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2024 ANNUAL CONVENTION

It’s Okay to Dispense: Applying NCPA and NABP’s PhARM-OUD Guidelines to Improve Access to Buprenorphine in your Pharmacy

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speakers

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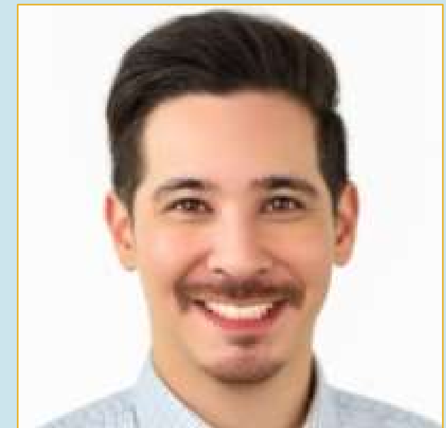

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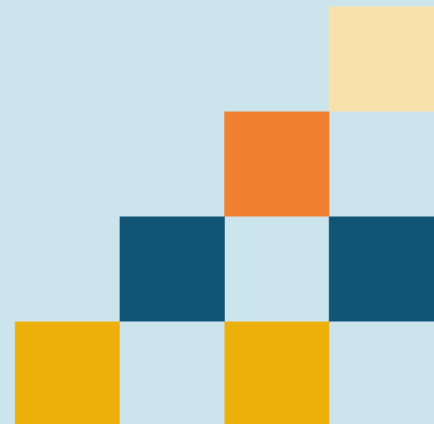

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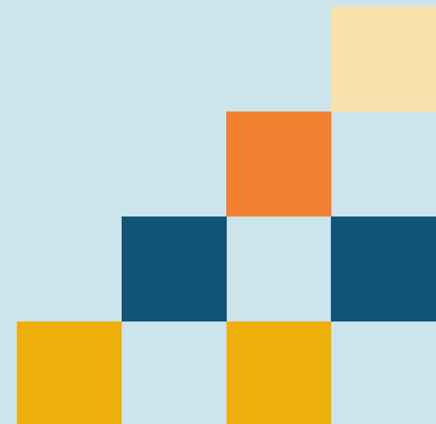
Pharmacist and Technician Learning Objectives

1. Summarize current barriers to buprenorphine access in community pharmacies.
2. Review the PhARM-OUD Guidelines and the objectives of the guidance document.
3. Discuss common practice scenarios where the PhARM-OUD guidelines can be applied.



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About FORE

Founded in 2018, the **Foundation for Opioid Response Efforts (FORE)** is a 501(c)(3) private, national, grantmaking foundation focused on one urgent public health emergency – the opioid and overdose crisis.

Vision

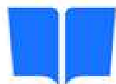
To inspire and accelerate action to end the opioid crisis

Mission

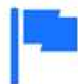
To convene and support partners advancing patient-centered, **evidence-based solutions** addressing the opioid crisis

Focus

With **patients at the center**, our focus includes:


Professional education

Payer & Provider strategies


Policy initiatives

Public awareness

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FORE Grantee Portfolio

Grants to date: **107**

Amount awarded: **$43.4M**

See all FORE Grantees on our website::
https://www.ForeFdn.org/Our-Grantees/

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FORE's Grantmaking Programs

FORE grantmaking programs to date have focused on:

- Access to treatment for vulnerable populations
- Responding to the COVID-19 pandemic through recovery services and evaluation of regulatory policies
- Innovation challenge to tackle some of the opioid crisis' most intractable problems (such as stigma, as well as generating more timely and actionable data)
- Family- & community-based prevention for children and families at high risk
- Supporting Community-Based Organizations responding to the overdose crisis
- Fellowship and Training programs to prepare early career professionals to serve individuals and families impacted by the opioid crisis

FORE Resources

Through issue and policy briefs, webinars, and articles, we are contributing current vital information to inform communities, providers, and policymakers on best practices and solutions.

See all FORE Grantees on our website:
https://www.ForeFdn.org/Our-Grantees/

Grantees Improving Access to MOUD in Pharmacies

HOWARD UNIVERSITY

UK University of Kentucky®

THE UNIVERSITY OF RHODE ISLAND

USC

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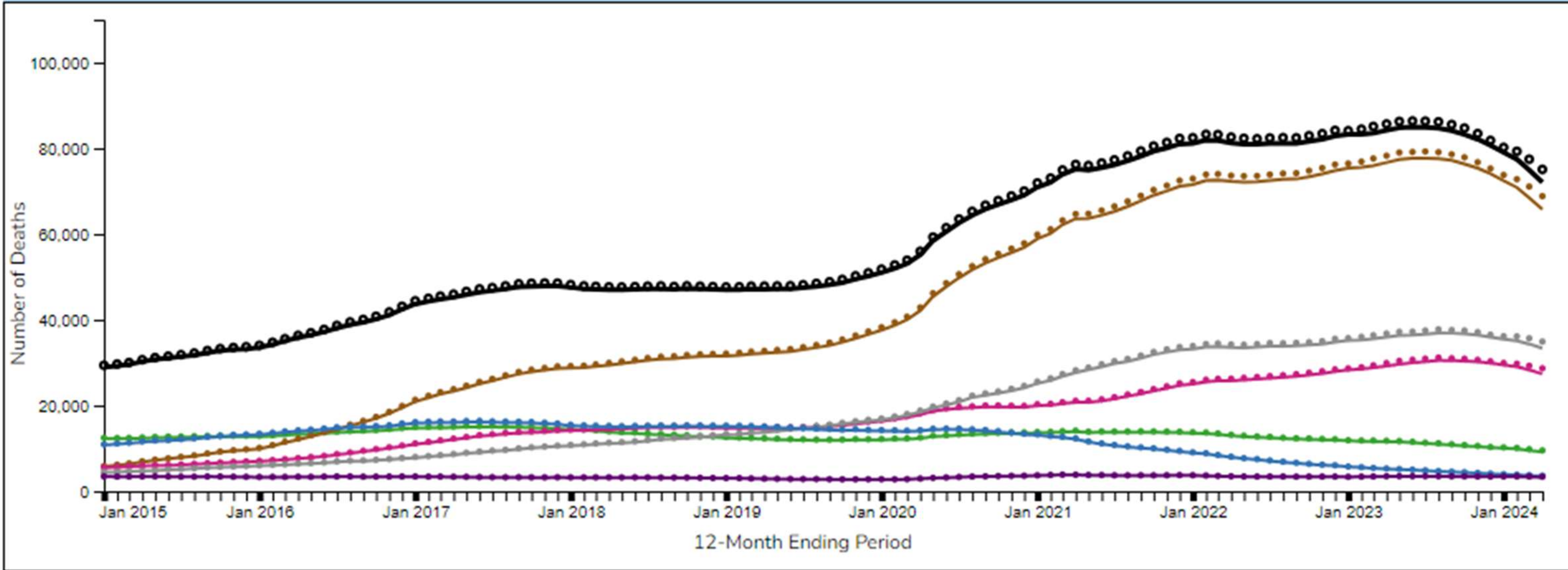
RS0

Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Legend for Drug or Drug Class

Cocaine (T40.5)
Heroin (T40.1)
Methadone (T40.3)
Natural & semi-synthetic opioids (T40.2)
Opioids (T40.0-T40.4,T40.6)
Psychostimulants with abuse potential (T43.6)
Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

O Predicted Value

Provisional Drug Overdose Death Counts. National Vital Statistics System. Centers for Disease Control and Prevention. Accessed September 2024.

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Slide 11

RS0 Suggest making the image bigger to fit the slide

Rebecca Snead, 2024-10-16T11:39:45.274

Pandemic Telehealth Flexibilities for Buprenorphine Treatment:

- Activated provisions of the Ryan Haight Online Pharmacy Act that allowed providers to initiate a controlled substance prescription without an in-person visit.
- Allows buprenorphine to be initiated and monitored via audio-only visit.

Mainstreaming Addiction Treatment Act, 2022:

- Eliminates the requirement for prescribers to obtain a separate DEA registration prior to prescribing buprenorphine.
- Any DEA registered prescriber can issue a prescription for buprenorphine.

Modernizing Addiction Treatment Act:

- Will broaden the ability of prescribers outside of the opioid treatment program setting to prescribe methadone for the treatment of OUD
- Expected to expand methadone availability from 49% to 86% of US census tracts.

Joudrey PJ, Halpern D, Lin Q, Paykin S, Mair C, Kolak M. Methadone prescribing by addiction specialists likely to leave communities without available methadone treatment. *Health Aff Sch*. 2023;1(5):qxad061. doi:10.1093/haschl/qxad061

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	Methadone	Naltrexone	Buprenorphine
	Medications for Opioid Use Disorder (MOUD)		
Mechanism	Opioid Full Agonist	Opioid Antagonist	Opioid Partial Agonist
Metabolism	Primarily CYP-3A4 (+ Others) t ½: 8 to 59 Hours	CYP-2D6	CYP-3A4 SL t ½: 37 Hours
CS	CS-2	Non-CS	CS-3
Requirements	SAMHSA OTP Certification Provider State License & DEA Registration OTP: Office Treatment Program (No Rx's Written)	Only a Provider State License IM Administered in Provider Office	Provider State License & DEA Registration OBOT: Office-Based Opioid Treatment (Rx's & Community Pharmacies)
Uses	OUD & Pain	OUD (+ AUD)	OUD & Pain
Dosage Forms	• Oral Concentrate Drops • Oral Solution • Oral Dispersible Tablet • Oral Tablet	• IM ER Monthly Injection • PO 50mg Tablet (Daily, etc.) • PO LDN FDA Orphan Drug for CRPS	• OUD (mg): Sublingual tablets/films (+/- naloxone) & Monthly/Weekly injectables • Pain (mcg): Buccal strips & transdermal patches
Useful Information	• PDMP State Reporting Inconsistency • ECG Monitoring • Monitor Respiratory Concerns	• Patient retention (Observable concern) • Initiation requires at least one week of opioid abstinence	• Opioid μ receptor high affinity • Respiratory Depression "Ceiling effect" • MAT Act: Eliminated "X-Waiver" • MATE Act: Requires Universal 8-hour SUD Training

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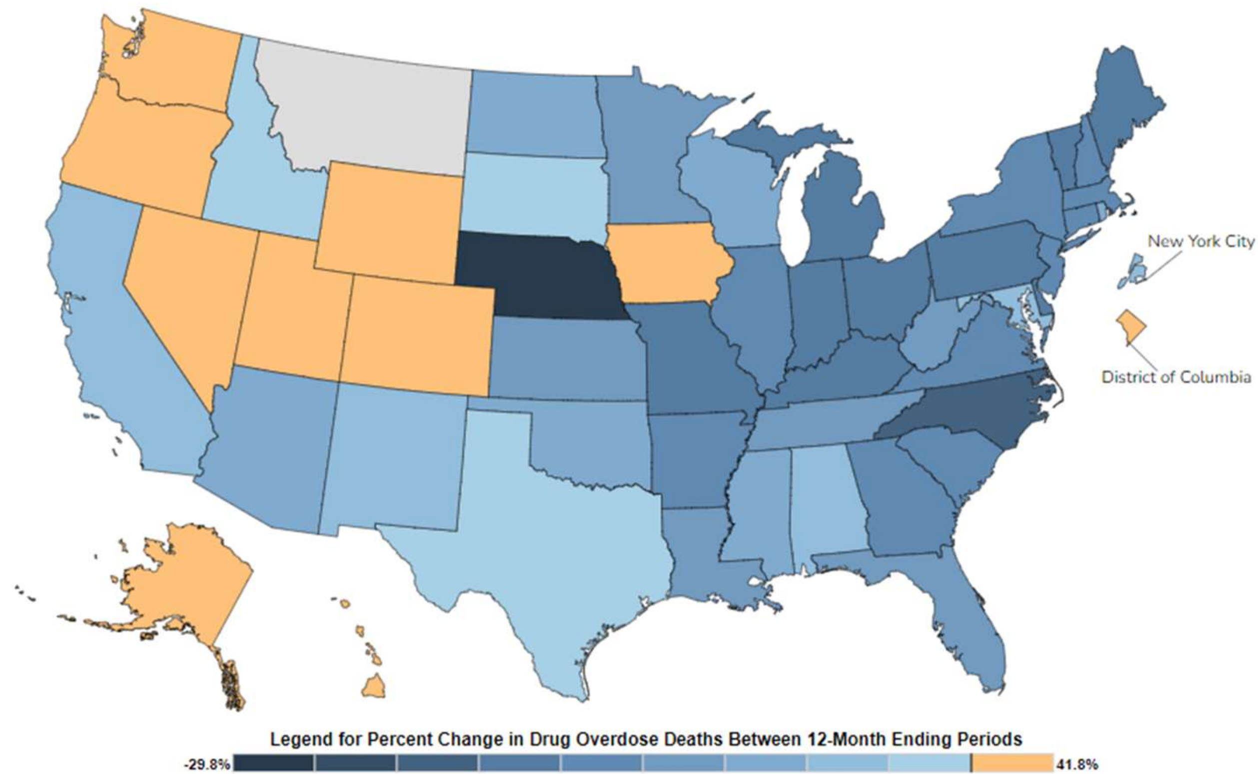
Clinical Pharmacology Online Database.

Evolving crisis or evolving data?



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Provisional Drug Overdose Death Counts. National Vital Statistics System. Centers for Disease Control and Prevention. Accessed September 2024.

Buprenorphine monoproduct is safe.

- Only 2.6% of opioid overdose deaths involve buprenorphine
- Naloxone's affinity for the μ opioid receptor is 10X lower than that of buprenorphine:
  - Naloxone is less effective in the presence of buprenorphine

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Injunctive Relief and Buprenorphine

D. For purposes of the Injunctive Relief Terms, "*Red Flags*" are defined as follows:

1. **Ordering ratio of Highly Diverted Controlled Substances to non-Controlled Substances:** Analyze the ratio of the order volume of all Highly Diverted Controlled Substances to the order volume of all non-Controlled Substances to identify Customers with significant rates of

Dear DEA Registrant,

In 2022, 6.1 million people in the United States had an opioid use disorder (OUD). Among them, only 18.3% received medication-assisted treatment. The removal of the Drug Addiction Treatment Act of 2000 "x-waiver" in December 2022 eliminated a significant barrier to treatment for OUD, dramatically increasing the number of medical professionals who can prescribe buprenorphine from the previously eligible 130,000 prescribers.

As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay. DEA has posted a guidance document on its portal related to this issue: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf.

(*i.e.*, buprenorphine without naloxone)

highly-abused formulations of oxycodone. On an annual basis (or as otherwise necessary), high-risk formulations of Highly Diverted Controlled Substances may be added, removed, or revised based on the Injunctive Relief Distributors' assessment and regulatory guidance.

Anne M. Milgram
Administrator,
Drug Enforcement Administration
Department of Justice

Rachel L. Levine, M.D.
ADM, USPHS
Assistant Secretary for Health
Department of Health and Human

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Department of Health and Human Services

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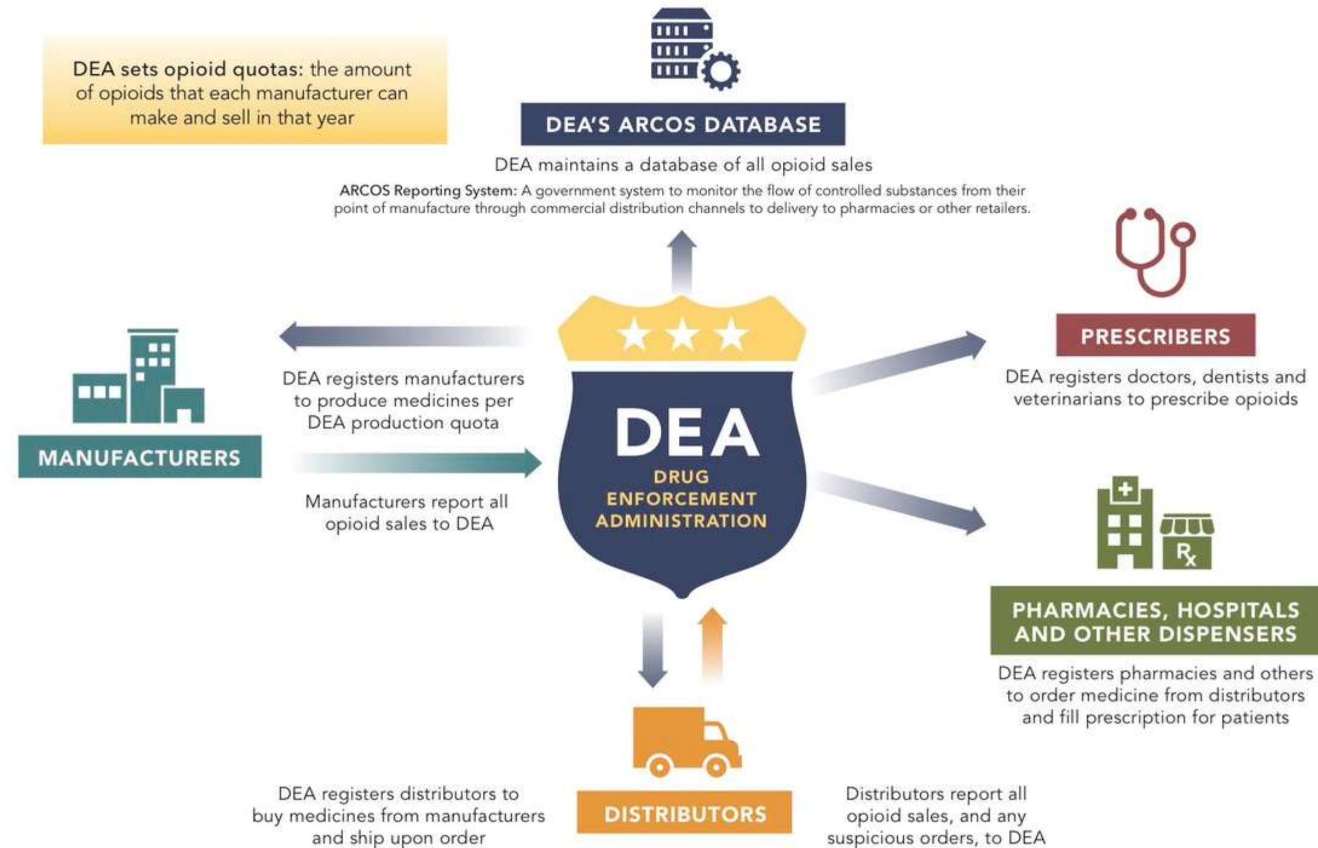
DEA, the primary regulator of controlled substances, oversees every part of the supply chain



Healthcare Distribution Alliance. Available at: https://www.hda.org/getmedia/47b10bf8-5af9-4ef9-81ca-dda2496246f5/HDA-Infographic-on-Controlled-Substances-Regulation.pdf. 2017.

“Nobody will sell insulin needles unless you have an injectable prescription at that pharmacy, and there's no law against it. The problem is that at the first pharmacy that does it, there will be people going to get needles and a 17-year old girl will be ringing up all these people and you know and so nobody wants that business. I feel like how would the community [sic], what would the community perception be?”

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Slide 18

RS0 I don't know how this fits, I am sure it will be explained but it sems out of place.   Can we provide attribution? ...if if anonymous is it a pharmacy owner saying this?

Rebecca Snead, 2024-10-16T11:51:38.589

Payment Models
Maintenance Pharmacotherapy
Buprenorphine Monotherapy
Prescription Drug Monitoring Programs
Stigma and Compassionate Care
Provider Communication
Early Refills
Red Flags
Buprenorphine Wholesale
Telehealth
Counseling and Point of Care
Employer Oversight
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The PhARM-OUD Guidelines

Elicitation Study

14 vignettes representing barriers to buprenorphine supply

Delphi Round 1

Expert Panel (N=22):

- Regulatory Affairs (n=3)
- Drug Enforcement (n=3)
- Drug Policy (n=4)
- Pharmaceutical Distribution (n=3)
- Psychiatric Pharmacist (n=4)
- Addiction Psychiatry (n=4)
- Pharmacy Technician: (n=1)

Recommendations from panelists distilled into 79 unique statements

Delphi Round 2

63 statements reached consensus

16 statements modified with panelist feedback

Delphi Round 3

13 statements reached consensus

3 statements modified with panelist feedback

Delphi Round 4

1 additional statement reached consensus

Draft Guidance to Pharmacists

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The Pharmacy Access to Resources and Medication for Opioid Use Disorder (PhARM-OUD) Guideline outlines steps pharmacists can take to ease access to buprenorphine

- Maintain a sufficient supply of buprenorphine
- Recognize that opioid use disorder is a chronic disease with adverse outcomes that can be prevented by treatment
- Use prescription drug monitoring programs to supplement rather than substitute for clinical judgment when making dispensing decisions
- Don't assume that because a person had to travel to fill a prescription or is paying cash that the person is misusing or diverting buprenorphine
- Review telehealth prescriptions and prescriptions from in-person encounters with the same criteria
- Recognize reasons providers may elect to prescribe buprenorphine monotherapy
- Consider dispensing a minimal partial quantity of the prescription if there is a delay in communicating with prescribers
- Treat people living with OUD with empathy, compassion, and support

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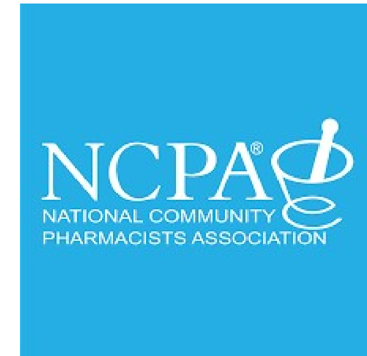

Slide 21

RS0 NABP's logo?

Rebecca Snead, 2024-10-16T11:55:27.339

Threshold Change Request

USER GUIDE

"Although purchase thresholds may periodically impact a pharmacy's ability to order buprenorphine, they should not be used as a reason to deny prescriptions."

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....

(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. ______

To require the Administrator of the Drug Enforcement Administration to temporarily exempt buprenorphine from the Suspicious Orders Report System for the remainder of the opioid public health emergency.

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“Pharmacy policies defined by numerical thresholds, such as distance to prescriber, distance to home or days’ supply, should not be used to guide clinical decision making. Numerical thresholds should not be used to deny buprenorphine prescriptions.”

“I only fill controlled prescriptions for patients who live in the same zip code”

- Rural patients live a median distance of 46 miles from their buprenorphine providers.
- Urban patients live a median distance of 33 miles from their buprenorphine provider

“When are they going to taper off of this? They’ve been on it for years”

- There is no known maximum duration of buprenorphine therapy.
- Mortality risk increases by nine times in the first 14 days off of treatment

“This patient only got fourteen days in their last prescription. I’m not giving them 30 this time.”

- Frequent trips to the pharmacy make care less convenient and decrease the chances that a patient will remain adherent to treatment.

Saloner B, Landis RK, Jayakrishnan R, Stein BD, Barry CL. A Bridge Too Far? Distance to Waivered Physicians and Utilization of Buprenorphine Treatment for Opioid Use Disorder in West Virginia Medicaid. *Subst Abuse*. 2022;43(1):682-690. doi:10.1080/08897077.2021.1986882

Cornish R, Macleod J, Strang J, Vickerman P, Hickman M. Risk of death during and after opiate substitution treatment in primary care: prospective observational study in UK General Practice Research Database. *BMJ*. 2010;341:c5475. doi:10.1136/bmj.c5475

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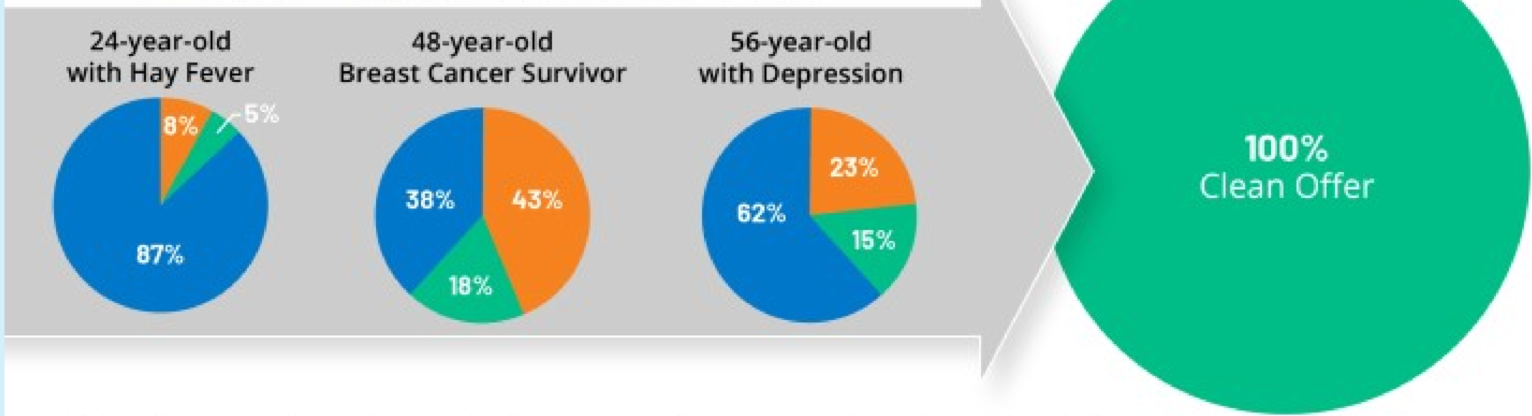
"I'm just not comfortable letting them pay cash when I know they have insurance."



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“I keep seeing prescriptions for ridiculously high doses of buprenorphine. The labeling says no more than 16 mg/day.”

- Buprenorphine labeling was developed before widespread fentanyl use.
- Emerging evidence and recommendations from ASAM support up to 32 mg/day.

Journal of Addiction Medicine
The Official Journal of the American Society of Addiction Medicine

Clinical Considerations

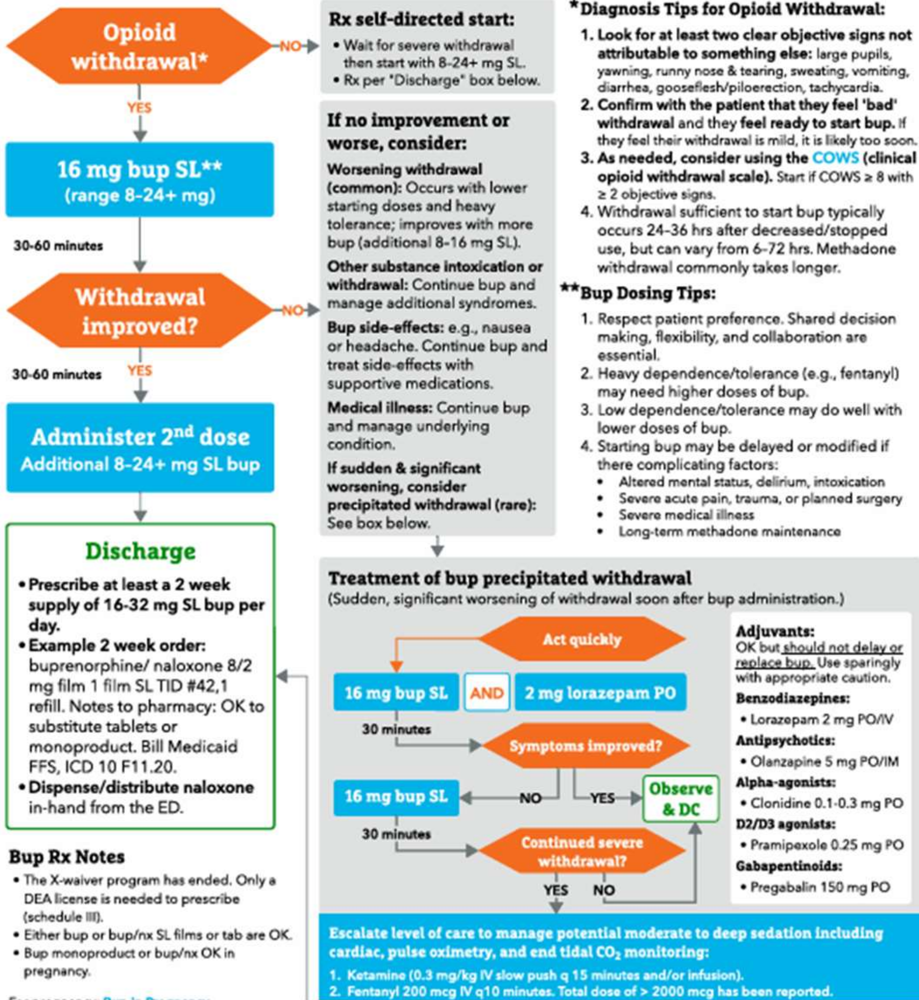
- For mild to moderate OWS during buprenorphine initiation, treatment with buprenorphine >24 mg SL on day 1 may be considered for patients with clinically apparent high opioid tolerance.
- For mild to moderate OWS during buprenorphine initiation, alpha-2 agonists and other symptom-targeted treatments may be helpful in addition to more buprenorphine.
- For intractable cases of OWS, treatment escalation involves transition to an ED or hospital for additional buprenorphine and consideration of high-affinity FAO, benzodiazepines, ketamine, or dexmedetomidine.

News Release

Higher buprenorphine doses associated with improved retention in treatment for opioid use disorder

NIH-funded study suggests need to reevaluate opioid addiction treatment recommendations in the era of fentanyl

Weimer MB, Herring AA, Kawasaki SS, Meyer M, Kleykamp BA, Ramsey KS. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. *J Addict Med*. 2023;17(6):632. doi:10.1097/ADM.0000000000001202



Blueprint for Hospital Opioid Use Disorder Treatment. Bridge to Treatment. Accessed July 18, 2024. https://bridgetotreatment.org/resource/blueprint-for-hospital-opioid-use-disorder-treatment/

"That's something you work up to though, right? I see people start at higher doses and that's a big red flag for me."

Discharge

- **Prescribe at least a 2 week supply of 16-32 mg SL bup per day.**
- **Example 2 week order:** buprenorphine/ naloxone 8/2 mg film 1 film SL TID #42,1 refill. Notes to pharmacy: OK to substitute tablets or monoproduct. Bill Medicaid FFS, ICD 10 F11.20.
- **Dispense/distribute naloxone** in-hand from the ED.

Patient Case

"A 24 year old male with opioid use disorder comes into the pharmacy to fill his 30 day supply prescription of buprenorphine 8 mg tablets by mouth once daily. When the pharmacist goes into his patient profile, they identify that the last time he received the prescription was 17 days ago and he should have a 9 days worth of the medication available. The pharmacist informs the patient of this, and he responds to the pharmacist saying he does not have any tablets left and that his doctor told him he was going to increase his prescription to 8 mg by mouth twice daily. The pharmacist double-checks the prescription, and it says 8 mg tablet by mouth once daily."

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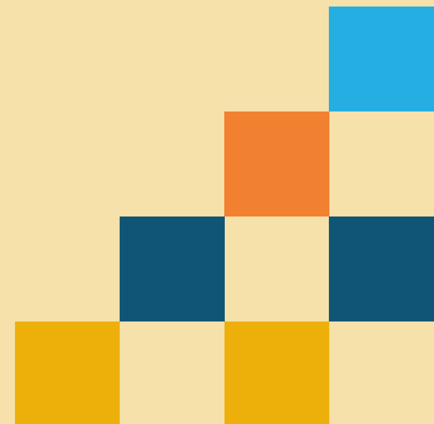
Patient Case:

1. What information do you need to make a dispensing decision?
2. How would you start your discussion with the patient's prescriber?
3. What are the risks of declining to dispense buprenorphine to the patient?



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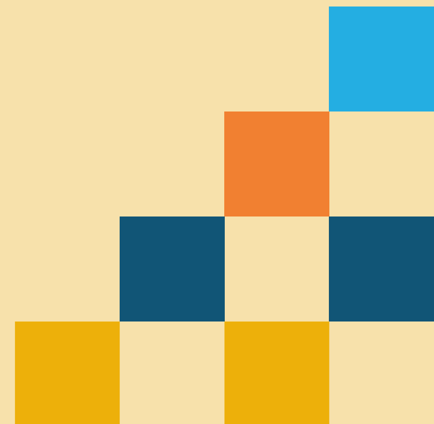
Patient Case

Your pharmacy receives an electronic prescription for buprenorphine from an unrecognized provider for a patient with opioid use disorder. The patient is a 53-year-old female, well known to your pharmacy, with a history of type two diabetes and hypertension. The prescription is from an out-of-state-provider who works for an online mental health clinic. The patient's PDMP profile reveals a two-year history of oxycodone use and the last prescription was dispensed by another pharmacy four months ago. You have never dispensed a controlled substance for this patient.

Patient Case:

1. Why would this patient need buprenorphine if she discontinued prescription opioid use four months ago?
2. What are your concerns?
3. What can you do to address your concerns?
4. What are the risks of declining buprenorphine for this patient?



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"A first prescription for any medication should be viewed as a critical transition of care. When a patient with no known history of pharmacotherapy for OUD presents to a community pharmacy with a new buprenorphine prescription, this is an opportunity for a pharmacist to provide, rather than deny, care."

-PhARM-OUD Guidelines, P. 14

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Questions?

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