


CONSIDERATIONS FOR BUPRENORPHINE INITIATION AND MAINTENANCE CARE

PUBLIC MEETING SUMMARY

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REAGAN-UDALL
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The background of the page is an abstract composition of flowing, overlapping lines in various shades of purple and blue. The lines originate from the left side and curve towards the right, creating a sense of movement and depth. The colors range from deep, dark purples to lighter, more vibrant blues, with some areas appearing as soft gradients.

This activity is one part of a multi-part Foundation project related to substance use disorder. The multipart project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of \$902,109 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA, NIDA, SAMHSA, HHS, or the U.S. Government. For more information, please visit **FDA.gov**.

Table OF Contents

ONE

Introduction.....	4
Background.....	4

TWO

Clinical Guidelines.....	6
--------------------------	---

THREE

Buprenorphine Initiation and Maintenance.....	9
Considerations for Buprenorphine Use in the Inpatient and Community Settings.....	10
Precipitated Withdrawal.....	11
Buprenorphine in Populations with Special Considerations.....	12

FOUR

Product Needs and Opportunities to Address Treatment Needs through Product Development.....	13
Formulations.....	15
Packaging.....	17
Labeling, Coverage, Use.....	18
Research to Support Product Development and Treatment Guidelines.....	18
Regulatory Pathways for Drug Development.....	19

FIVE

Promoting Access to Buprenorphine in the Real-World Setting.....	22
--	----

SIX

Conclusion/Future Directions.....	26
-----------------------------------	----

APPENDICES

A. Buprenorphine Products.....	28
B. Barriers Throughout the Treatment Journey.....	30
C. Meeting Agenda.....	31

ONE | INTRODUCTION

The Reagan-Udall Foundation for the FDA, in partnership with the U.S. Food and Drug Administration (FDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), held a two-part virtual public meeting titled “*Considerations for Buprenorphine Initiation and Maintenance Care.*” The public meeting explored real-world experiences and scientific evidence for initiation of buprenorphine,¹ as well as medication dosing and management during continued treatment across different care settings. To support efforts to develop products and approaches to treat opioid use disorder (OUD), presentations and discussions included people with lived experience, harm reduction programs, health professionals from inpatient and outpatient settings, academic researchers, and federal partners. This document summarizes the presentations and panel discussions from the meeting. This document does not represent the official views of FDA, SAMHSA, or any other government agencies.

Background

OUD remains a major public health issue. Buprenorphine² is a safe and effective prescription medication used for the treatment of OUD.³ Yet, according to data from the 2021 National Survey of Drug Use and Health (NSDUH), it is estimated that only 22% of the 2.5 million people aged 12 or older with past-year OUD received medication for OUD. Treatment rates are even lower among people of color.⁴ The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, removed a perceived barrier to the provision of buprenorphine by eliminating the DATA-Waiver. The DATA-Waiver previously required practitioners to submit a notification of intent to SAMHSA prior to prescribing buprenorphine for the treatment of OUD, and to certify to the receipt of training (8 hours for MD/DOs, and 24 hours for other eligible practitioners), and ability

¹ Also known as “induction;” “initiation” and “induction” are used interchangeably in this report.

² “Buprenorphine” refers to both the buprenorphine-only and combination product with naloxone, unless otherwise explicitly stated.

³ Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. <https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report>

⁴ Andraka-Christou B. Addressing racial and ethnic disparities in the use of medications for opioid use disorder. *Health Affairs* 2021;40(6). <https://doi.org/10.1377/hlthaff.2020.02261>

to provide counseling and ancillary services. As of December 29, 2022, any licensed provider with a current DEA registration that includes Schedule III authority may now prescribe buprenorphine.⁵ While not discussed during this meeting, other medications to treat OUD include methadone and naltrexone.

An increasing incidence of fentanyl in the illicit drug supply has further complicated buprenorphine initiation and maintenance. This is because patients dependent on fentanyl appear to be more vulnerable to precipitated withdrawal when initiating treatment with buprenorphine. Current evidence underlying the best strategy for initiating and maintaining treatment with buprenorphine is mixed. A better understanding of the landscape of available tools and strategies for best practices in OUD care with buprenorphine is needed to advance the development of and access to evidence-based treatment for OUD, a priority under the FDA Overdose Prevention Framework⁶ and the U.S. Department of Health and Human Services (HHS) Overdose Prevention Strategy.⁷

⁵ Substance Abuse and Mental Health Services Administration. Waiver elimination (MAT Act). Accessed August 3, 2023. [https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act#:~:text=Section%201262%20of%20the%20Consolidated,opioid%20use%20disorder%20\(OUD\).](https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act#:~:text=Section%201262%20of%20the%20Consolidated,opioid%20use%20disorder%20(OUD).)

⁶ Center for Drug Evaluation and Research. Food and Drug Administration Overdose Prevention Framework. U.S. Food and Drug Administration. Accessed August 3, 2023. <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework>.

⁷ Assistant Secretary for Public Affairs (ASPA). Together we can save lives. Overdose Prevention Strategy. November 30, 2022. Accessed August 3, 2023. <https://www.hhs.gov/overdose-prevention/>.

TWO | Clinical Guidelines

The American Society of Addiction Medicine (ASAM) published a clinical practice guideline for the treatment of OUD in 2015. This was followed by a focused update in 2020, which included 14 buprenorphine initiation and treatment recommendations. Highlights from the forthcoming 2023 Buprenorphine Clinical Considerations⁸ document, which were subsequently released in July, were presented at this meeting. Table 1 describes the different levels of evidence and review in the development of ASAM clinical documents.

Table 1: Clinical Document Types⁹

Clinical Practice Guidelines	<ul style="list-style-type: none">▶ the most scientifically rigorous, time-intensive documents▶ require a formal systematic literature review to inform the recommendations
Clinical Consensus Statements	<ul style="list-style-type: none">▶ informed by evidence▶ include a broader scope of evidence, such as case studies and reviews, including scoping literature reviews▶ use expert clinical consensus on high-priority topics that may have conflicting or limited evidence
Clinical Considerations	<ul style="list-style-type: none">▶ address issues that are immediately clinically relevant▶ may have limited evidence▶ typically informed by narrative literature reviews and based on expert clinical consensus

⁹ Weimer MB. Buprenorphine Clinical Considerations; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

Dr. Weimer's presentation on Buprenorphine Clinical Considerations addressed three pertinent clinical questions:

1. What specific clinical situations favor the use of low- or high-dose buprenorphine initiation strategies?
2. After buprenorphine initiation, what range of buprenorphine dosing and/or dosing strategies can be considered during stabilization and long-term treatment?
3. What are the indications for injectable extended-release buprenorphine for OUD treatment compared to sublingual formulations?

Key recommendations in response to these questions include individualization of induction regimens, clinical situations that may require higher buprenorphine doses, and considerations for using an extended-release (XR) formulation. The buprenorphine initiation regimen is best individualized by clinical setting – low- or high-dose regimens in the emergency department (ED), inpatient, or outpatient settings – and patient preference. Patients with high opioid tolerance and pregnant people may require higher buprenorphine doses > 24 mg per day. Lastly, consider XR buprenorphine formulations for individuals who are unable to stabilize on the shorter-acting sublingual tablets and films, e.g., people with a history of multiple overdoses or those in unsafe living environments.

In addition to ASAM guidelines and resources, SAMHSA has a number of resources available to support buprenorphine prescribing:

1. TIP 63 Medications for Opioid Use Disorder. <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002>
2. SAMHSA's Buprenorphine Quick Start Guide. <https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf>
3. Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings. <https://store.samhsa.gov/product/practical-tools-for-prescribing-promoting-buprenorphine-primary-care-settings/pep21-06-01-002>

4. Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants. <https://store.samhsa.gov/sites/default/files/d7/priv/sma18-5054.pdf>
5. Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings. <https://store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf>
6. Use of Medication-Assisted Treatment in Emergency Departments. https://store.samhsa.gov/product/use-of-mat-in-emergency-departments/pep21-pl-guide-5?referer=from_search_result

THREE | Buprenorphine Initiation and Maintenance

First and foremost, it is important to view OUD within the framework of a chronic health condition. OUD is similar to other chronic and relapsing health conditions to the extent that the disorder and the individual's engagement with treatment can change over time. Some people will start treatment with medications, stabilize, and continue on maintenance treatment indefinitely, whereas others may intermittently relapse. In this way, it is incumbent on practitioners to meet those with OUD where they are in recovery and to engage in shared decision making. OUD can be complex with physical, behavioral, psychosocial, and environmental factors all contributing to the clinical picture.

Speakers and panelists underscored the importance of respect, patient autonomy, and shared decision-making when initiating buprenorphine for the treatment of OUD.¹⁰ Person-centered care puts the experiences, needs, and priorities of the individual front and center and focuses the conversation around treating the person rather than on drugs or a disorder.

Considerations for Buprenorphine Use in the Inpatient and Community Settings

Buprenorphine is safe and effective and is associated with improved treatment outcomes and decreased morbidity and mortality for people with OUD.¹⁰

Buprenorphine initiation is not necessarily a one-time experience – individuals may stop and start buprenorphine over the course of managing their OUD. Although the original intention was for this product to be used primarily in outpatient provider offices, settings have expanded to include the hospital ED and inpatient unit, pharmacies, and emergency medical services (EMS).

Goals of buprenorphine treatment initiation are to individualize the treatment regimen while

- ▶ Minimizing withdrawal symptoms, and
- ▶ Supporting abstinence from illicit opioids.

¹⁰ Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. *JAMA Netw Open.* 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622

“Induction is not the goal in itself, but a means to stable buprenorphine maintenance.”¹¹

Many regimens for buprenorphine initiation exist – largely due to the diverse ways in which individuals present, thus requiring different treatment approaches. Selection of an induction regimen depends on the clinical setting, time available with the patient (e.g., in the inpatient setting, are they being discharged in a few hours or will they be an inpatient for a few days), and patient goals and preferences. Selection of the buprenorphine formulation to use for initiation and maintenance therapy often depends on insurance coverage and pharmacy availability. The ultimate goal is to reach a dose that prevents withdrawal symptoms and cravings, without inducing precipitated withdrawal, and leads to cessation of illicit, short-acting, highly reinforcing opioids as soon as possible. The 2023 ASAM Clinical Considerations Document on Buprenorphine Treatment for OUD provides an overview of standard and emerging approaches for buprenorphine induction and consideration of induction regimens based on the clinical setting and level of opioid withdrawal in tables 2 and 3, respectively.¹²

Whether to use a buprenorphine-only or buprenorphine-naloxone combination product depends on the initiation regimen, medication availability, cost, and insurance coverage as well as a patient’s tolerability to the buprenorphine product. During her presentation, Dr. Kelly Dunn, from Johns Hopkins University, shared, “Many of our patients report an aversion to the naloxone, and we’ve actually seen in our clinic that if we do shift people from the combination to the [buprenorphine-only] product, that we do see a reduction in the withdrawal severity that they have on those first few days.”¹³

In addition to buprenorphine, adjunctive medications can be used to relieve anxiety or any withdrawal symptoms that may occur. Supportive medications can create a more positive induction experience, which increases the likelihood that the person will continue to buprenorphine maintenance.

¹¹ Raheemullah A. Buprenorphine Initiation in the Inpatient Setting; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

¹² Weimer M, Herring AA, Kawasaki S, et. al. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. Journal of Addiction Medicine. Published online July 28, 2023. doi:<https://doi.org/10.1097/adm.0000000000001202>

¹³ Dunn K. Opportunities to Address Treatment Needs Through Product Development; May 11, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

As noted by Dionna Berkholder, a peer care coordinator with the North Colorado Health Alliance, *“We initiate these folks not just to get them past their overdose or to get them past their withdrawal that they’re in the emergency department for. Ultimately, the goal is to get these folks into long-term recovery or at least connected with services that they’re not going to return to heavy opioid use disorder.”*

Additional induction support services include:

- **Counseling and social supports**
 - ▶ Working to overcome adverse social determinants of health, which may have precipitated OUD, is pivotal to long-term recovery
- **Peer support**
 - ▶ A peer support specialist or substance use navigator provides support, keeps the person motivated, and encourages them to keep moving forward
- **Education**
 - ▶ Reinforcing that buprenorphine is a very safe medication
 - ▶ Addressing misconceptions that the person may have about buprenorphine treatment
- **Linkage to ongoing care, including physical and behavioral health services**
 - ▶ Risk of losing a patient to follow-up is highest during transitions of care
 - ▶ Wraparound services are important to help people stay in treatment
 - ▶ Many individuals with OUD suffer concurrent physical and behavioral health conditions that must be addressed as part of whole-person care
 - ▶ Example: HEALing Communities study in Kentucky, Massachusetts, New York, and Ohio¹⁴

Precipitated Withdrawal

The risk of buprenorphine-precipitated withdrawal is not an inevitable consequence of buprenorphine induction. The risk of precipitated withdrawal is increased as a function of higher doses of buprenorphine, a shorter time interval between the exposure to the full agonist opioid and buprenorphine administration, higher levels of physical dependence, and pharmacological properties of the opioid agonist that a patient is dependent on.¹⁵ Precipitated withdrawal symptoms are generally intense

¹⁴ <https://heal.nih.gov/research/research-to-practice/healing-communities>

¹⁵ Rosado J, Walsh SL, Bigelow GE, Strain EC. Sublingual buprenorphine/naloxone precipitated withdrawal in subjects maintained on 100mg of daily methadone. Drug and alcohol dependence, 2007;90:261–269. <https://doi.org/10.1016/j.drugalcdep.2007.04.006>

and distressing; they can include excessive vomiting and diarrhea, intense sweating, cramping, muscle aches and pains, agitation, restlessness, and anxiety. However, precipitated withdrawal can be successfully managed in ED, outpatient, and inpatient settings. The experience of precipitated withdrawal may reduce the likelihood of a successful induction and willingness to engage in OUD treatment in the future. Therefore, successfully managing precipitated withdrawal is important in all induction settings to ensure we do not deter people from an effective intervention.

It is important to distinguish precipitated withdrawal from opioid withdrawal or anticipatory anxiety symptoms a person may be experiencing. Discussing the person's withdrawal symptom history and anxiety about OUD treatment provides an educational opportunity about the types of withdrawal, symptom management, and when to seek medical attention.

FOUR | Product Needs and Opportunities to Address Treatment Needs Through Product Development

Speakers and panelists provided many recommendations for product development and ideal buprenorphine products. Recommendations were made for formulations, packaging, and labeling. The tables below summarize current needs and potential product development ideas.

Buprenorphine in Populations with Special Considerations

Additional considerations exist for some populations when it comes to buprenorphine access, initiation, and maintenance. In particular, three populations were discussed during the meeting.

Pregnancy and Postpartum

Dr. Caitlin Martin from Virginia Commonwealth University discussed pregnancy as a window of opportunity for treatment initiation and access. She noted that *“mental health conditions, in particular overdose, have now become the leading cause of pregnancy-associated deaths in this country...”* and that most of those overdose-related deaths are occurring in the six- to twelve-month postpartum period.¹⁶

Buprenorphine-only and buprenorphine/naloxone combination products are safe to use in pregnancy and the postpartum period (defined as a year after delivery or a year after the end of a pregnancy).¹⁷ Research is needed to guide buprenorphine dose optimization through the pregnancy and postpartum period, as well as on XR formulation in pregnancy and postpartum, including people who are breastfeeding or chestfeeding.

¹⁶ Additional references: a) Bruzelius E, Martins SS. US trends in drug overdose mortality among pregnant and postpartum persons, 2017–2020. *JAMA* 2020;328(21):2159–2161. b) Barbosa-Leiker C, Campbell A, McHugh RK, et. al. Opioid use disorder in women and the implications for treatment. *Psychiatric Research and Clinical Practice* 2021;3(1):3–11. c) Maeda A, Bateman BT, Clancy CR, et. al. Opioid abuse and dependence during pregnancy: Temporal trends and obstetrical outcomes. *Anesthesiology* 2014;121(6):1158–1165.

¹⁷ Link HM, Jones H, Miller L, et. al. Buprenorphine-naloxone use in pregnancy: a systematic review and metaanalysis. *Am J Obstet Gyn* 2020;3(2):100179. <https://doi.org/10.1016/j.ajogmf.2020.100179>

Due to the physiologic changes during and post-pregnancy, consider the following:

- ▶ Individualize induction and maintenance dosing
- ▶ Monitor symptoms, cravings, and withdrawal closely
- ▶ Assess whether the taste of the film or tablets is tolerable – nausea and changes in sensitivity to tastes or smells during pregnancy may affect medication tolerance
- ▶ As patients progress through pregnancy, changes to their daily dosing may be necessary for 24-hour symptom control – increasing the dose and split dosing; some patients may need dose increases >24 mg/day, which requires additional paperwork that can be a burden to care
- ▶ Dose adjustments may also be needed postpartum – continuation of the same dose used during pregnancy may work for some patients, but others will need doses increased or decreased
- ▶ XR formulations may be beneficial, especially during the postpartum period – taking medication every day can be difficult with a newborn infant at home; when using XR formulations, continue to monitor closely for withdrawal symptoms and cravings – the administered dose may not provide adequate symptom control
- ▶ Recommend continuation of buprenorphine for 12 months postpartum

Children and Adolescents

Dr. Andrea Bonny, from Nationwide Children’s Hospital in Columbus, OH, discussed the use of buprenorphine in pediatrics. Children and adolescents may require induction doses of up to 24 mg/day plus supportive care with adjunctive medications, especially in the age of fentanyl. Buprenorphine has been very safe and effective in her patient population, and published guidelines endorse safety and efficacy in children.¹⁸

Two issues may arise when prescribing buprenorphine for OUD in children and adolescents, as well as young adults who receive health insurance coverage from their parents. First is the issue of consent. Parents may need to provide consent for OUD treatment, and institutional requirements may exist that seem counterproductive to reducing stigma and barriers to treatment. Also, some adolescents and young adults may hesitate to seek treatment. The second issue is medication handling, specifically determining who will be responsible for medication management and storage. This may be a significant challenge for those living in unstable households.

¹⁸ Medication-Assisted Treatment of Adolescents With Opioid Use Disorders. PEDIATRICS. 2016;138(3):e20161893-e20161893. doi:<https://doi.org/10.1542/peds.2016-1893>

People with Criminal/Legal System Involvement

Studies show that within the first two weeks of release from incarceration, a person’s overdose risk may be as high as 129 times that of the general population.^{19,20} Having buprenorphine available in correctional facilities, and immediately upon release, is essential for prevention of OUD recurrence and overdose death due to loss of opioid tolerance.²¹ However, either due to state laws or institutional policies, correctional facilities often do not allow buprenorphine during incarceration and are not obligated to connect the individual to OUD care upon release.

Formulations

Current buprenorphine formulations include sublingual tablets and films, buccal films, transdermal patches, and an XR injection (Appendix A). The availability of additional formulations would support buprenorphine initiation and maintenance treatment for OUD

Table 2: Formulations

Formulation	Current Issue	Meeting Participants’ Recommendation for Change
SL Tablets, Films	Commercially available doses for buprenorphine-only and combination products don’t meet the needs for titration or tapering	<p>Dosage forms < 2 mg</p> <ul style="list-style-type: none"> ▶ 0.25 mg, 0.5 mg tab/film
	<p>“I have to put 2 SL films, or worse, 2 tablets under your tongue right after I woke you up from an overdose, had this very difficult conversation while you’re still looking for whether you got robbed, or what else happened before we got there. And hopefully, you will not throw up from your withdrawal that we induced while I try to get this absorbed.”²²</p>	<p>Dosage forms > 8 mg</p> <ul style="list-style-type: none"> ▶ 16 mg tab/film
	<p>Tablet and film splitting can be inconsistent and unreliable and lacks consistent evidence for stability</p> <ul style="list-style-type: none"> ▶ Tablets crumble ▶ Films disintegrate 	<p>Scoring or marking film strips for cutting</p>

¹⁹ Nyaku, A. Buprenorphine Initiation and Maintenance in Special Populations panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>.

²⁰ Binswanger IA, Stern MF, Deyo RA, et.al. Release from prison--a high risk of death for former inmates. N Engl J Med 2007;356(2):157-65. doi: 10.1056/NEJMs064115. Erratum in: N Engl J Med. 2007 Feb 1;356(5):536.

²¹ Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

²² Carroll G. Buprenorphine Initiation in the Inpatient Setting panel discussion. May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations->

	<p>Taste of the SL and buccal products</p> <ul style="list-style-type: none"> ▶ Taste was listed as a barrier to treatment, including for pregnant people experiencing nausea or changes in taste <p>"It's been 12 years. I can still taste what it tastes like and that's that bad."²³</p>	<p>Improved and additional flavors</p> <p>Studies on how substances (i.e., hard candy) co-administered to counter the medication taste affect buprenorphine absorption²⁴</p>
	<p>Slow dissolution and absorption rates of SL and buccal products</p>	<p>Reformulation for quick dissolution and absorption</p>
Transdermal Patch	<p>Commercially available doses don't meet the needs for induction</p> <p>Limited product and dose options</p> <ul style="list-style-type: none"> ▶ XR products are important for those with greater social vulnerabilities, e.g., incarcerated persons, youth <p>Challenges of injection tolerability</p> <p>"Some of the things around extended-release buprenorphine is related to tolerability of receiving the injection. There's incredible burning sensation with the depot placement. It's a subcutaneous abdominal injection and so that often can cause people to discontinue treatment. They also end up with subcutaneous nodules that persist for months and months. And that too is something that is deterring people for wanting to uptake this even though it's really nice to not have to think about their medications a month at a time."²⁵</p>	<p>Dose > 20 mcg/hour</p> <p>Additional XR formulations, including a 7-day injectable²⁶</p> <p>Improved tolerability</p>

SL = sublingual (tablet, film) TD = transdermal (patch) XR = extended release

²³ Sabora, C, Face & Voices of Recovery. Buprenorphine Initiation and Maintenance in Special Populations panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

²⁴ There are dental concerns related to buprenorphine: <https://www.fda.gov/safety/medical-product-safety-information/buprenorphine-drug-safety-communication-fda-warns-about-dental-problems-buprenorphine-medicines>

²⁵ Nyaku, A. Buprenorphine Initiation and Maintenance in Special Populations panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

²⁶ A 7-day injectable was approved by FDA on May 23, 2023 (<https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option>).

Packaging

Innovations in packaging can facilitate adherence and completion of an induction regimen as well as reduce the risk of unintended exposure, especially in the outpatient setting and for home inductions.

Table 3: Packaging

Packaging	Current Issue	Meeting Participants' Recommendation for Change
Package Sizes	More package sizes to accommodate regimens in different settings (i.e., inpatient use vs. outpatient use) TD patch – “It’s \$150 at a minimum for a box of four, and no pharmacy’s going to cut that box just to give somebody one patch when they can’t give somebody else the other three.” ²⁷	Single TD patch per box rather than 4 per box
Varied Packaging	More packaging options to accommodate various induction, split dosing, and taper regimens and to support safe storage	Blister packs Single dose packaging Starter packs Stability data for alternate packaging
Co-Packaging	Co-packaging of commonly co-administered medications for convenience	Buprenorphine + PrEP* Buprenorphine + Contraceptives
Safe Storage	Using technology to advance safe, secure storage without perpetuating stigma	Fingerprint lock containers

*PrEP refers to preexposure prophylaxis for HIV

²⁷ Smith, MA. Buprenorphine Initiation in the Inpatient Setting panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

Labeling, Coverage, Use

These issues are impacted by the dynamics between research, labeling changes, and clinical and payor policy changes. Specifically, labeling changes may require sponsors to submit an efficacy supplement, requesting approval for a change to an approved product, such as a change to indication, dose, or dose regimen, with support from clinical trial data.²⁸

Table 4: Labeling, Coverage, Use

Current Issue	Meeting Participants' Recommendation for Change
<p>Although the label does not include an age limit, it does not state that buprenorphine is safe and effective for use in children < 16 years old</p> <ul style="list-style-type: none"> ▶ Insurance may require prior authorization or not cover the cost of medication ▶ Additional barriers may include getting approval from ethics, medical, and pharmacy boards 	<p>Evaluate data supporting safety/efficacy indication for < 16 years old</p>
<p>Although the label does not include a dose limit, there is a perception of a maximum dose of 24 mg/day; some people may need higher doses (e.g., pregnant/postpartum, high opioid tolerance)</p> <ul style="list-style-type: none"> ▶ Insurance may require prior authorization or not cover the cost of medication ▶ Additional barriers may include state/local regulations that set dosing caps 	<p>Evaluate data supporting safety/efficacy indication for doses >24mg/day</p> <p>Clarify FDA labeling to note that doses are determined by patient need/response</p>
<p>The currently available TD patch has an indication for pain treatment</p> <ul style="list-style-type: none"> ▶ Insurance may not cover the cost of medication when used for OUD 	<p>Evaluate data supporting TD patch formulation for OUD treatment indication</p>
<p>XR formulations require a 7-day lead-in period with SL buprenorphine prior to initiation</p> <ul style="list-style-type: none"> ▶ Insurance does not cover the cost of medication without the 7-day SL lead-in 	<p>Evaluate data supporting accelerated initiation regimens for XR formulations</p>

TD = transdermal (patch)

XR = extended release

²⁸ Center for Drug Evaluation and Research. New Drug Application (NDA). U.S. Food and Drug Administration. <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>

Research to Support Product Development and Treatment Guidelines

Innovations in OUD and buprenorphine research are ongoing, as presented by Dr. Iván Montoya from the National Institute on Drug Abuse (NIDA). Research is being done in drug and device development, management of buprenorphine side effects, and psychosocial interventions to improve the induction experience and treatment adherence.

However, numerous research gaps persist in the realm of product development and for evidence-based treatment guidelines. Priority areas and opportunities for additional research, as mentioned by speakers and panel members, include:

- ▶ Optimal starting doses for low- and high-dose buprenorphine induction regimens and how quickly to up-titrate as well as what formulations, monitoring, and protocols lead to the most adherence
- ▶ Effectiveness of cross-tapering and overlapping full opioid agonists with buprenorphine during initiation
- ▶ Precipitated withdrawal prevention and management, especially in the setting of polysubstance use
- ▶ Dosing and pharmacokinetic studies for adolescents and during pregnancy, the postpartum period, and while breastfeeding or chestfeeding
- ▶ Telemedicine outcomes, including successful inductions, adherence to induction and maintenance therapy, and patient satisfaction with this method of health care
- ▶ Effective solutions for transitions of care, e.g., warm hand-offs between EMS and the ED, ED to inpatient services, and inpatient to outpatient care
- ▶ How to best retain people in care as their treatment trajectory changes and recovery progresses or relapses

Regulatory Pathways for Drug Development

Multiple pathways exist for drug development. Sponsors are encouraged to reach out to FDA early. Available programs to speed the process of development and review include Fast Track²⁹ and Priority Review.³⁰ Examples of product development that may be suitable for drug development are low-dose transdermal, buccal, and sublingual formulations for OUD treatment.

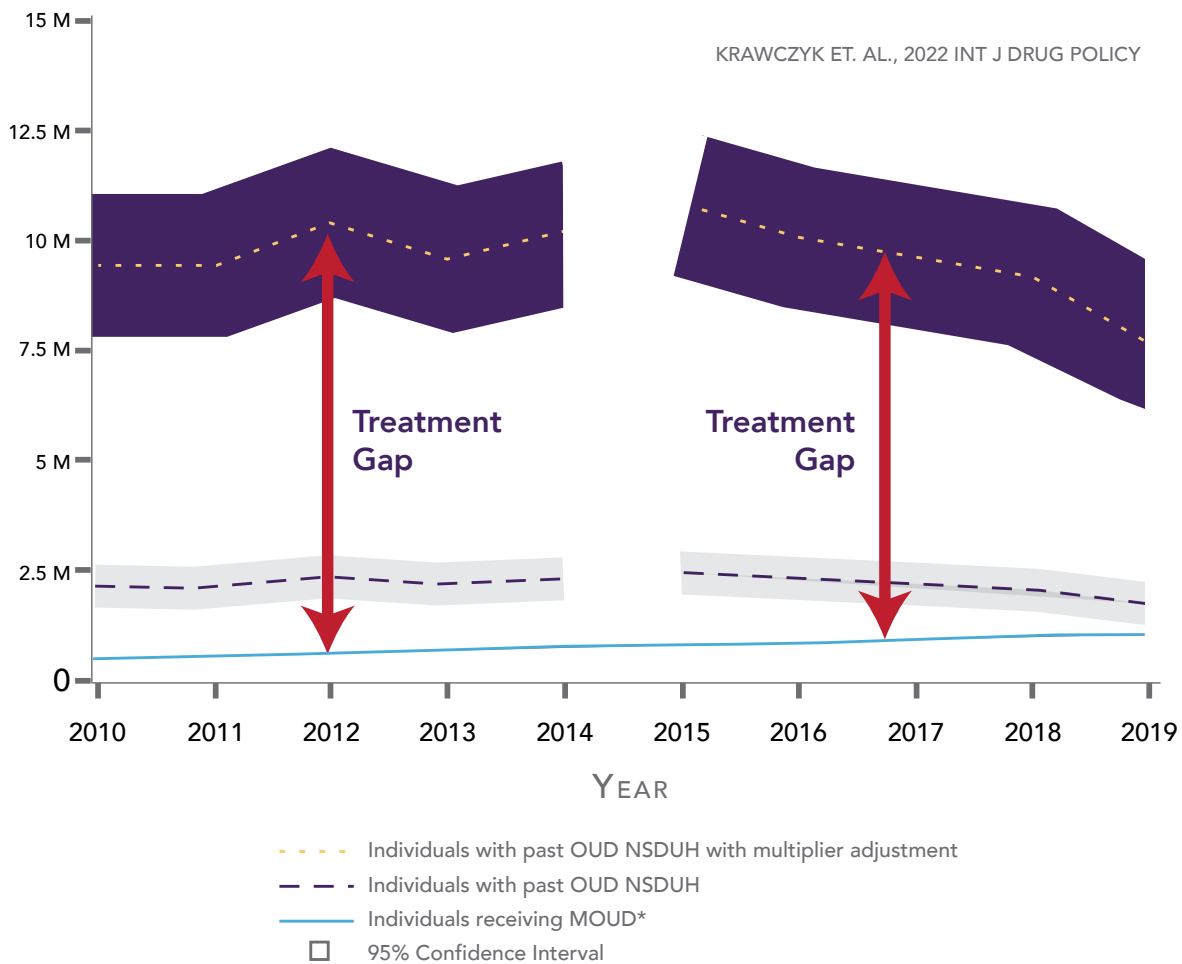
²⁹ Office of the Commissioner. Fast track. U.S. Food and Drug Administration. <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

³⁰ Office of the Commissioner. Fast track. U.S. Food and Drug Administration. <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review>

FIVE | Promoting Access to Buprenorphine in the Real-World Setting

As Dr. Andraka-Christou, from the University of Central Florida School of Global Health Management & Informatics, noted in her presentation, more than 7 million people in 2019 may have past-year OUD, according to one study attempting to account for OUD underestimation. Yet only around 1 million people in 2019 received medication for OUD, representing a potential 86% gap in care (Figure 1).^{31, 32}

FIGURE 1: OUD TREATMENT GAPS³³



³¹ Dunn K. Opportunities to Address Treatment Needs Through Product Development; May 11, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

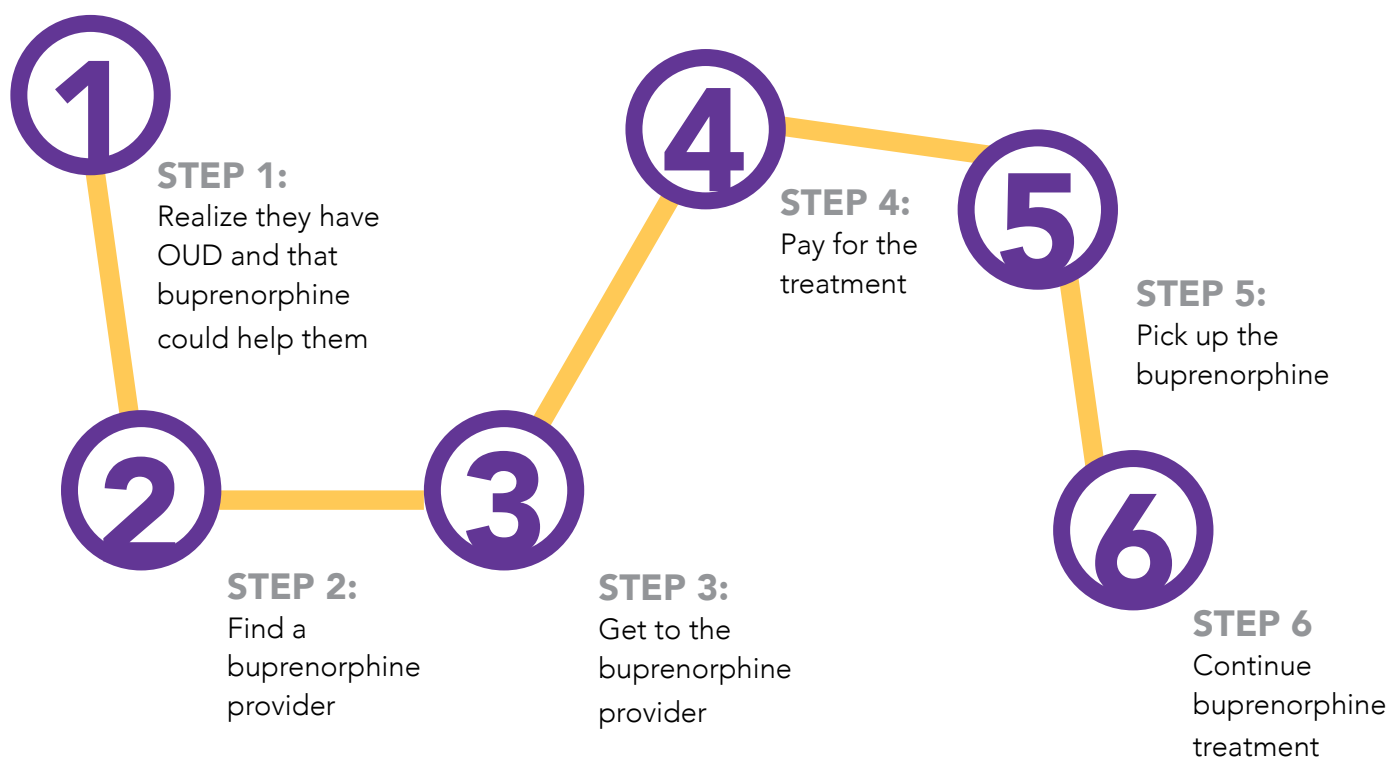
³² This number is higher than the gap identified by the 2021 National Survey of Drug Use and Health (NSDUH) because the cited research attempts to account for underestimation of OUD and uses different sources of data for estimating MOUD.

³³ Krawczyk N, Rivera BD, Jent V, et. al. Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019*. Int J Drug Policy 2022;110:103786. doi: 10.1016/j.drugpo.2022.103786.

Many steps need to be completed in order to access buprenorphine treatment, and barriers occur at all points of the journey (Figure 2, Appendix B). Table 5 below describes barriers existing at each step along with examples from lived experience and potential solutions for removing these barriers. This places a considerable burden on patients and those supporting OUD care.

“Imagine if these barriers existed to lifesaving treatment for other deadly health conditions (e.g., diabetes).” ³⁴

FIGURE 2: STEPS FOR PATIENTS ACCESSING BUPRENORPHINE ³⁵



Improving access to buprenorphine necessitates innovative and nontraditional methods to meet people where they are, including those who may not be able to or may not want to access treatment in a traditional fashion. This requires creativity, ingenuity, and partnering with both community organizations and people in the community.

³⁴ Andraka-Christou, B. Promoting Access to Buprenorphine in the Real-World Setting; May 11, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

³⁵ Ibid.

Barriers and Facilitators of Buprenorphine Access

Table 5: Buprenorphine Access

	Barriers	Meeting Participants' Facilitators and Potential Solution(s) to Address Barriers
Person with OUD	<ul style="list-style-type: none"> ▶ Misconceptions about buprenorphine ▶ Medication tolerability "I've definitely seen folks discontinue just because they get nauseous whenever they taste the flavor."³⁶ ▶ Precipitated withdrawal experience ▶ Transportation ▶ Lack of reliable internet access ▶ Housing instability ▶ Internalized stigma 	<ul style="list-style-type: none"> ▶ Evidence-based education about buprenorphine safety and effectiveness ▶ Person-centered care with shared decision making ▶ Medication formulation changes (see above) ▶ Protocols and standards of care for preventing and treating precipitated withdrawal ▶ Maintain telehealth flexibilities ▶ Improve internet access in rural areas and marginalized communities ▶ Adequately address stigma through practitioner and patient education
General Public	<ul style="list-style-type: none"> ▶ Stigma ▶ A lack of understanding about OUD and treatments 	<ul style="list-style-type: none"> ▶ Framing OUD as a chronic health condition ▶ Public Education and Public Service Announcements (PSAs) ▶ Decriminalization of opioid possession
Health System	<ul style="list-style-type: none"> ▶ Provider hesitancy to prescribe buprenorphine due to inadequate education on substance use disorders and interventions ▶ Complex systems of care that do not facilitate access, nor coordinate services ▶ Misconceptions about buprenorphine ▶ Inconsistencies in ED and first responder initiation of buprenorphine, if initiated at all ▶ Inadequate service transitions and failure to link individuals with OUD to ongoing care ▶ Requirements for treatment engagements – holding patients to a very high standard that is not often seen with other health conditions <ul style="list-style-type: none"> ▶ Conditioning treatment on maintaining a negative drug screen – if a test is positive, care is terminated ▶ Stigma ▶ Poor engagement with carceral settings and the justice system 	<ul style="list-style-type: none"> ▶ Removal of DATA-Waiver (completed facilitator) ▶ Student loan forgiveness and stipends for practitioners willing to treat OUD in underserved areas ▶ Framing OUD as a chronic health condition ▶ Cultural competence of disenfranchised populations ▶ Promote evidence-based and person-centered education on SUDs, pursuant to the CAA, 2023 ▶ Standards of care for ED and emergency responders in their response to overdose and buprenorphine initiation ▶ Warm hand-offs at each transition point in patient care ▶ Promote person-centered care that meets the individual where they are

³⁶ Hutchinson, E. Buprenorphine Initiation and Maintenance in the Community Setting panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

Pharmacy	<ul style="list-style-type: none"> ▶ Limited supplies of buprenorphine or the pharmacy refuses to stock the medication due to misinterpretation of DEA rules ▶ People are unable to fill their buprenorphine prescriptions and are required to go to extreme lengths just to obtain the medication (e.g., find a pharmacy that stocks what they need) ▶ Institutional stigma ▶ Continued perception of the DEA auditing and closing a pharmacy for dispensing too much buprenorphine ▶ Fear of legal action against pharmacies and individual pharmacists ▶ Pharmacies stigmatized as suspicious by distributors who focus solely on the ratio of controlled to non-controlled substances dispensed and dispensing patterns of buprenorphine-only compared to buprenorphine-naloxone combination product 	<ul style="list-style-type: none"> ▶ Clarify a standard of care for stocking buprenorphine ▶ Respect person-centered care – allowing for individualization of regimens using formulations that will work best for the patient ▶ Cultural competence of disenfranchised populations ▶ Create mechanisms for medical practitioners to share buprenorphine treatment plans with the pharmacy ▶ Address and improve mechanisms for monitoring pharmacy stocking and dispensing of buprenorphine for legitimate patient populations including revised distribution calculations ▶ Institute “green flags” that indicate use of medication-assisted therapy (MAT) medications into the NarxCare score of Prescription Drug Monitoring Programs (PDMPs)
Institutional Settings	<ul style="list-style-type: none"> ▶ SUD facilities not readily providing buprenorphine ▶ Correctional facilities not allowing buprenorphine during incarceration and not connecting the individual to OUD care upon release 	<ul style="list-style-type: none"> ▶ Requiring licensed SUD facilities to provide or connect patients to buprenorphine, where clinically indicated ▶ Mandating justice institutions dispense buprenorphine ▶ State laws mandating residential treatment facilities accept people using buprenorphine or methadone to treat OUD
Supply Chain	<ul style="list-style-type: none"> ▶ Drug and formulation availability 	<ul style="list-style-type: none"> ▶ Ensuring that there is enough buprenorphine available in the supply chain
Coverage & Reimbursement	<ul style="list-style-type: none"> ▶ Low reimbursement and resource value units for OUD care, buprenorphine prescribing, maintenance of care, and the stocking and dispensing of buprenorphine ▶ Providers only accepting cash or not accepting Medicaid due to low reimbursement ▶ Complex payor structures that are difficult to navigate by patients and health care providers alike ▶ Prior authorization (PA) <ul style="list-style-type: none"> ● Extensive paperwork to prescribe > 24 mg for pregnant people ● For the XR formulation ● For indefinite maintenance therapy ▶ Inconsistencies in how XR formulations are covered by insurance plans <ul style="list-style-type: none"> ● Sometimes covered as a pharmacy benefit and sometimes covered as a medical benefit, each requiring different processes ▶ Restrictions on coverage that are not evidence-based <ul style="list-style-type: none"> ● Not covering buprenorphine for a person < 16 years old with OUD ● PA for doses outside of a certain range, when no age range exists in the labeling ▶ Treatment duration limits on buprenorphine therapy 	<ul style="list-style-type: none"> ▶ Higher reimbursement for OUD services and medication dispensing ▶ Update billing codes to reflect the level of care being provided ▶ State laws prohibiting prior authorization requirements ▶ State laws mandating coverage of buprenorphine, regardless of formulation or patient population ▶ Federal quality measurements and standards for diagnosing and treating OUD

State and Federal Regulations

- ▶ State restrictions on advanced practice clinician prescribing
 - ▶ State-imposed buprenorphine prescribing barriers
 - ▶ State-mandated frequency of visits, requisite lab tests, and counseling mandates
 - ▶ Wide variations in state regulations and misalignment between state and federal regulations related to buprenorphine prescribing and dispensing
 - ▶ Misalignment with medical institutions, medical boards, and institutional policies
 - ▶ Lack of clarity and hegemony on rules or guidelines surrounding co-prescribing of short-acting full agonist opioids during certain buprenorphine induction protocols for outpatient treatment – barrier to low-dose outpatient inductions
 - ▶ High risk for loss of follow-up after rapid buprenorphine induction by EMS outside of the health care setting due to an inability to provide a short-term medication supply and access to treatment practitioners for the person to continue buprenorphine
 - ▶ Greater restrictions on buprenorphine and buprenorphine/naloxone due to being Schedule III medications
 - ▶ Stigma – within state and federal agencies and as part of policymaking
 - ▶ Expand the independence of advanced practice clinicians (nurse practitioners, physician assistants, clinical pharmacists)
 - ▶ Eliminate state-imposed prescribing barriers
 - ▶ Eliminate visit mandates that prevent buprenorphine initiation
 - ▶ Clarify the regulatory standards of care for OUD
 - ▶ Expand the use of short-acting, pharmaceutical doses of opioid agonists during low-dose inductions in order to a) manage withdrawal symptoms, and b) prevent the use of illicit opioid agonists to manage these symptoms
 - ▶ Provisions for EMS to provide a 72-hour supply of medication to individuals undergoing rapid buprenorphine induction in the field
 - ▶ Reduce or eliminate the controlled substance status of buprenorphine and buprenorphine/naloxone formulations
 - ▶ Framing OUD as a chronic health condition
 - ▶ Cultural competence of persons writing and enacting legislation regarding disenfranchised populations
 - ▶ Expand community education on the benefits of treatment for OUD
-

With regard to state-mandated services, which are important to offer: *“but when you mandate them for an entire population of patients, and you hold treatment hostage... we know that to be unhelpful and we know that to be a barrier to treatment.”*³⁷

Despite the barriers detailed above, advances in health services provision continue. Innovative practices facilitating access to buprenorphine include:

- ▶ **Pharmacies as a bridge to care** – physician-delegated induction and maintenance care provided by pharmacists. Results from a pilot study conducted in Rhode Island showed that 89% of people receiving pharmacy-based care continued to attend visits at 1 month compared to 17% receiving usual care.³⁸
- ▶ **EMS** – administration of high-dose buprenorphine by EMS personnel following an overdose. Individuals are then connected to substance use services for ongoing care.³⁹
- ▶ **Mobile treatment vans** – health care professionals travel to areas of need. This is especially promising for providing care in rural and underserved areas.

³⁷ Clear B. Bicycle Health. Future Directions; May 11, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>

³⁸ Green TC, Serafini R, Clark SA, et al. Physician-delegated unobserved induction with buprenorphine in pharmacies. N Engl J Med 2023; 388:185-186.

³⁹ Carroll G, Solomon KT, Heil J, et al. Impact of administering buprenorphine to overdose survivors using emergency medical services. Ann Emerg Med. 2023;81:165-175.

SIX | Conclusion/Future Directions

Buprenorphine is a safe and effective medication that is underused for the treatment of OUD. Evidence supports the use of buprenorphine, and there is a need to optimize access to this medication for the people who will benefit. We cannot solve the current overdose crisis by relying on existing strategies. We need new ideas, innovative public health interventions, and renewed investment in research and product development to spur progress. *“If it’s easier to get fentanyl on the illicit market in your neighborhood than Suboxone, you’re doing something wrong.”⁴⁰*

Oftentimes, rules, regulations, and policies in our own states and health systems run counter to patient-centered care, create barriers to accessing treatment for OUD, and perpetuate stigma. In 2023, a person can walk into any ED with chest pain and receive a certain standard of care without fear of being turned away. The same should be true for the evaluation and treatment of acute symptoms associated with any chronic health condition. However, this is not the case for OUD, overdose management, and buprenorphine initiation. Quality of care is highly variable, and in some institutions, it is not provided to evidence-based standards. A complex network of policies and regulations, insufficient training and experience among health professionals, a lack of insurance coverage, and stigma all contribute to patients not being able to access acute and ongoing care and life-saving medication.







Buprenorphine saves lives. Elimination of the DATA-Waiver requirement is a first step in facilitating buprenorphine access. Speakers at the May 2023 meeting emphasized that now is the time to build on that momentum and replace policies and regulations impeding access with those that support evidence-based, non-stigmatized support for the treatment of OUD.

⁴⁰ Sabora C. Face & Voices of Recovery. Buprenorphine Initiation and Maintenance in Special Populations panel discussion; May 10, 2023. <https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care>



Appendices

BUPRENORPHINE MONOPRODUCT

	Brand Name	Formulation	Strengths	Frequency	Label Indications
	Generic Buprenorphine (GENERIC)	SL tablet	(bup/nal): 2mg/0.5mg, 8mg/2mg	Daily to multiple times per day	Opioid Dependence
	Belbuca Buprenorphine (GENERIC)	Buccal Film	75mcg, 150mcg, 300mcg, 450mcg, 600mcg, 750mcg, 900mcg	Daily to multiple times per day	Pain
	Butrans Buprenorphine (GENERIC)	Transdermal	5mcg/hr, 7.5mcg/hr, 10mg/hr, 15mcg/ hr, 20mg/hr	Every 7 days	Pain
	Buprenex Buprenorphine (GENERIC)	Injection (IV, IM)	0.3 mg/ml	Multiple times per day	Pain
	Sublocade Buprenorphine XR	Subcutaneous injection	100mg/0.5ml syringe, 300mg/1.5mg syringe	Every 26-30 days	Moderate-Severe OUD
	Brixadi (NDA) Buprenorphine XR	Subcutaneous injection	Weekly: 8mg, 16mg, 24mg, 32mg Monthly: 64mg, 96mg, 128mg	Weekly or monthly	Moderate-Severe OUD

INFORMATION FROM PRODUCT PACKAGE INSERTS AND ADAPTED FROM TABLE IN

[HTTPS://WWW.ASAM.ORG/QUALITY-CARE/CLINICAL-GUIDELINES/NATIONAL-PRACTICE-GUIDELINE](https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline)

Sublingual (SL) – tablet or film strip that dissolves under the tongue

Buccal – tablet or film strip that dissolves between the cheek and gums





Transdermal (TD) – patch that delivers medicine through the skin

Subcutaneous injection (SC) – medication given using a short needle into the tissue just under the skin

Intravenous injection (IV) – medication given into a vein

Intramuscular injection (IM) – medication given as a shot into the muscle

BUPRENORPHINE/NALOXONE COMBINATION PRODUCT

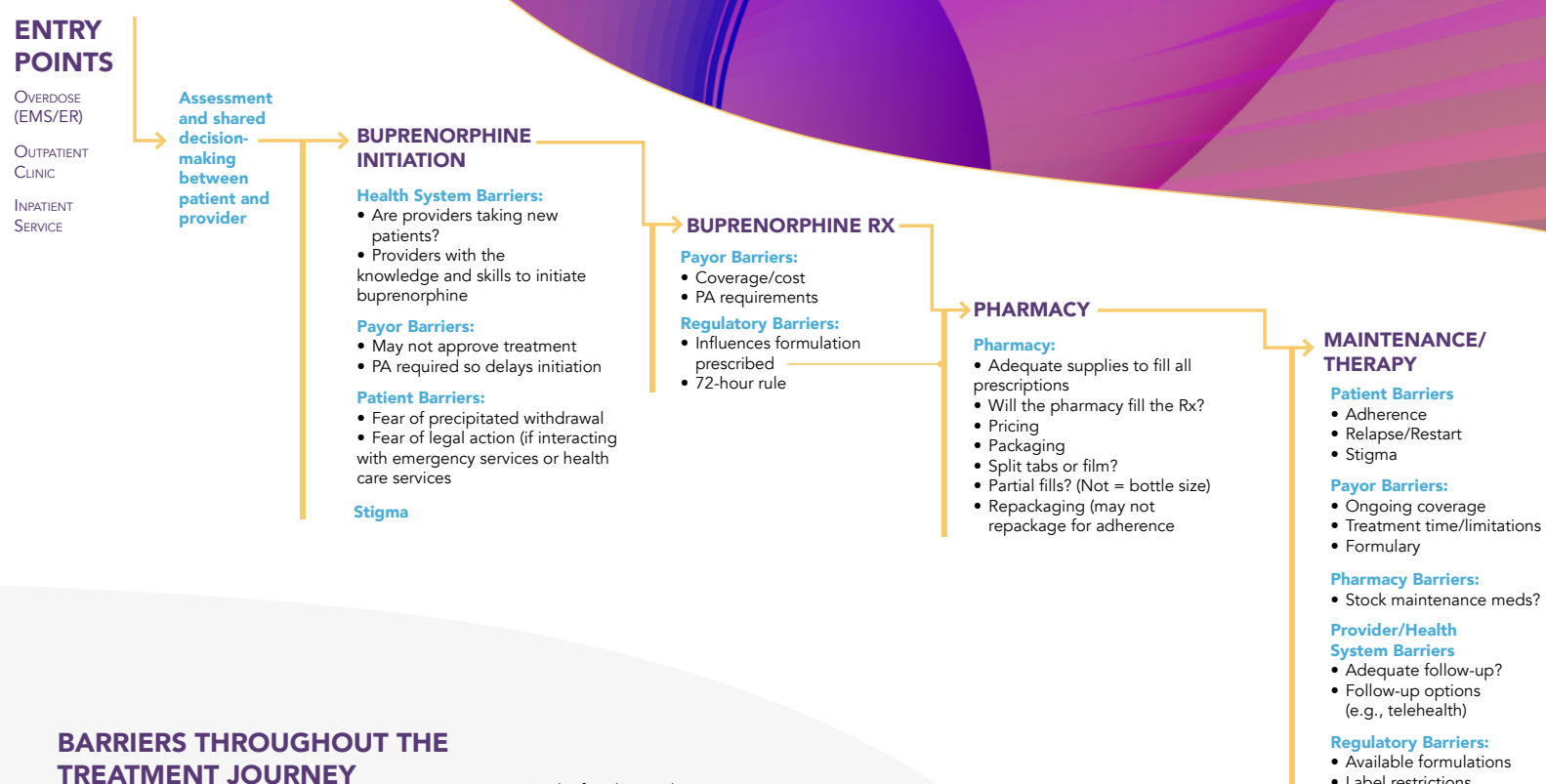
	Brand Name	Formulation	Strengths	Frequency	Label Indications
	Generic Buprenorphine & naloxone (GENERIC)	SL tablet	(bup/nal): 2mg/0.5mg, 8mg/2mg	Daily to multiple times per day	Opioid Dependence
	Generic Buprenorphine & naloxone (GENERIC)	Buccal/SL Film	(bup/nal): 2mg/0.5mg, 4mg/1mg, 8mg/2mg, 12mg/3mg	Daily to multiple times per day	Opioid Dependence
	Zubsolv Buprenorphine & naloxone	SL tablet	(bup/nal): 0.7mg/0.18mg, 1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg	Daily to multiple times per day	Opioid Dependence
	Suboxone Buprenorphine & naloxone (GENERIC)	Buccal/SL Film	(bup/nal): 2mg/0.5mg, 4mg/1mg, 8mg/2mg, 12mg/3mg	Daily to multiple times per day	Opioid Dependence

INFORMATION FROM PRODUCT PACKAGE INSERTS AND ADAPTED FROM TABLE IN

[HTTPS://WWW.ASAM.ORG/QUALITY-CARE/CLINICAL-GUIDELINES/NATIONAL-PRACTICE-GUIDELINE](https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline)

Sublingual (SL) – tablet or film strip that dissolves under the tongue

Buccal – tablet or film strip that dissolves between the cheek and gums



BARRIERS THROUGHOUT THE TREATMENT JOURNEY

- Accessibility (to providers, clinics, treatment, inventory)
- Disconnect between clinical guidelines, state/local regulations, and federal regulations
- Lack of coordinated support services
- Lack of understanding about buprenorphine
- Paraphernalia laws
- Stigma
- Systemic racism/bias



Meeting Agenda



DAY 1

1p.m. Welcome

PRESENTER:

SUSAN C. WINCKLER, RPH, ESQ, Chief Executive Officer, Reagan-Udall Foundation for the FDA

1:05 p.m. Opening Remarks on Current Regulatory Landscape

PRESENTER:

YNGVILD K. OLSEN, MD, MPH, Substance Abuse and Mental Health Services Administration

MARTA SOKOLOWSKA, PHD, U.S. Food and Drug Administration

1:25 p.m. Session 1: Overview of Clinical Guidelines

PRESENTER:

MELISSA WEIMER, DO, MCR, Yale University, American Society of Addiction Medicine

1:45 p.m. Session 2: Buprenorphine Initiation in the Inpatient Setting

PRESENTER:

AMER RAHEEMULLAH, MD, Stanford University

PANELISTS:

DIONNA BERKHOLDER, North Colorado Health Alliance

GERARD CARROLL, MD, FAAEM, EMT-P, Cooper University Health Care

GAIL D'ONOFRIO, MD, MS, Yale University

MICHAEL A. SMITH, PHARMD, BCPS, University of Michigan Health

2:50 p.m. BREAK

3:00 p.m. Session 3: Buprenorphine Initiation and Maintenance in the Community Setting

PRESENTER:

MICHELLE LOFWALL, MD, DFAPA, DFASAM, University of Kentucky

PANELISTS:

JEFFREY BRATBERG, PHARMD, FAPHA, University of Rhode Island

JEREMY DUBIN, DO, FASAM, Front Range Clinic

ELIZA HUTCHINSON, MD, Packard Health

JADE WAITS, Boulder Care

4:00 p.m. Session 4: Buprenorphine Initiation and Maintenance in Special Populations

PANELISTS:

ANDREA BONNY, MD, Nationwide Children's

CAITLIN MARTIN, MD, MPH, Virginia Commonwealth University

AMESIKA NYAKU, MD, MS, Rutgers University

CHAD SABORA, MS, JD, Faces & Voices of Recovery

4:45 p.m. Adjournment



DAY 2

1 p.m. Opening Remarks and Recap of Day 1

SPEAKER:

SUSAN C. WINCKLER, RPH, ESQ, Chief Executive Officer, Reagan-Udall Foundation for the FDA

1:05 p.m. Session 5: Promoting Access to Buprenorphine in the Real-World Setting

PRESENTER:

BARBARA ANDRAKA-CHRISTOU, PHD, JD, University of Central Florida

PANELISTS:

DWAYNE DEAN, RCPF, CPRS, RPS, Peer Recovery Training and Support Services

TOM MENIGHAN, MBA, SCD, FAPHA, Catizone, Luce & Menighan

MATTHEW STRAIT, MS, Drug Enforcement Administration

ROBERT BAILLIEU, MD, MPH, FAAFP, Substance Abuse and Mental Health Services Administration

3:20 p.m. BREAK

3:30 p.m. Session 7: Future Directions

SPEAKERS:

BRIAN CLEAR, MD, Bicycle Health

MICHELLE LOFWALL, MD, DFAPA, DFASAM, University of Kentucky

YNGVILD K. OLSEN, MD, MPH, Substance Abuse and Mental Health Services Administration

MARTA SOKOLOWSKA, PHD, U.S. Food and Drug Administration

NORA VOLKOW, MD, National Institute on Drug Abuse

4:30 p.m. Adjournment

The logo features the text "REAGAN-UDALL" in a white, sans-serif font, arched over a white, curved line. Below this line, the word "FOUNDATION" is written in a larger, bold, white, sans-serif font. Underneath "FOUNDATION", the text "for the Food and Drug Administration" is written in a smaller, white, sans-serif font.

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