



The Pharmacist's Role In Increasing Access To Treatment for Opioid Use Disorder

Careen-Joan Franklin, Pharm.D.

Clinical Assistant Professor and Director of Residency Programs

Howard University College of Pharmacy

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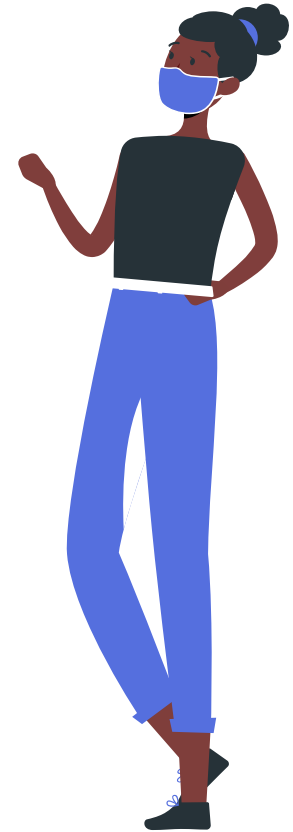
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Disclosures

“I have no relevant financial relationships or conflicts of interest to disclose”

● CJ Franklin



Learning Objectives

01

Outline treatment approaches for opioid use disorder

02

Explain the differences between pharmacologic treatment options for the management of opioid use disorder

03

Summarize the findings of available data regarding the pharmacist-driven interventions for the management of opioid use disorder.





Background: What Are Opioids?

- Opioids diminish the perception of and reaction to pain
- Produce feelings of euphoria
- Respiratory Depression, miosis, sedation
- Natural, or synthetic
- The misuse of opioids can result in opioid overdose and death
- Opioids have been cited to be the main cause of drug overdose deaths in the United States.





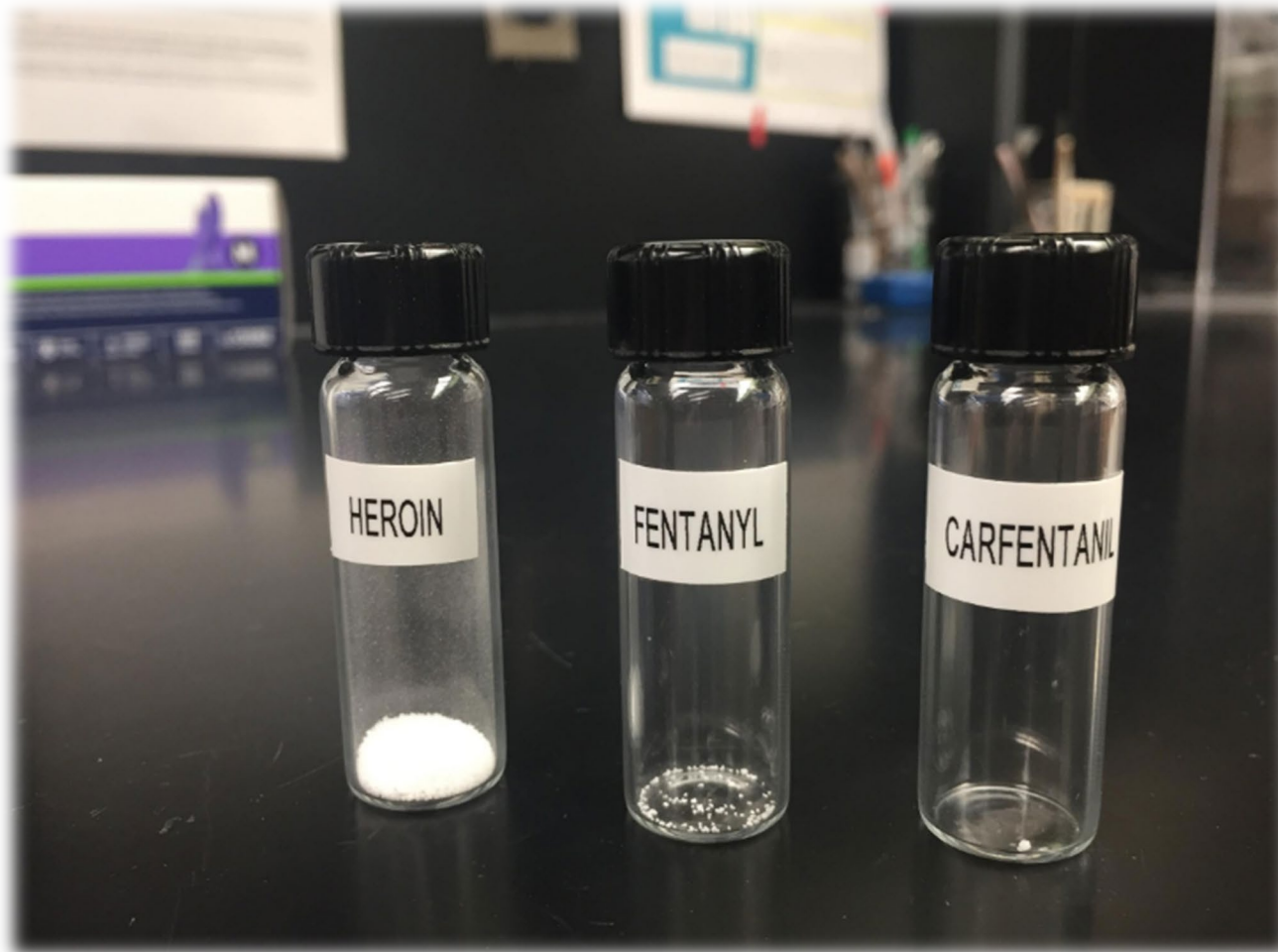
Background: Examples Of Opioids

Type	Name
Natural Opiates	Morphine, codeine, thebaine
Semi-synthetic Opioids	Heroin, hydromorphone, hydrocodone, oxycodone, buprenorphine
Fully synthetic Opioids	Fentanyl, methadone, merperidine, tramadol





Background: Lethal Doses





Background: What is Opioid Use Disorder (OUD)?



“A problematic pattern of opioid use leading to clinically significant impairment or distress”





Biopsychosocial Model of OUD





Background: Opioid Overdose

Excessive opioid receptor agonism

- Unintentional ingestion
- Intentional abuse
- Therapeutic Use

Effects

- Reduced sensitivity to changes in O₂ and CO₂
- Reduced tidal volume and respiratory frequency
- Respiratory depression and death due to hypoventilation

What are some signs of an opioid overdose?

- unconsciousness
- very small pupils
- slow or shallow breathing
- vomiting
- an inability to speak
- faint heartbeat
- limp arms and legs
- pale skin
- purple lips and fingernails





The Economic Toll of The Opioid Crisis

In 2020, the Opioid Crisis Cost \$400 Billion More Than in 2017

U.S. cost of opioid use disorder and fatal opioid overdose in 2020 dollars (trillions)



Source: The 2017 cost estimate is from "The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdoses in the United States, 2017," Florence et al. The 2018-2020 cost estimates are JEC calculations that adopt Florence et al's methodology and use annual data from SAMHSA and the CDC's National Vital Statistics System. All cost estimates are adjusted to 2020 dollars.

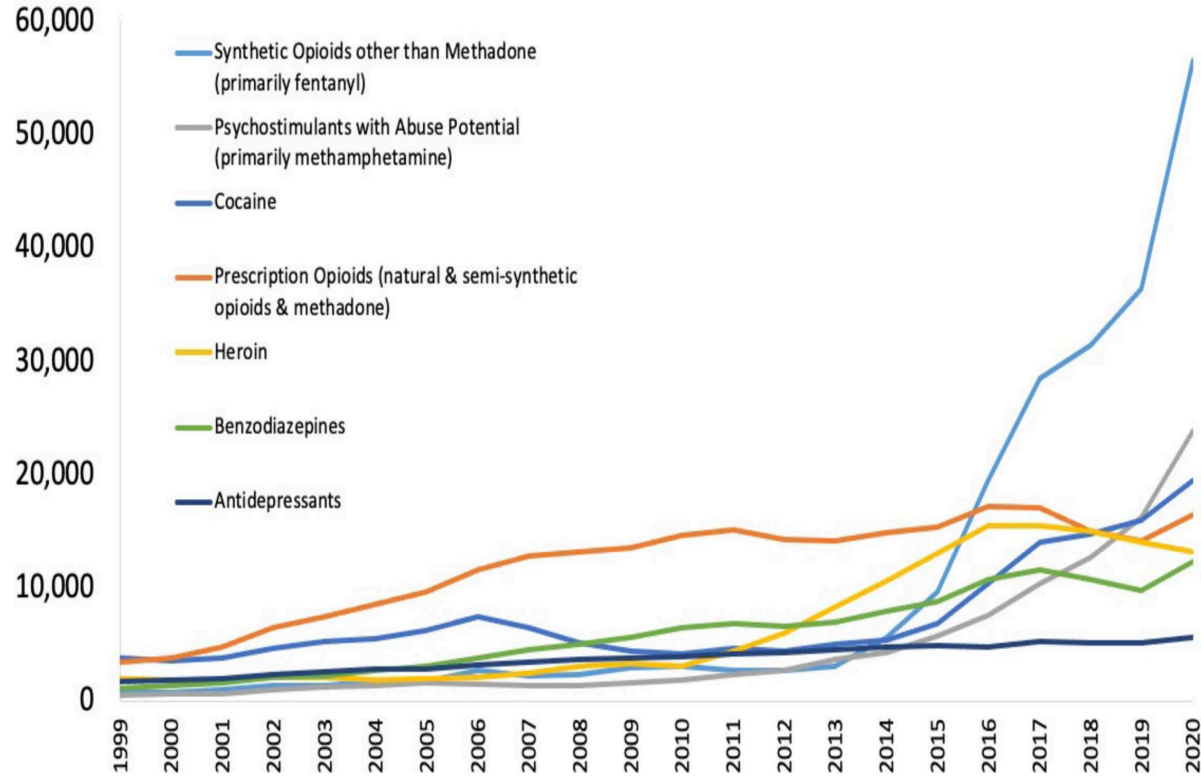
Source: Joint Economic Committee Democrats: The Economic Toll of the Opioid Crisis Reached Nearly \$1.5 Trillion in 2020



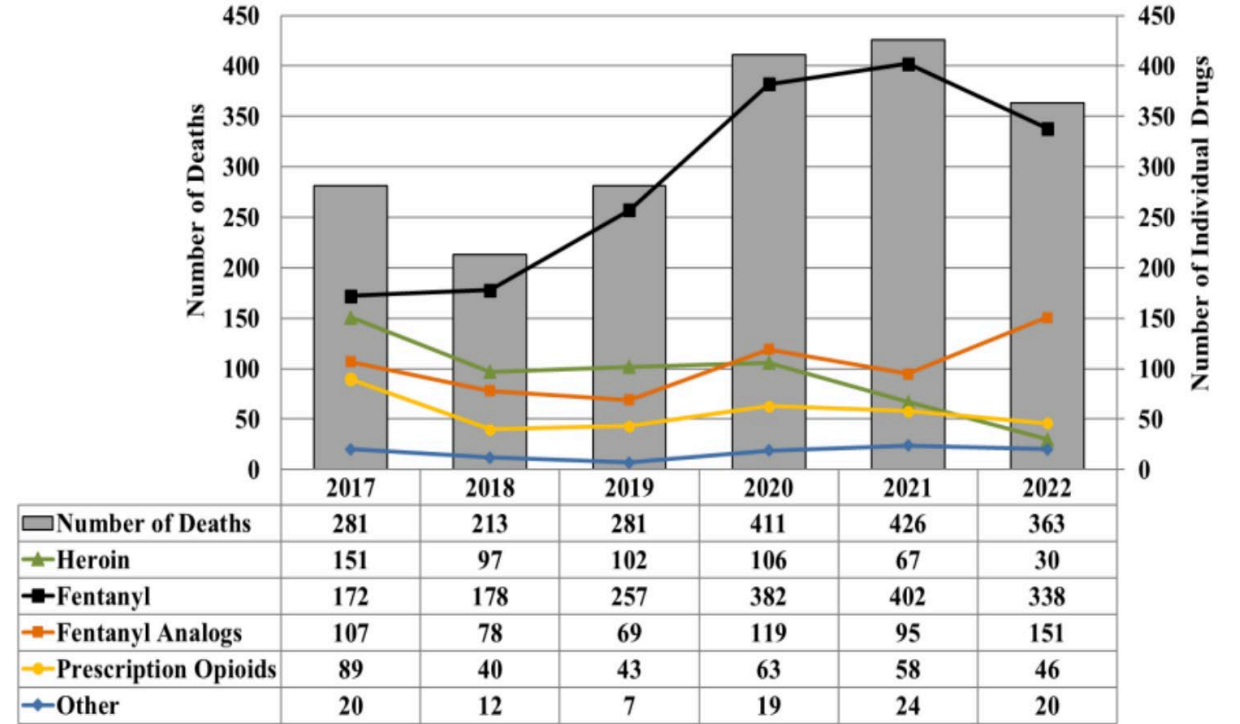
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Drug-Involved Overdose Deaths



Source: CDC WONDER



Source: DC Office of the Chief Medical Examiner



Drug-Involved Overdose Deaths

WHAT IS FENTANYL?



Fentanyl is a synthetic opioid that is approximately **50X MORE POTENT THAN MORPHINE¹**

Many people are exposed to fentanyl without knowledge while others use it intentionally because of its potency.

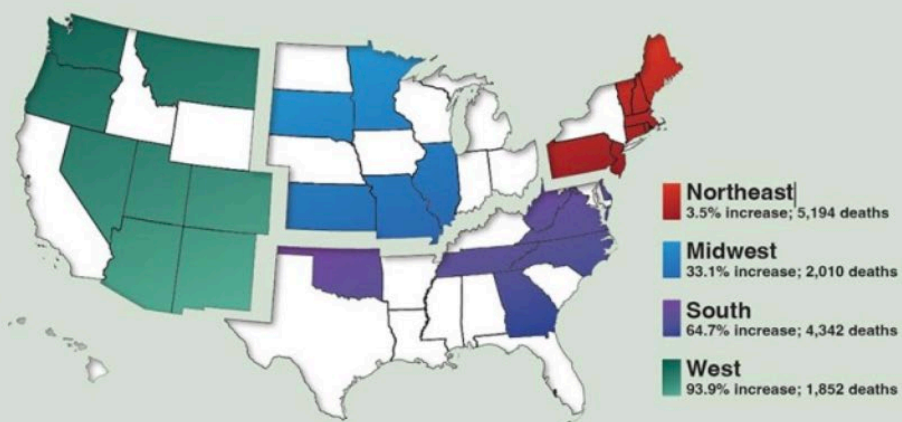
OVERDOSE DEATHS IN THE UNITED STATES EXCEEDED 100,000 IN A 12-MONTH PERIOD FOR THE FIRST TIME!

64% of these deaths involved synthetic opioids, mainly illicitly manufactured fentanyls (IMFs) (May 2020-April 2021)²

This is up from the more than 91,000 overdose deaths that occurred the previous year. (December 2019-December 2020)³



Although the northeast region continues to suffer the highest overdose deaths, several regions of the country showed sharp increases in IMF related deaths.²

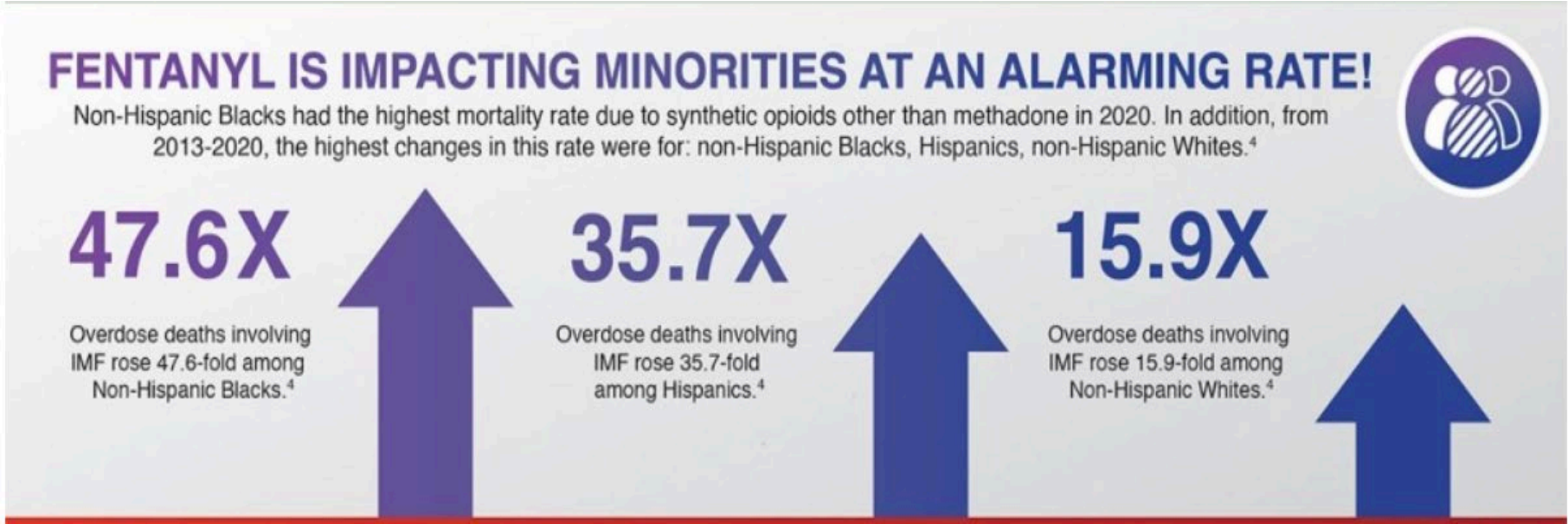


*In jurisdictions participating in State Unintentional Drug Overdose Reporting System (SUDORS).





Who Is Affected By OUD?



Opioid Overdose Death Rate for U.S. Black Population Is Higher Than for White



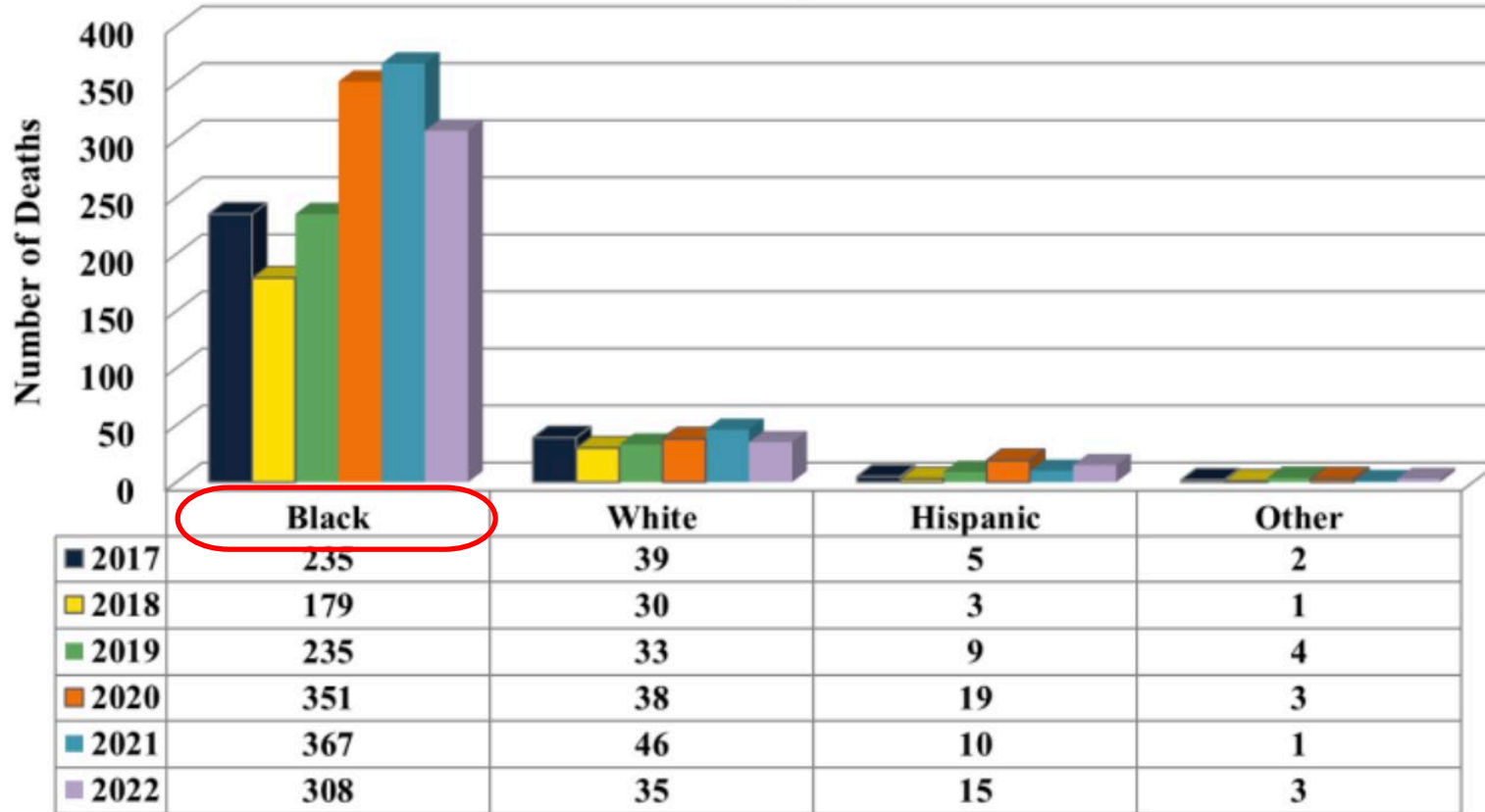
Fentanyl use exploded while government slept. Here's what to do now.





Who Is Affected By OUD?

Fig. 6: Number of Drug Overdoses due to Opioid Use by Race/Ethnicity and Year



Source: DC Office of the Chief Medical Examiner



Who Is Affected By OUD?

Fig. 8: Number of Drug Overdoses due to Opioid Use by Jurisdiction of Residence and Year

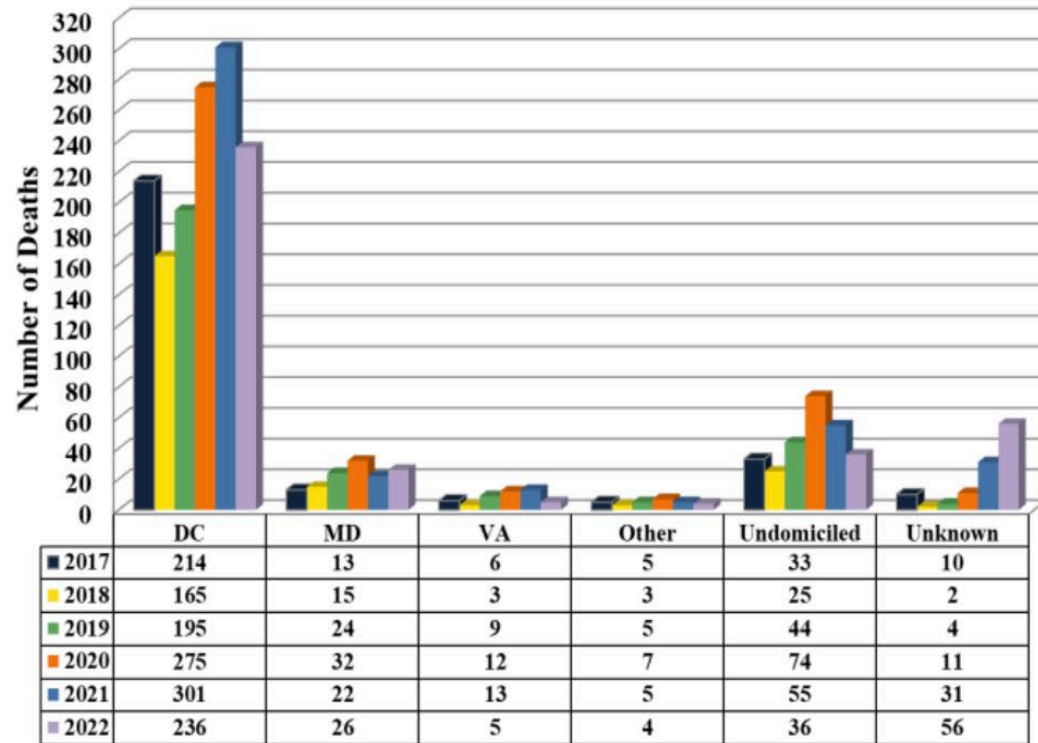
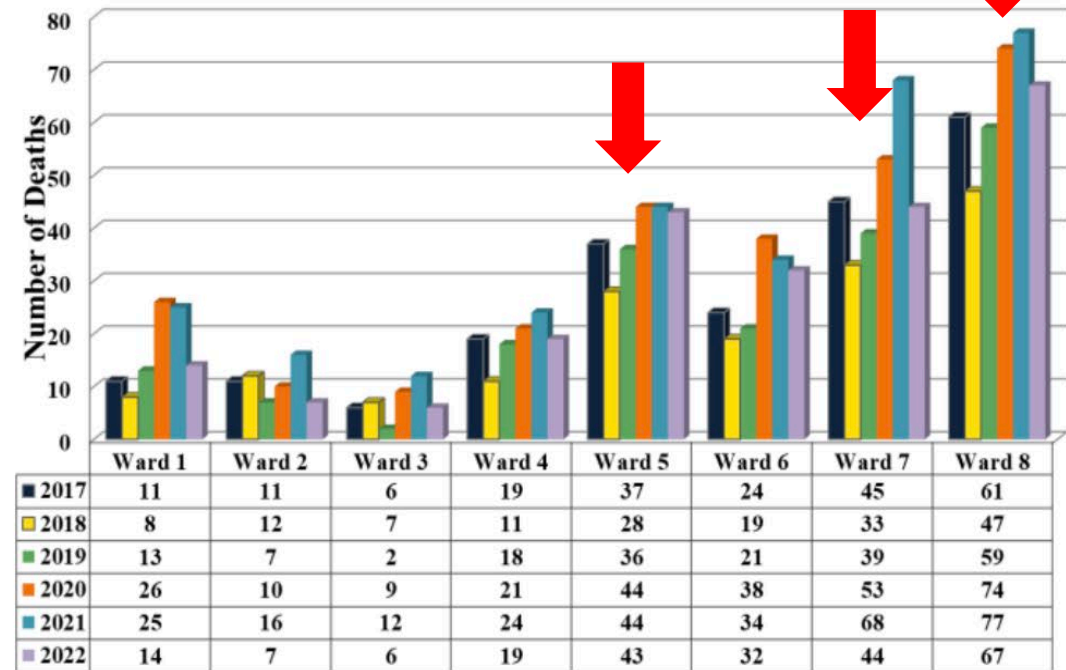


Fig. 9: Number of Drug Overdoses due to Opioid Use by Ward of Residence and Year



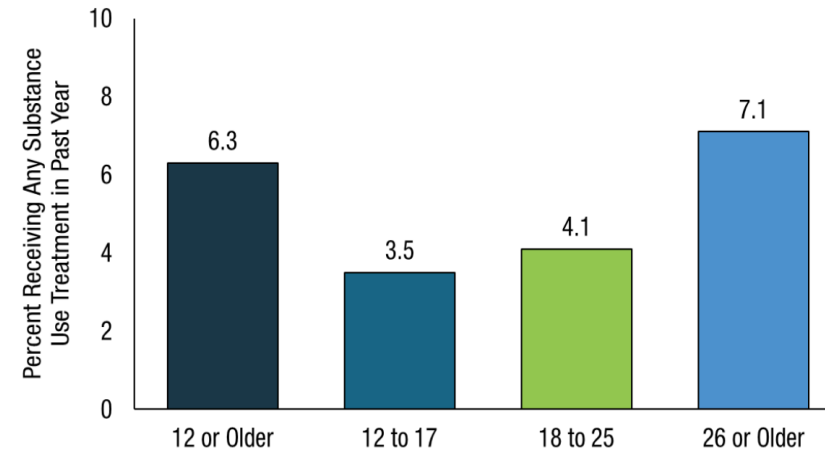
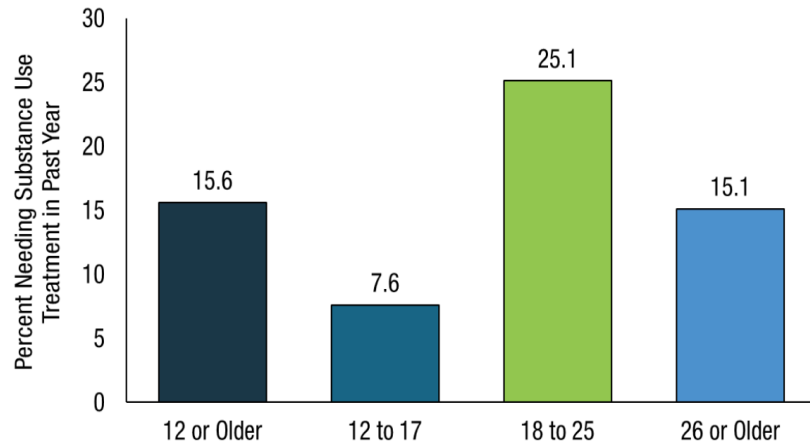
Source: DC Office of the Chief Medical Examiner



Substance Use Treatment

Need for Substance Use Treatment in the Past Year: Among People Aged 12 or Older; 2021

Received Any Substance Use Treatment in the Past Year: Among People Aged 12 or Older Who Had an Illicit Drug or Alcohol Use Disorder in the Past Year; 2021



Note: Need for Substance Use Treatment is defined as having an illicit drug or alcohol use disorder in the past year or receiving substance use treatment at a specialty facility.



Source: Substance Abuse and Mental Health Services Administration



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Access Barriers to OUD Treatment

	Patient-Identified	Provider-identified	Administrator-identified or systems level
Stigma	Social stigma Self-stigma Buprenorphine stigma	Social stigma Stigma of patients with OUD Buprenorphine stigma	
Treatment experiences and beliefs	Willpower more important than treatment Treated poorly by treatment center staff Rigid treatment structure	Lack of patient need/demand for buprenorphine Lack of interest/motivation in prescribing	Perception of anti-pharmacotherapy attitudes among providers
Knowledge Gaps	Lack of education on OUD treatment Uncertainty about where to obtain care	Lack of training on OUD Lack of confidence in treating OUD Perception that OUD medication not effective	Lack of provider awareness of buprenorphine
Logistics	High out of pocket costs Long wait times “Fist-fail” policies	Time constraints Low insurance reimbursement Inability to refer to psychosocial supports Diversion concerns Lack of institutional support	Prior authorizations Cost Requirements for concurrent counseling or Stepped treatment

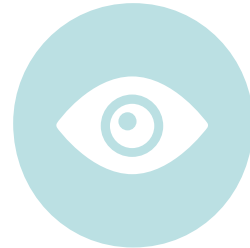




Substance use disorder took my son. When will we treat people with this horrific disease?

Approach To Treatment

The Prescription Drug Monitoring Program should be checked regularly



The venue for treatment should be considered carefully



All FDA approved medications and naloxone should be available for all patients.



Patients referral for psychosocial treatment based on psychosocial needs

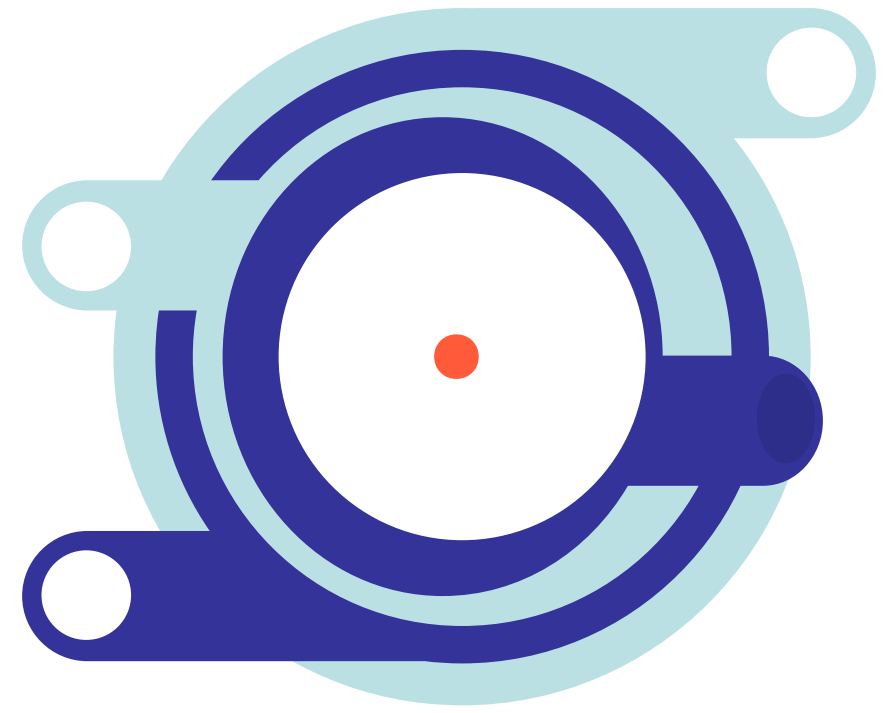




Goals of Treatment

Reduction in dependency on substance

Reduction in withdrawal symptoms



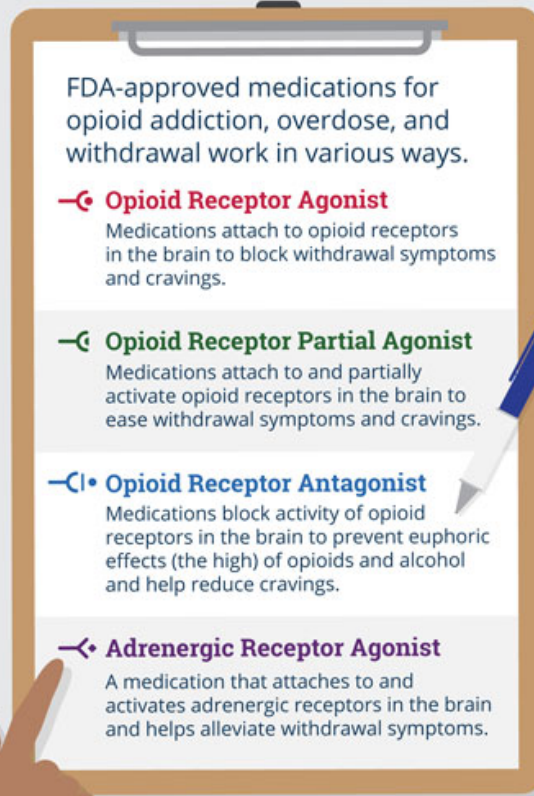
Prevention of death from substance



MEDICATIONS FOR OPIOID OVERDOSE, WITHDRAWAL, & ADDICTION

Medications for opioid **overdose**, **withdrawal**, and **addiction** are safe, effective and save lives.

The National Institute on Drug Abuse supports research to develop new medicines and delivery systems to treat opioid use disorder and other substance use disorders, as well as other complications of substance use (including withdrawal and overdose), to help people choose treatments that are right for them.



FDA-approved medications for opioid addiction, overdose, and withdrawal work in various ways.

- Opioid Receptor Agonist**
 Medications attach to opioid receptors in the brain to block withdrawal symptoms and cravings.
- Opioid Receptor Partial Agonist**
 Medications attach to and partially activate opioid receptors in the brain to ease withdrawal symptoms and cravings.
- Opioid Receptor Antagonist**
 Medications block activity of opioid receptors in the brain to prevent euphoric effects (the high) of opioids and alcohol and help reduce cravings.
- Adrenergic Receptor Agonist**
 A medication that attaches to and activates adrenergic receptors in the brain and helps alleviate withdrawal symptoms.

REDUCES OPIOID USE AND CRAVINGS

Methadone
Daily liquid or tablet
Dolophine®, Methadose®
Generics available



Naltrexone
Monthly Injection
Vivitrol®



Buprenorphine
Daily tablet
Monthly injection
Sublocade®
Generic tablets available



Buprenorphine/Naloxone
Daily film under the tongue or tablet
Zubsolv®, Suboxone®
Generics available




TREATS WITHDRAWAL SYMPTOMS

Lofexidine
As-needed tablet
Luexmyra®



REVERSES OVERDOSE

Naloxone
Emergency nasal spray or injection
Kloxxodo®, Narcan®, Zimhi™
Generics available





Treatment

	Methadone (CII)	Extended Release Injectable Naltrexone (XR-NTX)	Buprenorphine (CIII)
MOA and Pharmacology	Full mu-opioid receptor agonist , long half-life, once daily dosing	Mu-opioid receptor antagonist , not addictive and does not provide analgesia	Partial mu-opioid receptor agonist , long half-life (SL up to 36 hrs.), ceiling effect , blocks intoxicating effects of opioids
Side Effects	Resp. depression, constipation, sedation, QTc prolongation	Injection site reactions, toothache, LFT elevation, insomnia, nasopharyngitis	Resp. depression, constipation, sedations, vomiting, dizziness, blurred vision, SL film: oral hypoesthesia, mucosal erythema or glossodynia, dental problems
Routes of Administration used in MAT	Orally as solid or commonly as liquid concentrate	IM	SL, buccal tablet, buccal film. SQ* and subdermal**
Phase of Treatment	Medically supervised withdrawal, maintenance	Prevention of relapse to opioid dependence	Medically supervised withdrawal, maintenance

*Provider and pharmacy must be certified in REMS program and only dispense to provider for administration

**Prescribers must be certified in REMS program to insert/remove implants





Contraindications and precautions

Medication	Contraindication	Warning and Precaution
Methadone	Hypersensitivity, resp. depression, severe bronchial asthma/ hypercapnia, paralytic ileus	Qtc prolongation, diversion, misuse and physical dependence are possible, RD with CNS depressants, head injury, increased intracranial pressure, liver disease, CYP3A4,2C19,2B6, 2C9, 2D6 interactions , concomitant SUD and psychiatric disorders
Buprenorphine (all formulations)	Hypersensitivity	Diversion, misuse and physical dependence are possible, RD with CNS depressants, neonatal withdrawal, not recommended with severe hepatic impairment, possible sedation, precipitated withdrawal
Naltrexone (oral and injectable)	Hypersensitivity to drug or diluent, patients dependent on opioids, patients receiving opioid, patient in acute opioid withdrawal	Vulnerability to overdose, injection site reactions, precipitated opioid withdrawal, monitor for depression and suicidality, emergency reversal of opioid blockade may require critical care setting, eosinophil pneumonia has been reported, administer IM with caution patients with thrombocytopenia or coagulation disorder



Evaluation of Therapeutic Outcomes

01

Monitor for withdrawal reactions using validated scale

02

Assess medication side effects and drug interactions

03

Regular urine drug screens and PDMP profile review

04

Continue patient education to ensure proper medication administration and safety

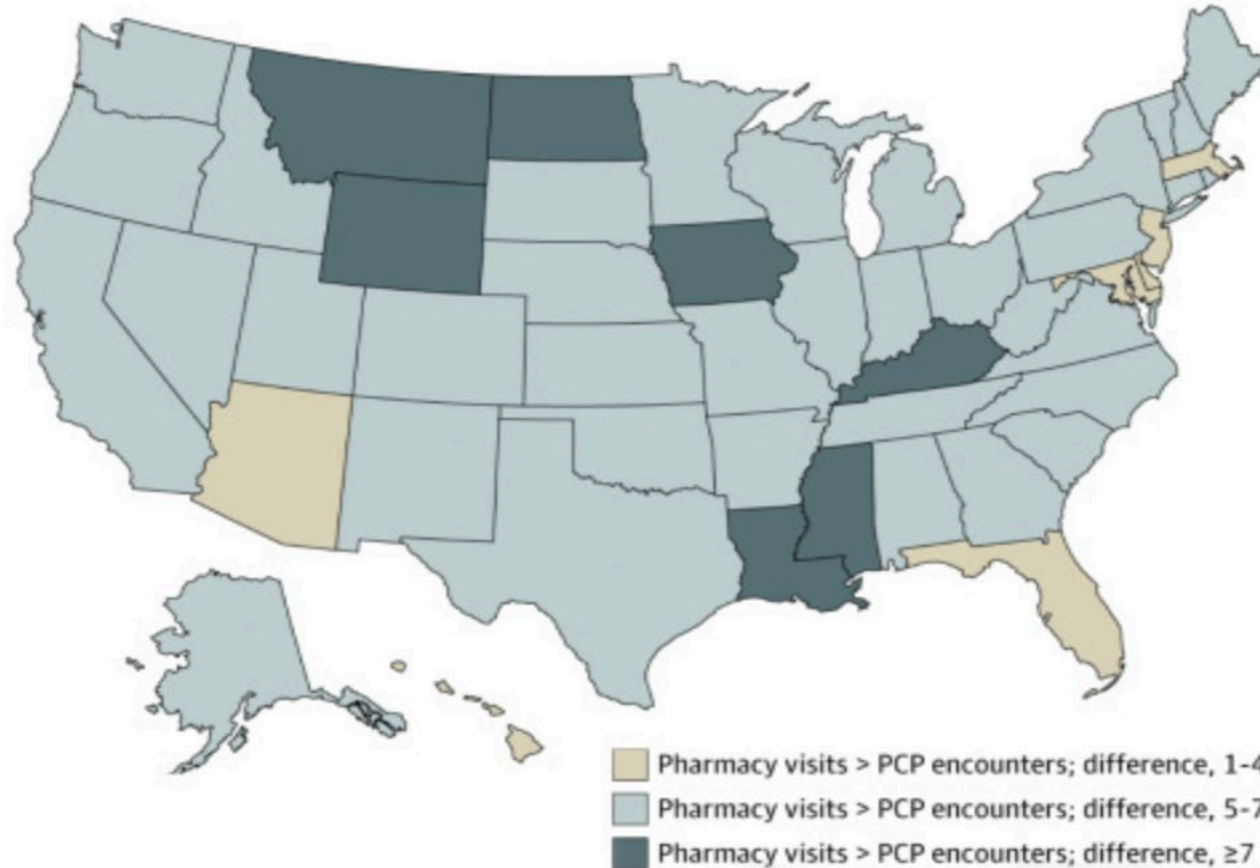
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Ongoing psychosocial support





HOW OFTEN DO PATIENTS SEE THEIR PHARMACIST?



Most Texas pharmacies are not prepared to dispense buprenorphine/naloxone films & naloxone nasal spray

A cross-sectional telephone audit with a secret shopper approach conducted in Spring 2020

704 pharmacies audited
471 chains
233 independents

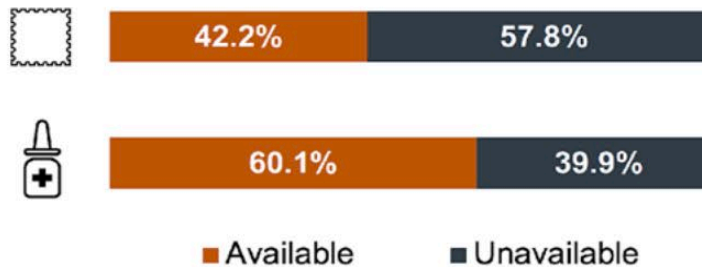


BUP/NX 8/2mg generic #14 films



NNS 4mg brand #1 box

34.1% reported availability of both medications for prompt dispensing



62.2% without BUP/NX available were willing to order it (M = 2 days)

Availability & willingness to order were higher in chains vs independents



	BUP/NX & NNS Available	Willing to Order BUP/NX
Pharmacy Chains	45.0%	73.9%
Independent Pharmacies	12.0%	48.0%

Pharmacy Related Barriers



LACK OF TIME



Insufficient Knowledge

Pharmacy Related Barriers





ENDING THE STIGMA OF ADDICTION

Learn about stigma



See how stigma affects the opioid epidemic



Learn how you can help





Talking To Patients About Buprenorphine And Naloxone

Instead of...	Use...
Addict	Person with substance use disorder
User/ Substance or drug abuser/ Junkie	Person with opioid use disorder/ Patient
Former addict / Reformed addict	Person in recovery/ Person who previously used drugs
Habit	Substance use disorder /Drug addiction
Abuse	Use/ Misuse/ Used other than prescribed
Clean	Abstinent from drugs/ Testing negative Being in remission or recovery
Dirty	Person who uses drugs/ Testing positive
Addicted baby	Baby born to mother who used drugs while pregnant





MAT Act's passage is a critical step in overdose prevention

December 2022

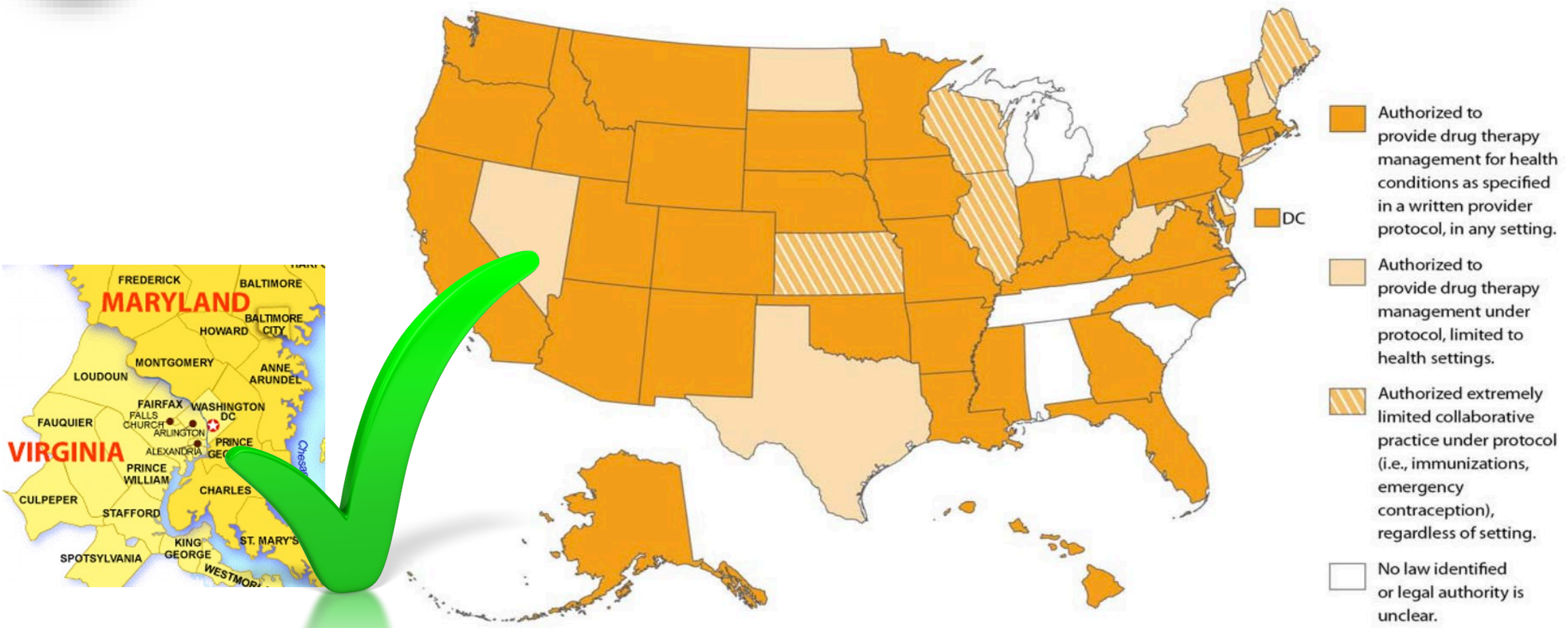




MAT Act: What's New?

	Pre-MAT Act	MAT Act
X-Waiver Registration, DEA "X" prescribing number	✓	✗
Patient Limits	✓	✗
Eligible providers to prescribe buprenorphine for OUD.	✓	✗
X-Waiver training requirement	✓	✗

Figure 1. Map of States with Laws Explicitly Authorizing Pharmacist Collaborative Practice Agreements, 2012



Note: Physician delegation is considered permissive in MI and WI, allowing physicians and pharmacists to enter into CPAs.



Evidence



EXPERIENCE | VOLUME 55, ISSUE 2, P187-192, MARCH 2015

Physician–pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients

Bethany A. DiPaula, PharmD, BCPP   • Elizabeth Menachery, MD

DOI: <https://doi.org/10.1331/JAPhA.2015.14177>

DiPaula BA, Menachery E. Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. *J Am Pharm Assoc* (2003). 2015;55(2):187-192. doi:10.1331/JAPhA.2015.14177



INNOVATIVE PRACTICE

Open Access

Development and implementation of a physician-pharmacist collaborative practice model for provision and management of buprenorphine/naloxone

Lindsay M. Mailloux, PharmD¹; Matthew T. Haas, PharmD, BCPP, BCPS²;
Janel M. Larew, PharmD, BCPS³; Beth M. DeJongh, PharmD, BCPP, BCPS⁴

Mailloux LM, Haas MT, Larew JM, DeJongh BM. Development and implementation of a physician-pharmacist collaborative practice model for provision and management of buprenorphine/naloxone. *Ment Health Clin* [Internet]. 2021;11(1):35-9. DOI: 10.9740/mhc.2021.01.035.



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Addiction (Abingdon, England)

Author Manuscript

HHS Public Access

Buprenorphine physician-pharmacist collaboration in the management of patients with opioid use disorder: Results from a multisite study of the National Drug Abuse Treatment Clinical Trials Network

Li-Tzy Wu, William S. John, [...], and Paolo Mannelli

Wu LT, John WS, Ghitza UE, et al. Buprenorphine physician-pharmacist collaboration in the management of patients with opioid use disorder: results from a multisite study of the National Drug Abuse Treatment Clinical Trials Network. *Addiction*. 2021;116(7):1805-1816. doi:10.1111/add.15353

American Journal of Health-System Pharmacy: AJHP

Oxford University Press

Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic

Alyssa M Peckham, PharmD, BCPP, Jennifer Ball, PharmD, BCACP, BCGP, [...], and Tran H Tran, PharmD, BCPS

Peckham AM, Ball J, Colvard MD, et al. Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic. *Am J Health Syst Pharm*. 2021;78(7):613-618. doi:10.1093/ajhp/zxab003



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Evidence



The NEW ENGLAND
JOURNAL of MEDICINE

Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies

Green TC, Serafinski R, Clark SA, Rich JD, Bratberg J. Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies. *N Engl J Med.* 2023;388(2):185-186.
doi:10.1056/NEJMc2208055





Pharmacists Authority to Administer LAI MOUD



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THE PHARMACIST'S ROLE

Collaborate with physicians

Counsel patients to address patient-specific needs

Educate patients, family members and caregivers

Provide naloxone to high risk patients





THE PHARMACIST'S ROLE

Check PDMP for adherence and prescribing habits

Address naloxone skepticism

Obtain medical histories and assess for overdose risk

Perform CMR's and Med. Recs





THE PHARMACIST'S ROLE

Use screening tools

De-stigmatize buprenorphine and naloxone use

Make recommendations to improve existing laws

Work with state and local organizations to advocate for patient safety





Thanks!

Do you have any questions?
Email me
careenjoan.franklin@howard.edu



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