ASAM American Society *of* Addiction Medicine

THE ASAM
Treatment of Opioid Use Disorder Course

Includes waiver qualifying requirements

About ASAM

ASAM, founded in 1954, is a professional medical society representing over 6,600 physicians, clinicians and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction.

More information available at
https://www.asam.org/about-us/about-asam

Course Announcements: Log of Trainees

- You MUST sign in and out on the log of trainees twice.
- If you do not sign your name twice, you will not be eligible for the waiver and your name will not be submitted with our attendance report.
- You must sign in at the beginning of the course and again at the conclusion of the course.

Course Announcements: Waiver Application

- You can fill out the online waiver application form on SAMHSA's website or through their mobile app MATx.
- SAMHSA Certificate Submission: You will need to submit a copy of your certificate to the SAMHSA Center for Substance Abuse Treatment (CSAT) after you submit the online waiver application by emailing it to: infobuprenorphine@samhsa.hhs.gov or by faxing it to 301-576-5237.

Course Announcements: NPs and PAs

- If you are an NP or PA, this 8-hour course will count toward the 24-hour education requirement under CARA.
- ASAM offers the additional 16 hours needed free of cost. Please contact education@ASAM.org to learn how to enroll in the completely online offering.

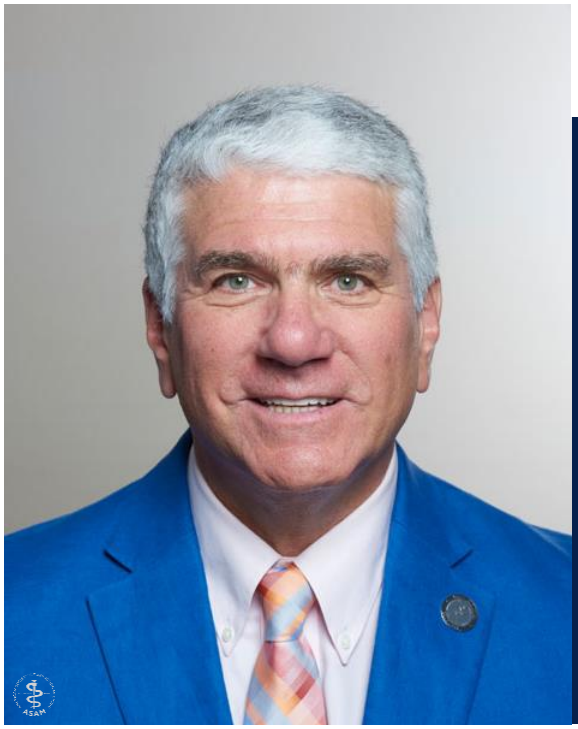
Course Announcements: Claiming CME

- Evaluation:
  - Complete the CME evaluation in the ASAM e-Learning Center.
- CME Certificate:
  - Claim your credits after completing the evaluation.
  - Click the blue “Claim Medical Credits” button to view/save your certificate.
  - Return to this page at any time to view/save your certificate.

Course Announcements: Acknowledgment

The ASAM Treatment of Opioid Use Disorder Course has been made available in part by an unrestricted educational grant from Indivior, Inc.

Funding for this initiative was made possible (in part) by grant no. 1H79TI026793-01 from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.



Faculty

Edwin Salsitz, MD, DFASAM

Dr. Salsitz has been an attending physician at Mt. Sinai Beth Israel, Division of Chemical Dependency, in New York City since 1983, and is an Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai. He is the principal investigator of the Methadone Medical Maintenance (office-based methadone maintenance) research project. He is certified by the American Board of Addiction Medicine (ABAM) and the Board of Internal Medicine and Pulmonary Disease. He has published and frequently lectures on addiction medicine topics.

Disclosure Information

[Faculty Name, Credentials]

[No Disclosures]
[Company Name – For What Role – What Was Received]

Course Learning Objectives

1. Identify, assess, and diagnose patients with opioid use disorder while considering severity, chronicity, individual characteristics, and psychiatric and medical comorbidities.
2. Develop an individualized, patient-centered treatment plan including negotiating treatment goals by evaluating appropriate medication- and psychosocial-based treatment options.
3. Monitor progress and modify treatment plan based on patient needs and progress toward treatment goals.
4. Implement best practices for office systems including team-based care to support treatment with medications for opioid use disorder.
5. Examine misconceptions, stigma, and complexities (bioethical, social, clinical, public health) associated with opioid use disorder and the use of medications to treat opioid use disorder.

Introduction and Context Setting

Case-Based Learning

What is it?

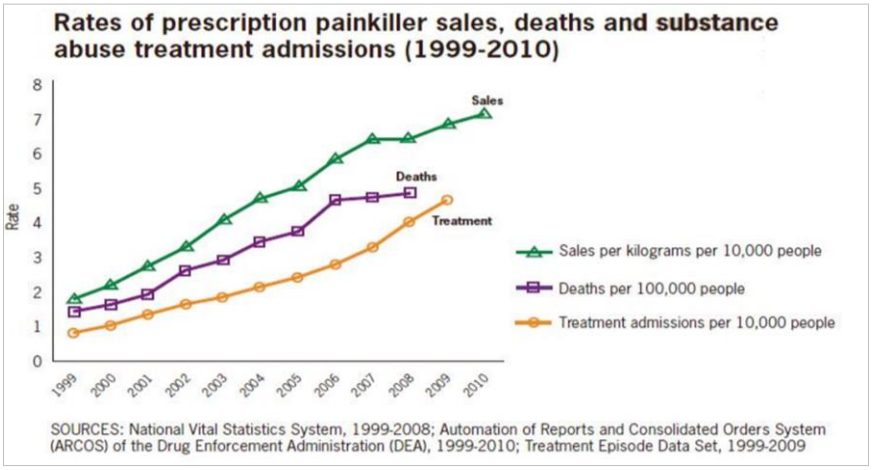
We will follow a case-based learning approach where we will explore scenarios that resemble or typically are real-world examples. This approach is learner-centered and links theoretical knowledge to practice by giving opportunities for the application of knowledge.

Session 1

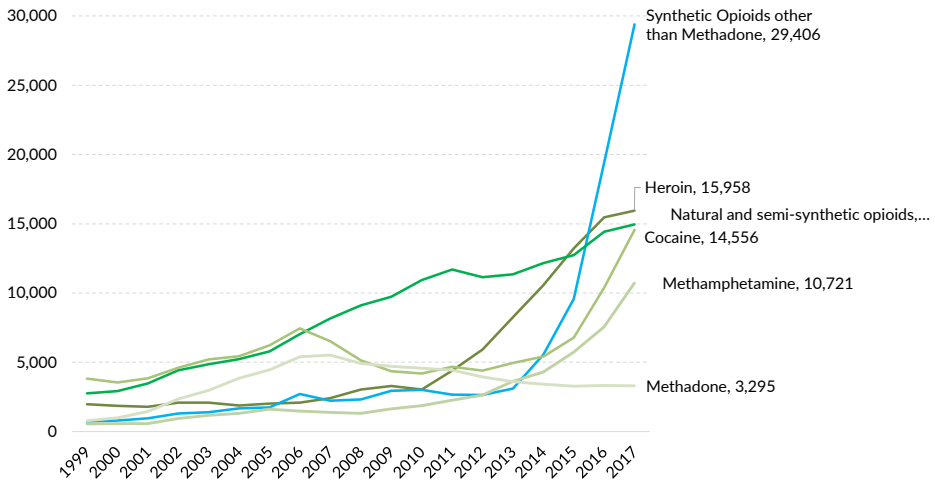
Module 1 Highlights

History of Opioids

Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, United States, 1999 - 2010



Drugs Involved in US Overdose Deaths, 1999 - 2017



Source: CDC WONDER

Lethal Dose

- *Morphine* = 1x
- *Fentanyl* = 100x
- *Carfentanil* = 10,000x

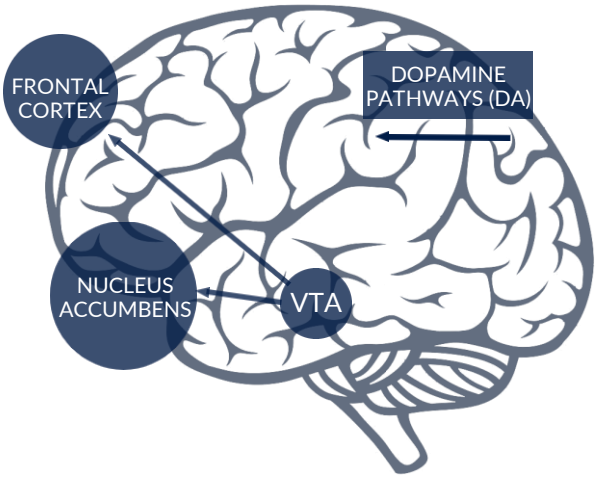
Lethal doses of heroin compared to "synthetic" opioids.

DEA Schedule I II II Legal Implications

"Death pill": fentanyl disguised as other drugs linked to spike in US overdoses.

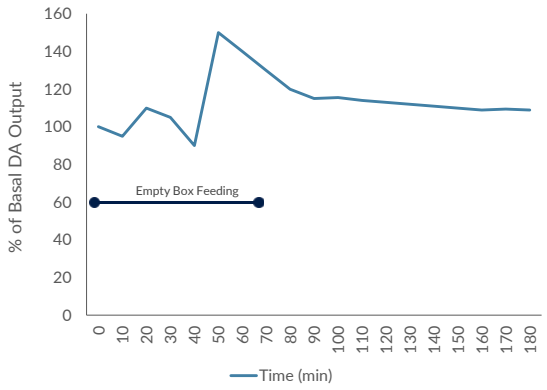
Reward Pathways

Mesolimbic Dopaminergic Circuitry (Limbic System)

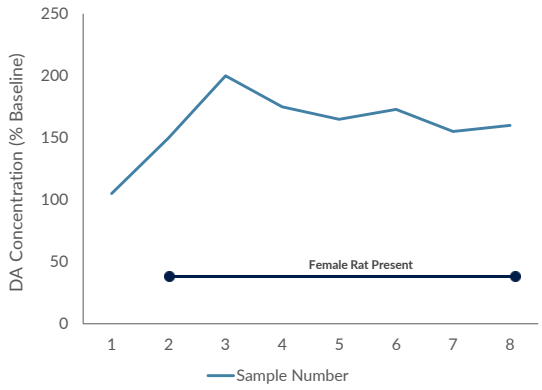


Natural Rewards Elevate Dopamine Levels

Food *(in rodents)*



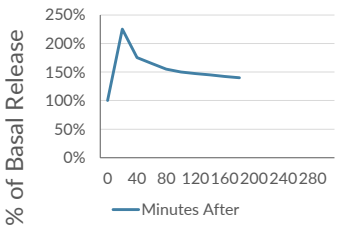
Sex *(in rodents)*



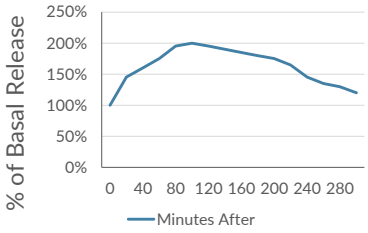
Di Chiara et al., Neurosci, 1999.Fiorino and Phillips, J. Neurosci, 1997

Drugs Elevate Dopamine More/Longer

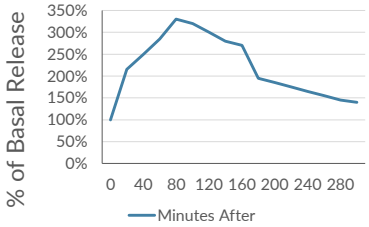
Nicotine *(in rodents)*



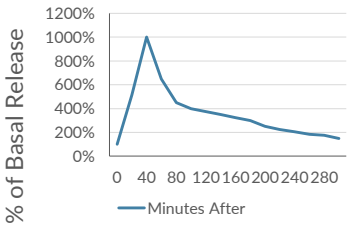
Morphine *(in rodents)*



Cocaine *(in rodents)*

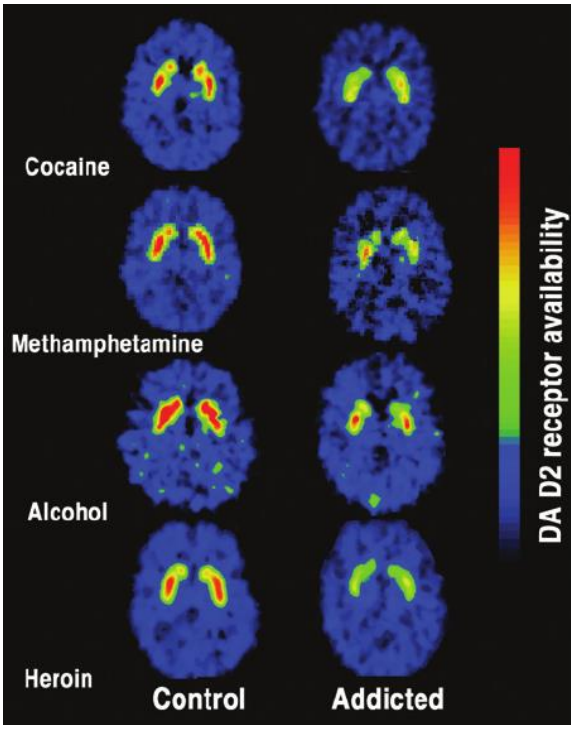


Amphetamine *(in rodents)*

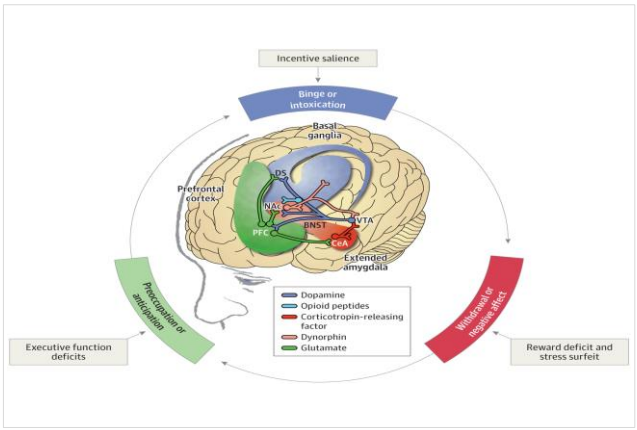


Di Chiara G, Imperato A. Proc Natl Sci. 1988

Dopamine D2 Receptors are Decreased in the Addicted Brain



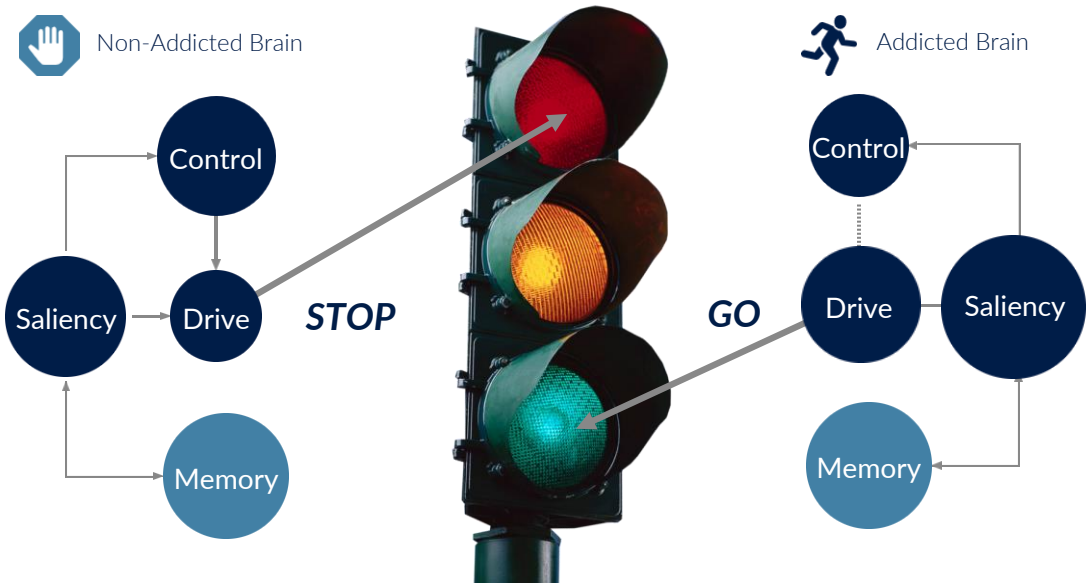
Three Stages of the Addiction Cycle and Associated Neural Circuits

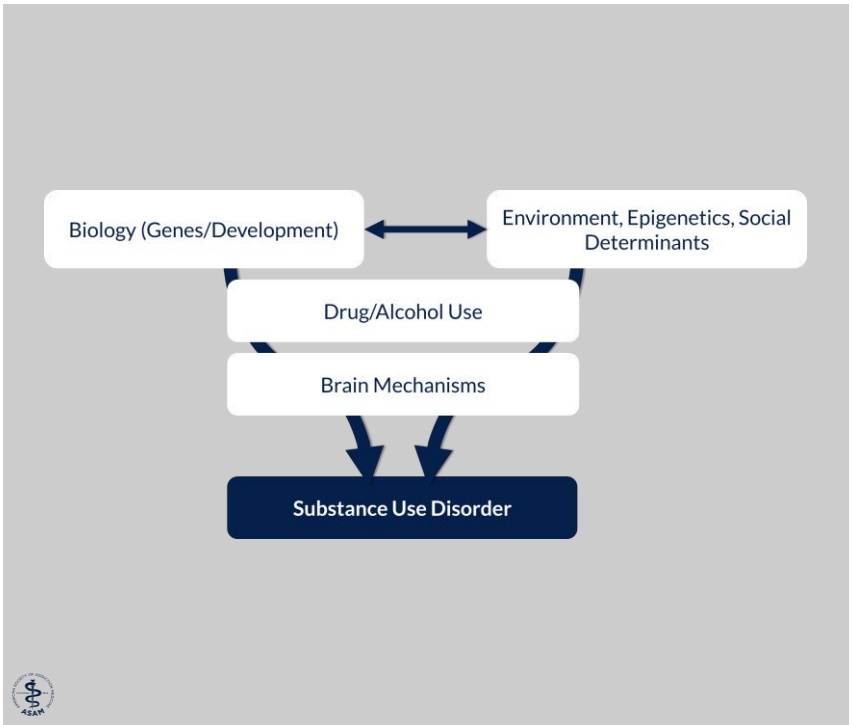


- **Stage 1:** Binge or Intoxication
- **Stage 2:** Negative Affect or Withdrawal
- **Stage 3:** Preoccupation or Anticipation (Craving)

Volkow, N. D., Jones, E. B., Einstein, E. B., & Wargo, E. M. (2019). Prevention and treatment of opioid misuse and addiction: A review

Non-Addicted Brain V. Addicted Brain





Development Of Substance Use Disorders Involves Multiple Factors

Concurrent Sedative-Hypnotics

Relative Contraindications

- Alcohol and other sedative-hypnotics are relative, not absolute, contraindications to buprenorphine
- *Deaths have resulted from injecting high potency benzodiazepines*

Identification and Referral

- Identify and refer patients who are willing and able to undergo medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives

Substance Use Disorder: DSM-5 Criteria

1. Tolerance*
2. Withdrawal*

**Not valid if opioid taken as prescribed*

Loss of Control

3. Larger amounts and/or longer periods
4. Inability to cut down on or control use
5. Increased time spent obtaining, using, or recovering
6. Craving/Compulsion

Use Despite Negative Consequences

7. Role failure: work, home, school
8. Social, interpersonal problems
9. Reducing social, work, recreational activity
10. Physical hazards
11. Physical or psychological harm

Mild (2-3),
Moderate (4-5),
Severe (≥6)

APA. (2013). DSM (5th ed.)

Session 2

Module 2 Highlights

Patient Limits

Beginning 1st Year
- 30 patients per practitioner during first year of the waiver.
- May start at 100 patients when meeting certain requirements.

After 1st Year
- Can increase to 100 patients – a new waiver must be obtained.

After 2nd Year
- Can increase to 275 patients – a new waiver must be obtained.

Census: Patient remains on your census until the last prescription has run out.

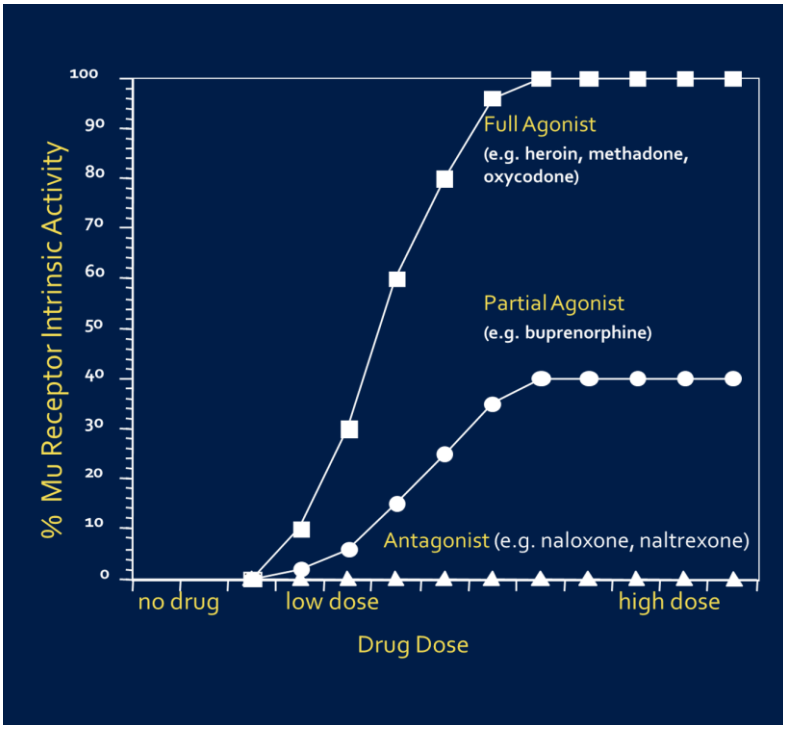
Hospitalized Patients: w/ primary admitting diagnosis other than OUD, buprenorphine can be ordered by non-waivered physician.

DEA Compliance

DEA continues routine practitioner inspections to assess:

- Compliance with the 30/100/275 patient limit.
- Record keeping.
- Security measures related to on-site drug storage if buprenorphine is dispensed or administered from the office.

Opioid Agonists and Antagonists



Receptor Affinity

Buprenorphine's Affinity

- ***Affinity*** is the strength with which a drug physically binds to a receptor.
- ***Buprenorphine's affinity*** is very high; it will displace full agonists.
- ***Receptor binding strength,*** high or low, is NOT the same as receptor activation (agonist or antagonist).

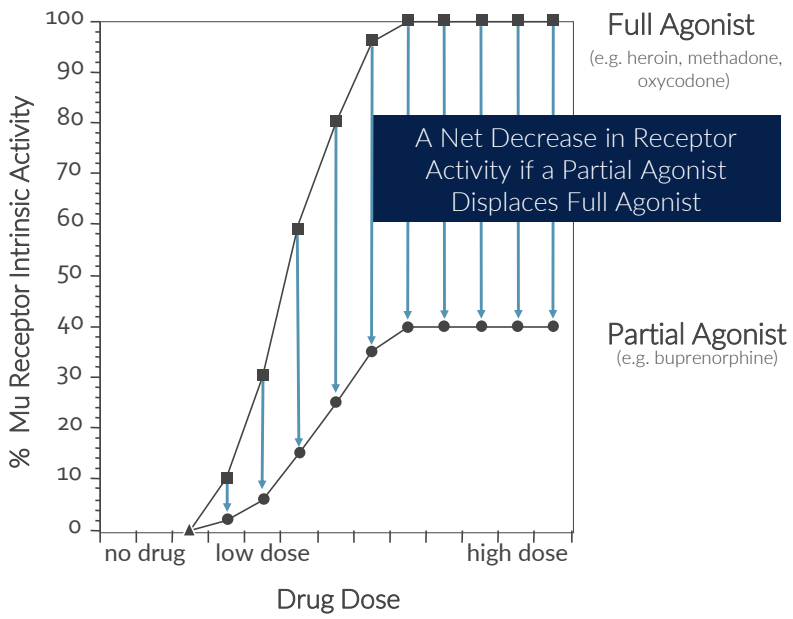
Receptor Dissociation

Dissociation

- ***Dissociation*** is the speed (slow or fast) of disengagement of the drug from the receptor.
- ***Buprenorphine's dissociation*** is slow.
- ***Buprenorphine stays on the receptor*** for a long time and blocks full agonist from binding.

Precipitated Acute Withdrawal

Buprenorphine will precipitate withdrawal when it displaces full agonist off the Mu receptors.



Methadone Safety

Half-Life

- Long, variable, unpredictable half-life
- Serum t½ 20-120 hours
- 4-7 days to reach steady state: "Start low, go slow"

QTc Prolongation, Risk of Torsades de Pointes

- Dose-related: >100mg daily
- Multifactorial : ↓K, ↓Mg, other drugs ↑QTc
- CYP450: 3A4, 2D6 interactions
- QTc > 500 msec → Torsades de Pointes

Wedam E et al. JAMA Internal Medicine. 2007. The Medical Letter. 2017, 59(1522): 89-95.

Naltrexone Summary

Benefits:

- Good for patients who do not want opioid agonist therapy.
- No risk of diversion (not a controlled substance).
- ***No risk of overdose by drug itself.***
- Can be administered in any setting (office-based or OTP).
- Long-acting formulation.
- Treats both opioid use disorder and alcohol use disorder.

VS

Limitations:

- Difficulty starting—must be fully withdrawn from opioid; > short-acting (6 days); long-acting opioids (7-10 days).
- Not suitable for patients with severe liver disease.
- Loss of tolerance to opioids increases the risk of overdose if return to pretreatment use occurs.
- Not recommended for pregnant women. Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine.

ASAM National Practice Guideline for the Treatment of Opioid Use Disorder - 2020 Focused Update.

Combination: Buprenorphine/Naloxone

If dissolved sublingually:	*If swallowed:*	*If injected or used intranasally:*	*Not time-released:*
Buprenorphine is active	Buprenorphine not active (minimal oral bioavailability)	Buprenorphine is active	Tablets/film strip can be split
Naloxone is not active	Naloxone not active	Naloxone active x 20 minutes so attenuates the parenteral "rush"	

Adverse Effects of Medications

MEDICATION	ADVERSE EFFECTS
Methadone	Constipation, hyperhidrosis, respiratory depression (particularly combined with benzodiazepines or other CNS depressants), sedation, QT prolongation, interactions with other medications that alter cytochrome P450 metabolism, sexual dysfunction, severe hypotension including orthostatic hypotension and syncope, misuse potential, NOWS
Buprenorphine (with or without naloxone)	Constipation, nausea, precipitated withdrawal, excessive sweating, insomnia, peripheral edema, respiratory depression when with benzodiazepines or other CNS depressants, misuse potential, NOWS Implant: Nerve damage during insertion/removal, accidental overdose or misuse if extruded, local migration or protrusion Subcutaneous: Injection site itching or pain, death from intravenous injection
Naltrexone	Nausea, anxiety, insomnia, precipitated withdrawal, hepatotoxicity, vulnerability to opioid overdose, depression, suicidality, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders Intramuscular: Pain, swelling, induration (including some cases requiring surgical intervention)

LFT Recommendations

Level of Evidence: Moderate

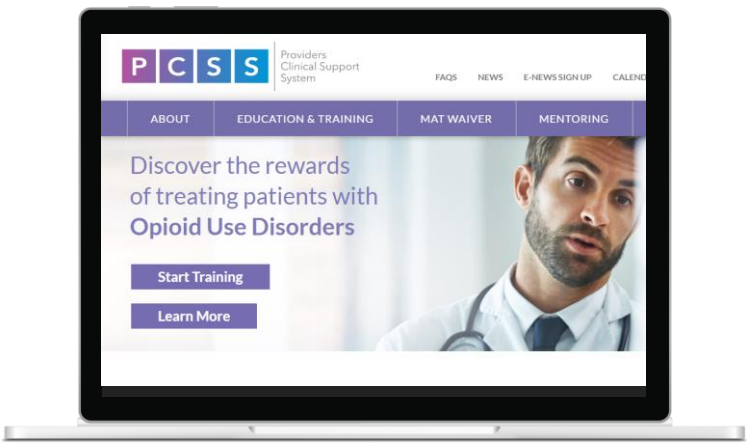
- **Prior to induction: obtain LFTs, INR, hepatitis serologies.**
  - Avoid delay in starting treatment, can obtain LFTs at same time as induction.
- **Monitor LFTs.**
  - No empirical evidence to guide the frequency. Semi-annual is adequate if no other risk factors.
- **If patient does have clinical/laboratory evidence of hepatotoxicity, evaluate possible causes of liver injury.**
  - Consideration should be given to lowering dose or discontinuing.
- **Subsequent studies have NOT shown significant increases in LFTs during SL buprenorphine treatment for patients with and without chronic hepatitis C.**

Non-Pharmacological Treatment

- **Psychosocial services are often helpful.** Psychosocial services encourage utilization.
- **Additional Behavioral Therapy:** Three trials showed that additional behavioral therapy does NOT significantly improve outcomes over that achieved by buprenorphine PLUS “medical management” or “medical counseling.”
- **Patients should not be denied medication** should they refuse psychosocial services or if psychosocial services are not available.

Weiss RD et al. Arch Gen Psychiatry. 2011.; Fiellin DA et al. Am J Med. 2013.; Ling W et al. Addiction. 2013.

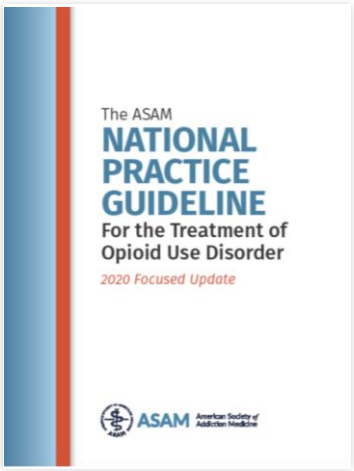
Providers Clinical Support System (PCSS)



Through trainings and clinical coaching programs, PCSS’s mission is to increase healthcare providers’ knowledge and skills in the prevention, identification, and treatment of substance use disorders with a focus on opioid use disorders.

https://pcssnow.org/

ASAM National Practice Guideline to Treat Opioid Use Disorder



- The ASAM National Practice Guideline (NPG) was updated in 2020.
- It provides information on evidence-based treatment of opioid use disorder (TOUD).
- It is the first text to address all the FDA-approved medications available to treat addiction involving opioid use and opioid overdose in a single document.

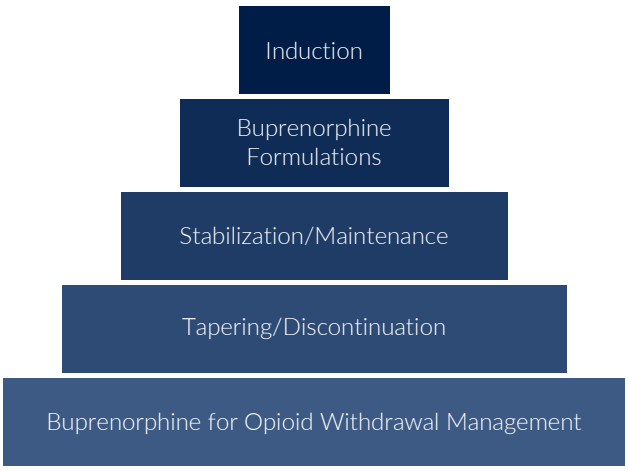
Session 3

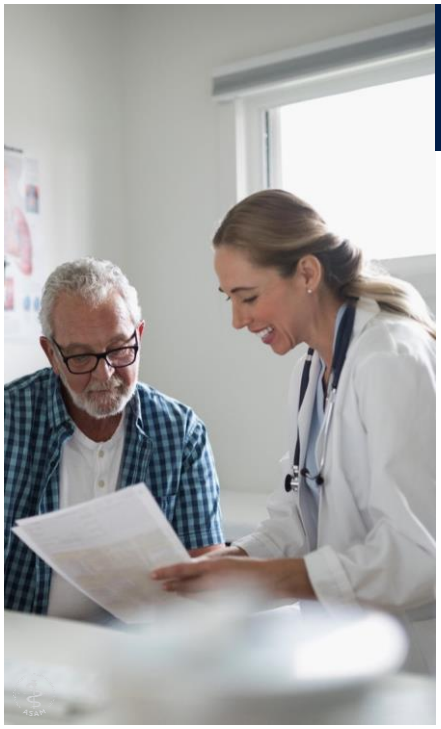
Implementing Office-Based Opioid Treatment

Session Learning Objectives

1. Monitor progress using face-to-face visits, urine drug tests, pill/film counts, and PDMP checks.
2. Discuss relapse prevention with patients.
3. Assess cause of relapse and modify treatment plan based on patient needs to progress toward treatment goals.
4. Describe procedures for setting up office systems including team-based care to support medication prescribing for opioid use disorders.
5. Implement, update, and maintain best practices for office systems to support treatment with medication for opioid use disorder.

Clinical Uses of Buprenorphine





Buprenorphine Induction: Early Stabilization

***Overall Goals:** To find the buprenorphine dose at which the patient experiences:*

- Suppression of opioid withdrawal symptoms.
- Marked reduction or discontinuation of illicit opioid use.
- Decreased opioid cravings.
- Blunted or blocked euphoria after illicit opioid use.
- Minimal/no side effects.
- Provide effective blockade preventing lethal overdose.

Buprenorphine Induction

1 Office-based (Options)

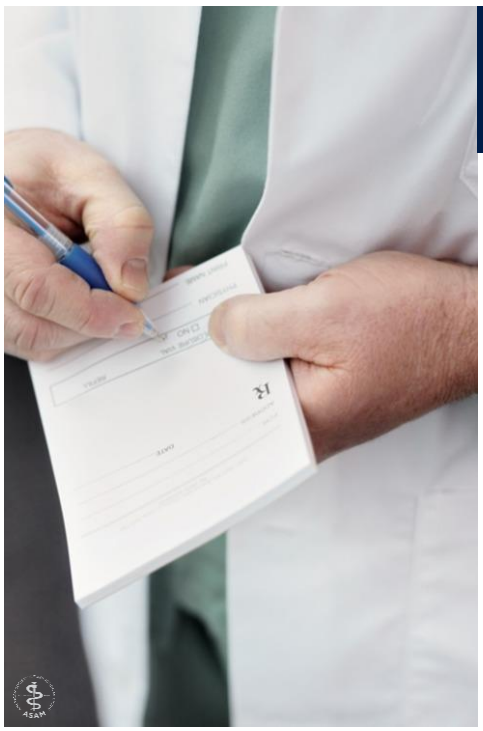
2 Home-based (Unobserved)

Buprenorphine Induction

Office-Based (Options):

- ***Keep medication in the office for inductions.***
  - Must keep records required by federal and state law for maintaining controlled substances for administering or dispensing.
  - Records are audited by the DEA.
- ***Have the patient:***
  - Fill a prescription for the first day's dose.

  OR
  - Bring medication to the office for administration.
- ***Fax prescription to pharmacy, then have it delivered.***



Buprenorphine
The First Prescription

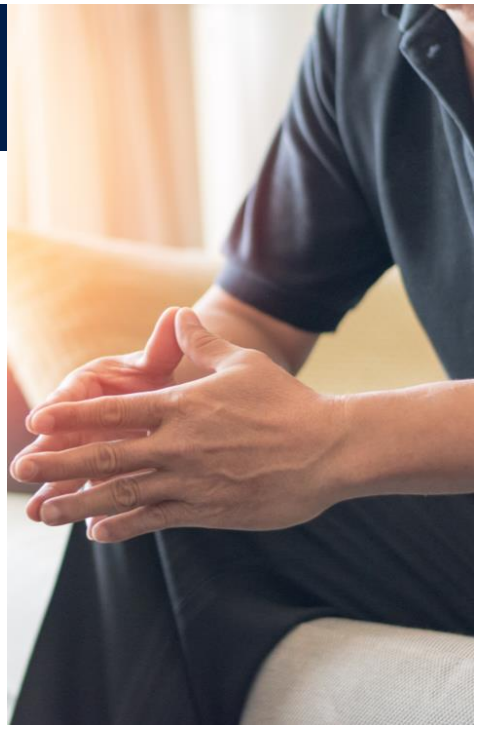
The amount of buprenorphine prescribed for induction and stabilization depends on many factors:

- Will this be an office-based or home induction?
- How adherent is the patient?
- Is there a significant other who can secure and dispense the medication? (Particularly important with younger patients.)
- How are co-pays managed? Is it reasonable to fill prescriptions every few days?
- Prior authorizations.

Buprenorphine Office-based Induction

Patient Instructions:

- Don't plan to drive home.
- Plan to be at clinic or office for up to 3 hours.
- Be ready to give urine sample.
- Bring all prescribed, OTC, and herbal medications with you.
- Bring medication bottle or have it delivered if applicable (prescribe vs. dispense).
- Be accompanied by trusted family member or friend when possible.
- Come to office in ***mild*** opioid withdrawal.



Acute Opioid Withdrawal

	Symptoms / Signs
Mild ↓ *Severe*	Anxiety, drug craving
	Yawning, sweating, runny nose, tearing eyes, restlessness, insomnia
	Dilated pupils, gooseflesh, muscle twitching, muscle & joint aches
	Nausea, extreme restlessness, elevated BP, heart rate > 100, fever
	Vomiting, diarrhea, abdominal cramps, curled-up body position

Clinical Opiate Withdrawal Scale (COWS):
pulse, sweating, restlessness & anxiety, pupil size, aches, runny nose & tearing, GI sx, tremor, yawning, gooseflesh

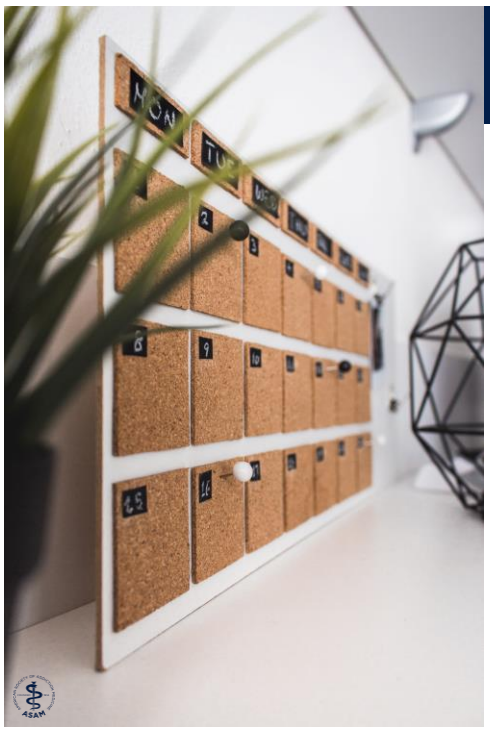
- *5-12 mild*
- *13-24 moderate*
- *25-36 moderately severe*
- *>36 severe*

Buprenorphine Induction

Unobserved "Home" Option:

- Numerous observational studies demonstrate that unobserved "home" inductions are both **effective and safe, however, there is no comparison from RCTs.**
- Should be performed in properly selected patients. Patients should be able to describe and rate opioid withdrawal and understand dosing instructions.
- Providers and patient/significant other should be able to **communicate during the induction**.
- Same protocol as in office-based induction.

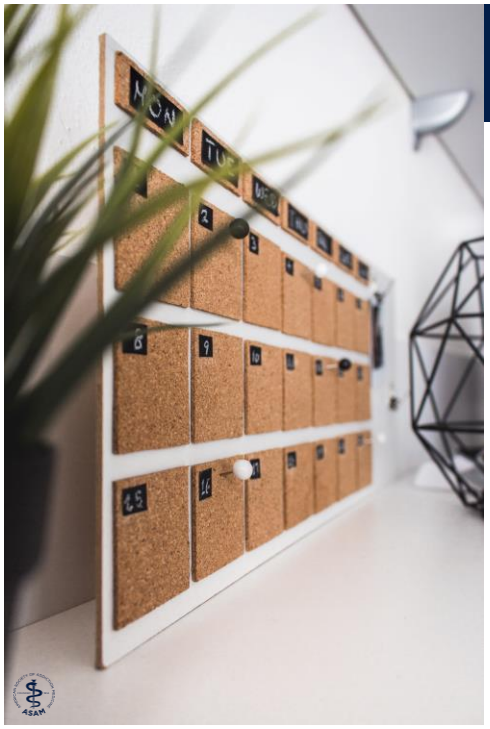
Alford DP et al. J Gen Intern Med. 2007., Lee JD et al. J Gen Intern Med. 2008., Cunningham CO et al. J Subst Abuse Treat. 2011., Sohler NL et al. J Subst Abuse Treat. 2011., Lee JD et al. J Addict Med. 2014.



Induction – Day 1

If the patient is <u>NOT currently physically dependent</u> on opioids:

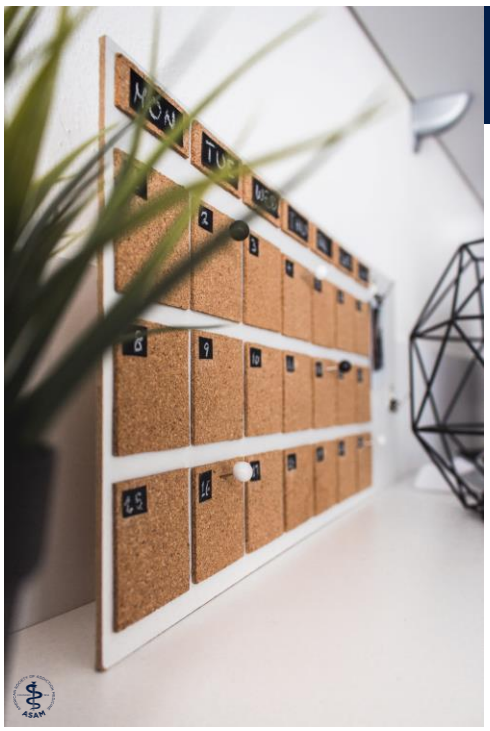
- *Post-withdrawal management, post-incarceration, post-hospitalization*
- Can still meet *DSM-5 OUD criteria*
- No precipitated withdrawal concerns
- *Start low (2 mg)* and go slow to avoid opioid side effects
- *Patients are very good at titrating* buprenorphine if given dosing schedule and parameters (e.g., maximum dose)



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

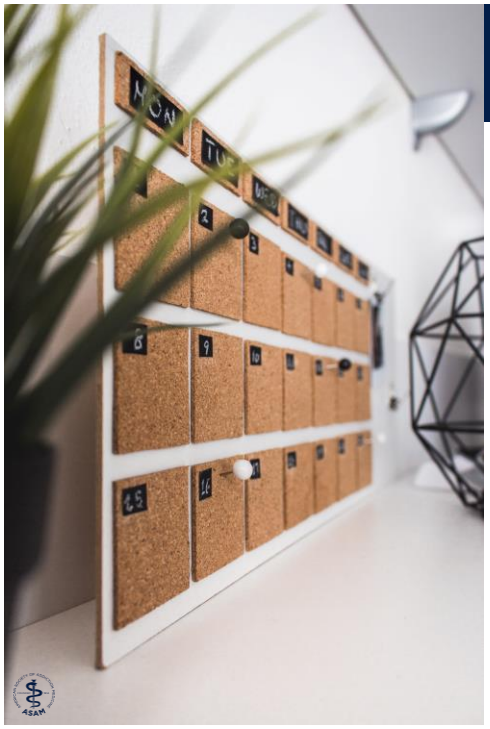
- *Instruct patients to abstain from any opioid use for 12-24 hours (so they are in mild withdrawal at time of first buprenorphine dose).*
- If the patient is not in opioid withdrawal at time of arrival in office:
- *Assess time of last use and consider:*
  - Have them return another day
  - Waiting in the office until evidence of withdrawal is seen
  - Or leaving office and returning later in day (with strict instructions to not take opioids while away from the office)



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

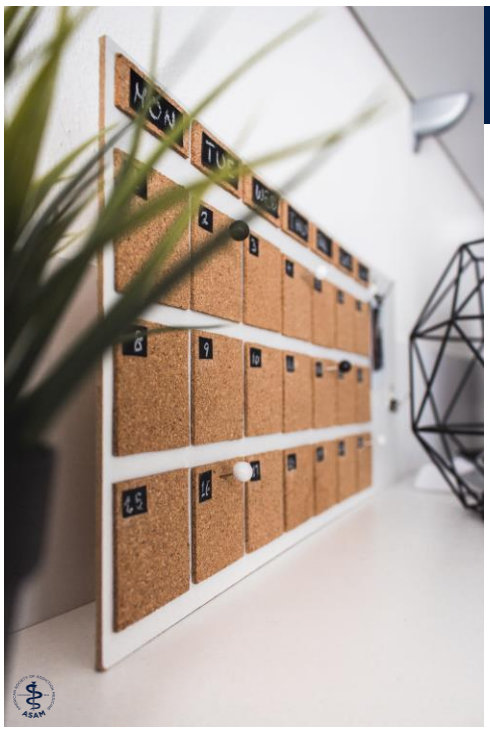
- *First dose: 2/0.5-4/1 mg SL* buprenorphine/naloxone.
- *Dose can take 3-10 minutes to dissolve fully.*
- *Monitor in office for 1-2 hours* after first dose and each subsequent dose.
- *Relief* of opioid withdrawal should begin within 30-45 minutes.
- *Period of greatest severity of buprenorphine-related precipitated withdrawal* occurs in the first few hours (1- 4 hours) after a dose.



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

- *The length of time the patient is monitored in the office varies, depending upon:*
  - The *clinician's* familiarity with:
    - the patient
    - prescribing buprenorphine
  - The patient's level of support at home



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

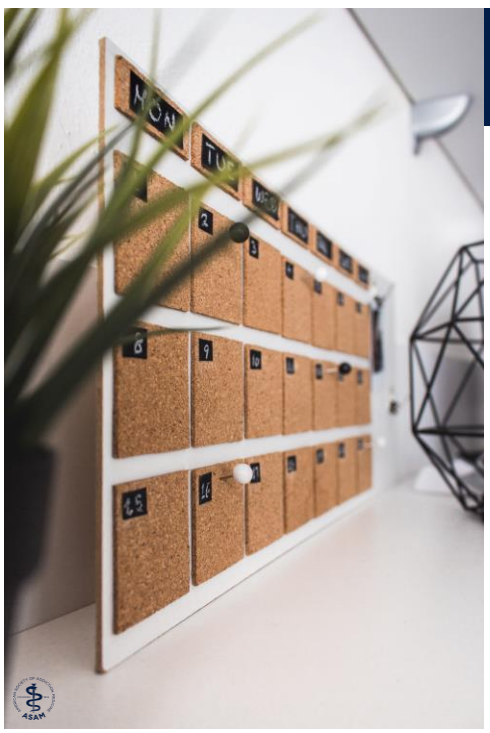
- *Can re-dose if needed* (every 1-2 hours, if opioid withdrawal subsides then reappears).
- *Maximum first day dose of buprenorphine/naloxone = 8mg -16mg.*
- Dose equivalent of other formulations (e.g., 5.7mg - 11.4mg of branded SL tablets).

Inducting Patients

The patient on Fentanyl Patch:

- According to the Fentanyl product insert, it takes >17 hours after removal for a 50% decrease in serum concentrations to be attained.
- Buprenorphine sublingual induction should follow the same general guidelines as with any other full opioid agonist.
- *Methadone should be considered if buprenorphine induction fails.* Fentanyl has a high potency and methadone may be better as a potent full agonist in comparison with buprenorphine.
- *Limited evidence available to guide this process.*

Huhn, A. S., Hobelmann, J. G., Oyler, G. A., & Strain, E. C. (2020). Protracted renal clearance of fentanyl in persons with opioid use disorder. Drug and alcohol dependence, 214, 108147.



Induction – Day 1

If the patient is <u>physically dependent</u> on long-acting opioid:

- *Recommendations vary about optimal dose of long-acting opioid for transfer* (TIP 63 states 30-40 mg/d methadone and remain on that dose for at least 1 week).
- *Begin induction at least 48-72 hours* (sometimes up to 4-5 days) after last dose of methadone, and 36 hours after last dose of sustained release oxycodone (or longer).
- *Patient should be in mild withdrawal* at time of first buprenorphine dose.
- *Use similar induction procedures to "physically dependent on short-acting opioids."*

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018

Induction – Day 1

Options for Managing Precipitated Withdrawal

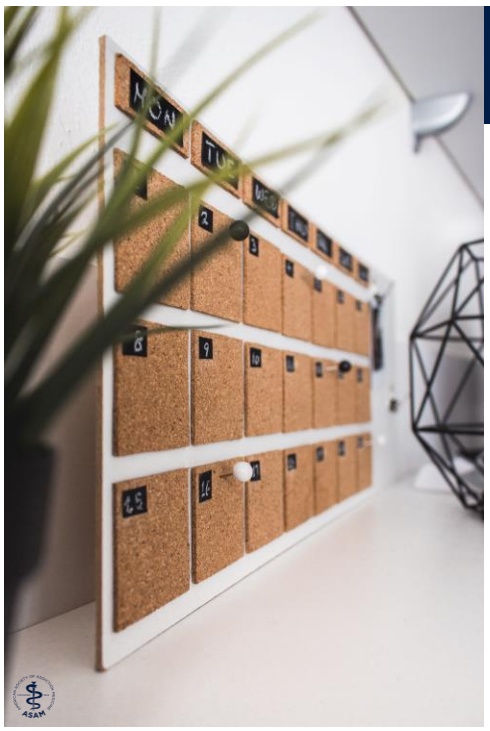
Option 1:
Give another dose of buprenorphine 2-4 mg

Attempting to provide enough agonist effect to suppress withdrawal symptoms.

VS

Option 2:
Stop induction

Treat withdrawal symptoms.
Restart induction the next day.



Induction – Day 1

Options for managing symptoms of precipitated withdrawal:

- Clonidine*, tizanidine*, lofexidine (hyperadrenergic state)
- NSAIDS (muscle cramps and pain)
- Benzodiazepines (insomnia)
- Dicyclomine (abdominal cramps)
- Bismuth subsalicylate (diarrhea)

Since stopping the induction risks loss of the patient, the first option should be considered.

**Off-label use.*

Use of Microdoses for Induction of Buprenorphine

- Even with precautions, for many patients, the induction of buprenorphine is a difficult experience due to withdrawal symptoms.
- Overlapping induction of buprenorphine maintenance treatment with full μ-opioid receptor agonist use is feasible. It may be associated with better tolerability and acceptability in some patients compared to the conventional method of induction.
- Cases illustrate that overlapping induction of buprenorphine while being on full μ-agonists is feasible, but further research is needed.

Hämmig, R., Kemter, A., Strasser, J., von Bardeleben, U., Gugger, B., Walter, M., ... & Vogel, M. (2016). Use of microdoses for induction of buprenorphine treatment with overlapping full opioid agonist use: the Bernese method. Substance abuse and rehabilitation, 7, 99.

Acute Opioid Withdrawal
(Off-label for Pain)

Drug	Formulations	Maintenance Dose
Buprenorphine		
Generic	2, 8 mg SL tabs	16 mg/d
Probuphine®	74.2 mg SD implant	4 implants/6m
Sublocade®	100 mg, 300 mg SQ injection	100 mg/m
Buprenorphine/Naloxone		
Generic	2/0.5, 8/2 mg SL tabs	16/4 mg/d
Bunavail®	2.1/0.3, 4.2/0/7, 6.3/1 mg buccal film	8.4/1.4 mg/d
Suboxone®	2/0.5, 4/1, 8/2, 12/3 mg SL film	16/4 mg/d
Zubsolv®	1.4/0.36, 5.7/1.4 mg SL tab	11.4/2.8 mg/d

The Medical Letter 2018; 60(1541):35-37

Corresponding Doses of Bup/Nx

Generic SL tablets	*Suboxone® SL films*	*Zubsolv® SL tablets*	*Bunavail® Buccal films*
2 mg bup / 0.5 mg naloxone	2 mg bup / 0.5 mg naloxone	1.4 mg bup / 0.36 mg naloxone	
	4 mg bup / 1 mg naloxone	2.9 mg bup / 0.71 mg naloxone	2.1 mg bup / 0.3 mg naloxone
8 mg bup / 2 mg naloxone	8 mg bup / 2 mg naloxone	5.7 mg bup / 1.4 mg naloxone	4.2 mg bup / 0.7 mg naloxone
	12 mg bup / 3 mg naloxone	8.6 mg bup / 2.1 mg naloxone	6.3 mg bup / 1 mg naloxone
		11.4 mg bup / 2.9 mg naloxone	

Kampman, K. et al. (2015). The ASAM National Practice Guideline

Audience Response

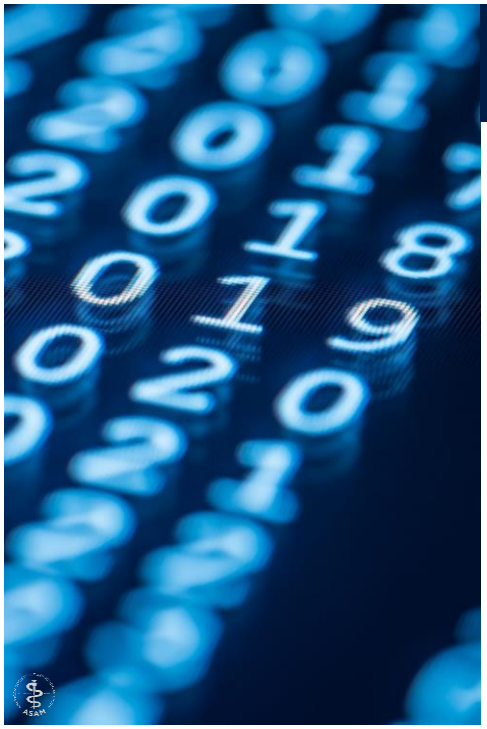
Which of the following is true of the first day of induction?

A. You should always have the patient start medication in the office.

B. Patients who start medication in the office have higher success rates than patients who start at home.

C. Starting medication at home may be preferred by patients as they can be more comfortable with withdrawal.

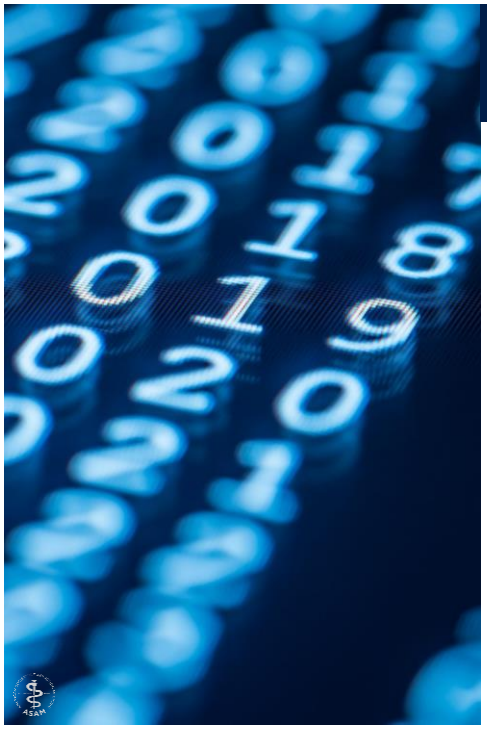
D. Starting medication at home may be preferred due to space constraints in the office for such a long appointment.



Stabilization and Maintenance

Day 2 and Beyond:

- Be in contact with patient (in office, via phone, etc.).
- Adjust dose accordingly based on patient's experiences the first day.
- Continue adjusting dose by 2/0.5-4/1 mg increments until patient is out of withdrawal—this typically occurs at dose of 8/2.
- Generally 24mg of buprenorphine is considered a maximal dose, but rarely patients may require a higher dose up to 32mg.



Stabilization and Maintenance

Day 2 and Beyond:

- After the first day of induction for patients who are physically dependent on either short-acting or long-acting opioids, the procedures are the same.
- Adjust dose according to the patient's experiences:
  - Lower dose if patient was over-medicated at end of Day 1.
  - Higher dose if there were withdrawal symptoms after leaving your office and/or if patient used opioid agonists
- Don't assume abstinence after the first day's dose.

Buprenorphine Dosing

> 24 – 32 mg/day → Unusual: Full Review of Medical/Behavior Issues

> 16 – 24 mg/day → Possible

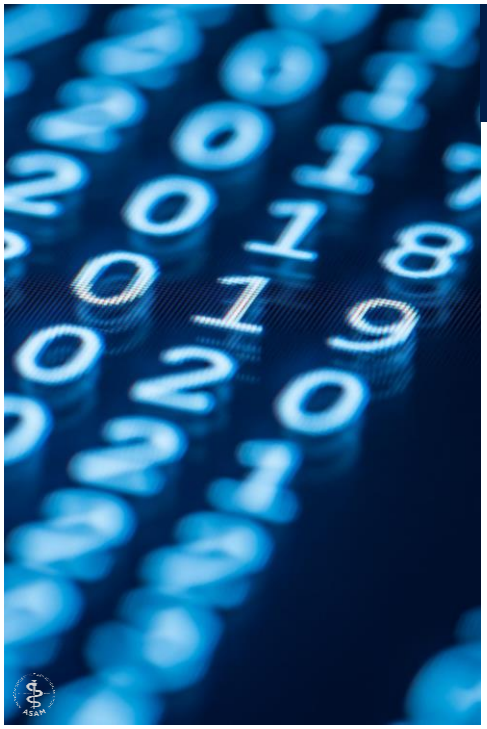
< 16 mg/day → Typical

Zubieta et al., 2000; Greenwald et al. 2003; Product Information Suboxone 2005; personal communication RE Johnson, June, 2007.

Stabilization and Maintenance

The patient should receive a daily dose until stabilized:

- Patient should be dosed once daily or twice daily, but not more frequently than twice daily.
- Multiple daily doses which mimic addictive behavior is not recommended.
- Splitting the dose to Q6-8 is indicated if treating concurrent OUD and pain.



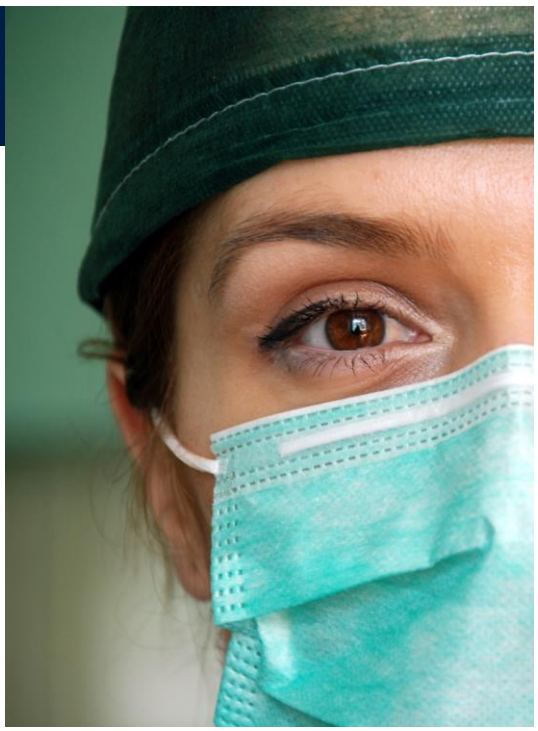
Stabilization and Maintenance

For OBOT patients, daily dosing is the norm:

- Once stabilized, the patient can be shifted to alternate day dosing (e.g., every other day, M-W-F, or every third day, M/Th).
- Non-daily dosing is most appropriate if the patient is receiving observed dosing in an OTP.
- Increase dose on dosing day by amount not received on other days (e.g., if on 8 mg/d, switch to 16/16/24 mg M-W-F).

Buprenorphine Implants *(Probuphine®)*

- No longer on the market in the USA.
- Subdermal four implants (0.5-1 ng/ml); low continuous levels for 6 months.
- Requires certification (live training) to prescribe, insert and remove implants.
- ~30-minute procedure: follow-up in one week.
- After 1 insertion in both arms, transition to SL buprenorphine.



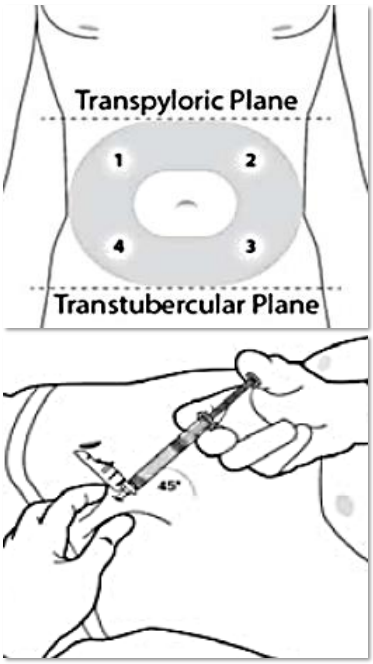
SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018

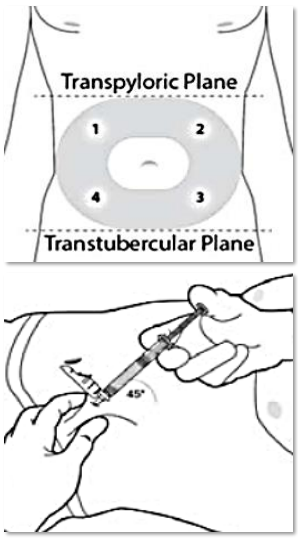
Buprenorphine Extended-Release (ER)

Subcutaneous Injection (Sublocade®)

- FDA-approved for moderate to severe OUD.
- Biodegradable delivery system.
- Releases buprenorphine at controlled rate over one month.

The Medical Letter Feb 26, 2018





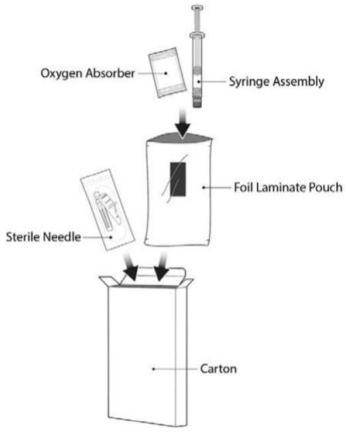
Buprenorphine Extended-Release (ER)

Subcutaneous Injection (Sublocade®)

Releases buprenorphine at controlled rate over one month:

- Mean plasma concentration with monthly 100 mg is about 10% higher than 24 mg/d of SL tablets.
- Each of the 1st two monthly SQ doses should be 300 mg/1.5 ml prefilled syringe. Doses should be separated by at least 26 days
- Subsequent doses should be 100 mg/o.5 ml prefilled syringe. Some patients may need to increase maintenance dose to 300 mg monthly.

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018



Buprenorphine ER Injection

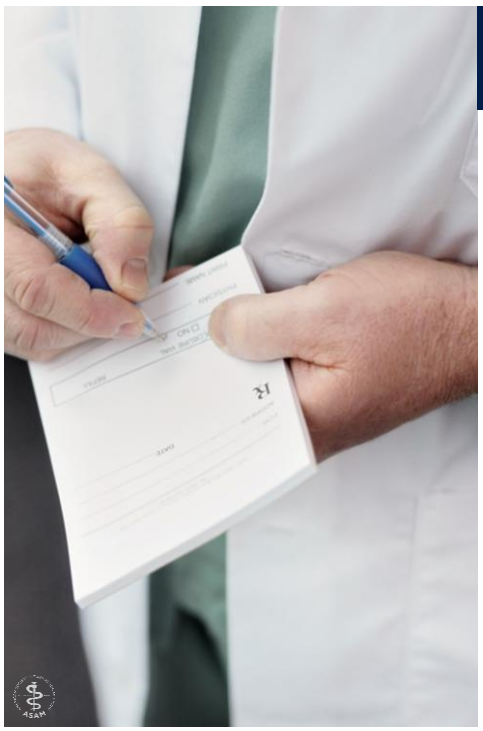
(Sublocade®)

- Pharmacies need special certification to order and dispense.
- Before initiating, patient should be stabilized on transmucosal buprenorphine (8 mg-24 mg daily) for at least seven days.
- There is insufficient data on its use in pregnancy.
- ***Inform patient:***
  - Medication only available in specific pharmacies as IV self-administration can be fatal.
  - After abdominal injection, a lump may be present at the injection site for a few weeks. Patients should not rub or massage the lump or let belts rub against it.

Finding REMS certified pharmacies:

https://www.sublocaderems.com/Content/pdf/certified-pharmacies.pdf

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018



Buprenorphine Maintenance

How long should buprenorphine maintenance continue?

- Patients should take medication as long as they benefit from it and wish to continue.
- There is no known duration of treatment after which patients can stop medication and be certain that they will not return to illicit opioid use.
- Given the chronic nature of OUD and potentially fatal consequences of unintended opioid overdose, ***it is critical to base length of time in treatment on patients' individual needs***.

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018

Buprenorphine Discontinuation

Important Considerations: Part 1

- How has the patient responded to treatment so far?
- Why do they want to taper?
- What do they expect will be different after the taper?
- Do they understand the risk of overdose associated with return to use?
- Do they have a safety plan?

Buprenorphine Discontinuation

Important Considerations: Part 2

- **Do they understand the risks and benefits of continuing vs discontinuing treatment?**
  - Many studies show high relapse rates with tapering and withdrawal from maintenance agonist medications.
  - Some studies show normalization of brain function with maintenance.

Buprenorphine Discontinuation

Important Considerations: Part 3

- **Patients should continue to be followed by provider after discontinuation.**
- Patients should be told they can resume buprenorphine treatment if cravings, lapses, or relapses occur.
- Psychosocial treatments should continue if applicable.
- Consider naltrexone.
- Associated with relapse? Do they have a safety plan?

Tapering

- ***Short-term taper ("detox") is not recommended as a stand-alone treatment.***
  - However, patients may taper from buprenorphine as part of a treatment plan.
- There is no ideal protocol but titrate slowly and carefully.
- Patient should be educated on risk of relapse after taper.
- ***ASAM does not recommend limiting length of treatment.***

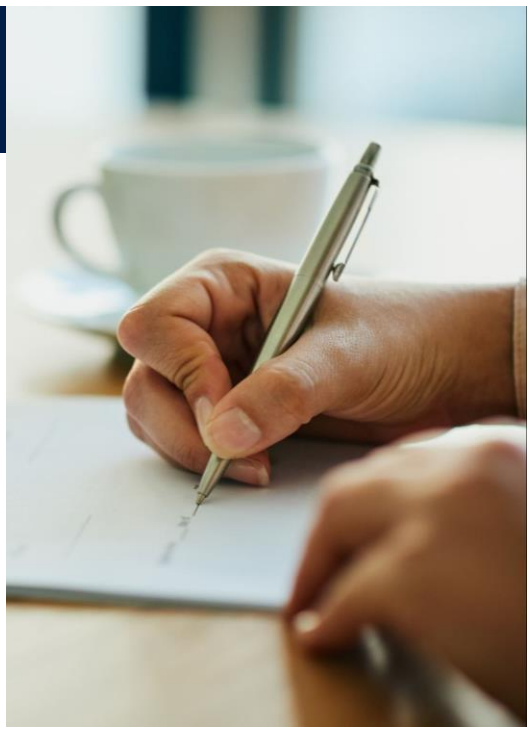
Naltrexone Formulations

Naltrexone	Formulation	Target Maintenance Dosage
Oral		
Generic Revia®	50 mg tablets	50 mg per day
Extended-Release IM injection (XR-NTX)		
Vivitrol®	380 mg ER suspension	380 mg IM q month

The Medical Letter 2017

Prior to Starting Naltrexone Treatment

- **Review and sign agreement with consents and treatment plan**
  - Release information as needed to coordinate care with outside providers and supports
- **Labs reviewed and appropriate**
  - LFTs < 3-5x normal
  - Pregnancy test for women of childbearing age



Naltrexone Initiation

- **Insurance prior authorization completed if needed and medication ordered.**
  - Some private insurers require a PA.
  - Many MCOs will cover naltrexone but ordering through specialty pharmacy takes time.
- **Medical Alert identification to patient.**
- **Urine drug tests negative for all opioids prior to starting naltrexone.**
  - Patients with OUD must be fully withdrawn from all opioids, typically no use for 7-10 days.

Naltrexone Challenge Test

- ***An oral naltrexone challenge test should be performed if there is a risk of precipitating opioid withdrawal:***
  - Recommended prior to initial injection of XR-NTX and any lapse in treatment.
- In office, watch patient self-administer 25-50mg oral naltrexone.
- Observe patient for opioid withdrawal signs for minimum of 45-60 min.
- If opioid withdrawal occurs – ***DO NOT*** give XR-NTX.

Naltrexone Challenge Test

Naloxone Withdrawal

- In physically dependent individuals, naloxone will precipitate withdrawal within 5-10 min and dissipate within 30 min.
- Can be measured using standard instruments (e.g., COWS).
- Severity of withdrawal is proportional to the level of physical dependence.
- Any change from baseline, particularly objective signs = Positive Test.

Naltrexone Challenge Test

Naloxone Administration

- Naloxone is given IM 0.8-1.2 mg (2-3 cc).
- To minimize risk of significant opioid withdrawal, may administer in 2 stages, 0.4 mg followed by 0.8 mg.

Naltrexone Challenge Test

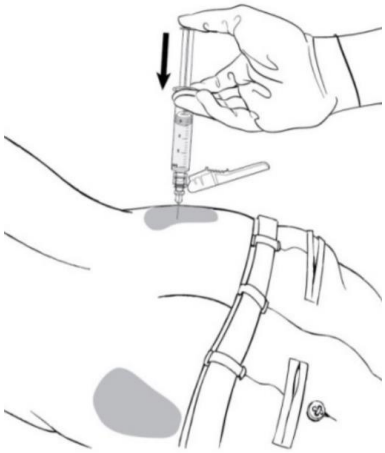
Next steps:

- With negative test →
  - Full dose XR-NTX can be started.
- With positive test
  - XR-NTX should NOT be given.
  - Naloxone challenge can be repeated the next day.

XR-NTX Injection

- **Keep refrigerated**
  - Needs to come up to room temp (~45 minutes) prior to administration
- **Can stay out for a total of 7 days**
- **Reconstitute medication after patient arrives for visit**
- **Once mixed**
  - Give injection immediately so that the medication does not solidify
- **There will be 2 needle sizes 1.5" and 2"**
  - Ensure injection goes into muscle
  - Do not substitute manufacturer carton components
- **Alternate sites**

Injectable Naltrexone (XR-NTX)
Vivitrol® Package Insert



1. Using a circular motion, clean site with the alcohol swab.
2. Administer the suspension by deep IM injection into a gluteal muscle, alternating buttocks per monthly injection.
3. If blood aspirates or the needle clogs, do not inject. Change to the spare needle and administer into an adjacent site in the same gluteal region.
4. Inject the suspension in a smooth and continuous motion.
5. It must **NOT** be given **intravenously or subcutaneously.**

XR-NTX Practical Considerations

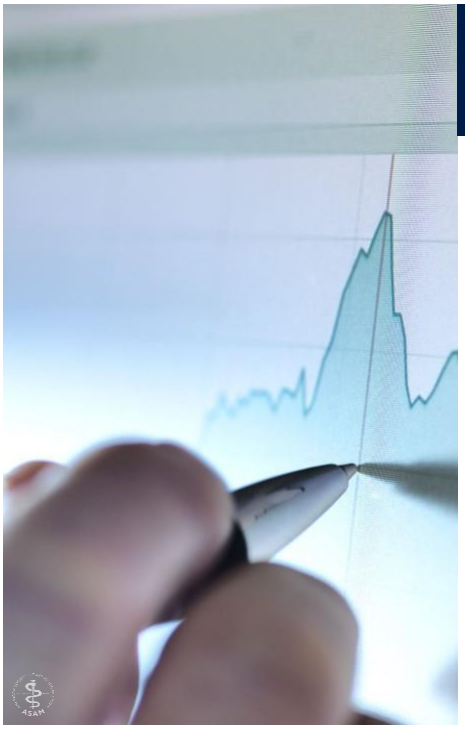
How long should I treat for?

- Unknown
- Pivotal trial 6 months of XR-NTX, then an open-label extension phase
- Reimbursement for 6-24+ months is standard

When XR-NTX stops?

- Return to non-antagonized, low tolerance
- Resume 'baseline' risk of relapse, overdose
- No evidence of otherwise higher OD risk

Lee, JD et al. Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention. Lancet. 2018 Jan 27;391(10118):309-318.



Medically Supervised Withdrawal: *Outcomes*

- Low rates of retention in treatment
- High rates of relapse post-treatment
- < 50% abstinent at 6 months
- < 15% abstinent at 12 months
- Increased rates of overdose due to decreased tolerance

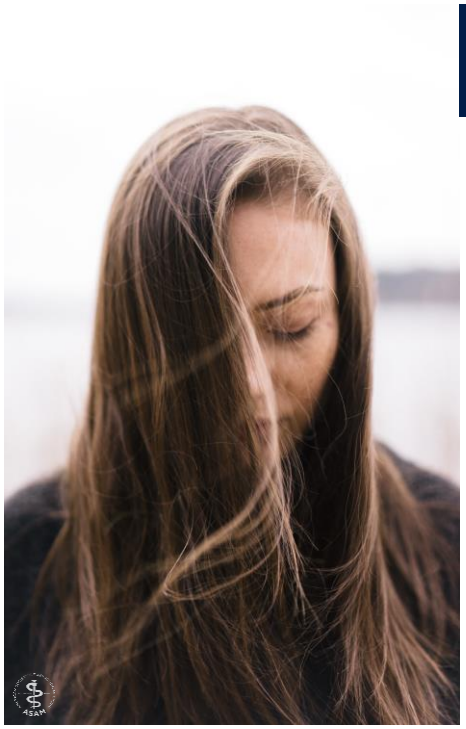
O'Connor PG. JAMA. 2005. Mattick RP, Hall WD. Lancet. 1996; Stimmel B et al. JAMA. 1977.

Audience Response

The ideal patient for injectable naltrexone is:

A. Someone who has tapered off of agonist-based therapy only.
B. Someone who does not want to be on a controlled substance.
C. Someone who is involved with the criminal-legal system.
D. Someone who does not need counseling.

PAULA'S CASE



Activity 6: Case Discussion – Paula

- **Task:** Whole Group Discussion
- **Discuss:** Let's review Paula's case.
- **Time Allocated:** 25 minutes

Paula's Case

Paula is 23-year-old graduate student in social work who is addicted to heroin. Her mother calls your office seeking treatment for her daughter. She agrees to having her mother come in with her for the consultation and evaluation. She is comfortable and not yet in opioid withdrawal during the initial consultation. You get Paula's history while her mother sits in the waiting room. She relates feeling anxious most of her life.

She started smoking marijuana and drinking alcohol on the weekends in high school. In college, she fractured her ankle playing basketball and was treated with oxycodone. She noticed that in addition to pain control, her anxiety decreased, and she reported feeling "normal" and "peaceful."

Paula's Case

She continued requesting oxycodone refills even though her pain had resolved. When the orthopedist refused to continue prescribing oxycodone she started buying them from friends, increasing to ~200mg daily.

A year ago she entered a 28-day residential program, never followed up in after care, and relapsed 6 weeks later. She has never been on medications for her opioid use disorder. Due to cost and availability she switched from oxycodone to snorting heroin, ~10 bags daily. Her last use was four hours ago. Paula agrees to have her mother present to discuss treatment options.

Paula's Case

You present the following options:

1. opioid agonist maintenance therapy (methadone, buprenorphine).
2. antagonist maintenance with naltrexone.
3. another attempt at withdrawal management and medication-free treatment.

Paula's Case

Paula and her mother have done their research; Paula has a friend doing well on buprenorphine and they decide on buprenorphine.

- They understand that you recommend some form of counseling as part of the treatment plan.
- Paula has insurance, so access is not a problem.

Paula's Case

Key Treatment Considerations:

1. Is Paula ready for buprenorphine induction currently?
2. If not, how will you decide when she is ready?
3. Is the patient a candidate for unobserved "home" induction?

You explain that since Paula is physically dependent on opioids, she must be in mild-moderate spontaneous withdrawal to avoid precipitated withdrawal. She understands. You tell her to discontinue all opioids for at least 12 hours. She has decided on doing the induction the next morning.

Paula's Case

- She returns the next day with her mother. She is visibly uncomfortable and has a COWS score of 12.
- Question:
  - ***Is she ready for the induction?***
- You instruct her that buprenorphine/naloxone is always administered sublingually or via the buccal mucosa—never swallowed whole.
- She is instructed on the proper administration procedures to maximize buprenorphine bioavailability.

Paula's Case

- You give her buprenorphine 4/1 mg.
- Questions:
  - ***How long until initial effect?***
  - ***How long until peak effect?***
- After her initial dose, you give her another 4/1 mg for continued withdrawal symptoms.
  - ***When can she leave the office?***
  - ***Can she take more buprenorphine after leaving the office?***
  - ***When should she contact you?***

Paula's Case

Key Treatment Considerations:

4. Should the stabilization dose be divided or taken once per day?
5. How often should stabilization doses be increased?
6. Once dose stabilization occurs, are maintenance dose increases due to tolerance common or are lower doses required over time?

She remained on buprenorphine/naloxone 16/4 mg per day for the next 6 months and had no relapses. She was adherent with weekly counseling and office monitoring including urine drug tests and pill counts. There were no concerning behaviors on the PDMP.

Paula's Case

Key Treatment Considerations:

7. How long should Paula be maintained on the buprenorphine?
8. How will you decide if and when she is ready to be tapered?
9. How would you taper her buprenorphine?

Patient Management: *Monitoring*

Follow-up Visits: Part 1

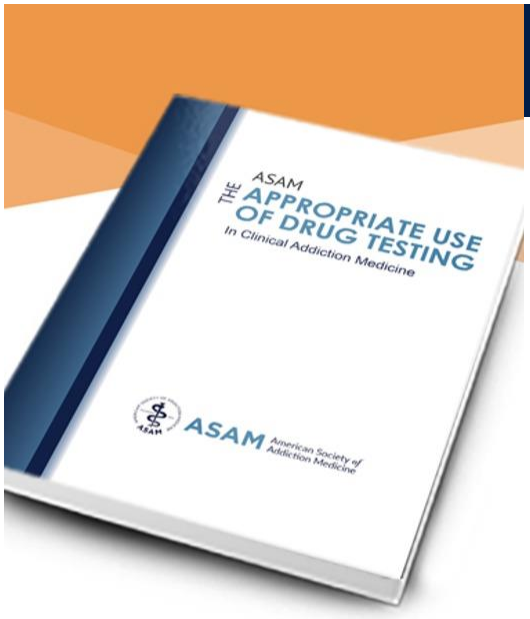
- Face-to-face visits to check safety and adherence.
- Initial Frequency should be every 1-2 weeks until stable, then monthly once stabilized.
- Check dosing, intervals, and sublingual technique.
- Safety issues include side effects and safe storage.

Follow-up Visits: Part 2

- Withdrawal/craving/triggers
- Tobacco, alcohol, and other drug use
- Drug tests and pill counts
- Prescription Drug Monitoring Program (PDMP)
- Confirm or reassess motivation for behavioral treatment
- Medical problems and symptoms

Follow-up Visits: Part 3

- Emotional/behavioral problems and symptoms
- Outside medications and providers
- Housing
- Reliable transportation
- Employment
- Family/relationships
- Legal Issues



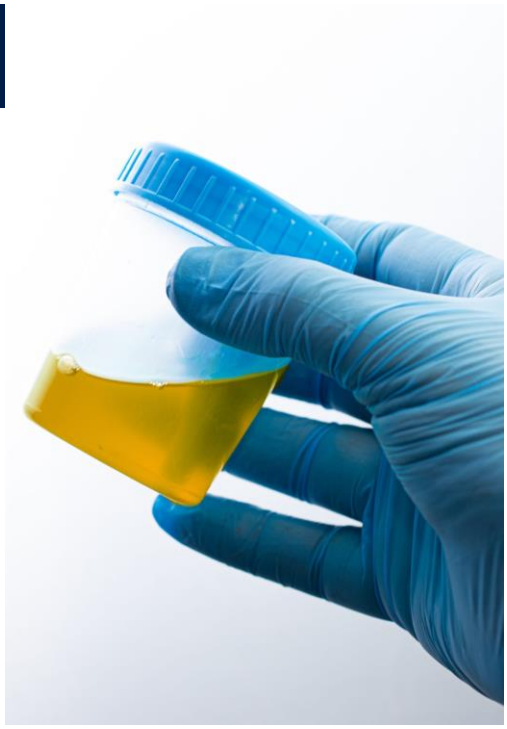
Urine Drug Testing (UDT)

- ***Objective information:***
  - Evidence of therapeutic adherence
  - Evidence of use or non-use of illicit drugs
- Monitoring of treatment progress and safety
- Reinforces success with treatment, but no evidence that UDT improves outcomes
- Part of standard of care
- Identify those who may need higher level of care

ASAM's Appropriate Use of Drug Testing in Clinical Addiction Medicine Consensus Statement 2017

UDT: Frequency

- *SAMHSA TIP 63 (2018): "Periodic random testing" frequency is clinically determined.*
- At least at time of initial evaluation and initiation of medication then weekly → monthly.
- Regulation and reimbursement vary among states and insurers.
- Urine is preferred medium for testing due to:
  - Ease of obtaining sample, lowest cost
  - Ideal detection time (2-3 days)
  - Presence and persistence of metabolites
  - Availability of office-based testing tools



SAMHSA TIP 63 Medications for Opioid Use Disorders, 2018 ASAM's Consensus Statement 2017.

UDT: Implementation

- *Discuss with patient:*
  - This is for safety and this is the standard of care.
- *Know scope and limits of tests and lab:*
  - Beware false negatives and positives.
- *Consider random versus scheduled testing.*
- *Incorporate quality control procedures (temperature strip).*
- *Consider establishing consult lab linkage:*
  - GCMS/LCMS confirmatory testing.
  - Expert consultation on test interpretation.
  - Online reporting of results.

ASAM's Appropriate Use of Drug Testing in Clinical Addiction Medicine Consensus Statement 2017

UDT: Immunoassays

Pros:

- Point of care or lab-based
- Fast
- Cheap
- Specific tests available for many drugs
  - Oxycodone
  - Buprenorphine
  - Fentanyl
- Can be used as screening with option for confirmation

VS

Cons:

- Qualitative tests
  - Cutoff ng/ml
    - Opiates: 300
    - Cocaine metabolite: 300
- False positives
  - Cross-reactivity
  - Contamination
- False negatives
  - Below the cutoff

ASAM's Consensus Statement 2017

UDT: Immunoassay Detection Windows in Urine

Drug/Medication	Primary Metabolite	Ave. Detection Time (days)
Opiates (heroin, morphine)	Morphine	2-3
Semisynthetic Opioids (oxycodone, hydrocodone)	Variable Must be tested specifically	2-3
Methadone	EDDP	2-3
Buprenorphine	Nor-buprenorphine	2-3
Cocaine	benzoylecgonine	2-3
Amphetamines		2-3
Benzodiazepine	Varies by medication type	Variable with half life Unreliable immunoassays
Cannabis Occasional Cannabis Chronic	THC	1-3 Up to 30

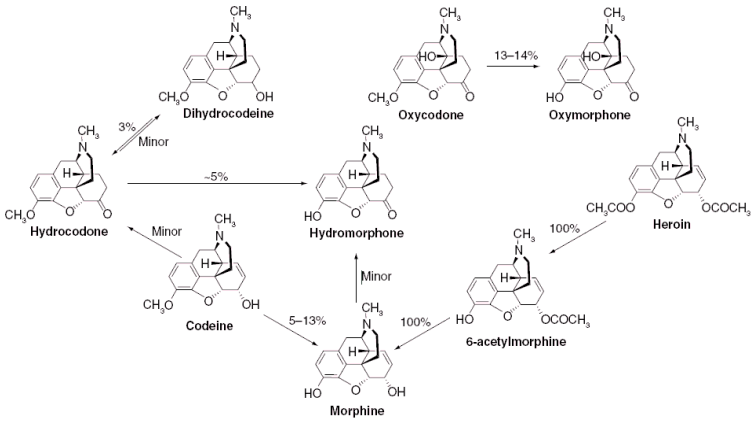
ASAM's Consensus Statement 2017

UDT: GCMS/LCMS

- *Gas or liquid chromatography, mass spectrometry*
- *Quantitative*
- *Limitations*
  - More costly
  - Requires specialized lab
  - Levels do not indicate amount of medication taken!
    - *Variables:*
      - time of dosing
      - metabolism
      - GFR
      - hydration

ASAM's Consensus Statement 2017

UDT: Opioid Metabolism



Pill Counts

- ***Objective information:***
  - Confirm medication adherence.
  - Minimize diversion.
- Frequency varies with patient progress.
- Best option when diversion suspected.
- Patient brings in medication supply.
- Confirm patient ID and fill date on bottle/box.
- Have patient count them in front of staff member.
- All tablets should be identical.
- Amount should match expected quantity.

Prescription Drug Monitoring Program (PDMP)

- ***State-wide System Tracking Prescriptions:***
  - Decreasing or preventing misuse of medications.
  - Improving clinical decision-making.
- ***Pharmacies:***
  - Report information to state.
- ***Information Varies:***
  - Schedule II +/- other schedules.
  - Some selected non-scheduled medications with misuse potential: e.g., gabapentin, ephedrine.
- ***Data Availability:***
  - Format and medications reported vary by state.

PDMP: Limitations

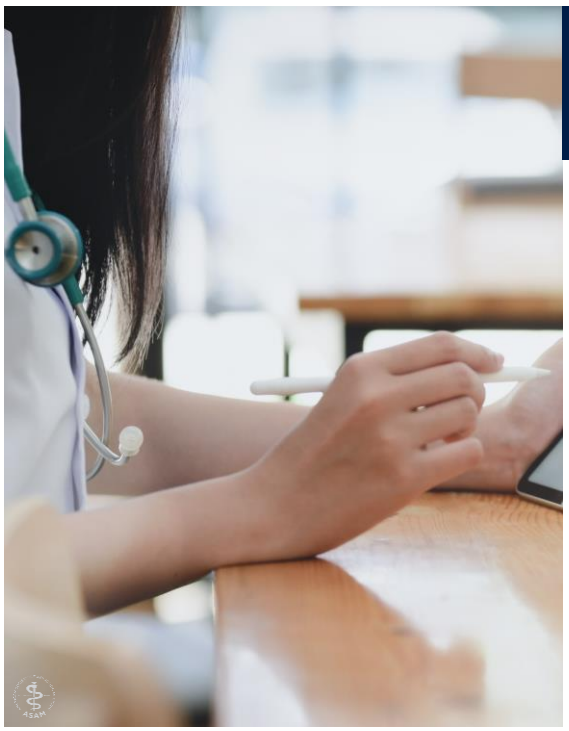
- Methadone and buprenorphine dispensed from OTPs are not listed on PDMPs.
- Not all data is readily available to providers.
- There is a lack of communication between all state programs.
- Time is needed to access reports.
- There are limitations in who can access reports.
- There is a mandatory vs. voluntary use of PDMP.

Audience Response

Which of the following is a monitoring practice that is evidence-based?

A. Checking your state's PDMP only on initiating buprenorphine.
B. UDT to make sure the patient is taking the medication and to discharge the patient if negative.
C. Random pill counts on all patients.
D. UDT to determine if the patient would benefit from additional support.

Relapse



Relapse: Prevention & Management

Relapse is a process in which return to substance use occurs in response to stressors and stimuli.

Relapse Precipitants:

- Present a negative affect (anger, fatigue, boredom, family conflict)
- Present cravings/cues (people, places and things)
- Feel social pressure/stress
- Begin using drug again

Doyle TJ, et al. Addressing Unhealthy Alcohol Use in Primary Care, 2013.

Relapse: Prevention & Management

- *Educate patients about how to anticipate/avoid/cope with these precipitants.*
- After initial use (a lapse), patients may experience guilt and shame which results in a heavy return to use.
- *Maintaining treatment is a learning process, lapses provide valuable lessons. A lapse is not a failure, but a mistake from which one can learn.*
- Returning to substance use requires prompt evaluation and review of treatment plan as well as a possible referral to additional or higher level of care.

Doyle TJ, et al. Addressing Unhealthy Alcohol Use in Primary Care, 2013.

SOPHIA'S CASE

Sophia's Case

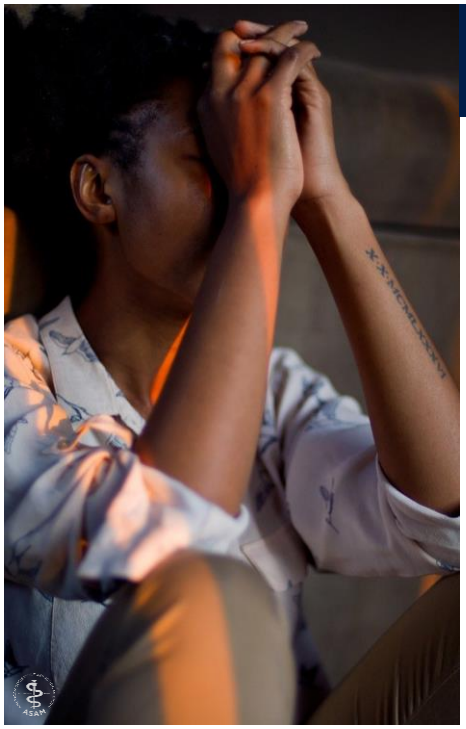
38-year-old woman followed for ongoing management of her opioid use disorder. She is presented to the buprenorphine induction clinic for induction and was quickly stabilized on bup/nx 16/4 mg SL a day. She kept all her appointments and had six weeks of urine drug tests which were negative for opioids and all other tested drugs.

Since coming into treatment with you, she has kept biweekly appointments x3, and monthly appointments x4, is reporting satisfaction with the treatment and is increasing productivity at work as a research assistant.

Sophia's Case

After her 8th visit with you, her urine drug test was positive for benzodiazepines, and confirmation reveals alprazolam and metabolites. She admits to using a friend's alprazolam (Xanax®) one night to help sleep. "With all the work stress, I just couldn't get to sleep."

She notes that she is doing much better in her life now than before when she was spending all her money on heroin and struggling to keep a job. She does not want to discontinue buprenorphine and go back to that life.



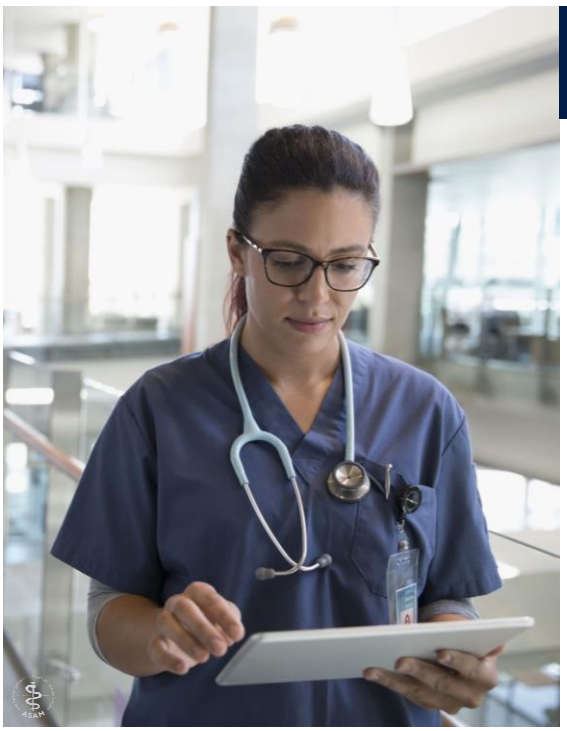
Activity 7: Case Discussion – Sophia

- **Task:** Whole Group Discussion
- **Discuss:**
  - How would you respond to these results?
  - Does the nature of the substance (benzos vs. stimulants) affect how you talk to Sophia?
  - How would you respond to these results?
- **Time Allocated:** 10 minutes

Sophia's Case

- She does not believe she has "a problem" with alprazolam.
- She denies further use.
- Repeat testing at this visit comes back positive again for benzodiazepines, with +alprazolam and metabolites.
- Question:
  - ***How would you respond to Sophia now?***

Office Management



Medication Treatment Settings

Office-Based Opioid Treatment (OBOT):

- Buprenorphine or naltrexone
- Not methadone
- Primary care (different models)
- Specialty (e.g. Infectious Disease, GI, Psychiatry, Hospitalist, Emergency Department)
- SUD treatment clinics

Implementing OBOT: Buy-in

- Do staff understand the need or gap in services?
- Do staff have accurate information about the disease of addiction and treatment options?
- Will patients be different from the ones we treat now?
- Does staff have the requisite knowledge, tools, and equipment to be successful?

https://www.niatx.net/PDF/NIATx-MAT-Toolkit.pdf

Treatment Agreement

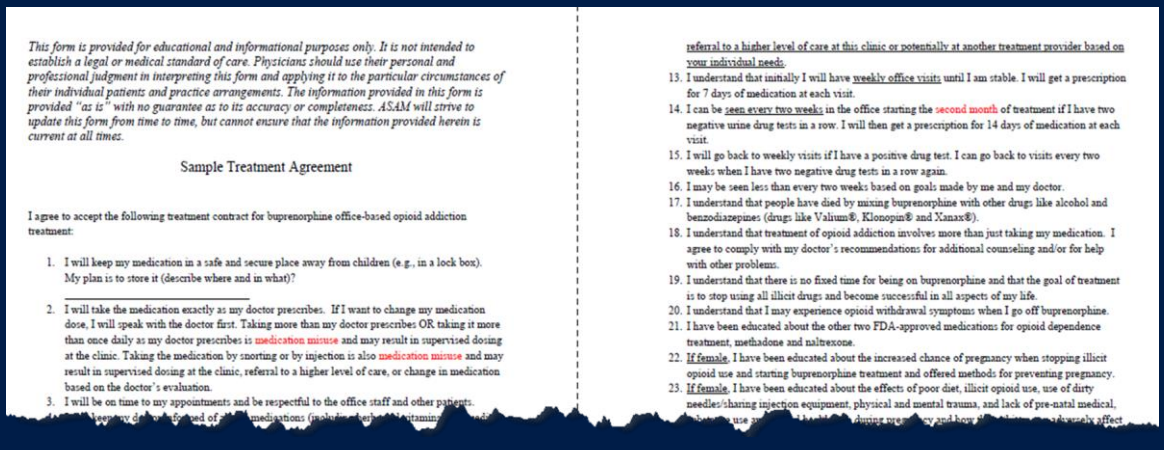
Patient Expectations:

- No medication diversion
- Adherence to treatment protocols
- Induction, maintenance
- Monitoring strategies (i.e., urine drug tests, pill counts)
- Additional treatment
- Appointments and refills
- No disruptive behavior
- Contact with other caregivers and pharmacies
- Safe storage

Provider Expectations:

- Scheduling visits
- Medication supply and refills
- Night coverage
- Response to “lost” prescriptions
- Unexpected UDT results
- Nonadherence or unexpected results
- Maintenance vs. taper

Treatment Agreement



This form is provided for educational and informational purposes only. It is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting this form and applying it to the particular circumstances of their individual patients and practice arrangements. The information provided in this form is provided "as is" with no guarantee as to its accuracy or completeness. ASAM will strive to update this form from time to time, but cannot ensure that the information provided herein is current at all times.

Sample Treatment Agreement

I agree to accept the following treatment contract for buprenorphine office-based opioid addiction treatment:

1. I will keep my medication in a safe and secure place away from children (e.g., in a lock box). My plan is to store it (describe where and in what)?
   _____
2. I will take the medication exactly as my doctor prescribes. If I want to change my medication dose, I will speak with the doctor first. Taking more than my doctor prescribes OR taking it more than once daily as my doctor prescribes is medication misuse and may result in supervised dosing at the clinic. Taking the medication by snorting or by injection is also medication misuse and may result in supervised dosing at the clinic, referral to a higher level of care, or change in medication based on the doctor's evaluation.
3. I will be on time to my appointments and be respectful to the office staff and other patients.

referral to a higher level of care at this clinic or potentially at another treatment provider based on your individual needs.

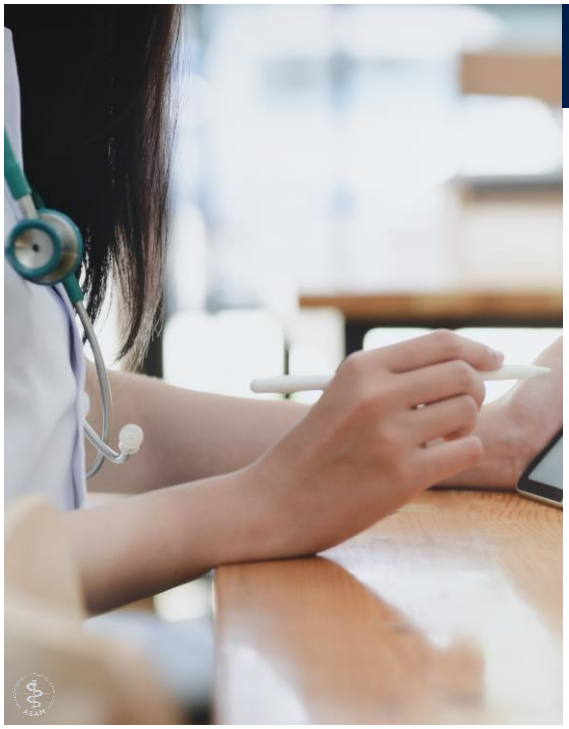
13. I understand that initially I will have weekly office visits until I am stable. I will get a prescription for 7 days of medication at each visit.
14. I can be seen every two weeks in the office starting the second month of treatment if I have two negative urine drug tests in a row. I will then get a prescription for 14 days of medication at each visit.
15. I will go back to weekly visits if I have a positive drug test. I can go back to visits every two weeks when I have two negative drug tests in a row again.
16. I may be seen less than every two weeks based on goals made by me and my doctor.
17. I understand that people have died by mixing buprenorphine with other drugs like alcohol and benzodiazepines (drugs like Valium®, Klonopin® and Xanax®).
18. I understand that treatment of opioid addiction involves more than just taking my medication. I agree to comply with my doctor's recommendations for additional counseling and/or for help with other problems.
19. I understand that there is no fixed time for being on buprenorphine and that the goal of treatment is to stop using all illicit drugs and become successful in all aspects of my life.
20. I understand that I may experience opioid withdrawal symptoms when I go off buprenorphine.
21. I have been educated about the other two FDA-approved medications for opioid dependence treatment, methadone and naltrexone.
22. If female, I have been educated about the increased chance of pregnancy when stopping illicit opioid use and starting buprenorphine treatment and offered methods for preventing pregnancy.
23. If female, I have been educated about the effects of poor diet, illicit opioid use, use of dirty needles/sharing injection equipment, physical and mental trauma, and lack of pre-natal medical,

Download from https://tinyurl.com/yanouybg

Informed Consent

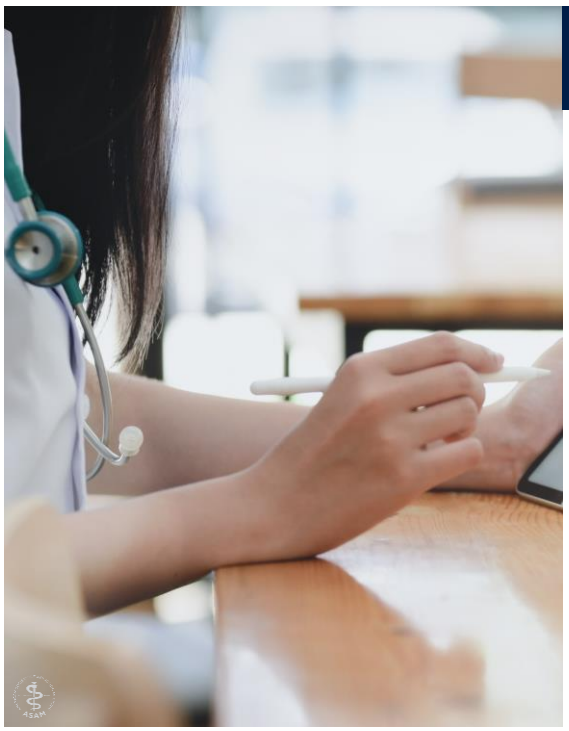
Must Address:

- Physical dependence
- Side effects:
  - Constipation
  - Sweating
  - Hypogonadism
- Risk of impairment, overdose
- Possible medication interactions
- Neonatal Abstinence Syndrome or Neonatal Opioid Withdrawal Syndrome
- Other treatments available: methadone, naltrexone, nonmedication-based treatments



Anticipate Insurance Issues

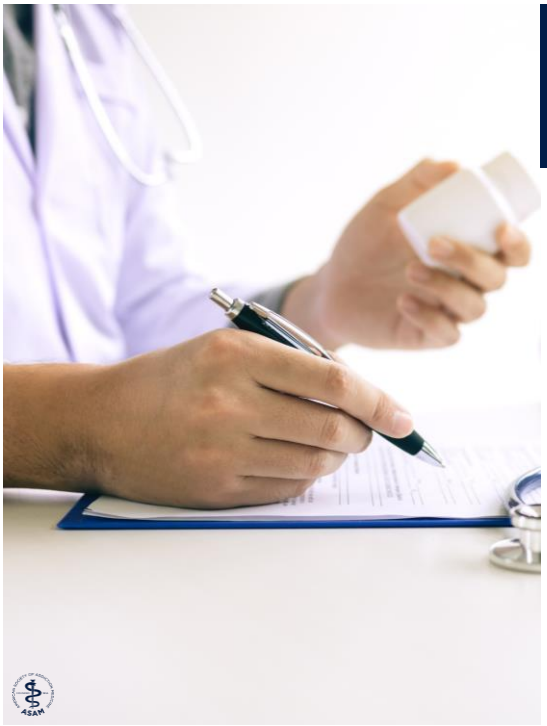
- *Is buprenorphine a covered benefit?*
  - Which formulation (tabs, film)
  - What tier?
  - What co-pays?
- Are lab services covered?
- Are there restrictions on duration of treatment?
- Is behavioral treatment covered?
- *Be aware of behavioral health carveouts*



Anticipate Insurance Issues

Anticipate prior approval procedures:

- Collect forms from each payer
- Submit forms in advance of fill
- Monitor patient's pharmacy benefits
- 340B coverage in some Community Health Centers



Office-Based Opioid Treatment (OBOT) Billing

- *OBOT is standard medical care: billing procedures are standard.*
- Physicians billing codes: (CPT) billing codes, are accepted by most payers in most states.
- *The ICD-10 Code for opioid use disorder is F11.20.*
  - The fifth (x) digit sub-classifications are: 0=unspecified, 1=continuous, 2=episodic, 3=in remission.
- *No specific addiction medicine codes.* Same codes as other ambulatory care services.

IMPLEMENTING OFFICE-BASED OPIOID TREATMENT

End of Session 3

THE ASAM
Treatment of Opioid Use Disorder Course

Includes waiver qualifying requirements

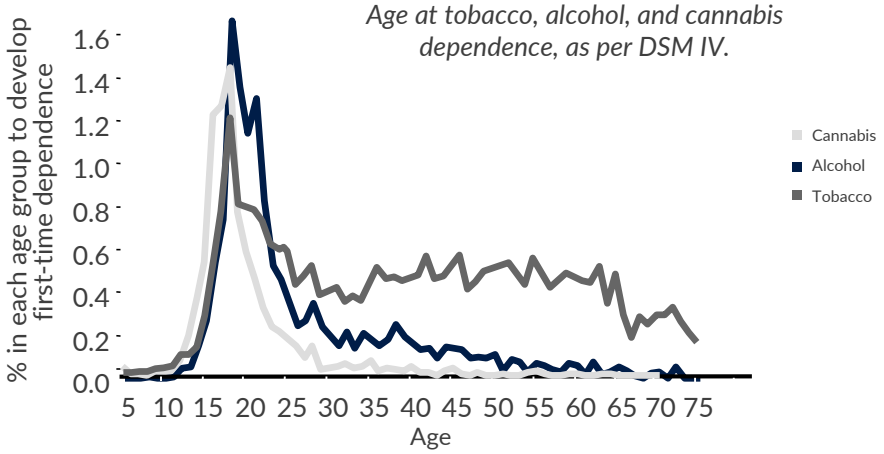
Session 4

Special Populations

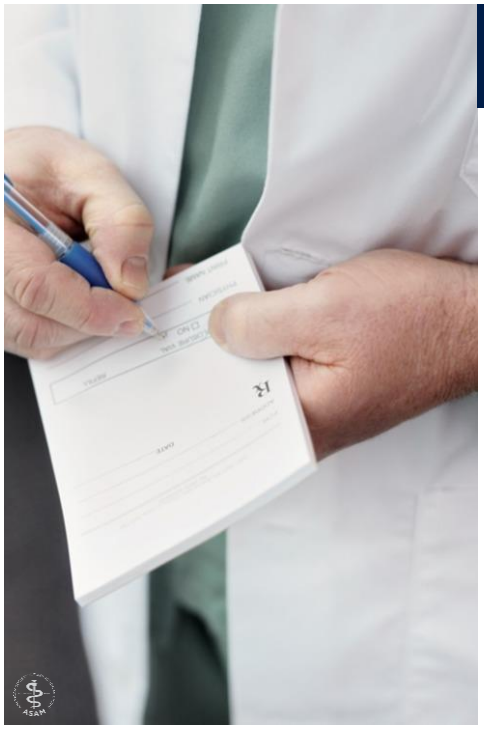
Session Learning Objectives

1. Describe unique issues of treating adolescents, young adults, pregnant and postpartum patients, elderly patients, and healthcare professionals maintained on medications for opioid use disorders.
2. Summarize acute (e.g., postoperative pain) and chronic pain management strategies for patients with an opioid use disorder.

Addiction is a Developmental Disease
Often Starts in Childhood and Adolescence



National Epidemiologic Survey on Alcohol and Related Conditions, 2003



Medications for Adolescents with OUD

- *Buprenorphine vs. Clonidine for 28-day withdrawal management.*
  - Participants 13-18 years old (N=36).
  - Compared to clonidine, patients who received 4 weeks of buprenorphine treatment:
    - Had fewer positive opioid drug tests.
    - Stayed in treatment longer.
    - Were more likely to continue treatment after 4-week trial period.

Young Adults

Methadone (OTP)

Methadone may be a good option for young adults (18+) with unstable living arrangements; daily visits provide structure and eliminate the need to manage medications at home.

Sanchez-Samper X, Levy S. Opioid use by adolescents. Office-Based Buprenorphine Treatment of Opioid Use Disorders. 2nd edition. 2018

Naltrexone

Naltrexone is also an option for adolescents; may be clinically useful for adolescents/young adults living away from home, or patients with co-occurring alcohol use disorder.

*There are no published studies on the efficacy of naltrexone for OUD in adolescent patients

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Medication-Assisted Treatment of Adolescents With Opioid Use Disorders

COMMITTEE ON SUBSTANCE USE AND PREVENTION

Effective treatments are underutilized; resources are available for this age group.

Levy S, et al. Pediatrics. 2016;138(3).

Barriers for Care

Stigma

- Significant misinformation about what medication treatment is and its benefits.

Lack of Training

- Only 1% of waivered providers identify as pediatricians.

Coordinating Care

- These cases are complicated, involve state agencies, families, and children. These cases can be hard to ensure that a consistent plan is offered and implemented.

Maintaining Engagement in School

- *Substance use disorder often interferes with education.*
  - Maintaining education with the most effective combination of pharmacotherapy and psychosocial treatment is important.
- *Properly administered, buprenorphine, methadone, and naltrexone do not impair cognitive function.*
  - After being stabilized, adolescents and young adults should be encouraged to return to school.

Confidentiality

Teens Presenting With Parents

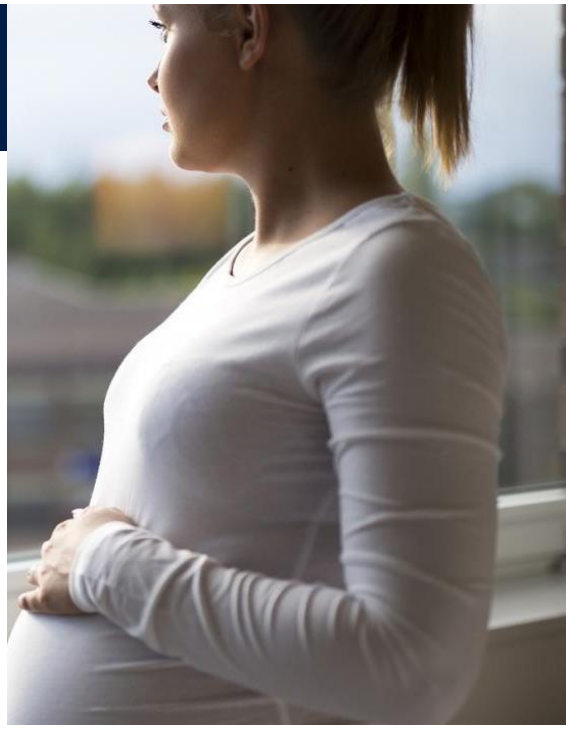
- In many cases, adolescents will present for treatment with the knowledge and support of parents.
- Teens often turn to their parents for help first.
- Managing confidentiality is a clinical decision of what information to share with parents in the context of parents already being aware of the "big picture."

Teens Presenting Without Parents

- Teens may present for treatment without the knowledge or consent of their parents.
- In most states, adolescents above a certain age may consent for treatment for SUD without their parents, though details vary.

Pregnancy: Substance Use Disorder

- *Women with SUD often experience dysregulation of their menstrual cycle.*
  - Chronic opioid use alters dopamine/prolactin levels in hypothalamic-pituitary axis leading to amenorrhea and unpredictable cycles.
  - Menstrual cycle alterations can lead to unplanned and often unrecognized pregnancies with delayed initiation of prenatal care.



Pregnancy: Opioid Agonist Maintenance Therapy Remains the Standard of Care

There are safe and effective treatment options in pregnancy.

- Opioid agonist pharmacotherapy with methadone or buprenorphine is endorsed by the American College of Obstetricians and Gynecologists (ACOG) as the optimal treatment for OUD during pregnancy.

Fischer et al. 1998, 1999. Jones et al. 2010. Terplan M, et al. Obstetrics & Gynecology. 2018.

Benefits of Opioid Agonist Therapy

Maternal Benefits

- 70% reduction in overdose related deaths.
- Decrease in risk of HIV, HBV, HCV.
- Increased engagement in prenatal care and treatment.

Klaman SL, et al. J Addict Med. 2017.

Fetal Benefits

- Reduces fluctuations in maternal opioid levels thus reducing fetal stress.
- Decrease in intrauterine fetal demise.
- Decrease in intrauterine growth restriction.
- Decrease in preterm delivery.

Use of Buprenorphine During Pregnancy

- *Buprenorphine/Naloxone*
  - No known teratogenic effects in animals.
  - Controlled studies have not been conducted in humans.
  - Increasing evidence that buprenorphine/naloxone may be safe in pregnancy.
  - Evidence demonstrates safety of combination formulation in pregnancy.

Pregnancy: Induction of Maintenance Therapy

Goal

Goal is to reach the dose just high enough to stop use and block cravings.

Management

Management of dose should be individualized and based on patient's symptoms.

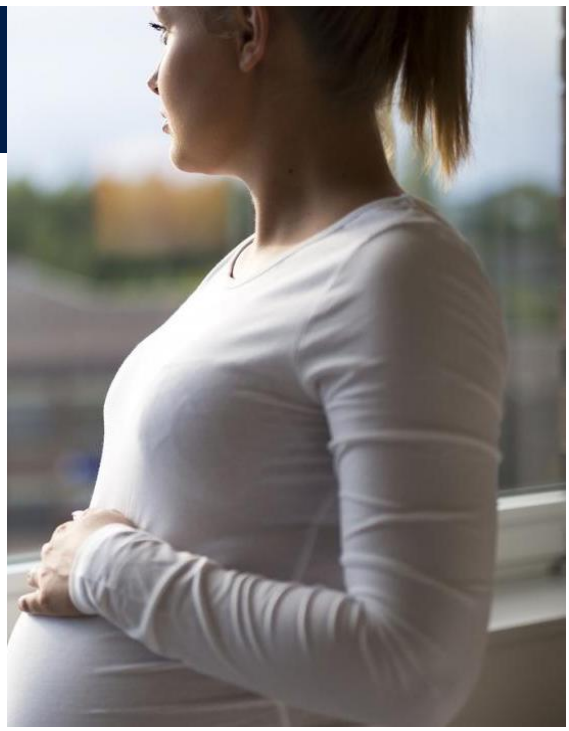
Adjustments

Dose adjustments may be necessary with advancing gestational age based on pregnant physiology.

Split dosing may be required in pregnancy to meet the accelerated metabolic clearance of pregnancy.

Patient on Buprenorphine

- *Stable patients who become pregnant.*
  - Combination therapy has been avoided due to the unknown exposure risk of naloxone in pregnancy.
  - However, recent studies suggest combination therapy is safe and effective in pregnant/breastfeeding patients.



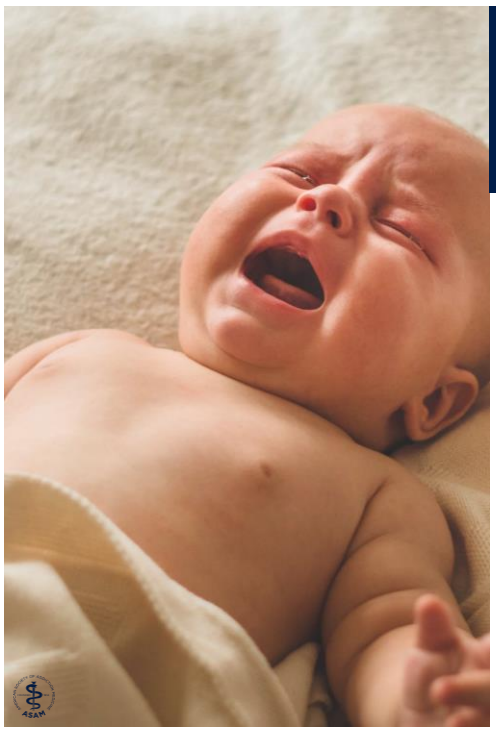
Wieggland SL et al. 2015.

Should Women Undergo Withdrawal During Pregnancy?

Studies have demonstrated:

- ⊖ Fetal distress and 5-fold increase in still birth rates with antepartum withdrawal management.
- ⊖ Withdrawal management can be safe for the fetus, however, maternal relapse rates prior to delivery range from 70-98%.
- ⊕ **Maintenance therapy in pregnancy has been shown to increase retention in prenatal care, addiction treatment, and in-hospital deliveries.**

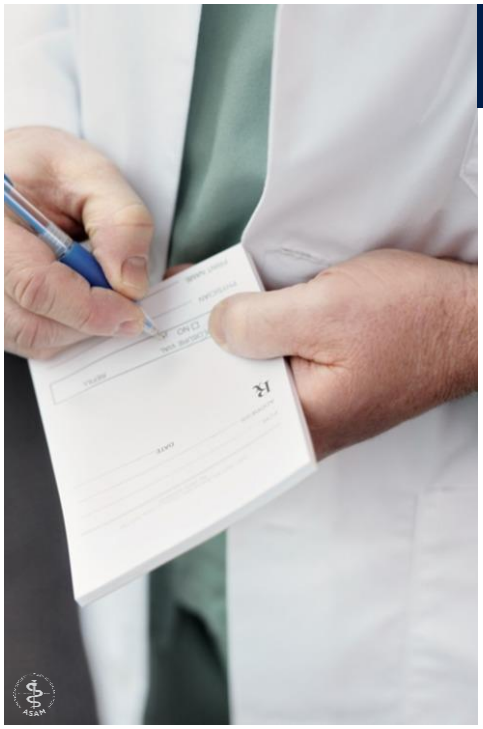
Zuspan et al. 1975; Rementeria et al. 1973.
Bell J et al. 2016; Luty et al. 2003; Maas et al. 1990; Dashe et al. 1998.
Jones et al. 2008.



Neonatal Abstinence Syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS)

- Results from abrupt discontinuation of opioids at birth after a fetus has become physically dependent through exposure in utero.
- Risk of NAS is greater if opioids are taken close to delivery or for longer periods and if the drugs have short half lives.
- Rate of opioid clearance influences severity.

Volkow ND. BMJ 2016



NAS Management

Non-Pharmacologic Approaches

- Quiet and dimly lit room, handled gently, swaddling, pacifier, gentle rocking
- Rooming: Keeping mother and baby together reduces NAS length of stay and cost
- Non-insertive acupuncture
- Breastfeeding recommended as it soothes agitated infants

Pharmacotherapy

- Oral morphine is preferred first-line medication

Bagley SM et al. Addiction Science & Clinical Practice. 2014

Maintenance Therapy in Pregnancy: NAS

Meta-analysis of 12 studies from 1996-2012

Neonates exposed to buprenorphine (515) compared to methadone (855) had:

- ☑ Shorter mean length of hospital stay (-7.23 days, 95% CI: -10.64, -3.83).
- ☑ Shorter NAS treatment duration (-8.46 days, 95% CI: -14.48, -2.44).
- ☑ Lower morphine dose (-3.60 mg, 95% CI: -7.26, 0.07).

Brogly et al. Am J Epidemiol. 2014;180(7):673-86

Maternal Dose and NAS Severity

- No correlation between maternal opioid maintenance therapy dose and duration or severity of NAS.
- Tobacco use is strongly associated with NAS and NAS severity.

Berghella et al. 2003; McCarthy et al. 2005; Cleary et al. 2010; Isemann et al. 2010; Jones et al. 2010; Seligman et al. 2011.

Benefits of Breastfeeding for Newborns with NAS

NAS Development
30% decrease

Length of Stay
50% decrease of neonatal stay

Mother-Infant Bonding
Improves

Maternal Recovery
Positively reinforced

Pritham UA et al. J Obstet Gynecol Neonatal Nurs. 2012. Welle-Strand GK et al. Acta Paediatr. 2013. Wachman EM et al. JAMA. 2013. Abdel-Latif ME et al. Pediatrics. 2006.

Breastfeeding

- ***Maternal HCV infection is NOT a contraindication.***
- Unless mother develops cracked or bleeding nipples. If so, recommend to pump/dump until healed.

Klaman SL, et al. J Addict Med. 2017.

- ***Maternal HIV infection.***
- ***Current maternal substance use.*** Mother currently under influence.
- ***Recent heavy marijuana use.*** Lipophilic, concentration in breast milk. Note: recent study found little THC in breast milk (Baker et al. Ob Gyn. 2018).

Audience Response

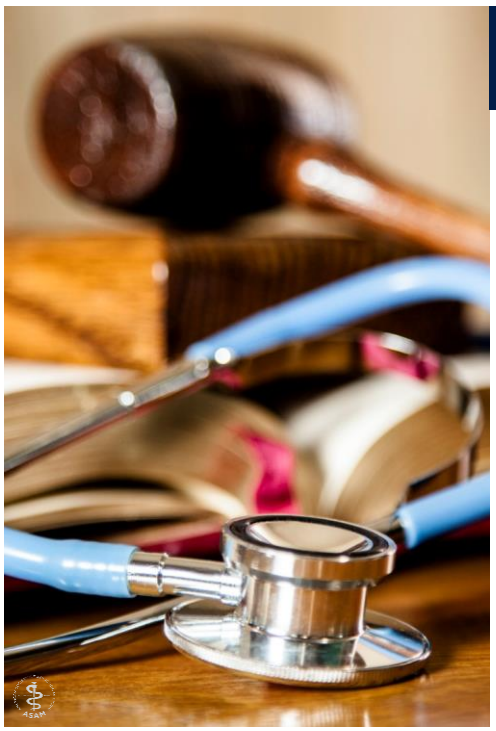
Which of the following is true during pregnancy and postpartum?

a. Patients should be encouraged to taper to lower doses of buprenorphine to reduce the risk of NAS
b. Patients should be instructed not to breastfeed with MOUD
c. Tobacco use is strongly associated with risk of NAS
d. The preferred treatment for NAS is to start with morphine

Older Adults
Caring for Patients

No restrictions on medications for OUD to older patients:

- Be aware of interactions with co-prescribed medications.
- Benzodiazepines commonly used; inquire about alcohol use.
- Decreased renal and/or hepatic function may require dose adjustments.
- Falls and cognitive impairment important in this population.
- Daily dose dispenser helpful reminder.
- Treatment outcome research: older adults do better in treatment than younger counterparts.



Healthcare Providers with SUD

Physician Health Program (PHP)

- 10-12% of physicians in US develop SUD.
- State-based PHPs often mandated for providers with SUD.
- Generally abstinence-based.

Healthcare Providers with SUD

Physician Health Program (PHP)

- About 75% of physicians in PHPs had positive outcomes after 5 years of treatment; *95% who completed the program were licensed and practicing.*
- Goals of PHPs are to help provider achieve long-term treatment, maintain medical career, protect the public, and maintain patient confidence in healthcare providers.

OUD and Increased Pain Sensitivity

- ***Patients with active OUD.***
  - No correlation between maternal opioid maintenance therapy dose and duration or severity of NAS.
- ***Patients with OUD on opioid agonist treatment have less pain tolerance than matched controls.***

Martin J (1965), Ho and Dole V (1979), Compton P (1994, 2001)

Acute Pain Management
Patients on Opioid Agonist Treatment

- ***Patients who are physically dependent on opioids:***
  - Must be maintained on daily equivalence ("opioid debt") before ANY analgesic effect is realized with opioids (or nonopioids) used to treat acute pain.
  - Opioid analgesic requirements are often higher due to increased pain sensitivity and opioid cross-tolerance.

Peng PW, Tumber PS, Gourlay D: Can J Anaesthesia 2005
Alford DP, Compton P, Samet JH. Ann Intern Med 2006

Methadone and Acute Pain

Treating Pain
- Methadone dosed every 24 hours does not confer analgesia beyond 6-8 hours.
- Increased pain sensitivity may necessitate higher doses at shorter intervals.
- Scheduled dosing, not "prn," during severe acute pain.
- Short course of opioid analgesics during severe acute pain unlikely to compromise recovery.

Alford DP, Compton P, Samet JH. Ann Intern Med 2006

Clinical Recommendations
- Non-opioid, non-controlled substance analgesia as first line.
- Continue usual verified methadone dose.
- Treat pain aggressively with conventional analgesics.
- Avoid using mixed agonist/antagonist opioids.
- Careful use and monitoring of combination products containing acetaminophen.
- Coordinate care.

Buprenorphine and Acute Pain

Treating Pain

- Analgesia from buprenorphine lasts 6-8 hours while treatment of OUD lasts over 24 hours.
- Buprenorphine has ceiling effect on CNS and respiratory depression, therefore safer than a full opioid agonist from an overdose risk.
- Uncertain if buprenorphine has an analgesic ceiling effect.

Alford DP. "Acute and Chronic Pain," Office-Based Buprenorphine Treatment of Opioid Use Disorder, 2018

Clinical Recommendations

- Continue buprenorphine in divided doses (every 8 hours) AND titrate short-acting opioid. analgesics for pain management
- OR, continue in divided doses and add additional low dose (e.g. 2 mg) buprenorphine every 8 hours.

Perioperative Protocol Resources Available

- ***Boston Medical Center***
  - Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence.
- ***Pain Medicine Editorial***
  - Patients maintained on buprenorphine for opioid use disorder should continue buprenorphine through the perioperative period.

Buprenorphine Maintenance
Treating Chronic Pain

- ***Buprenorphine can be prescribed in the office for OUD and chronic pain.***
  - Systematic review: 10 studies (low quality) reported effectiveness in treating chronic pain.
  - Buprenorphine for OUD requires X-number while use for chronic pain management (off-label) does not.
  - For pain, buprenorphine will need to be dosed every 8 hours.

Cotes J, Montgomery L. 2014

Naltrexone and Acute Pain

Naltrexone Blockade
- Analgesic effects of opioids blocked at conventional doses.
- Can be overcome by 6-20x usual analgesic dose without significant respiratory depression or sedation *under close observation*.
- Need setting equipped and staffed for resuscitation.

Dean RL et al. Pharmacol Biochem Behav 2008; Vickers AP, Jolly A BMJ 2006

Perioperative Management
- Consult anesthesia, consider nonopioids and regional anesthesia.
- Oral naltrexone blockade 50% gone after 72 hours.
- Extended-release naltrexone blockade decline begins in 14 days, delay elective surgery for a month after last dose.

Audience Response

Patients maintained of opioid agonist therapy for OUD who have an acute pain event should be:

a. Treated through collaboration with anesthesia, pain and addiction as appropriate to develop a comprehensive pain plan
b. Immediately tapered off buprenorphine to start full agonists therapy with plans to resume buprenorphine post-event
c. Maintained on their MOUD without dose adjustment or addition of other controlled substances
d. Continued on their MOUD with addition of non-opioid analgesia and opioid analgesia

Q&A

SAM'S CASE

Sam's Case

52-year-old male. Maintained on buprenorphine/ naloxone 16/4mg per day for the past 10 years.

His opioid use disorder began after a motorcycle crash resulting in multiple fractures and orthopedic surgeries. He was treated with high dose morphine and quickly escalated his use, losing control of his prescriptions.

He realized he had a problem when he ran out of his morphine and had severe withdrawal symptoms.

Sam's Case

He believes buprenorphine is a "miracle drug" that has saved his life. He is not in counseling but attends AA 3-4 meetings per week and has a sponsor.

He has a history of alcohol use disorder and has been sober for >20 years.

He has severe chronic right knee pain which he has been told is due to arthritis after his traumatic knee injury. His pain had been well controlled on split dose buprenorphine (8/2 mg TID), ibuprofen, and acetaminophen.

Now his pain is so severe, he has had to take time off from work.

Sam's Case

He is now being scheduled for an elective right total knee replacement.

He was told in the preoperative clinic:

- To get off his buprenorphine for at least 5 days before his surgery.
- That the buprenorphine will prevent the pain medication from working.
- That the pain medications will likely put him into withdrawal if he is still taking the buprenorphine.

He is nervous about stopping his buprenorphine and asks you what to do.

Activity 8: Case Discussion – Sam

Discuss:

Work with your group to assess a plan for Sam. What do you recommend regarding his buprenorphine maintenance perioperatively? What do you recommend regarding his pain management perioperatively? What additional information do you need?

10 minutes:

After the discussion, a few groups will share key takeaways with the whole class.

SPECIAL POPULATIONS

End of Session 4

THE ASAM
Treatment of Opioid Use Disorder Course

Includes waiver qualifying requirements

Session 5

Keeping Your Patient Safe

Session Learning Objectives

1. Examine misconceptions, stigma, and complexities (bioethical, social, clinical, public health) associated with OUD and the use of medications to treat opioid use disorder.

JENNIFER'S CASE

Jennifer:

32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from buprenorphine.

- Jennifer was diagnosed with OUD, which started with opioid analgesics and then segued into IN heroin.
- She has been on buprenorphine/ naloxone film strips, 12 mg daily, for 5 years. Patient had a positive response to the medication and has had negative UDTs, with the occasional +THC, for years.

Jennifer:

32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from buprenorphine.

- Jennifer is employed as an IT specialist at a law firm. She has been careful to “hide” her medication use from her family, friends, and co-workers, for fear of a negative reaction. She also thinks that if her co-workers knew about her OUD and medication, if a wallet were stolen, they would automatically suspect she was the thief.
- One year ago, Jennifer met her future wife at the law firm. Karishma is a paralegal at the firm and has no history of “drug” use.

Jennifer:

32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from buprenorphine.

- As their relationship developed, Jennifer was ambivalent and fearful about disclosing her history of OUD and current OAT with buprenorphine. A few months before their wedding, Jennifer did disclose and Karishma was taken aback, but said it was not a problem.
- On Jennifer's last visit with you, she inquires about "getting off" buprenorphine. She relates that Karishma has never really been okay with the medication. Karishma has heard that it's "just substituting one drug for another" or "one addiction for another."

Jennifer:

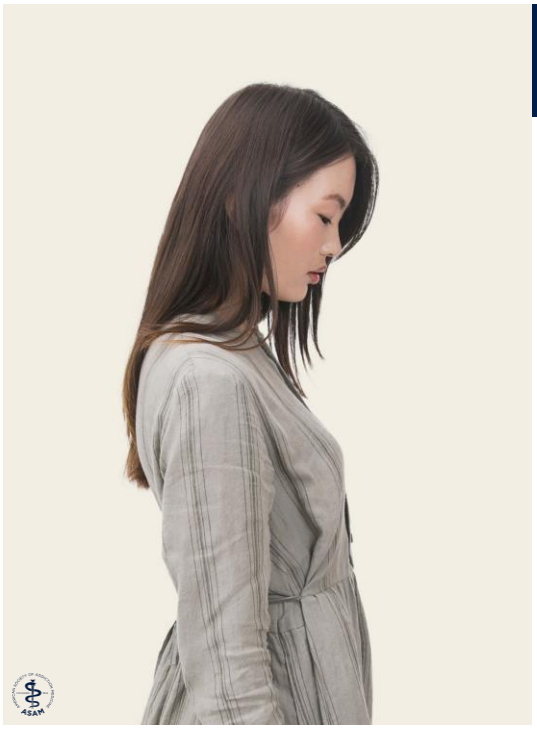
32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from buprenorphine.

- Karishma has a friend who has an AUD and attends AA meetings. The friend tells Karishma that her AA group is not okay with people on buprenorphine or methadone.
- Karishma and Jennifer had also planned on having a child, but Karishma is concerned that buprenorphine would be a problem if Jennifer were to be the birth mother.
- Jennifer has resumed weekly psychotherapy and they both see a couple's therapist.

Jennifer:

32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from buprenorphine.

- You are concerned that Jennifer wants to taper and withdraw from buprenorphine because of all these misconceptions, myths, and stigmas - which Karishma believes.
- You schedule an appointment with both Jennifer and Karishma to discuss each of the misconceptions individually and provide evidence for your suggestion that Jennifer continue with her successful treatment paradigm with buprenorphine.



Case Discussion – Jennifer

Discuss:

What stigmas and misconceptions would you address with Jennifer and Karishma?

What would you suggest for Jennifer's treatment plan?

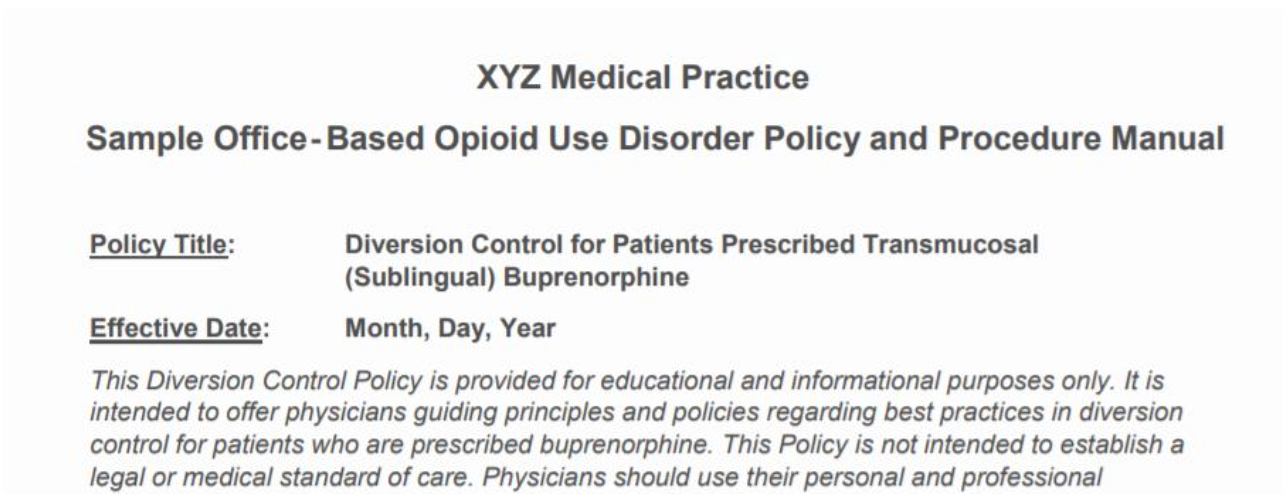
Should Jennifer still want to taper down, how would you proceed?

Diversion

People self-treating with diverted buprenorphine reported:

- 97% take it to prevent cravings
- 90% take it to prevent withdrawal
- 29% take it to save money

Why? Limited access to treatment, lack of health insurance.



XYZ Medical Practice

Sample Office-Based Opioid Use Disorder Policy and Procedure Manual

Policy Title: **Diversion Control for Patients Prescribed Transmucosal (Sublingual) Buprenorphine**

Effective Date: **Month, Day, Year**

This Diversion Control Policy is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding best practices in diversion control for patients who are prescribed buprenorphine. This Policy is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional

ASAM Sample Diversion Control Plan

Available online: http://bit.ly/diversionpolicy

Potential Diversion
Common Signs

- Requests for early refills (medication lost or stolen).
- Inconsistent laboratory testing (e.g., bup negative).
- Claims of being allergic to naloxone and requesting monotherapy.
- Police reports of patient selling in streets.
- Reports of concerning behavior.
- Inconsistent appointments (e.g., missed).

Risk Management:
Educate Patients about Harms of Diversion of Misuse

Misuse and Diversion

- Can lead to harmful medical and social consequences, overdose, and an increase in stigma for patients and providers.

Legislation

- Periodically re-evaluated by DEA and SAMHSA for risks and benefits.

What patients do with their medications matters for us all!

Responding to Misuse and Diversion

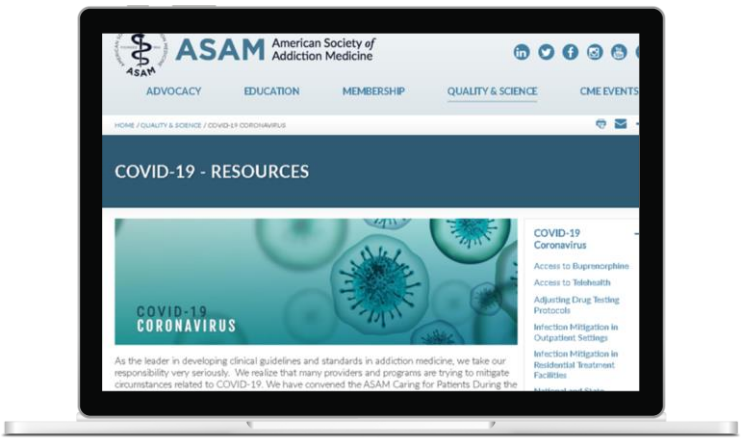
Evaluate
and reassess treatment plan and patient progress.

Intensify Treatment
or refer to higher Level of Care.

Document and Describe
clinical thinking that supports a clinical response, should be aimed at minimizing risk and treating patient at the level of care needed.

*Buprenorphine and Naltrexone for OUD: **COVID-19***

Treating OUD During the COVID-19 Pandemic



Guidance for:

- Infection mitigation
- OTPs
- OBOT
- Telehealth
- Virtual Support Groups

- ***Overview of Federal and State Policy Changes related to COVID-19***

Methadone Access Under National COVID-19 Emergency - Highlights

- ***Telehealth***
  - Waiver of regulations related to HIPPA compliant telehealth platforms (e.g., Apple FaceTime, Facebook Messenger video chat, Google Hangouts, Skype).
  - Expansion of Medicare Coverage for telehealth.
  - Medicaid and private payer coverage varies by state and payer – check.
  - Check state laws/regulations on licensing.
- ***Existing Patients***
  - Can treat and dispense medication via telehealth (also use of telephone).
- ***New Patients***
  - Continued requirement for in-person physical exam for methadone initiation.
  - Take steps to minimize any exposures to provider or patient.

Methadone Access Under National COVID-19 Emergency - Highlights

- ***Take-home medications:***
  - States may request exceptions for stable patients to receive 28 days of take-home medications and for less stable patients to receive up to 14 days.
    - Providers should make decisions on an individual patient bases based on a risk-benefit analysis and considerations for risk related to both OUD and COVID-19.
  - Educate patients about safe storage, use, and management.
  - Ensure patients have access to naloxone.
  - Use telehealth/telephone to monitor patients.
  - Encourage patient participation in virtual support groups.

Methadone Access Under National COVID-19 Emergency - Highlights

- ***Alternative home delivery for isolated/quarantined patients:***
  - Allows designated staff members, law enforcement officers, or National Guard personnel to make deliveries of methadone, including “doorstep” delivery using an approved lockbox.
- ***Drug Testing:***
  - OTPs still required to provide a minimum of 8 drug tests/yr for each patient.
  - Consider pausing or exploring testing at a distance.

Methadone Access Under National COVID-19 Emergency - Highlights

- ***ASAM COVID-19 Resources:***
  - ASAM Methadone Access Guidance:
  - ASAM Telehealth Guidance: https://www.asam.org/Quality-Science/covid-19-coronavirus/access-to-telehealth
  - ASAM's Drug Testing Guidance: https://www.asam.org/Quality-Science/covid-19-coronavirus/adjusting-drug-testing-protocols
  - ASAM Support Group Guidance: https://www.asam.org/Quality-Science/covid-19-coronavirus/support-group

Buprenorphine Access Under National COVID-19 Emergency - Highlights

- ***Telehealth***
  - Waiver of regulations related to HIPPA compliant telehealth platforms (e.g., Apple FaceTime, Facebook Messenger video chat, Google Hangouts, Skype).
  - Expansion of Medicare Coverage for telehealth.
  - Medicaid and private payer coverage varies by state and payer – check.
  - Check state laws/regulations on licensing.
- ***Existing & Existing Patients***
  - New and existing patients can be evaluated and treated via telehealth including telephone; telehealth and phone for follow-up and monitoring.
  - Home induction to start new patients.
  - Do not require patients to participate in counseling – virtual or in-person – in order to access medication. (Generally recommended practice.)
  - Ensure patient access to naloxone.

Buprenorphine Access Under National COVID-19 Emergency - Highlights

- ***Flexibility prescribing using telehealth:***
  - DEA-registered practitioners may prescribe controlled substances to patients via telemedicine in states in which they are not registered with DEA.
- ***Use and Disclosure of Confidential Information (42CFR Part2):***
  - Patient information may be disclosed to medical personnel, without patient consent, to the extent necessary to meet a medical emergency.
  - Information disclosed to the medical personnel who are treating such a medical emergency may be re-disclosed for treatment purposes as needed.

Buprenorphine Access Under National COVID-19 Emergency - Highlights

- ***Oral vs. Injectable Formulations***
- ***Factors to weigh:***
  - Is the patient experiencing any symptoms consistent with COVID or have they had any potential exposures?
  - Any anticipated risk to the patient associated with switching formulations?
    - Are they likely to be compliant with the oral medication?
  - The risk to the patient associated with an in-person visit:
    - Are they at high risk for severe illness?
    - Are they living with or caring for someone at high risk?
    - Would they need to take mass transit to the visit?
    - What is their level of anxiety around coming to an in-person visit?
  - Does your facility have sufficient staff and PPE to provide injections?

Buprenorphine Access Under National COVID-19 Emergency - Highlights

- ***Drug testing:***
  - Consider pausing or exploring testing at a distance.
- ***ASAM COVID-19 Resources:***
  - ASAM Buprenorphine Access: https://www.asam.org/Quality-Science/covid-19-coronavirus/access-to-buprenorphine
  - ASAM Telehealth guidance: https://www.asam.org/Quality-Science/covid-19-coronavirus/access-to-telehealth
  - ASAM's drug testing guidance: https://www.asam.org/Quality-Science/covid-19-coronavirus/adjusting-drug-testing-protocols

Extended-Release Naltrexone Access Under National COVID-19 Emergency - Highlights

- Continued need for in-person patient contact for injection.
- Take steps to minimize any exposures to provider or patient.
- Oral naltrexone has not been proven to be effective for the treatment of OUD due to low compliance. But could be considered under limited circumstances.
  - See *ASAM's National Practice Guidelines for the Treatment of OUD*:
    - https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline

Pregnant Women with OUD: ***COVID-19***

Pregnant women with OUD in the Context of COVID-19: Buprenorphine

- ***Telehealth:***
  - Waiver of regulations related to HIPPA compliant telehealth platforms (e.g., Apple FaceTime, Facebook Messenger video chat, Google Hangouts, Skype.)
  - Expansion of Medicare Coverage for telehealth.
  - Medicaid and private payer coverage varies by state and payer – check.
  - Check state laws/regulations on licensing.

Pregnant women with OUD in the Context of COVID-19: Buprenorphine

- ***Existing Patients:***
  - Existing patients can be evaluated and treated via telehealth including telephone; telehealth and phone for follow-up and monitoring.
  - Do not require patients to participate in counseling – virtual or in-person – in order to access medication. (Generally recommended practice.)
  - Ensure patient access to naloxone to save the mother's life.

Audience Response

COVID-19's effects on persons with opioid use disorder include:

a. Decreased risk for opioid overdose death
b. Increased risk for social isolation
c. Decreased access to telehealth treatment
d. Decreased risk of new initiation to opioids

Activity 9

Challenges to Providing Care

Share your thoughts and/or concerns with office-based treatment of OUD.

Prompting Questions

- What issues do you foresee facing in treating OUDs?
- What challenges do you anticipate that were not covered in the course material?

10 minutes

KATIE'S CASE

Katie:

35-year-old woman who presents for follow-up care. She has diagnoses of severe opioid use disorder and moderate cocaine use disorder.

- She has been treated with buprenorphine/ naloxone 16/4 mg daily for 6 months and has stopped using heroin, which is confirmed by urine drug testing.
- However, her urine drug tests show evidence of continuous cocaine use.
  - *How will you respond to Katie's continued cocaine use?*

Activity 10

Susan, Emma, Jonathan

Assess the assigned cases and identify an appropriate treatment approach for each case. Determine if the patient meets DSM-5 criteria for an opioid use disorder.

Prompting Questions

What more information do you need to decide on a diagnosis(es) and treatment plan? Is the patient a suitable candidate for OBOT? Was your group in agreement or did you disagree? If you decide the patient is a good candidate for OBOT, what will the treatment plan include?

35 minutes

After the discussion, one member of each group shares key takeaways with the whole class.

SUSAN'S CASE

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She started using oxycodone with her roommate and has been using intranasal heroin (1 gram) daily for the last 15 months.
- Some of her friends are now switching to intravenous use because it takes less heroin to keep from getting sick.
- She does not want to inject drugs but may be "forced" to because she cannot keep paying the "extra cost" of sniffing heroin.

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She has used all the money her parents gave her for school expenses to buy heroin, her credit cards are maxed out, and she has borrowed money from her friends.
- Until last semester, she had an overall B average, but this semester she is struggling academically and has been told she will be put on academic probation if her grades don't improve.

Susan:

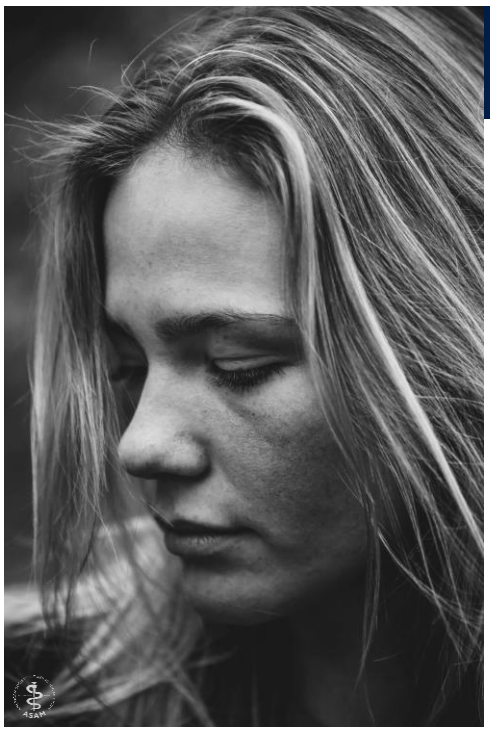
20-year-old community college student requesting treatment for her heroin addiction.

- When she doesn't use heroin, she has anxiety, muscle aches, diarrhea, and can't sleep.
- She recognizes the symptoms as heroin withdrawal. She was surprised because she thought she could not develop withdrawal from only sniffing drugs.

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She smokes one pack of cigarettes per day.
- She drinks alcohol on the weekends, up to 3 drinks per occasion.
- She denies other drug use.
- She has no prior history of addiction treatment.



Case Discussion – Susan

Discuss:

- **Does she meet the criteria for DSM-5 moderate to severe OUD?**
- Is she a candidate for office-based opioid treatment with buprenorphine/ naloxone?
- What additional information would you need to make that decision?
- If you decide to treat Susan, what are your treatment plan and goals?

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She was induced on buprenorphine in the office and given a prescription for 6-day supply of bup/nx (16/4 mg/day) and was told to participate in the clinic's 2x per week relapse prevention group and to schedule individual counseling at an off-site program.
- She was told she needed to attend the relapse prevention group in order to get her next bup/nx prescription.

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She returns in 6 days for her next bup/nx refill.
- She has not attended the relapse prevention group nor arranged for counseling.
  - *What will be your treatment approach at this time?*

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She was only partially adherent with the recommended counseling for 3 weeks including attending all but 1 of the relapse prevention groups but never started counseling.
- She states she has been too busy to go to counseling. She goes to school 5 days a week and has a new job working evenings as a waitress at a pub.
  - *Should you require Susan to attend counseling? Why? Why not?*

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She then returns in 4 days (3 days before her follow up appointment) and states that one of her friends stole her bup/nx tablets.
- Her urine is buprenorphine negative and opiate positive. She states she is sniffing heroin again to prevent withdrawal after running out of bup/nx.

Susan:

20-year-old community college student requesting treatment for her heroin addiction.

- She has been missing too many classes and has had to change her status to part-time student. She told her parents that she needs time away from school to figure out what her major should be.
- She wants "one more chance" to restart bup/nx treatment.
  - *What would you recommend for Susan at this point?*

EMMA'S CASE

Emma:

26-year-old assistant department store manager who has been using nonprescribed oxycodone on and off since age 18.

- Emma uses oxycodone when she feels down or socially isolated and it helps her deal with the stress of her work.
- No history of withdrawal management or addiction treatment.
- Stopped on her own for 6 months but relapsed 3 months ago and is now using daily.

Emma:

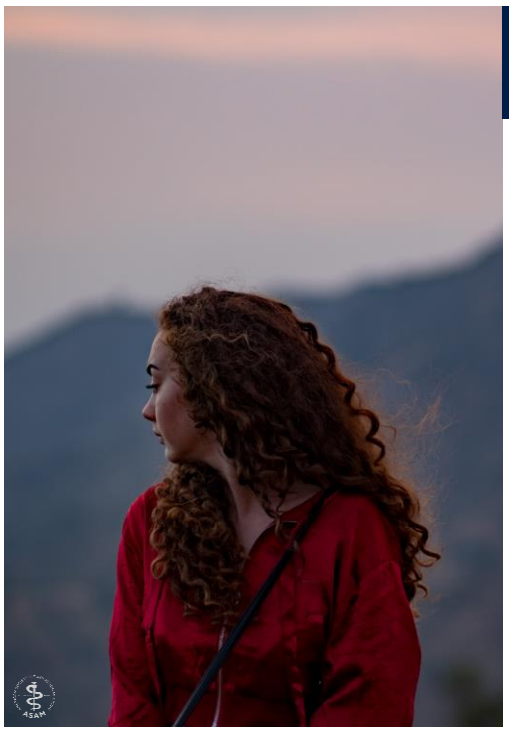
26-year-old assistant department store manager who has been using nonprescribed oxycodone on and off since age 18.

- She lives in an apartment with her fiancé.
- In the past, her boyfriend was concerned about the amount of money she spent on illicit opioids.
- Her boyfriend does not know about her current use of oxycodone.
- She is at risk of losing her job due to absenteeism.

Emma:

26-year-old assistant department store manager who has been using nonprescribed oxycodone on and off since age 18.

- No family history of alcoholism or substance use.
- She drinks alcohol "socially" with friends.
- She smokes ½ pack cigarettes per day.
- She denies other drug use.
- Her only current medical problem is mild asthma.
- She does not know her hepatitis C and HIV status.



Case Discussion – Emma

Discuss:

- **Does she meet DSM-5 criteria for an opioid use disorder?**
- Is Emma's OUD mild, moderate, or severe?
- What more information would you like before deciding on a diagnosis(es) and treatment plan?

JONATHAN'S CASE

Jonathan:

48-year-old engineer requesting transfer from methadone maintenance to office-based buprenorphine treatment.

- On methadone maintenance treatment program for 12 years but is tired of all the strict rules and policies.
- Current methadone dose is 95 mg.
- His 13-day take-homes were recently discontinued when he missed his 2nd group counseling session in 3 months. He is now required to have daily observed dosing.

Jonathan:

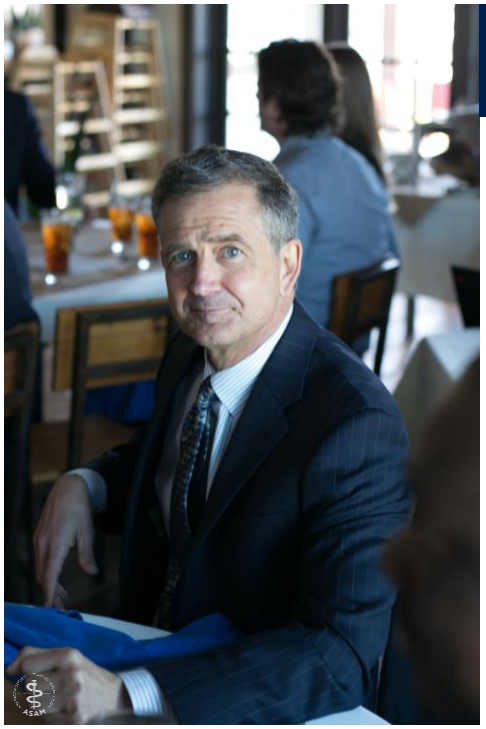
48-year-old engineer requesting transfer from methadone maintenance to office-based buprenorphine treatment.

- He does not think the group counseling is helping him anymore. He thinks it was helpful in the beginning but now it is just a burden.
- He is caring for his sick parents along with working full time which makes it difficult for him to reliably attend his weekly afternoon counseling session.
- Prior to methadone maintenance, he had an 8-year history of intravenous heroin use.
- Since starting methadone maintenance, he has been abstinent from heroin use.

Jonathan:

48-year-old engineer requesting transfer from methadone maintenance to office-based buprenorphine treatment.

- He is hepatitis C positive (never treated) and HIV negative.
- He has been in a stable relationship with a non-drug-using girlfriend for the past 7 years.
- He wants to discontinue methadone maintenance ASAP and transfer to buprenorphine so that he can “get on with my life.”



Case Discussion – Jonathan

Discuss:

- **Is Jonathan a good candidate for OBOT?**
- What additional information do you need?
- If you decide he is a good candidate for transfer to OBOT with buprenorphine/ naloxone, what will the treatment plan include?

Activity 11

End of Course Reflection

Take five minutes to revisit the training goal you wrote down at the beginning and jot down what you found most valuable from the course, where you could use the knowledge gained in your work, and challenges you anticipate in prescribing medication for OUD.

Prompting Questions

- What are some strategies and solutions for overcoming challenges when treating opioid use disorder?

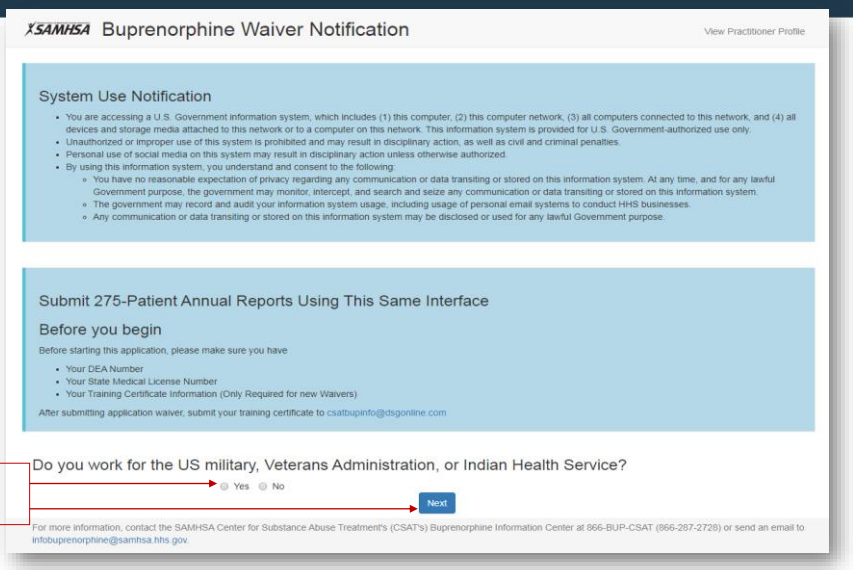
10 minutes

After the discussion, one member of each group shares key takeaways with the whole class.

Entering a 30 Patient Notification

Buprenorphine Waiver Notification Form

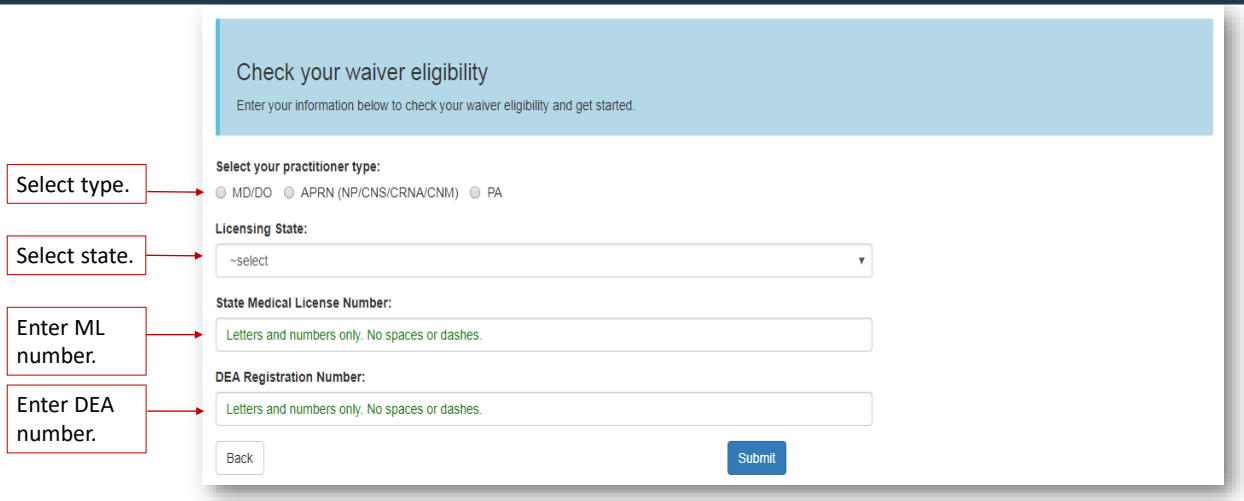
Go to this link: **http://buprenorphine.samhsa.gov/forms/select-practitioner-type.php**



Select “Yes” or “No.”
Click “Next.”

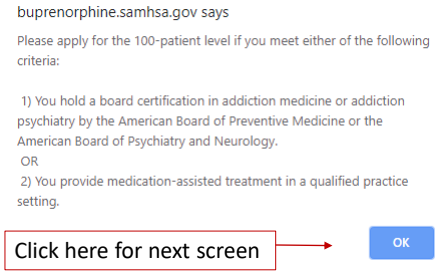
SAMHSA
Substance Abuse and Mental Health Services Administration

Look up your DEA number and address on file here: **https://apps.deadiversion.usdoj.gov/webforms/validateLogin.jsp**



SAMHSA
Substance Abuse and Mental Health Services Administration

You will receive a prompt to apply for the 100-patient level if you meet certain criteria.



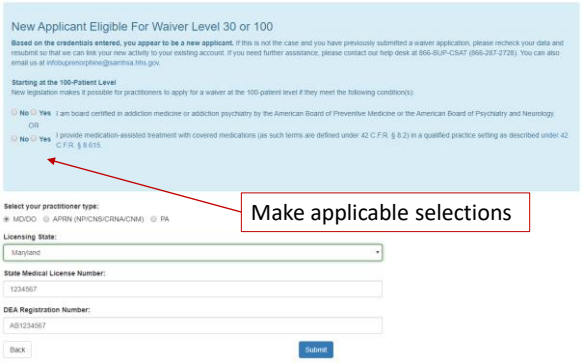
What is a Qualified Practice Setting?

- A qualified practice setting is a practice setting that:
  i. provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
  ii. provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
  iii. uses health information technology systems such as electronic health records;
  iv. is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law; and
  v. accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

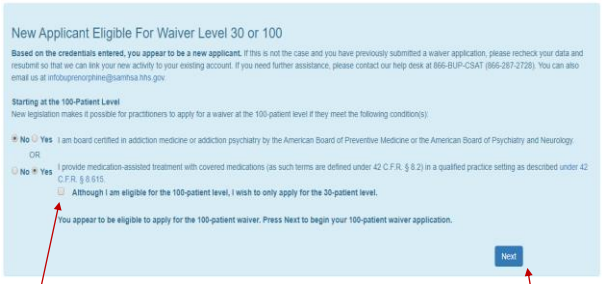
Please note, all five criteria must be met.

SAMHSA
Substance Abuse and Mental Health Services Administration

We encourage eligible providers to apply for the 100-patient waiver. This does not mean you have to treat 100 patients.



Make applicable selections



You can apply for the 30-patient waiver, even if you are eligible for a 100 patient waiver. Check this box to apply for the 30-patient waiver.

Click here for next screen

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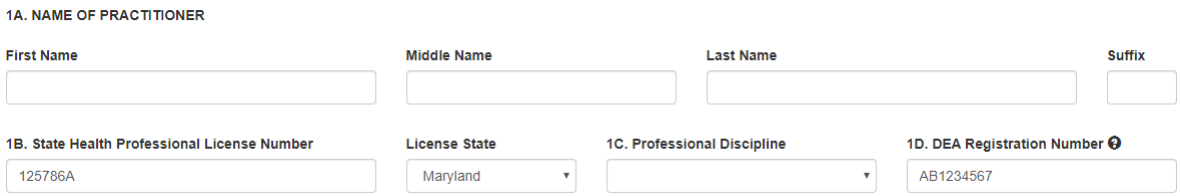
1A. Type in name.
1B. (Auto populated).
1C. Select professional discipline.
1D. (Auto populated).



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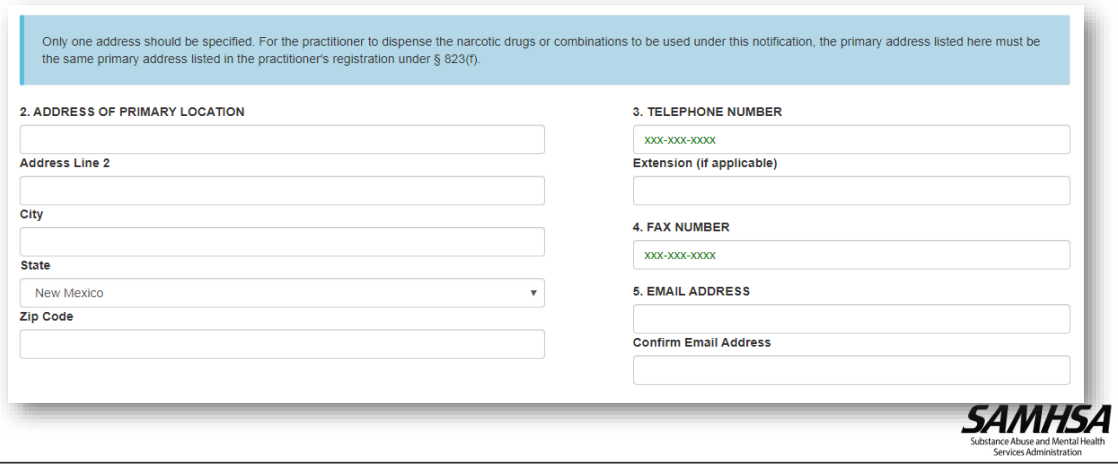
2. Type in primary/service address where you intend to practice.
3. Type in primary/service phone number.
4. Type in fax number (optional).
5. Type in e-mail twice. (This e-mail is where you will receive your approval letter.)



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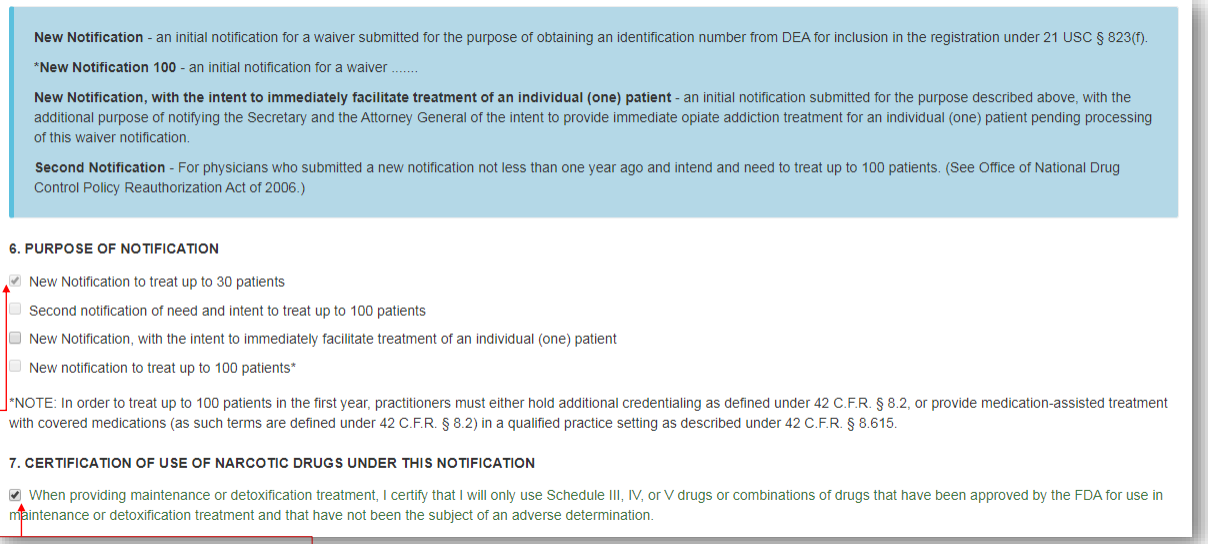

6. (Auto selected for 30 or 100).
7. Check off box.

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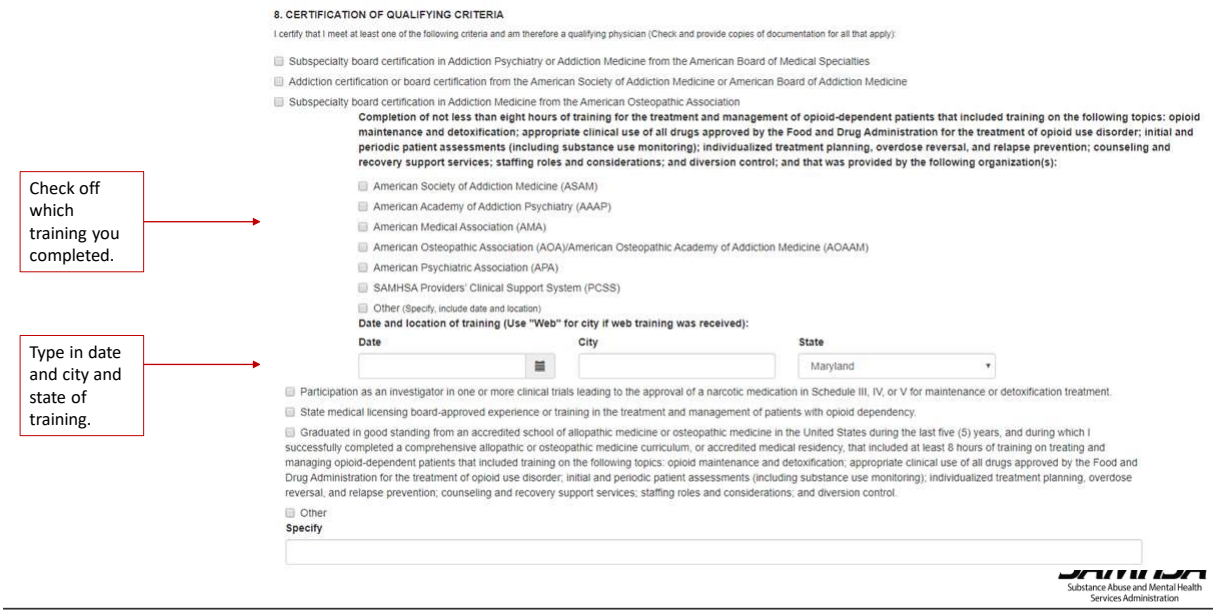
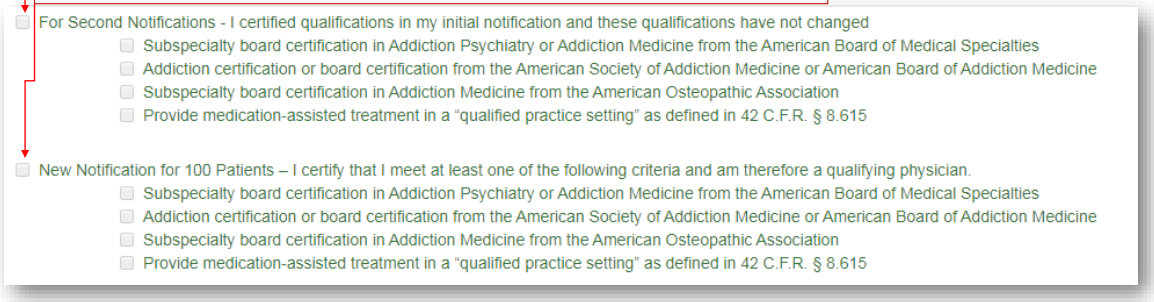


Check off which training you completed.

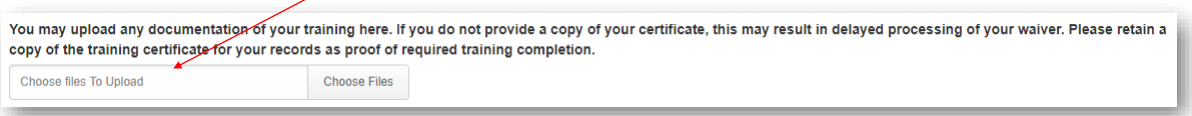
Type in date and city and state of training.

Leave "For Second Notifications" unchecked.

For 100-patients, select the "New Notifications for 100" and the applicable selection below. Leave blank for 30-patient Notifications



Upload completed training certificate and a copy of your medical license.



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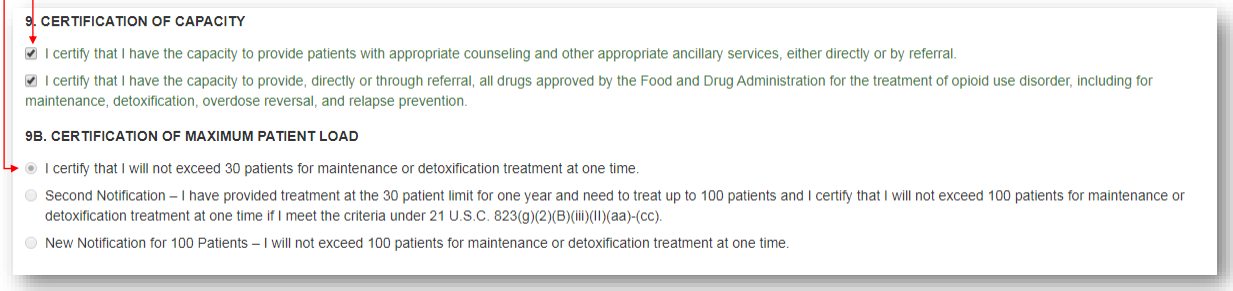
9. Check off both boxes.
9B. (Auto selected for 30 or 100).



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Check a box indicating whether or not you consent.

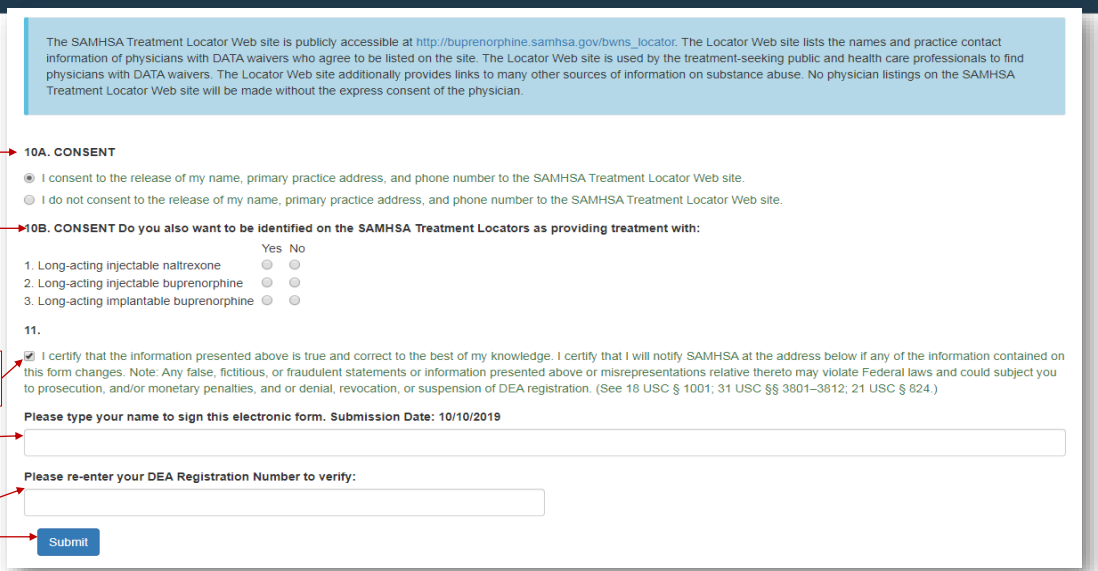
Check "yes" or "no"—whichever applies to you.

Check off box.

Sign.

Re-enter DEA number.

Hit the "submit" button.



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PLEASE NOTE THE FOLLOWING:

DATA Waiver Team Email Address: InfoBuprenorphine@samhsa.hhs.gov

Confirmation e-mails are sent immediately after your application is submitted.

Approval Letters are e-mailed within 45 days of your complete application submission.

*Please check your junk and spam folders if you have not already added InfoBuprenorphine@samhsa.hhs.gov to your contacts.

Any questions or inquiries should be directed to InfoBuprenorphine@samhsa.hhs.gov or call 1-866-287-2728.

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Q&A

KEEPING YOUR PATIENTS SAFE

End of Session 5

Contact Us

Address

11400 Rockville Pike,
Suite #200
Rockville, MD 20852

Phone

Phone: (301) 656 – 3820
Fax (301) 656 - 3815

Online

www.ASAM.org
education@asam.org