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.
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.

Jennifer:
32-year-old woman who has been your patient for the past five years. She wants to taper and withdraw from 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?
Stigma and Treating OUD

**Provider Myths**
- It’s substituting one drug/addiction for another.
- It’s not really “recovery.”
- The shorter the duration of therapy, the better.
- You can’t be on buprenorphine if you are pregnant or breastfeeding.
- I’m worried about the DEA storming into my office.

**Patient Myths**
- It’s substituting one drug/addiction for another.
- It’s not really “recovery.”
- The shorter the duration of therapy, the better.
- Other people may relapse, but not me.
- It must be damaging my liver, brain, kidney, heart, or bones.
- They won’t be able to treat my pain.
- The pre-employment drug test will disqualify me.
- If I miss a dose, I’ll go into terrible withdrawal.

Addiction Terminology

**Correct**
- Person with substance use disorder.
- Babies born with an opioid dependency.
- Substance use disorder or addiction, use or misuse, risky or unhealthy use.
- Person in recovery, abstinent, not drinking or taking drugs.
- Treatment or medication for addiction, medication for OUD/AUD, positive/negative results.

**Incorrect**
- Substance abuser, drug abuser, alcoholic, addict, user, abuser, drunk, junkie.
- Addicted babies, born addicted.
- Drug habit, abuse, problem.
- Clean.
- Substitution or replacement therapy, medication-assisted treatment, clean/dirty.
General Language

• Use gender/sexuality-inclusive language.
  • Be mindful of gender use in language, specifically during anecdotes and question response. Avoid assumptions.
  • Use “they,” “one,” and “who” as opposed to “he” or “she.”
  • Avoid jokes at the expense of patient and stigmatizing/offensive language.

Where Patients Experience Stigma

**Healthcare Setting**
- Waiting room
- Intake with MA/nurse
- Pharmacy
- Other healthcare provider's practice
- Emergency Department
- Mutual help group

**Outside Healthcare Setting**
- Significant other
- Work
- Friend group
- Family
- Interest/hobby group
- Religious institution
- Media representation
ASAM Sample Diversion Control Plan

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.

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

Diversion
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.

### Harm Reduction

1. Naloxone and Overdose Education
2. Syringe Service Programs
3. Polysubstance Use
4. HIV, PrEP and PEP
5. Safer Sex
Opioid Mu Receptor Agonist Drug Effects

- **Acute Exposure**
  - Euphoria, nausea, vomiting, depressed respiration, sedation, analgesia.

- **Large Dose Acute Exposure**
  - Non-responsive, pinpoint pupils, hypotension, skin cyanotic, pulmonary edema.

- **Chronic Use Effects**
  - Physical dependence, withdrawal, tolerance, lethargy, constipation.

Opioid-induced Respiratory Depression

*Opioids depress the brain stem's response.*

- Depression of the medullary respiratory center.
- Decreased tidal volume and minute ventilation.
- Decreased respiratory response to elevated CO2.
- Hypercapnea, hypoxia and decreased oxygen saturation.
- Life threatening hypoxia.
- Sedation occurs before significant respiratory depression, and, therefore, is a warning sign.
Naloxone Formulations

**Injection**
1 dose = 0.4mg/1ml Intramuscular

**Nasal w/atomizer**
“Multi-step”
1 dose = 2mg/2ml Intranasal

**Nasal spray**
“Single-step”
1 dose = 4mg/0.1ml Intranasal

**Auto-injector**
1 dose = 0.4mg/1ml Intramuscular

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Naloxone

**Prevent Overdose**
- Broader provision of naloxone has been shown to prevent opioid overdose morbidity and mortality.

**Co-Prescribe**
- U.S. Department of Health and Human Services urges that all patients receiving medications for OUD be co-prescribed naloxone.

Evaluations of Overdose Education and Naloxone Distribution (OEND) Programs

- Feasibility
- Increased knowledge and skills
- No increase in use, increase in drug treatment
- Reduction in overdose in communities
- Cost-effective


Overdose Education and Naloxone
Communicate to Patients

- Don’t use opioids alone. Beware of fentanyl.
  - Known overdose risk factors: mixing substances, abstinence, using alone, unknown source.
  - Opportunity window: heroin overdoses take minutes to hours; fentanyl takes seconds to minutes.
  - Call 911 before administering naloxone.
Overdose Education

*Education for Providers and Patients*

**Audience Response**

**Overdose education is important for which of the following groups?**

a. Injection opioid users themselves
b. Family and friends of opioid users
c. Community members who may be exposed to opioid use
d. All of the above
### Polysubstance Use

**Tobacco, Alcohol, Cannabis**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Medication Options</th>
<th>Psychosocial Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco</td>
<td>Nicotine replacement therapy (patch, gum, lozenge); bupropion; varenicline</td>
<td>Cognitive behavioral therapy (CBT); mindfulness; telephone support and quitlines; mutual help</td>
</tr>
<tr>
<td>Alcohol</td>
<td>Naltrexone; acamprosate; disulfiram</td>
<td>CBT; motivational enhancement therapy; martial/family counseling; mutual help</td>
</tr>
<tr>
<td>Cannabis</td>
<td>No FDA-approved medications</td>
<td>CBT; contingency management; motivational enhancement therapy; mutual help</td>
</tr>
</tbody>
</table>

### Polysubstance Use

**Cocaine, Methamphetamine, Benzodiazepines**

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</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td>No FDA-approved medications</td>
<td>CBT; contingency management; therapeutic communities; mutual help</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>No FDA-approved medications</td>
<td>CBT; contingency management; mutual help</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Diazepam and gradual dose reduction</td>
<td>CBT; contingency management; mutual help</td>
</tr>
</tbody>
</table>
Tobacco

- **~480,000 Deaths**
  Leading cause of preventable death (CDC)

- **2-4 times higher**
  Smoking rates higher in patients with SUD than general public

- **~67% smoke**
  Smoking rates among SUD patients who enter treatment

- **Death from tobacco**
  SUD patients more likely to die from tobacco than other substances

HIV and Injection Drug Use

- **Injection drug use accounts for ~1 in 10 HIV diagnoses in US.**

  - Sharing equipment increases risk: HIV can survive on a used syringe for 42 days.
  - **4th generation HIV test important** (looks for HIV 1 & 2 antibodies and P24 antigen).
  - Educate patient on Syringe Service Programs (e.g., needle exchange).
  - Educate patient on safe practices (e.g., do not share needles).

**PrEP**

- **Pre-exposure prophylaxis:**
  
  when people who don't have HIV take HIV medicine every day to reduce their chances of getting HIV.

- **Reduces risk of getting HIV:**
  
  from sex by ~88%.
  from injection drug use by >74%.

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**Current FDA-Approved Medications**

- Emtricitabine (200mg)/Tenofovir Disoproxil Fumarate (300mg): Truvada®.
- Emtricitabine (200mg)/Tenofovir Alafenamide (25mg): Descovy®.

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**Which is best?**

- Truvada® vs Descovy® based on individual risk factors.
- Descovy® not for use in people assigned female at birth who are at risk of getting HIV through vaginal sex (effectiveness not yet studied).
PEP

- **Post-exposure prophylaxis:**
  when a patient takes HIV medicine very soon after possible exposure to HIV in order to prevent HIV infection.

- **Not meant for regular use:**
  PEP intended for emergency situations.
  Must be started within 72 hours after a possible exposure to HIV. The sooner, the better.

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**Current preferred medication regimen:**
- Tenofovir disoproxil (300 mg)/emtricitabine (200 mg) QD, PLUS.
- Raltegravir (400 mg) BID or dolutegravir (50 mg) QD.

**Length of treatment:**
- If prescribed PEP, patient will take HIV medicine every day for 28 days.
Safer Sex

- **People under the influence of drugs are more likely to engage in risky sex and could get HIV.**
  - Those who share needles/syringes are more likely to have unprotected sex.
  - Provider should educate patient on: contraception options, condoms, PrEP and PEP, regular STI testing.
  - Be aware of “club drug” use leading to unsafe sex.

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:**

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.

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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:**


- 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*:
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
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:
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?**

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**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.

**Promting 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: 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: 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?

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](http://buprenorphine.samhsa.gov/forms/select-practitioner-type.php)

Select "Yes" or "No." Click "Next."
Look up your DEA number and address on file here: [https://apps.deadiversion.usdoj.gov/webforms/validateLogin.jsp](https://apps.deadiversion.usdoj.gov/webforms/validateLogin.jsp)

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:
  1. provides professional coverage for patient medical emergencies during hours when the practitioner’s practice is closed;
  2. 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;
  3. uses health information technology systems such as electronic health records;
  4. is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law; and
  5. 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.
We encourage eligible providers to apply for the 100-patient waiver. This does not mean you have to treat 100 patients.

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.

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

1B. State Health Professional License Number
1C. Professional Discipline
1D. DEA Registration Number

Make applicable selections

Click here for next screen
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.)

6. PURPOSE OF NOTIFICATION
   - New Notification - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 U.S.C § 823(f).
   - New Notification 100 - an initial notification for a waiver.
   - New Notification, with the intent to immediately facilitate treatment of an individual (one) patient - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opioid addiction treatment for an individual (one) patient pending processing of the waiver notification.
   - Second Notification - For physicians who submitted a new notification not less than one year ago and intend and need to treat up to 100 patients. (See Office of National Drug Control Policy Reauthorization Act of 2006.)

7. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION
   - When providing maintenance or detoxification treatment, I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.

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

You may upload any documentation of your training here. If you do not provide a copy of your certificate, this may result in delayed processing of your waiver. Please retain a copy of the training certificate for your records as proof of required training completion.
9. Check off both boxes.

9B. (Auto selected for 30 or 100).

9. CERTIFICATION OF CAPACITY
   - I certify that I have the capacity to provide patients with appropriate counseling and other appropriate ancillary services, either directly or by referral.
   - I certify that I have the capacity to provide, directly or through referral, all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention.

9B. CERTIFICATION OF MAXIMUM PATIENT LOAD
   - I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time.
     - Second Notification – I have provided treatment at the 30 patient limit for one year and need to treat up to 100 patients and I certify that I will not exceed 100 patients for maintenance or detoxification treatment at one time if I meet the criteria under 21 U.S.C. 833(h)(v)(V)(XIV)(A)(ii)(cc)
     - New Notification for 100 Patients – I will not exceed 100 patients for maintenance or detoxification treatment at one time.

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.
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.
KEEPING YOUR PATIENTS SAFE

End of Session 5

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