Buprenorphine 101:

Physicians and Community Pharmacists Collaborating to Improve Access to Medication-Assisted Treatment

Discussion Guide

ASAM American Society of Addiction Medicine

APhA AMERICAN PHARMACISTS ASSOCIATION

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SAMHSA's State Targeted Response Technical Assistance (STR-TA) grant created the *Opioid Response Network* to assist STR grantees, individuals, and other organizations by providing the resources and technical assistance they need locally to address the opioid crisis.

Technical assistance is available to support the evidence-based prevention, treatment, and recovery of opioid use disorders.

The Opioid Response Network (ORN) provides local, experienced consultants in prevention, treatment, and recovery to communities and organizations to help address this opioid crisis.

The ORN accepts requests for education and training.

Each state/territory has a designated team, led by a regional Technology Transfer Specialist (TTS), who is an expert in implementing evidence-based practices.

» To ask questions or submit a request for technical assistance:

Visit www.OpioidResponseNetwork.org

Email orn@aaap.org

Call 401-270-5900

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Accreditation Information:

This discussion guide is meant to complement the home study webinar recording that can be found on the American Pharmacists Association website and the American Society of Addiction Medicine (ASAM) website. The discussion guide has not been developed for Continuing Pharmacy Education (CPE) credit or Continuing Medical Education (CME) credit.

Contents

Introduction

This Discussion Guide provides an overview of medications for addiction treatment,[1] also known as medication-assisted treatment (MAT), and highlights opportunities for physicians and pharmacists to collaborate to expand access to care. MAT is an important option for managing patients with OUD and has been demonstrated to improve the likelihood that patients will remain in recovery. This discussion guide is intended to expand upon the information presented in the webinar.

In addition, for those interested in sharing the webinar more broadly, this Discussion Guide is intended to help engage attendees and provide supplemental information.

Background Information

Opioid Misuse and Dependence in the United States

The misuse and diversion of opioids (including prescription pain medications and illicit substances such as heroin and fentanyl) in the United States has risen dramatically since the 1990s and is a serious public health problem. It is estimated that in 2018, 10.3 million people misused prescription opioids and 2 million had an opioid use disorder. An estimated 47,600 people died from opioid overdoses, which averages to more than 130 people each day.[HHS] It is estimated that the costs associated with prescription opioid misuse in the United States is $78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.[NIDA]

Substance use disorder (SUD) is treatable, however, there is a shortage of available treatment providers to address patient needs in the United States. Increasing access to treatment is an important focus of efforts to address the misuse of opioids. However, approximately 90% of Americans struggling with addiction are not currently receiving treatment.[HHS2] Interventions are needed to facilitate patient access to treatment for substance use disorder.

The Disease of Addiction

Addiction is defined by the American Society of Addiction Medicine (ASAM) as "a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences."[ASAM]

Addiction affects neurotransmission and interactions within reward structures of the brain, such that motivational hierarchies are altered, and addictive behaviors supplant healthy, self-care–related behaviors.

However, the neurobiology of addiction encompasses more than the neurochemistry of reward.

The connections between the frontal cortex and circuits of reward, motivation, and memory are fundamental in the manifestations of altered impulse control. The frontal lobes are still maturing during adolescence, and early exposure to substance use is another significant factor in the development of addiction.

1 Note: The American Society of Addiction Medicine's preferred meaning of "MAT" is "Medication for Addiction Treatment" instead of "Medication-Assisted Treatment". ASAM's definition changed in 2019.

Genetic factors account for about half of the likelihood that an individual will develop addiction. Environmental factors interact with the person's biology and affect the extent to which genetic factors exert their influence. [NIDA]

According to ASAM, "People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases."[ASAM]

Patient adherence rates to medications for opioid use disorder are similar to adherence or relapse rates for other chronic diseases. For example, relapse rates for drug addiction range from 40–60%, which is similar to that of type I diabetes (30–50%), hypertension (50–70%) and asthma (50–70%) (McLellan AT, Lewis DC, O'Brien CP, Kleber HD. Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation. *JAMA.* 2000;284(13):1689–1695. doi: *https://doi.org/10.1001/jama.284.13.1689*).

Medications for Addiction Treatment or Medication-Assisted Treatment (MAT)

MAT is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Three medications—methadone, buprenorphine, and naltrexone—are approved by FDA for treatment of opioid dependence.[SAMHSA] MAT can be short- or long-term treatment, including as part of medically supervised withdrawal and as maintenance treatment. Patients receiving MAT for opioid use disorder are considered in recovery. [SAMHSA] The following section provides a brief overview of the medications used to treat opioid use disorder. More detailed information regarding buprenorphine is provided in this discussion guide since community pharmacists are more likely to see patients using buprenorphine than the other medications used to treat opioid use disorder.

Buprenorphine. Unlike methadone treatment, buprenorphine may be prescribed in more care settings to help increase treatment access. Under the Drug Addiction Treatment Act of 2000 (DATA 2000), qualified U.S. physicians, and mid-level practitioners with an X-waiver license (or DATA waiver) can offer buprenorphine for opioid dependency in various treatment settings, including a physician's office, among others. There are limits in the number of patients that can be treated by providers with an X-waiver license. Opioid treatment programs (OTPs) can administer and dispense buprenorphine without a DATA waiver. More information regarding buprenorphine is noted below. [SAMHSA]

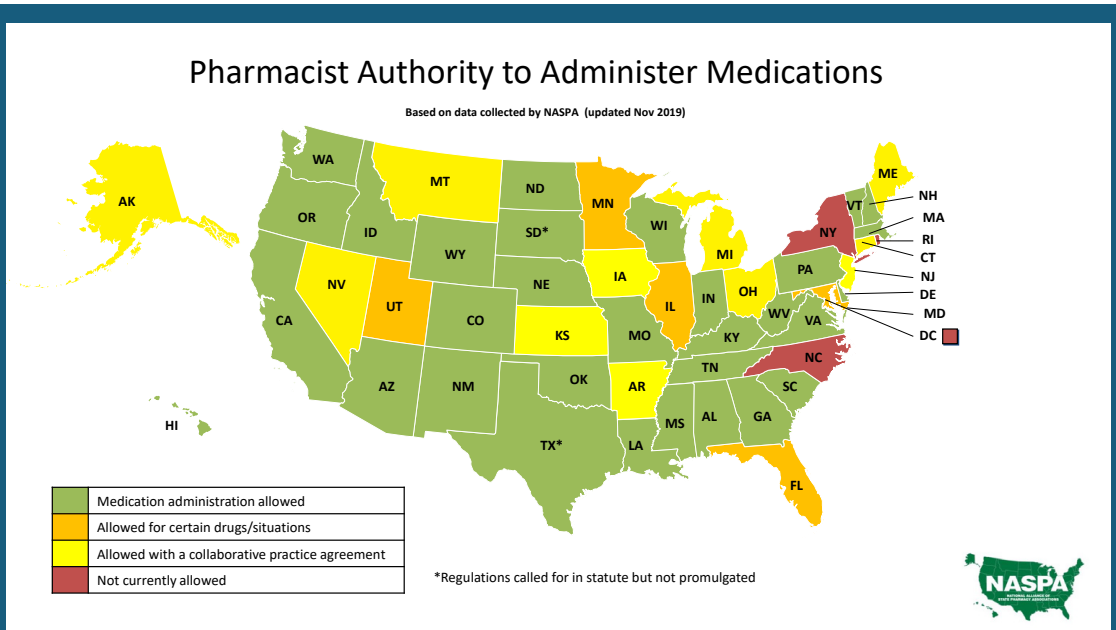

Figure 1. A map indicating pharmacists' authority to administer medications by state. A growing trend within the states is allowing pharmacists to administer medications, such as naltrexone, to improve patient access. Note: The information compiled in this map is for educational purposes. The information provided is not a NASPA legal review or interpretation. While every effort has been made to verify the accuracy of this information, legal authorities, requirements, and interpretations may vary from jurisdiction to jurisdiction. Pharmacists should have their legal counsel review applicable laws and regulations to ensure compliance. Additionally, pharmacists should also contact their state's board of pharmacy if there are questions regarding compliance.

Methadone. Only federally certified, accredited OTPs can dispense methadone to treat OUD. Considering pharmacology, methadone is a synthetic opioid with primarily mu-opioid agonist activity. Methadone is indicated for detoxification treatment and maintenance treatment of OUD, and for moderate or severe pain. Methadone has unique adverse events such as an increased potential for arrhythmias and sudden cardiac death.

Buprenorphine

Buprenorphine offers several benefits to those with OUD and to others for whom treatment in an OTP is not preferred or is less convenient. MAT with buprenorphine is most effective in combination with counseling services, which can include different forms of behavioral therapy and self-help programs. [SAMHSA]

The pharmacological properties of buprenorphine decrease the potential for misuse and decrease the effects of physical dependency to opioids (e.g., withdrawal symptoms, cravings). Because buprenorphine is a partial opioid agonist, it is less likely to produce euphoria or respiratory depression at low to moderate doses than other opioids and reduces mortality in overdose situations. Buprenorphine is long acting, and has a reduced risk of misuse, dependence, or side effects.

In several products, naloxone is added to buprenorphine to decrease the likelihood of diversion and misuse of the combination drug product. For example, when the combination of buprenorphine and naloxone is taken as a sublingual tablet, buprenorphine's opioid effects dominate and mitigates opioid withdrawals. If the sublingual tablets are crushed and injected, the naloxone effect dominates and can block the euphoric effect and potentially bring on opioid withdrawal symptoms.

Ideal candidates to receive buprenorphine meet the following criteria: [SAMHSA]

- Have been objectively diagnosed with opioid dependency
- Are willing to follow safety precautions for treatment
- Do not have contraindications to buprenorphine treatment
- Have reviewed other treatment options before agreeing to buprenorphine treatment

MAT with buprenorphine includes the following three phases: [SAMHSA]

The Induction Phase. Initiation of buprenorphine performed in a qualified physician's office or certified OTP. Buprenorphine is administered when a patient with OUD has abstained from using opioids for 12 to 24 hours and is in the early stages of opioid withdrawal. It is important to note that buprenorphine can precipitate withdrawal for patients who are not in the early stages of withdrawal and who have other opioids in their bloodstream.

The Stabilization Phase. After a patient has discontinued or greatly reduced their misuse of the problem drug, no longer has cravings, and experiences few, if any, side effects. The buprenorphine dose may need to be adjusted during this phase.

The Maintenance Phase. The patient is stabilized on a steady dose of buprenorphine. The length of time of the maintenance phase is tailored to each patient and could be indefinite.

Naloxone for Opioid Overdose Reversal

Naloxone has been used for decades to reverse opioid overdoses. It is an opioid antagonist that displaces other opioids from receptors. Timely administration of naloxone during overdose reduces morbidity and mortality, and it is an important component of efforts to reduce opioid overdose deaths. Of note, naloxone can produce symptoms of withdrawal in opioid-dependent patients.

Due to the time-sensitive nature of treating a patient who has stopped breathing during an opioid overdose, strategies that facilitate more rapid naloxone administration are needed and there have been widespread efforts to increase access. Most opioid overdoses are witnessed by others, often friends and family members who are with the overdose victim in a private home. Therefore, providing naloxone to individuals who are receiving prescription opioids can increase immediate access to naloxone in overdose situations.

Although naloxone is a prescription product, all states provide some mechanism allowing pharmacists to dispense naloxone without a prescription from a prescriber under certain conditions, such as through a collaborative practice agreement or allowing pharmacist-initiated prescriptions through mechanisms, such as statewide protocols or standing orders.

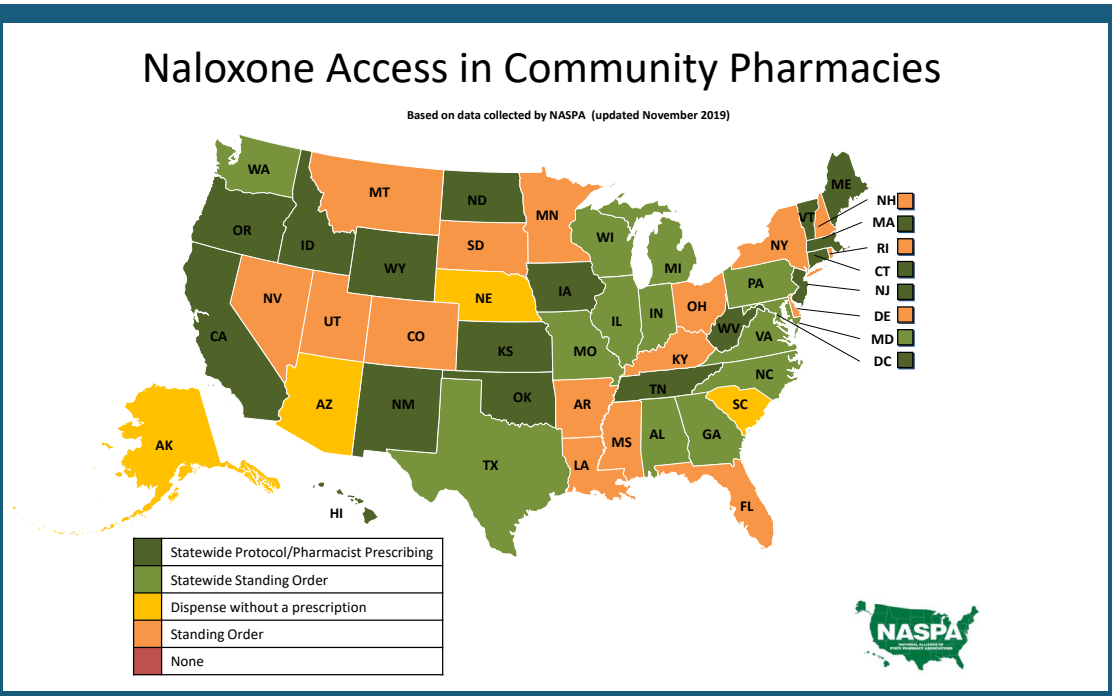

Figure 2. A map indicating different authorities and mechanisms employed by states to help facilitate patient access to pharmacist-furnished naloxone. Note: The information compiled in this map is for educational purposes. The information provided is not a NASPA legal review or interpretation. While every effort has been made to verify the accuracy of this information, legal authorities, requirements, and interpretations may vary from jurisdiction to jurisdiction. Pharmacists should have their legal counsel review applicable laws and regulations to ensure compliance. Additionally, pharmacists should also contact their state's board of pharmacy if there are questions regarding compliance.

Key Terms Related to Addiction

Term	Description
Addiction	As defined by the American Society of Addiction Medicine: "Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases." The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Medically supervised withdrawal (formerly called detoxification)	Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.
Opioid misuse	The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.
Opioid receptor agonist	A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system (CNS) that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.
Opioid receptor antagonist	A substance that has affinity for opioid receptors in the CNS without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.
Opioids	All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).
Opioid treatment program (OTP)	An accredited treatment program with SAMHSA certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.
Opioid use disorder (OUD)	Per DSM-5, a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what DSM-IV termed "opioid abuse" and "opioid dependence." An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period.

Recovery	A process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. Even individuals with severe and chronic substance use disorders (SUDs) can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.
Relapse	A process in which a person with OUD who has been in remission experiences a return of symptoms or loss of remission. A relapse is different from a return to opioid use in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting.
Remission	A medical term meaning a disappearance of signs and symptoms of the disease. DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving). Remission is an essential element of recovery.
Return to opioid use	One or more instances of opioid misuse without a return of symptoms of OUD. A return to opioid use may lead to relapse.
Source: *https://store.samhsa.gov/system/files/tip63_pt1_052919_508.pdf*	

Shared Responsibilities

It is important for prescribers and pharmacists to collaborate to support appropriate use of controlled substances, including medications used for OUD. Open and continuous channels of communication between pharmacists and prescribers help provide effective patient care. In addition, both prescribers and pharmacists have responsibilities enumerated by the Controlled Substances Act. Specifically, pharmacists and prescribers have a shared responsibility for the proper prescribing and dispensing of controlled substances. The DEA states:[DEA]

> *"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."*

Therefore, when providing patient care and satisfying state and federal requirements, the pharmacist may need to contact the prescriber(s) to learn more or obtain clarification regarding a prescription for a controlled substance. Collaboration and effective communication strategies between prescribers and pharmacists can help improve patient care and facilitate more seamless access to medications for patients.

Collaboration Opportunities	
Warm handoffs that include the patient as a team member; occurs between any two members of the health care team (e.g., prescriber, pharmacist)	Identify preferred methods of communication (e.g., fax, phone, specific timeframes)
Discuss current access barriers to jointly identify solutions	Share relevant patient information (e.g., over the phone, on the prescription)
Proactively consider coverage (e.g., prior authorization, quantity limits and dosages)	Collaborative Practice Agreements (more information from the Centers for Disease Control and Prevention, *Advancing Team-Based Care Through Collaborative Practice Agreements)*
Start a relationship with a planned introduction; consider meeting in person	Share information requested by pharmacies to help ensure access to medications (e.g., DATA waiver limit)
Consider other aspects of the patient's care	Specify roles
Identify joint goals	Proactively consider when/where patients will obtain their medications; there may be an opportunity to work with the pharmacy to more effectively help meet the patient's needs

Webinar Facilitation

This section provides an overview of the content provided on the slides. Where appropriate, information and questions for discussion, suggested points to make when answering questions, and additional resources are presented.

Learning Objectives

1. Discuss the clinical approach to using buprenorphine for medication-assisted treatment
2. Describe the differences between buprenorphine products for MAT and those for pain
3. Identify barriers to pharmacist dispensing buprenorphine for MAT and effective strategies in overcoming those barriers
4. Discuss effective approaches for physicians and community pharmacists to collaborate in ensuring access to MAT

Supplemental Information by Slides

Slides 1–9. Introduction to the Webinar and Accreditation Information

Slides 10–13. Self-Assessment Questions

These questions are designed to help participants assess their knowledge at the beginning and end of the webinar. The questions will be repeated at the end of the webinar. Do not reveal the correct answers until the end of the webinar.

Slides 14–16. Overview of substance use disorder in the United States

Slide 15 presents a portion of the short definition of addiction from the American Society of Addiction Medicine (ASAM). ASAM's new definition of addition is:

> *"Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.*
>
> *Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases."*

Addiction is often fatal without treatment.

Questions and Considerations for Discussion

- In what ways does the definition of addiction align with the definition of disease?
  - *Disease is designed as "any deviation from or interruption of the normal structure or function of any body part, organ, or system that is manifested by a characteristic set of symptoms and signs, and whose etiology, pathology, and prognosis may be known or unknown." Because addiction is characterized by changes in brain functions, it aligns with this definition.*

- How does misuse of an opioid differ from addiction to opioids?
  - *Misuse includes a wide range of behaviors, such as taking the medication at the wrong time or a condition for which it was not prescribed. Addiction is characterized in compulsive behaviors that often continue despite harmful consequences.*

- Are you aware of individuals in your community who consider substance use disorder to be a "moral failing"? How do you respond to those individuals?
  - *It is important to stress that addiction is characterized by changes in brain function. It fits with the definition of chronic disease and is responsive to treatment.*

Slides 17–20. Evidence for MAT, National Guideline Mentions, and Distribution of MAT Prescribers

Patients who are withdrawn from opioids and treated with psychosocial interventions alone often relapse without MAT. These slides present information demonstrating that there is a substantial body of evidence demonstrating the benefits of MAT, compared with withdrawal/abstinence alone. Benefits include the following:

- Increased treatment retention
- Decreased illicit opioid use
- Reductions in overdose deaths and all-cause mortality

Initiating buprenorphine treatment in the emergency department when indicated is appropriate. It reduces mortality and increases transfer to and participation in outpatient MAT. Buprenorphine itself is almost never associated with overdose mortality.

Questions for Discussion

Given these findings

- Why do you think use of MAT has been considered "controversial"?
  - *This may be because of lack of awareness of the nature of addiction as a chronic disease, misperceptions about the role of treatment in supporting patients with the disease, and lack of awareness of the potential benefits of treatment. It is important to stress that MAT significantly improves patient morbidity and mortality, and significantly reduces all-cause mortality.*

- What do you think could be done to increase the number of MAT prescribers?
  - *More education for prescribers about the impact of opioid use on patients and communities, and the possibility of improving patient outcomes could potentially lead more prescribers to undergo the necessary training to be prepared to prescribe MAT.*

- What do you think could be done to increase access to buprenorphine through community pharmacies?
  - *Similarly, more education for pharmacists about the benefits of MAT and how to implement it in practice could support more widespread access.*

Further reading:
U.S. Department of Health and Human Services (HHS), Office of the Surgeon General. *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*. Washington, DC: HHS, September 2018. Available at: https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf.

Department of Veterans Affairs, Department of Defense. VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders. Version 3.0—2015. Available at: https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf.

Slides 21–24; 26. Buprenorphine Medication Information
These slides address buprenorphine pharmacology, dosage forms, dosing, and dispensing guidelines. Dosing of buprenorphine should be patient dependent. Underdosing a patient is much more dangerous than overdosage with buprenorphine. Patient receptors can become unblocked after about 4 hours and patients can experience withdrawal symptoms if they aren't receiving dosing that matches their needs.

Slide 26 discusses the newest dosage forms.

More information about buprenorphine can be found at:

https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine

Questions for Discussion:

- When should buprenorphine be prescribed as a single entity? When should it be prescribed in combination with naloxone?
    - *Buprenorphine in combination with naloxone (e.g., Suboxone) has a lower potential for misuse than single-entity buprenorphine alone (e.g., Subutex) because sublingual administration of naloxone does not result in a pharmacologic effect. However, if Suboxone is injected intravenously, it is likely to precipitate withdrawal symptoms. Buprenorphine is usually prescribed in combination with naloxone to prevent misuse. However, single-entity products may be appropriate in certain situations, such as when initiating treatment.*

- In what situations would it be appropriate to prescribe buprenorphine at a dosage above 16 mg per day?
    - *Dosages should be individualized based on patient needs to prevent withdrawal symptoms and increase the likelihood of patient success. Receptor blockade must be maintained in order to prevent withdrawal. Various patient factors can lead to a need for increased dosage, such as the patient's genetics. Additionally, patients who were heavier users of illicit opioids may need higher dosages than lighter users.*
    - *Should dosage concerns arise, pharmacists are encouraged to communicate with the prescriber.*

Slide 25. Buprenorphine Dispensing Guidelines
Certain federal laws and regulations affect pharmacy practice regarding MAT.

Because buprenorphine is a schedule III drug, and laws and regulations that pertain to controlled substances also apply to MAT prescriptions, including the corresponding responsibility law for controlled substances. This law states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Therefore, pharmacists have a responsibility to ensure the appropriateness of prescriptions they received for MAT. It is important pharmacists and other health care providers are aware of processes and procedures that are used to assure the legitimacy of controlled substance prescriptions, including those used to treat OUD or pain. More information about the corresponding responsibility rule can be found at: *https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm*

Also, effective July 25, 2005, qualified practitioners must include their DATA 2000 waiver identification number (the Narcotic Addiction Drug Enforcement Administration Number [NADEAN]) on prescriptions for schedule III–V medications used to treat opioid dependency. Both their DEA registration and the NADEAN or "X number" must appear on prescriptions when buprenorphine is prescribed for MAT. When prescriptions are phoned in, pharmacists must have both these numbers on the prescription record. Practitioners must provide these numbers if they are not already on file.[NADEAN]

Billing third-party payers for MAT may require special steps. Some payers carve-out treatment of substance use disorders from other benefits. Medicare Part B recently finalized a bundled payment policy for coverage of opioid use disorder treatment services in office-based settings, however, the drug component of treatment is still to be covered by Part D. States may also have quantity or dosing limits in the place that can impact patient access. Therefore, prescribers and pharmacists may need to coordinate with payers to ensure appropriate billing processes are used, and other requirements are satisfied.

Finally, pharmacists and prescribers should ensure that they are familiar with any state-specific requirements.

Slides 26–27. Addiction vs. Physical Dependence and Tolerance

These slides focus on the key distinctions between addiction and physical dependence/tolerance. Concerns have been raised that MAT "substitutes one addiction for another." However, while there can be overlap within a patient, it is crucial to understand the difference between addiction and physical dependence. Refer to the table "Key Terms Related to Addiction" for detailed descriptions of various terms. Patients who are successfully treated with MAT stop exhibiting behaviors that are characteristic of addiction, such as loss of control and compulsive behavior, therefore, they are not considered to be addicted to MAT.

Questions for Discussion:

- What are the defining characteristics of addiction?
  - *Addiction is characterized by behaviors including impaired control over drug use, compulsive use, continued use despite harm, and craving.*

- Why is physical dependence different than addiction? Why is this important to remember when providing care?
  - *Physical dependence is a state of adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. A patient can be physically dependent on a medication without exhibiting the behaviors associated with addition.*

- Is buprenorphine treatment trading one addiction for another?
  - *No, a patient may be physically dependent on MAT without the behaviors of addiction. Therefore, the patient is not addicted to MAT. A patient who is receiving maintenance MAT is considered in recovery if he or she is not exhibiting behaviors associated with addiction.*

Slide 28. Tapering
This slide focuses on the duration of treatment for MAT. There is no defined time limit for MAT and many patients continue to receive MAT indefinitely. Patients are less likely to remain abstinent if they taper off MAT and are more likely to experience overdose and death. Therefore, the risks and benefits of ongoing treatment must be carefully considered when deciding whether to taper treatment.

Questions for Discussion

- Why can tapering off buprenorphine pose a risk to some patients?
    - *Tapering can precipitate withdrawal symptoms, which can result in a patient seeking opioids illicitly and returning to behaviors associated with addiction. Patients only have a 10% to 15% success rate in remaining abstinent when buprenorphine is tapered.*

Slides 29–32. Legal and Regulatory Considerations and Compliance
There are several entities involved in the oversight of MAT delivery, including the Drug Enforcement Administration (DEA), state boards of pharmacy (SBOP), and state boards of medicine (SBOM). These groups often have specific rules for MAT.

While qualified practitioners are required to have waivers to prescribe or dispense buprenorphine under DATA 2000 outside of opioid treatment programs, pharmacists and pharmacies are not required to have any credentials for dispensing these medications beyond those required for other Schedule III medications. Pharmacists should go to the Buprenorphine Pharmacy Lookup (*https://www.samhsa.gov/bupe/lookup-form*) to verify a practitioner's certification to prescribe buprenorphine. There are limits to how many patients can be treated by a prescriber under the DATA waiver program. There have been efforts to increase the number of patients that a provider can treat.

Pharmacists must also comply with confidentiality regulations specific to substance use disorder. More information about these requirements can be found at *https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs*

Pharmacists should also contact their state pharmacy associations for information about any state-specific requirements that they must comply with.

Slides 33–36. Misuse, Abuse, Diversion
There are important distinctions among misuse, abuse, and diversion. Misuse means that patients are not using medications as directed, and abuse involves a maladapted pattern of substance use that leads to significant impairment or distress. Diversion of prescription drugs involves behaviors such as stealing or selling the medications.

While the term "abuse" is included in the webinar, it is often viewed as a stigmatizing term. Replacing "abuse" with terms like "dependence" is preferred, especially when talking with patients.

As presented on slide 34, almost one-quarter of patients admit that they have shared their prescriptions with other patients or borrowed medications from others. Pain medications are among the most commonly shared medications, and medications used for MAT are also shared by 18% to 28% of patients. Therefore, pharmacists must carefully assess MAT prescriptions and remain alert for signs of inappropriate behaviors. Collaboration with prescribers and use of diversion/adherence monitoring techniques (e.g., random urine drug screens) can help assess whether patients are

using the medications as prescribed. Additionally, long-acting dosage forms of buprenorphine (e.g., monthly injections) may be appropriate for high risk patients.

It is important to note that behaviors that are red flags for opioid prescriptions for pain management are not necessarily red flags for MAT prescriptions. Pharmacists should carefully consider these differences when assessing prescriptions for buprenorphine for MAT so that access is not unnecessarily impacted. Additionally, pharmacists should consider that many medications (e.g., antibiotics, insulin) are shared among patients. Because buprenorphine is generally not used recreationally, sharing of buprenorphine among patients my not be associated with the same level of concern as sharing of other opioids.

Question for Discussion:

- What "red flags" may not be appropriate for buprenorphine for MAT compared with opioids for pain management?
    - *Some "red flags" for patients receiving opioids for pain management may not be seen as red flags for patients receiving MAT. For example, a patient with needle marks may have recently started MAT. A patient paying cash for the prescription may be less of an issue if the patient's prescription plan has onerous prior authorization requirements.*

Slides 37–41. Barriers: Stigma, Education, and Technology

Many patients with substance use disorders experience feelings of shame about their disorder, which can impede their ability to seek help. Stigma is defined as a discrediting characteristic within a social interaction that may lead to labeling, stereotyping, loss of status, and discrimination. Stigma associated with substance use disorders can increase patient feelings of shame and act as a barrier to effective treatment.[Link] Health care providers should be aware of the words that they use when discussing substance use disorders and focus on using patient-centered language. For example, the term, "patient with substance use disorder" is more supportive than "addict." Respectful interactions with patients may increase the likelihood that they will continue to receive treatment. Stigma reduces quality of care and produces isolation. Pharmacists should pay attention to their own biases as well as any that appear among other health care providers. Becoming aware of biases and working to address them can help reduce stigma. Using evidence about the value of MAT can help to dispel myths that perpetuate stigma.

In addition, ongoing continuing education, and use of technology to support appropriate treatment can help reduce barriers to effective treatment. Education that supports evidence-based prescribing and appropriate lengths of treatment and providing effective patient counseling is key. Pharmacists should also identify resources that are needed to support patients, including community resources and referrals to treatment centers that can support patients with substance use disorder. As with any controlled substance prescription, pharmacists should assess for red flags and diversion concerns. However, it is important pharmacists are cognizant that different explanations may exist when a red flag is apparent for a patient or patients seeking to fill medications indicated for opioid use disorder. Pharmacists can advocate for MAT and encourage more education and training to deliver MAT services.

Technology can be used to enhance communication among providers. Pharmacists should collaborate with other providers to assess the most efficient and effective strategies for communication, including preferred methods of communication. Technology can also be leveraged

for sharing important clinical information between the pharmacist and physician.

Technology is also important for managing inventory, utilizing prescription drug monitoring programs effectively, and maintaining open communication with the patient care team.

Questions for Discussion:

- What phrases have you heard regarding patients with substance use disorders and their treatment that might reinforce stigma? What phrases could you use instead?
  - *Examples include using "person with substance use disorder" rather than "addict" or "drug abuser," using "abstinent" or "not actively using" rather than "clean," using "testing positive for substance use" rather than "a dirty drug screen," using "person in recovery" rather than "reformed addict."*

- How can you leverage technology to support treatment of patients receiving MAT?
  - *Technology can be used to improve collaboration, communication, and warm handoffs among providers.*
  - *Prescription drug monitoring program reports can be used by a health care practitioner with other support tools (e.g., documentation templates, patient data reports and summaries, computerized alerts and reminders) when screening a new patient or monitoring a current patient. SAMHSA has made available, "Prescription Drug Monitoring Programs: A Guide for Health Care Providers" (https://store.samhsa.gov/system/files/sma16-4997.pdf) for those interested in learning more.*
  - *Utilize e-prescribing, including notes sections, to provide additional information to pharmacists.*
  - *Ensure X-waiver number and DEA number is made available to the pharmacist.*

- What other barriers have you encountered in your practice and how could they be addressed?
  - *[Open responses]*

Slides 42–46. Collaborating for MAT Access

These slides focus on strategies to use to support ongoing collaborations among prescribers and pharmacists to support patients. Strategies include

1. Maintain open communication: warm handoffs
2. Manage expectations
3. Work together to proactively address prescription cost concerns
4. Determine prescription delivery preferences
5. Invest in community buy-in

Questions for Discussion

- What strategies do you use to foster collaboration with other providers in your community?
  - *[Open responses]*

- How can these strategies be applied when caring for patients receiving MAT?
    - *[Open responses]*

Slides 47–48. Case Study 1: Mrs. S.

Questions for Discussion

- What next steps are appropriate to address concerns about dosage?
    - *Pharmacist–prescriber communication to learn more about the dosage selected since dosages have fluctuated and increased towards the higher end of recommended dosing*
    - *Consider reviewing clinical guidelines or other resources*
    - *Check the PDMP to learn more about the patient's medications and potentially other prescribers*
    - *Communicating with the patient their concerns and may try to learn more from the patient. The patient may not know what information is available to pharmacists, such as that her drug screens reflect she is taking her prescribed medications*
    - *The pharmacist should document information learned when determining the appropriateness of the prescription*
- What are appropriate collaborative options for the physician and pharmacist?
    - *Prescriber and pharmacist discuss the dosage and determine its appropriateness*
    - *Prescriber may consider sharing additional information about the patient*
    - *Proactive communications from the prescriber to the pharmacist about the patient's dosage and/or best methods of communication*
    - *The prescriber could ask the patient about which pharmacy they will go to*
    - *If an e-prescription is used, utilizing the notes section on the e-prescription to help inform the pharmacist*

Slides 49–50. Case Study 2: Ms. M.

Questions for Discussion

- What would the conversation look like between the patient, pharmacist, and physician?
    - *Since this is s a small community, the pharmacist and prescriber may already know one another and/or consider whether this relationship can be developed further*
    - *Strive for warm handoffs; more information is available from the Agency for Healthcare Research and Quality at: https://www.ahrq.gov/patient-safety/reports/engage/interventions/warmhandoff.html*
    - *The patient may not know that paying cash for the mono-product buprenorphine raises concerns (e.g., cash paying, mono-product has a higher potential for misuse and higher street value when compared with the combination product) [ACOG & ASAM]; it is important the pharmacist learn more information about the patient to alleviate those concerns while being sensitive. Communications with the prescriber may also be necessary, for example, to learn why mono-product buprenorphine was prescribed.*
- What action(s) could the physician and pharmacist take to alleviate cost concerns for the patient's medications?
    - *Discuss patient assistance programs*
    - *Consider different medications based on coverage and cost*

- *Proactively address cost with patients*
- *Be aware of medications that require prior authorization and be prepared to complete additional work to ensure coverage*
- *Consider telemedicine options; for more information see: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Using Telehealth to Support Opioid Use Disorder Treatment*

Slides 51–54. Self-Assessment Questions

These questions are designed to help participants assess their knowledge at the beginning and end of the webinar. When presenting the questions at the end of the webinar, allow participants the opportunity to attempt to answer the question, and then provide the correct answer and address any remaining questions.

Question 1. How can the agonist effect of buprenorphine be described?

a) At low doses, it exhibits sufficient agonist effect to mitigate withdrawal symptoms in patients that are addicted to opioids and attempting to discontinue use

b) It has no agonist effect

c) Only at high doses does it exhibit sufficient agonist effect to mitigate withdrawal symptoms in patients that are addicted to opioids and attempting to discontinue use

d) None of the above

Correct answer: A

Question 2. Which of the following medications is indicated for pain?

a) Extended-release injection (Sublocade)

b) Sublingual tablet (Subutex)

c) Intradermal implant (Probuphine)

d) Transdermal patch (Butrans)

Correct answer: D

Question 3. To avoid stigma, which words and/or phrases should you use?

a) "Person with substance use disorder" instead of "addict"
b) "Drug abuse" instead of "drug misuse"
c) "A clean drug screen" instead of "a negative drug screen"
d) "A dirty drug screen" instead of "a positive drug screen"

Correct answer: A

Question 4. Which of the following is not an example of how physicians and pharmacists should consider collaborating to improve patient access to buprenorphine?

a) Maintain open communication: warm handoffs
b) Manage expectations (e.g., Patient influx on clinic day, inventory status, staffing needs)
c) Work together to proactively address prescription cost concerns (e.g., Establish cost benefit with patient, determine price reduction strategies)
d) Check the PDMP and assume you do not need to communicate directly

Correct answer: D

Slide 55. Thank You

Thank participants for their attention and offer them resources that they can refer to in the future.

Additional Resources

- American Society of Addiction Medicine (ASAM) Educational Resources: *https://www.asam.org/education*
- American Pharmacists Association Continuing Education: *https://www.pharmacist.com/education*
- ASAM summary of major components of the HHS final rule to increase access to medication-assisted treatment with buprenorphine products in the office setting: *https://www.asam.org/resources/publications/magazine/read/article/2016/07/06/summary-of-the-major-components-of-the-hhs-final-rule-which-will-be-effective-on-august-5-2016*
- California Health Care Foundation. Buprenorphine: An Overview from Clinicians: *https://www.chcf.org/wp-content/uploads/2019/08/BuprenorphineOverviewClinicians.pdf*
- ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use: *https://www.asam.org/resources/guidelines-and-consensus-documents/npg*
- College of Psychiatric and Neurologic Pharmacists. Naloxone Access: A Practical Guideline for Pharmacists: *https://cpnp.org/guideline/naloxone*
- DEA requirements for DATA Waived Physicians: *https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm*
- National Academies of Sciences, Engineering, Medicine. Medications for Opioid Use Disorder Save Lives. https://www.nap.edu/catalog/25310/medications-for-opioid-use-disorder-save-lives
- Ohio Hospital Association. Opioid Response Initiatives: *https://ohiohospitals.org/Patient-Safety-Quality/Statewide-Initiatives/Opioid-Initiative/Hospital-and-Clinician-Resources-Resources*
- REMS information for Suboxone: *http://www.suboxonerems.com/pharmacist-information*
- Substance Abuse and Mental Health Services Administration (SAMHSA). Buprenorphine: *https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine*
- SAMHSA Substance Abuse Confidentiality Regulations: *https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs*
- Yale School of Medicine, ED-Initiated Buprenorphine: *https://medicine.yale.edu/edbup/*

References

American Society of Addiction Medicine. Definition of addiction. Available at: https://www.asam.org/resources/definition-of-addiction. Accessed December 2, 2019.

[HHS] Department of Health and Human Services. https://www.hhs.gov/opioids/about-the-epidemic/index.html

[HHS2] https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html

Link BG, Phelan JC. Conceptualizing stigma. *Annu Rev Sociol*. 2001;27:363–385.

[NADEAN] Substances Abuse and Mental Health Services Administration, Verify Practitioner Waivers (For Pharmacists) available at: https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/verify-practitioner-waivers

[NIDA] National Institutes on Drug Abuse, Opioid Overdose Crisis, available at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#two

[SAMHSA] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment (MAT), available at: https://www.samhsa.gov/medication-assisted-treatment

[NIDA] https://www.drugabuse.gov/publications/drugfacts/understanding-drug-use-addiction

[ACOG & ASAM**]** The American College of Obstetricians and Gynecologists and American Society of Addiction Medicine, ACOG Committee Opinion, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Opioid-Use-and-Opioid-Use-Disorder-in-Pregnancy?IsMobileSet=false

ASAM American Society of Addiction Medicine

APhA