need to be altered, including more frequent appointments, supervised administration, and increased psychosocial support.
5. When directly observed doses in the office are not practical, short prescription time spans can be considered.
6. Open communication with the patient is critical in situations where diversion is detected. Providers may consider injectable and implantable buprenorphine to reduce diversion once verified.

How can providers minimize diversion risk?

1. Early in treatment, patients are seen often and less frequently only when the provider determines they are doing well.
2. Providers should inquire about safe and locked storage of medications. Patients must agree to the safe storage of their medication.
3. Limit medication supply. Prescribe the amount needed to reach the next visit. Do not routinely provide an additional supply “just in case.”
4. Use buprenorphine/naloxone combination products when medically indicated—reserve daily buprenorphine mono products for pregnant patients.
5. Counsel patients on taking their medication as instructed and not sharing medication.
6. Ensure that the patient understands the practice’s treatment agreement and prescription policies.
7. Directly observe ingestion randomly when diversion is suspected.
8. Providers should order random urine drug testing to check for other drugs and metabolites of buprenorphine.
9. Doctors should schedule unannounced pill/film counts.
10. Providers should make inquiries with the Prescription Drug Monitoring program to detect prescriptions from other providers.
11. Ask the patient to sign a release of information for a family member or spouse to communicate concerns.

Maintenance Therapy

- Goal = once-daily dosing, no withdrawal between doses.
- Check PDMP regularly to ensure prescriptions are filled, and to check other prescriptions.
- Order urine drug testing (UDT) and consider confirmatory testing for unexpected results. UDT can facilitate open communication to change behavior.
- Assess for readiness for extended take-home dosing

Tapering Buprenorphine: Balancing Benefits and Risks

- Before considering buprenorphine tapering, patients should be informed of the potential risks, including relapse and increased risk of overdose and overdose death.
- The evidence on the most effective rate of tapering buprenorphine is limited, and there is no one-size-fits-all approach.
- One trial found that longer courses of buprenorphine with gradual tapering were more effective than rapid tapering for withdrawal.
- Close monitoring and ongoing support is crucial for patients during the tapering process and beyond.

Lee, J. D., Nunes, E. V., Jr, Novo, P., Bachrach, K., Bailey, G. L., Bhatt, S., … Rotrosen, J. (2018). Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial. Lancet (London, England), 391(10118), 309–318. https://doi.org/10.1016/S0140-6736(17)32812-X

Recovery and Medications

Discontinuing MOUDs is a personal decision

- Tapering medication for opioid use disorder (MOUD) is a personal decision for a patient because it involves their own goals, preferences, and values.
- The decision to taper MOUD should be made collaboratively between the patient and their healthcare provider, taking into account the patient's individual circumstances and goals.

National Institute on Drug Abuse. (2021). Medications to treat opioid use disorder: Frequently asked questions. Retrieved from https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-use-disorder/frequently-asked-questions.

Discontinuing Buprenorphine/Naloxone

- Most patients who attempt to withdraw from buprenorphine/naloxone fail.
- Review articles summarize the literature exploring and comparing methods for discontinuing buprenorphine/naloxone.
  - Dunn et al. (2018) compared 27 studies.
    - Median of 23% of participants provided opioid-negative samples at the first post-taper follow-up visit.
- Treatment barriers for patients at high risk for discontinuation should be addressed.

Reference: Dunn, K. E., Bergeria, C. L., Harris, A. H. S., & Nuzzo, P. A. (2018). Buprenorphine/naloxone for opioid dependence: Clinical practice and barriers to uptake. Journal of Addiction Medicine, 12(6), 441-452. https://doi.org/10.1097/ADM.0000000000000433

Tapering a MOUD can carry various risks

- Relapse: A study published in the Journal of Substance Abuse Treatment
  - Among the patients who tapered off buprenorphine, 64% relapsed within six months, compared to 26% of those who continued taking the medication.
- Withdrawal symptoms: Tapering off opioid medications can also cause withdrawal symptoms, which can be uncomfortable and even dangerous in some cases.
  - The severity can vary depending on the individual and the medication
- Overdose: Another risk of tapering medication for OUD is an increased risk of overdose.
  - According to a study published in the Journal of Substance Abuse Treatment, patients who tapered off buprenorphine were more likely to experience a non-fatal overdose than those who continued taking the medication. Among the patients who tapered off buprenorphine, 12% experienced a non-fatal overdose within six months, compared to 2% of those who continued taking the medication.

•Substance Abuse and Mental Health Services Administration. (2015). TIP 45: Detoxification and substance abuse treatment. https://store.samhsa.gov/product/TIP-45-Detoxification-and-Substance-Abuse-Treatment/SMA15-4131

Injury Rates in OUD Patient Relapse

- A study by Bohnert et al. (2017) found that OUD patients who relapsed had a significantly higher risk of injury compared to those who did not relapse
  - Among patients who relapsed, the injury rate was 13.7 per 100 person-years
  - Among patients who did not relapse, the injury rate was 2.9 per 100 person-years
  - Injuries included overdose, suicide attempt, and non-fatal unintentional injuries
- The World Health Organization (WHO) estimates the global injury rate for unintentional injuries at an injury rate of approximately 0.02 per 100 person-years.

Reference: Bohnert, A. S. B., Bonar, E. E., Cunningham, R., Chermack, S., Ilgen, M., & Blow, F. C. (2017). A pilot randomized clinical trial of an intervention to reduce overdose risk behaviors among emergency department patients at risk for prescription opioid overdose. Drug and Alcohol Dependence, 174, 79-87. https://doi.org/10.1016/j.drugalcdep.2017.01.003

Discontinuing Buprenorphine/Naloxone Maintenance for Compliance Reasons

- Bentzley et al. (2015) conducted a systematic review on discontinuing buprenorphine/naloxone maintenance
  - Most patients discontinued involuntarily due to failing to meet program requirements
  - Rates of relapse to illicit opioid use 1 month after discontinuation were over 50% in every study
  - Across all studies, 18% of patients were abstinent from opioids in the first month following discontinuance of buprenorphine/naloxone

Reference: Bentzley, B. S., Barth, K. S., & Back, S. E. (2015). Discontinuation of buprenorphine maintenance therapy: Perspectives and outcomes. Journal of Substance Abuse Treatment, 52, 48-57. https://doi.org/10.1016/j.jsat.2014.12.008

Transitioning Methadone to Bup/Nal to Nothing

- Breen et al. (2017) explored transferring patients from methadone to buprenorphine/naloxone and tapering off
- 75% of patients reached zero dosage, but only 31% were not using heroin or methadone at 1-month follow-up
- 13% switched to buprenorphine/naloxone and one tapered off, while 67% stopped tapers due to various reasons
  - Feeling unstable/withdrawal symptoms
  - Positive drug tests
  - Pain management issues

Reference: Breen, C., Degenhardt, L., Bruno, R., et. al (2017). Does swapping from methadone to sublingual buprenorphine stabilize patients on long-term methadone maintenance treatment? Journal of Substance Abuse Treatment, 81, 81-86.

Misconception: Discontinuing Medications is Necessary

- Stigma is a powerful force perpetuating negative attitudes toward opioid medications
  - Many view discontinuation as a desirable or a primary goal
- Methadone and buprenorphine/naloxone are dependence-producing medications
  - Many medications are dependence producing but less influenced by stigma
    - Synthetic thyroid, antidepressants, antipsychotics, antihistamines, blood pressure medications, and antiepileptic drugs

Weiss, R. D. (2016). Commentary on the SAMHSA opioid treatment guidelines: Clinical implications. Journal of Addiction Medicine, 10(2), 80-81. https://doi.org/10.1097/ADM.0000000000000204

Misconception: Treatment as a Moral Weakness

- The belief that receiving maintenance opioids reflects an illness, a defect, or moral weakness
- Family members and peers may devalue a patient's accomplishments if they remain on medication
- Patients may fear losing their jobs due to detection

Weiss, R. D. (2016). Commentary on the SAMHSA opioid treatment guidelines: Clinical implications. Journal of Addiction Medicine, 10(2), 80-81. https://doi.org/10.1097/ADM.0000000000000204

Misconception: If I just try harder

- The belief that the ability to discontinue opioid medications is solely a matter of willpower and effort

Weiss, R. D. (2016). Commentary on the SAMHSA opioid treatment guidelines: Clinical implications. Journal of Addiction Medicine, 10(2), 80-81. https://doi.org/10.1097/ADM.0000000000000204

Addressing Guilt-based Misconceptions

- Research suggests genetic factors play a role in vulnerability to opioid addiction
- Long-term opioid use can also alter neurobiological factors and make it difficult discontinuation difficult
- Opioid agonist treatment is a safe and effective long-term option

Weiss, R. D. (2016). Commentary on the SAMHSA opioid treatment guidelines: Clinical implications. Journal of Addiction Medicine, 10(2), 80-81. https://doi.org/10.1097/ADM.0000000000000204

Medication-based Misconceptions

- The “treating an opioid use disorder with an opioid” misunderstanding.
- The idea medications that are easier to taper are better for treating opioid use disorder
  - Is buprenorphine/naloxone really preferable?
  - No consistent relationship between ease of discontinuation and long-term abstinence
- Work collaboratively with patients to determine the best medication and treatment plan for their individual needs and circumstances

Weiss, R. D. (2016). Commentary on the SAMHSA opioid treatment guidelines: Clinical implications. Journal of Addiction Medicine, 10(2), 80-81. https://doi.org/10.1097/ADM.0000000000000204

Discontinuing Agonist Treatment Not Recommended

- Weinstein et al. (2016) found many patients want to discontinue opioid agonist treatment, few are successful, and efforts should be focused on overcoming barriers to long-term maintenance
- Discontinuing opioid agonist treatment is not recommended for most patients and that long-term maintenance should be the primary goal of treatment

Weinstein, Z. M., Gryczynski, J., Cheng, D. M., Quinn, E., Hui, D., Kim, H. W., . . . Samet, J. H. (2016). Tapering off and returning to buprenorphine maintenance in a primary care Office-Based Addiction Treatment (OBAT) program. Drug and Alcohol Dependence, 168, 66-72. https://doi.org/10.1016/j.drugalcdep.2016.08.640

The Recovery Capital Checklist

- A tool based on the Tapering Readiness Inventory providers can use when considering tapering.
- Guide patients to make their own assessment of readiness.
- Considers factors that contribute to recovery.
  - Physical health, psychological well-being, social support, etc
- Identify areas that may require additional attention and support.
- Helps patients build a foundation for long-term success.

Laudet, A., & White, W. (2010). What are your priorities right now? Identifying service needs across recovery stages to inform service development. Journal of Substance Abuse Treatment, 38(1), 51-59.

Recovery Capital: Patient Considerations

TABLE 1. The Recovery Capital Checklist (Patients and Counselors Section)

1.	Have you been abstaining from illegal drugs, such as heroin, cocaine, and speed?
2.	Do you think you are able to cope with difficult situations without using drugs?
3.	Are you employed or in school?
4.	Are you staying away from contact with users and illegal activities?
5.	Have you gotten rid of your drug paraphernalia?
6.	Are you living in a neighborhood that doesn't have a lot of drug use?
7.	And are you comfortable there?
8.	Do you have nonuser friends that you spend time with?
9.	Are you living in a stable household or family?
10.	Do you have friends or family who would be helpful to you during a taper?
11.	Do you have a spiritual practice?
12.	Have you been participating in counseling that has been helpful?
13.	Does your counselor think you are ready to taper?
14.	Do you think you would ask for help when you are feeling bad during a taper?
15.	Are you in good mental and physical health?
16.	Do you want to get off methadone or buprenorphine?

The purpose of this section of the Checklist is to help patients and counselors to decide if the patient is ready to taper or discontinue from MOU
important part of the process of being ready to discontinue MOUD.

The more questions that can honestly be answered "yes," the greater the likelihood that the patient is ready to taper from opioid medicati
represents an area that the patient and counselor probably need to work on to increase the odds of a successful taper and recovery. Circle th

Recovery Capitol: Provider Considerations

TABLE 2. Physician Risk Factor Checklist (Medical Providers Section)

1.	Any unexpected findings on PDMP*
2.	Frequent emergency department visits/minor injuries/MVCs†
3.	Recently appeared intoxicated/impaired
4.	Increased dose without authorization
5.	Needed to take medications belonging to someone else
6.	Patient or others worried about how patient is handling medications
7.	Had to make an emergency phone call or go to the clinic without an appointment
8.	Used pain medication for symptoms other than pain—sleep, mood, stress relief
9.	Changed route of administration
10.	Serious co-morbid mental illness
11.	Recent requests for early refills
12.	Recent reports of lost or stolen prescriptions
13.	Hoarding or stockpiling of medications
14.	Increasingly unkempt
15.	Attempted to obtain prescriptions from other doctors
16.	Concurrent benzodiazepine prescriptions
17.	Concurrent stimulant prescription
18.	Maintenance dose greater than 8 mg or buprenorphine or 80 mg methadone
19.	Current reports of disturbances in sleep
20.	Current reports of problems or lability in mood or energy

The purpose of this section of the Checklist is to help medical providers to assess potential signs or barriers that may lessen the patient's l

Interpreting the Recovery Capital Checklist

- It is not scored like a screening tool.
- The Physician section indicates warning signs that the patient is likely not stable enough to consider a taper.
- The patients and counselors section reviews factors associated with a readiness to discontinue methadone or buprenorphine/naloxone.
- More factors suggest a better chance.
- Fewer factors indicate greater chance of relapse.

Kreek, M. J., & Schluger, J. H. (2020). Informed Consent on Tapering of Methadone or Buprenorphine/Naloxone Maintenance Medication: New Tools Based on Updated Literature. Journal of Addiction Medicine, 14(5), 365-372.

A Patient-centered Clinical Stance

- Maintain a balance between respect for a patient's choice and realistic outcomes
- Provide honest feedback on what it will take to succeed
- If the patient chooses to remain on medication, plan for peer and family pressure
  - Education for both
- If the patient chooses to discontinue medication, monitor
  - If the patient is struggling recommend resuming medication
- Focus on achievements and recovery goals.

Don’t Forget Injectable Naltrexone XR

- Long-acting injectable naltrexone is an effective treatment
- When patients decide to discontinue buprenorphine/naloxone or methadone, long-acting naltrexone is a viable alternative
- Help patients make an informed decision about their treatment options

Lee, J. D., Nunes, E. V., Jr, Novo, P., et al. (2018). Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial. The Lancet, 391(10118), 309-318. https://doi.org/10.1016/S0140-6736(17)32812-X

Promote an “Abstinence” that works

“A patient is abstinent if he/she is not drinking alcohol or using illicit drugs and is using their medication as prescribed.”

National Institute on Drug Abuse. (2012). Principles of drug addiction treatment: A research-based guide (third edition). Retrieved from https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/what-drug-addiction-treatment.

Hope all is well with
you & the family. You are
the man sir! Thank you for
everything! I wouldn't be here
If it wasn't for you.

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- Zweben JE, Sorensen JL, Shingle M, Blazes CK. Discontinuing Methadone and Buprenorphine: A Review and Clinical Challenges. J Addict Med. 2021 Nov-Dec 01;15(6):454-460. doi: 10.1097/ADM.0000000000000789. PMID: 33323695; PMCID: PMC10082633.
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