Department of
Mental Health &
Substance Abuse Services

Medications for Opioid Use Disorder
Past, Present, and Future

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Disclosures

- Nothing to disclose

Objectives

- Compare and contrast recent drug trends and MOUD utilization
- Understand recent legislative updates related to MOUD
- Understand the multiple factors that impact buprenorphine access and proposed solutions

Current Trends: National

Overdose Deaths in 2022

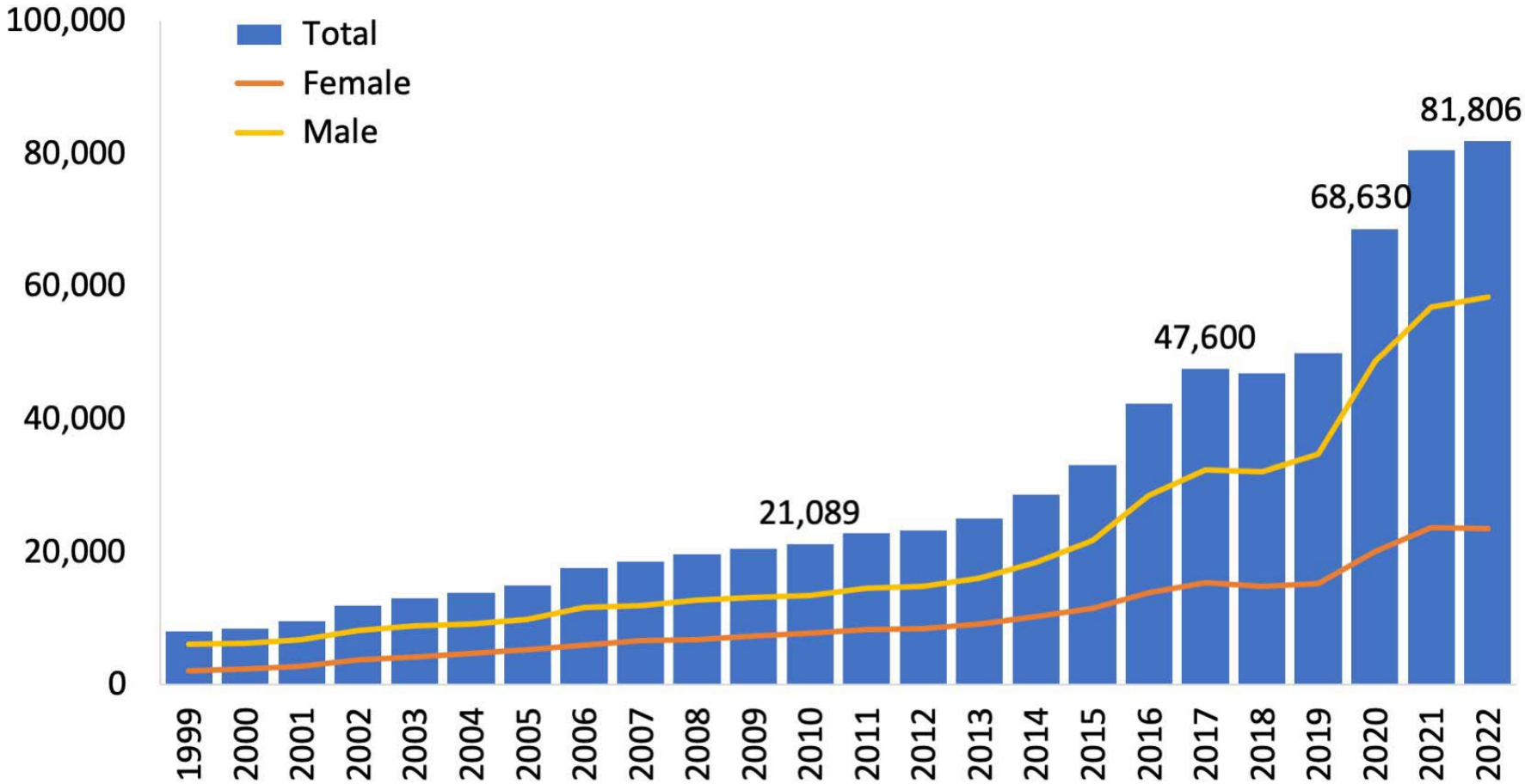
107,941

Or

296 per day

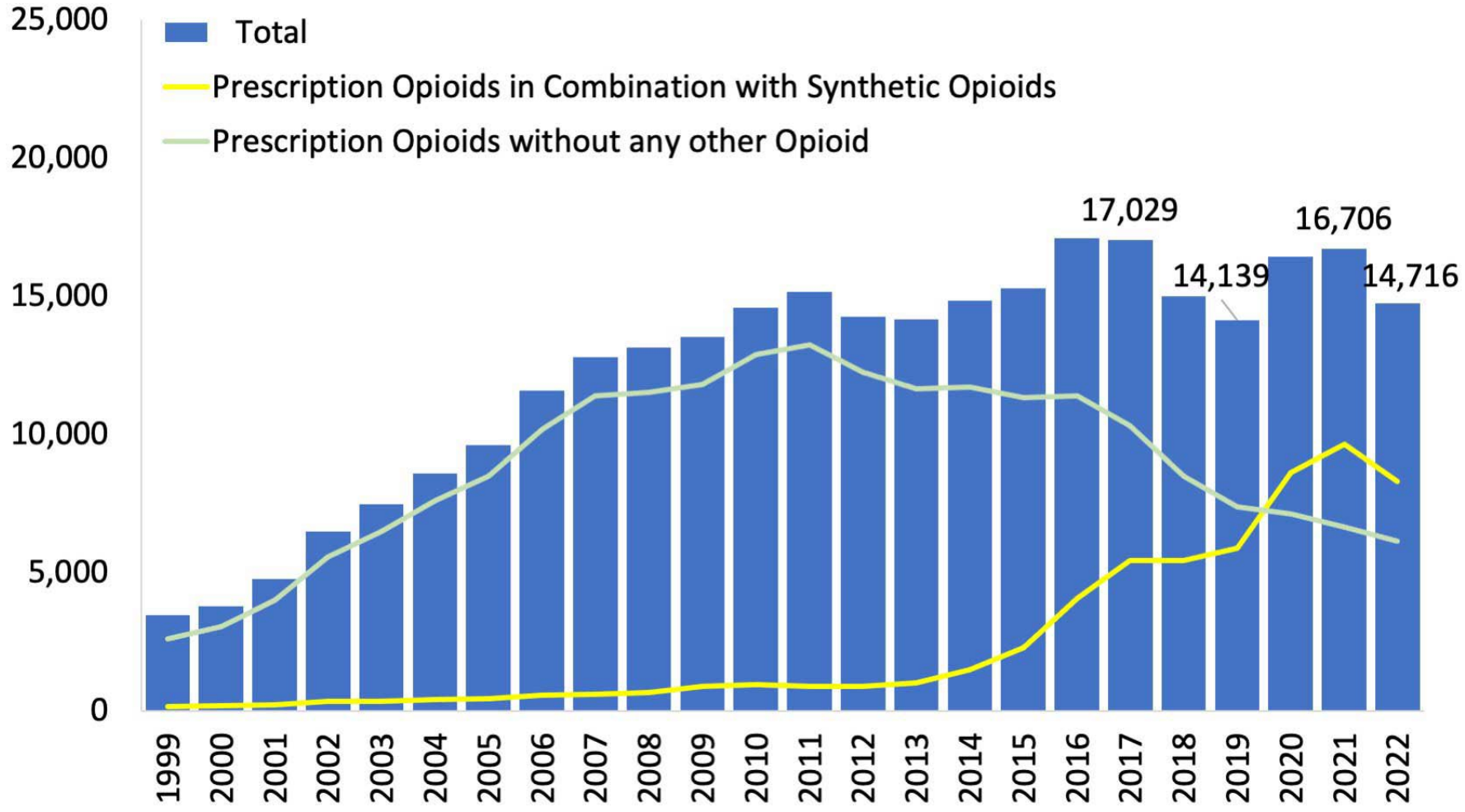
13 per hour

Figure 3. U.S. Overdose Deaths Involving Any Opioid* by Sex, 1999-2022



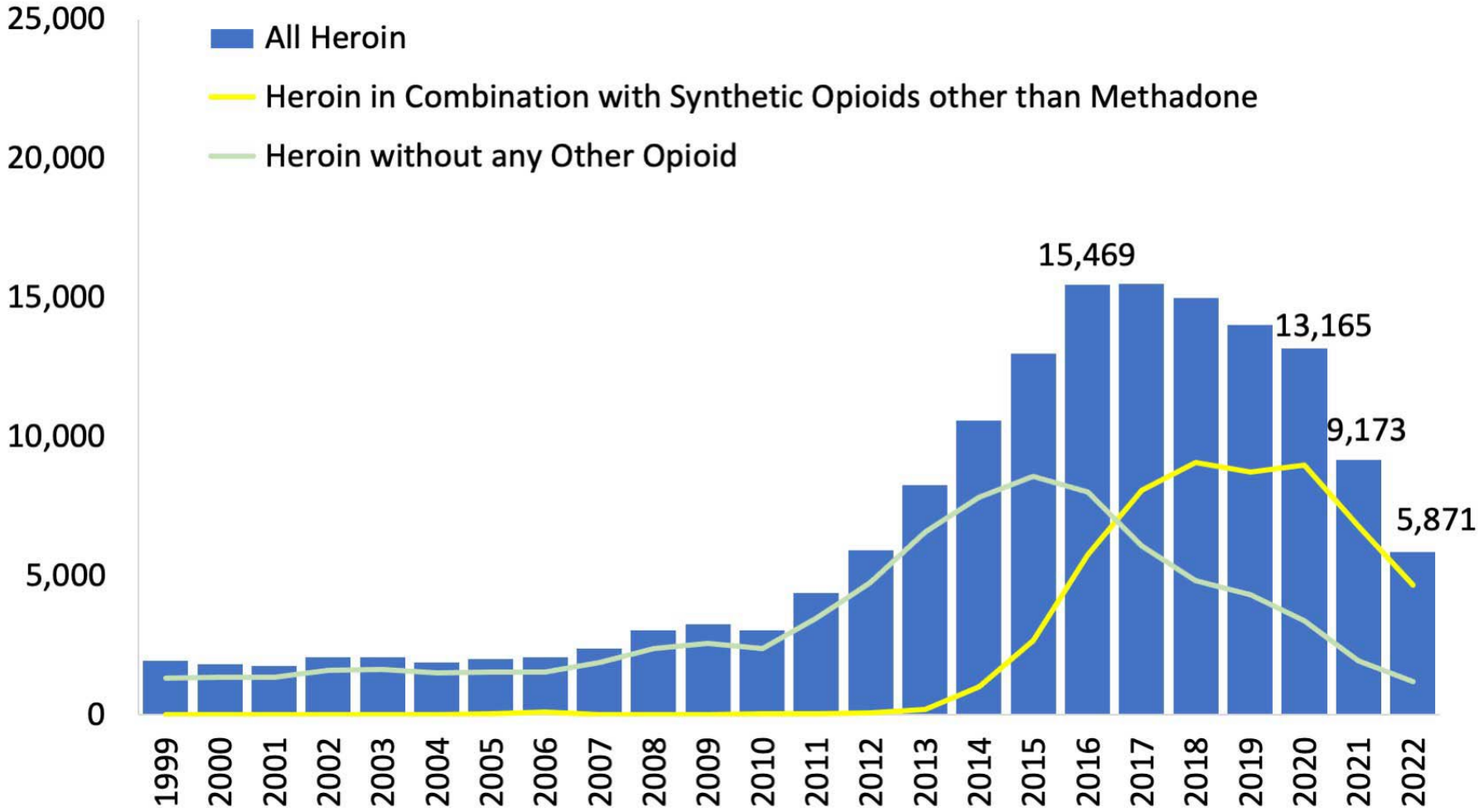
*Among deaths with drug overdose as the underlying cause, the "any opioid" subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Figure 4. U.S. Overdose Deaths Involving Prescription Opioids*, 1999-2022



*Among deaths with drug overdose as the underlying cause, the prescription opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2) or methadone (T40.3). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

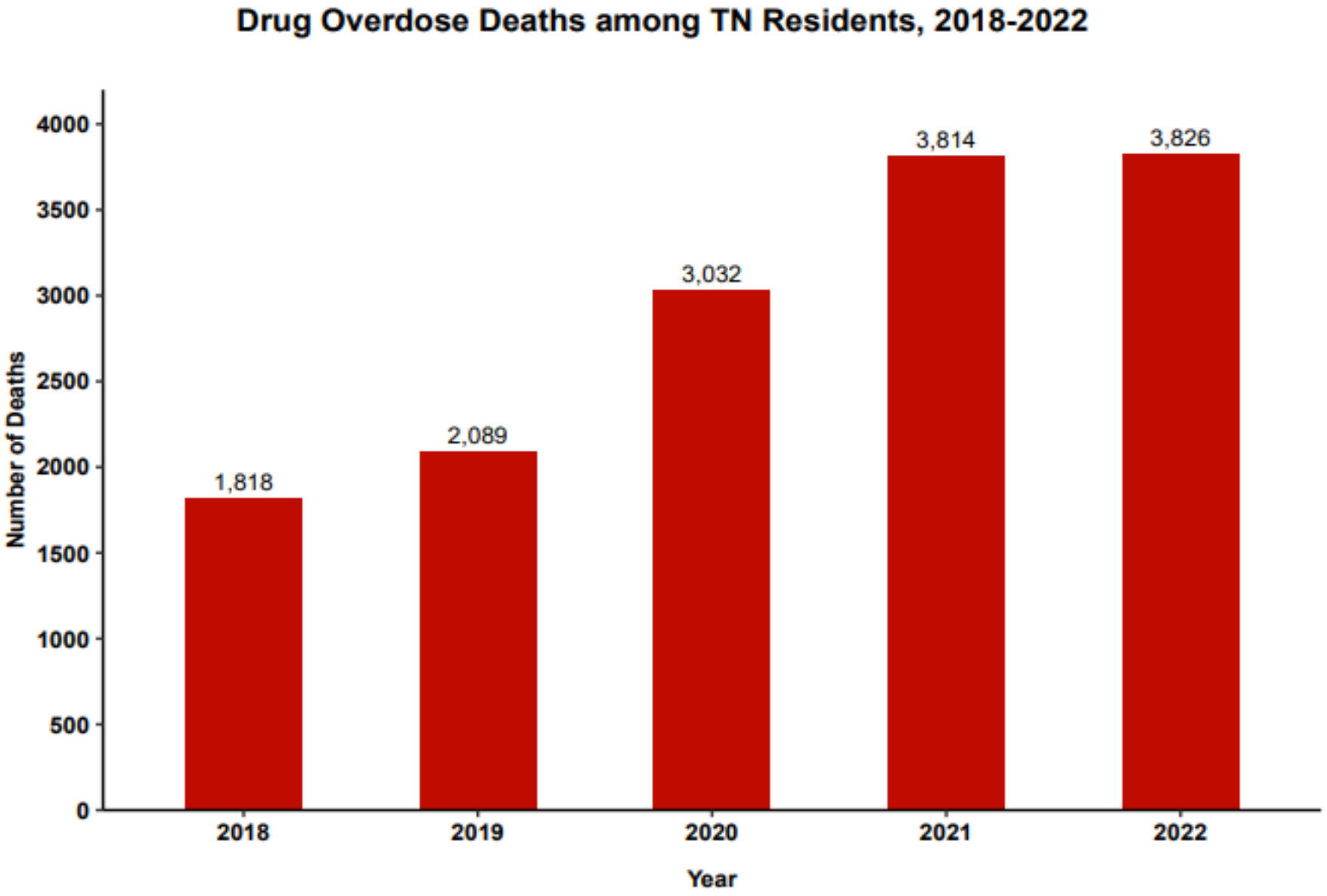
Figure 5. U.S. Overdose Deaths Involving Heroin*, by other Opioid Involvement, 1999-2022



*Among deaths with drug overdose as the underlying cause, the heroin category was determined by the T40.1 ICD-10 multiple cause-of-death code. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Current Trends: Tennessee

State-level Overview 2018 - 2022



Nonfatal Overdoses in TN

- In 2022, there were **26,211** all drug overdose hospital discharges among TN residents.
  - 6,473 (24.7%) were inpatient stays
  - 19,738 (75.3%) were outpatient visits

Let’s Open the Treatment Toolbox

DSM-5-TR – Opioid Use Disorder Diagnostic Criteria

- A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the followings: *
    1. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
    2. A markedly diminished effect with continued use of the same amount of an opioid.
11. Withdrawal, as manifested by either of the followings: *
    1. The characteristic opioid withdrawal syndrome
    2. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

Common Misconception with MAT

"Maintenance opioid agonists is just switching addictions and patients should not be on them long term"

- Research on maintenance treatment demonstrated:
  - Normalization of functioning
  - No euphoric, tranquilizing, or analgesic effects
  - No change in tolerance levels over time
  - Effectiveness when administered orally
  - Relief for opioid craving
  - Minimal side effects

  (Refer to DSM-5 OUD Diagnostic Criteria – Symptoms of OUD are not present when using medications appropriately and are engaged in recovery)

- Research on forced tapering demonstrated
  - Significant rate of relapse
  - Increased risk for drug overdose

Dependence vs. Addiction

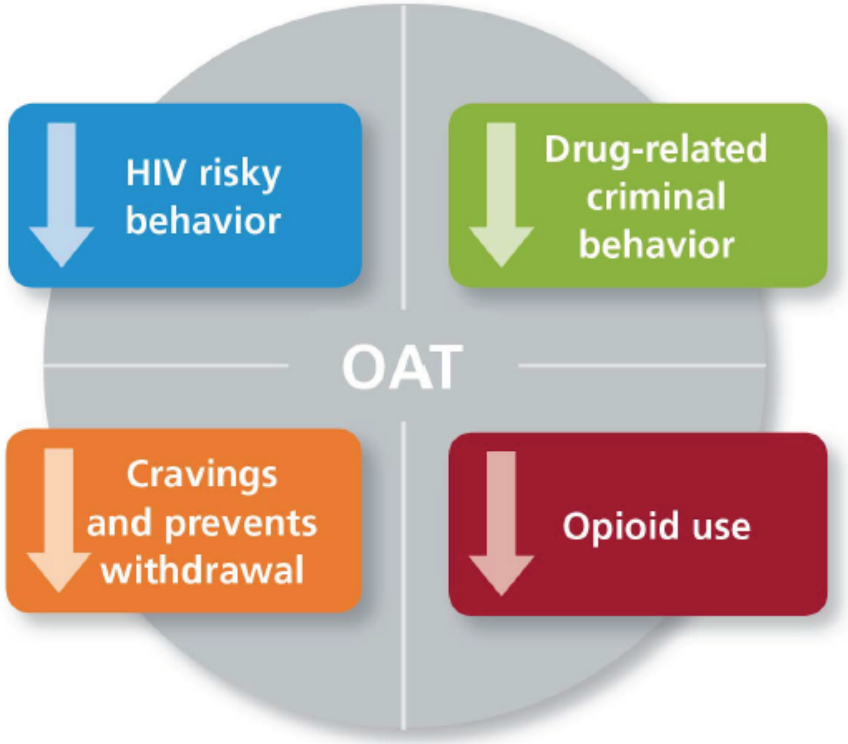
- Dependence:
  - The body will become dependent on any substance put into it.
    - E.g. caffeine, nicotine, sugar
  - Dependence is a normal bodily response to taking medications

- Addiction:
  - the fact or condition of being addicted to a particular substance, thing, or activity
  - Associated with continued behavior despite negative consequences

Common Misconception with MAT

OUD Pharmacotherapy

Figure 7. Opioid Agonist Therapy (OAT) is considered 1st line treatment for OUD.[16]



OAT allows the patient to focus more readily on recovery activities by preventing withdrawal and reducing cravings; helps achieve long-term goal of reducing opioid use and the associated negative medical, legal, and social consequences, including death from overdose.[17,18]

VA Clinician's Guide to Identification and Management of Opioid Use Disorder. VA Academic Detailing Service 2016

Medications for OUD

Medications for OUD

Opioid Antagonist:
Naloxone and Naltrexone

0%
Intrinsic Activity

Opioid Partial Agonist:
Buprenorphine

40%
Intrinsic Activity

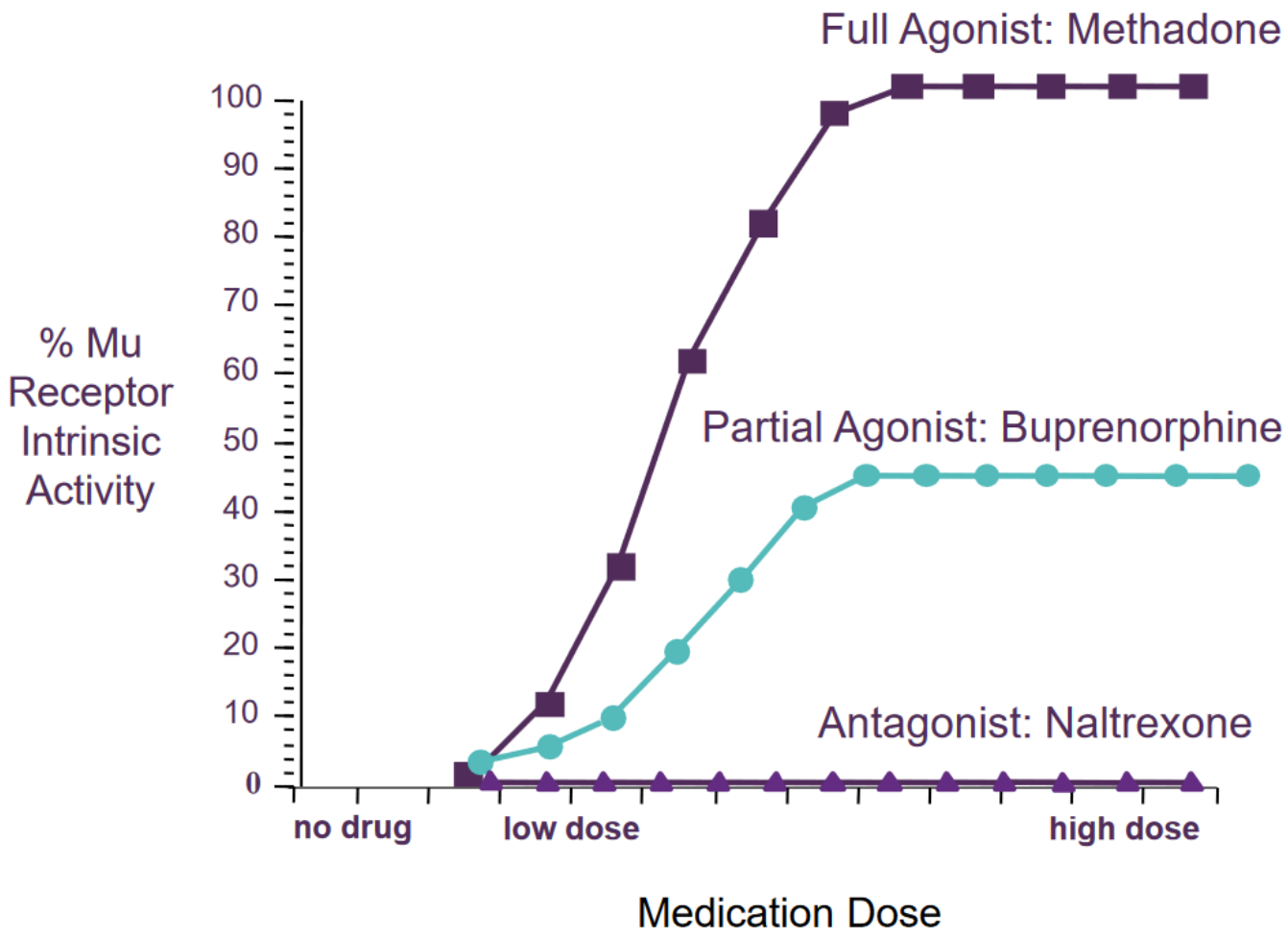
Full Opioid Agonist:
Methadone

100%
Intrinsic Activity

(Wyatt, 2017)

Medications for OUD

- Approved medications:

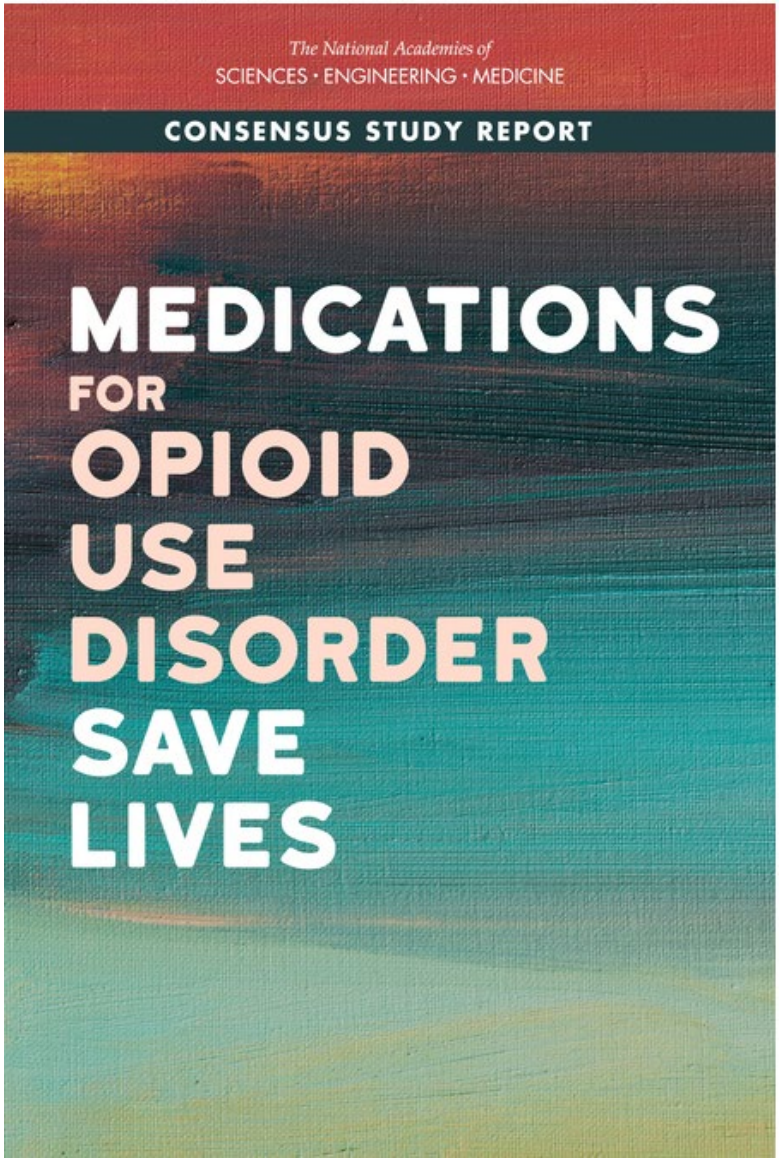


Medications for OUD

Purpose of Medications for OUD

- Allow reestablishment of homeostasis of the reward pathways in the brain away from substances
- Restore emotional and decision-making capacities
- Control symptoms of opioid withdrawal (agonists)
- Suppress opioid cravings
- Block the reinforcing effects of ongoing opioid use
- Promote and facilitate patient engagement in recovery-oriented activities
- Coupled with behavioral interventions
  - Enhance the salience of natural, healthy rewards
  - Reduce stress reactivity and negative emotional state
  - Improve self-regulation
  - Increase avoidance of relapse triggers

National Academies of Sciences, Engineering, and Medicine



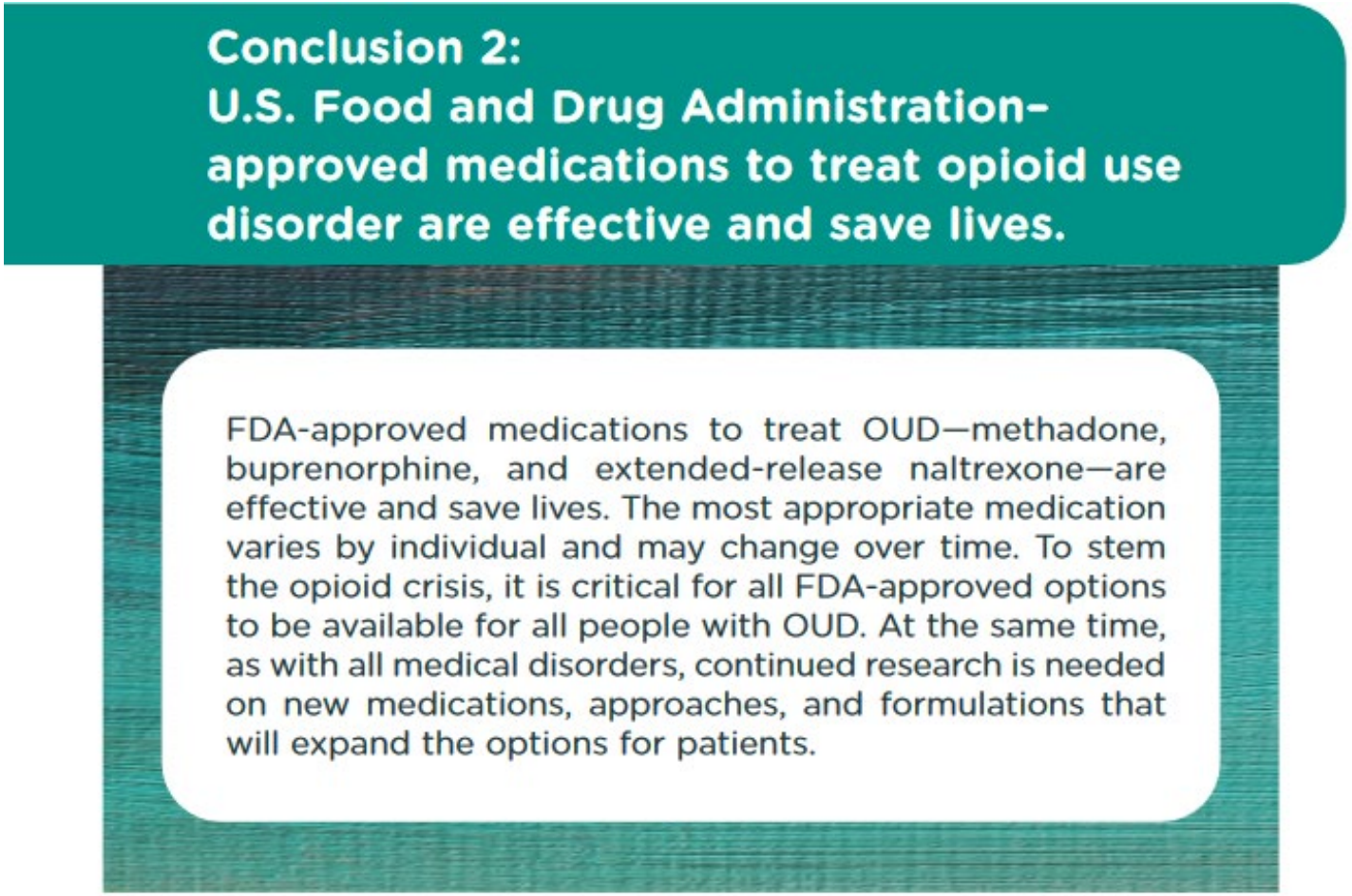
https://nap.nationalacademies.org/catalog/25310/medications-for-opioid-use-disorder-save-lives

National Academies of Sciences, Engineering, and Medicine

Conclusion 1:
Opioid use disorder is a treatable chronic brain disease.

OUD is a treatable chronic brain disease resulting from the changes in neural structure and function that are caused over time by repeated opioid use. The behavioral and social contexts are critically important to both its development and treatment. Stopping opioid misuse is extremely difficult. Medications are intended to normalize brain structure and function.

National Academies of Sciences, Engineering, and Medicine



National Academies of Sciences, Engineering, and Medicine

Conclusion 3:
Long-term retention on medication to treat opioid use disorder is associated with improved outcomes.

There is evidence that retention on medication for the long term is associated with improved outcomes and that discontinuing medication often leads to relapse and overdose. There is insufficient evidence regarding how the medications compare over the long term.

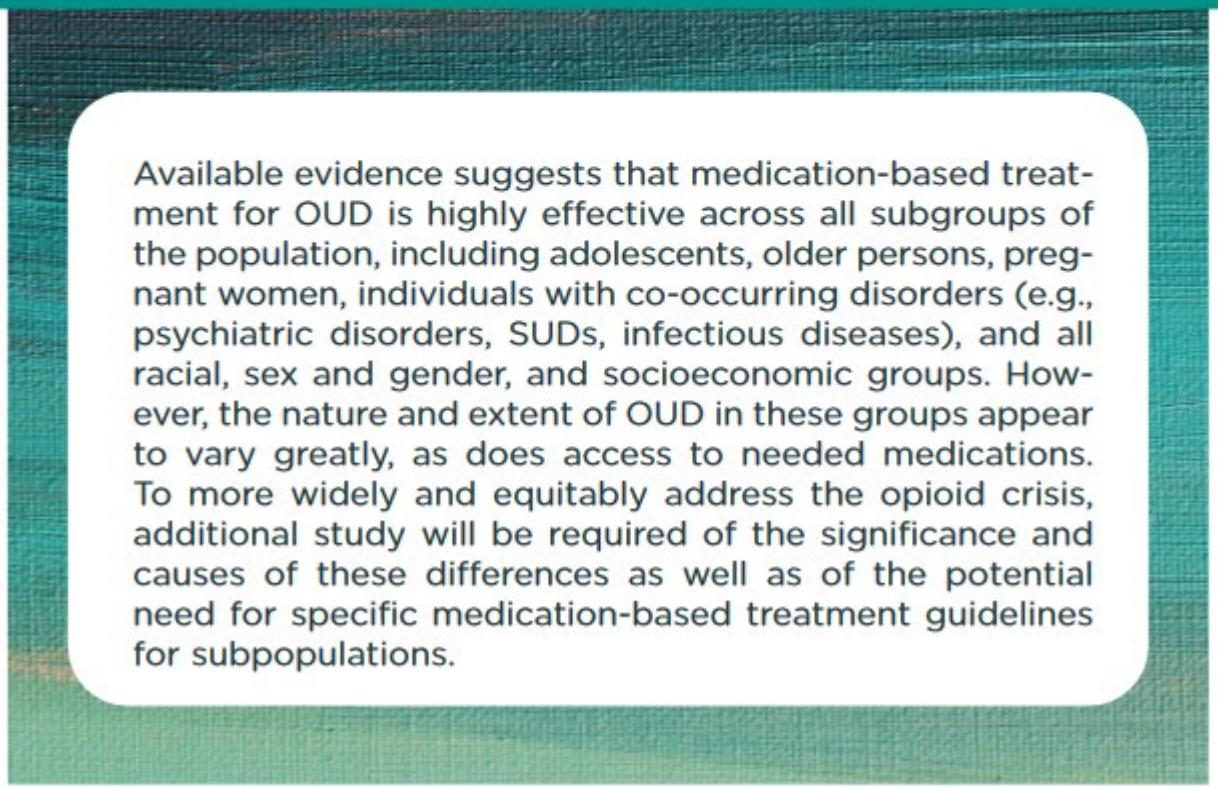
National Academies of Sciences, Engineering, and Medicine

Conclusion 4:
A lack of availability or utilization of behavioral interventions is not a sufficient justification to withhold medications to treat opioid use disorder.

Behavioral interventions, in addition to medical management, do not appear to be a necessary part of treatment in all cases. Some people may do well with medication and medical management alone. However, evidence-based behavioral interventions can be useful in engaging people with OUD in treatment, retaining them in treatment, improving their outcomes, and helping them resume a healthy functioning life. There is inadequate evidence about which behavioral interventions, when used in conjunction with medications for OUD, are most helpful for which patients, including evidence on how effective peer support is; more research is needed to address this knowledge deficit.

National Academies of Sciences, Engineering, and Medicine

Conclusion 5:
Most people who could benefit from medication-based treatment for opioid use disorder do not receive it, and access is inequitable across subgroups of the population.



Available evidence suggests that medication-based treatment for OUD is highly effective across all subgroups of the population, including adolescents, older persons, pregnant women, individuals with co-occurring disorders (e.g., psychiatric disorders, SUDs, infectious diseases), and all racial, sex and gender, and socioeconomic groups. However, the nature and extent of OUD in these groups appear to vary greatly, as does access to needed medications. To more widely and equitably address the opioid crisis, additional study will be required of the significance and causes of these differences as well as of the potential need for specific medication-based treatment guidelines for subpopulations.

National Academies of Sciences, Engineering, and Medicine

Conclusion 6:
Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available all U.S. Food and Drug Administration–approved classes of medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.

Treatment with FDA-approved medications is clearly effective in a broader range of care settings (e.g., office-based care setting, acute care, and criminal justice settings) than is currently the norm. There is no scientific evidence that justifies withholding medications from OUD patients in any setting or denying social services (e.g., housing, income supports) to individuals on medication for OUD. Therefore, to withhold treatment or deny services under these circumstances is unethical.

National Academies of Sciences, Engineering, and Medicine

Conclusion 7:
Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

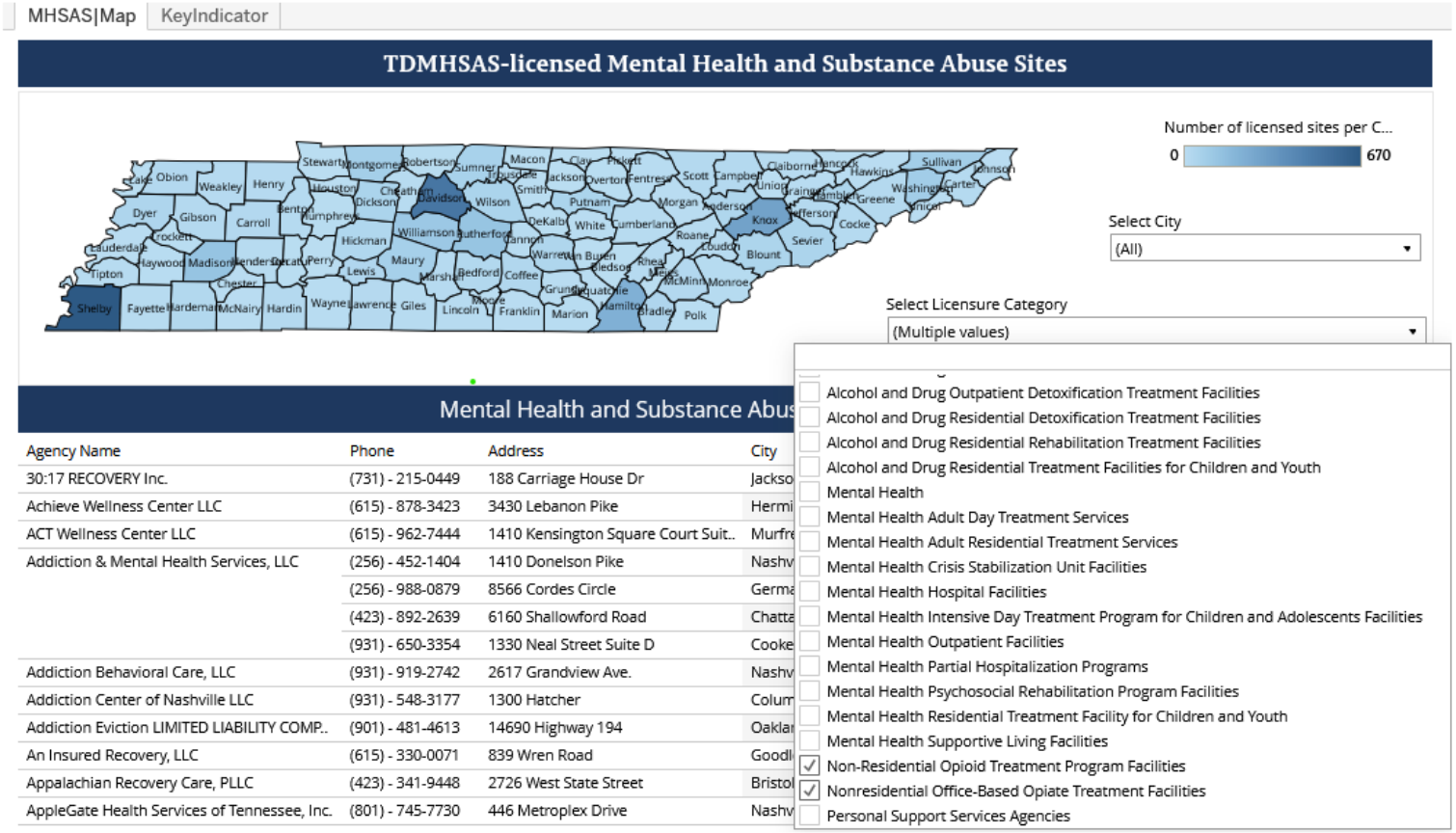
The major barriers to the use of medications for OUD include

- High levels of misunderstanding and stigma toward drug addiction, individuals with OUD, and the medications to treat it.
- Inadequate education of the professionals responsible for working with people with OUD, including treatment providers and law enforcement and other criminal justice personnel.
- Current regulations around methadone and buprenorphine, such as waiver policies, patient limits, restrictions on settings, and other policies that are not supported by evidence or employed for other medical disorders.
- The fragmented system of care for people with OUD and current financing and payment policies.

MOUD Utilization

MOUD Utilization

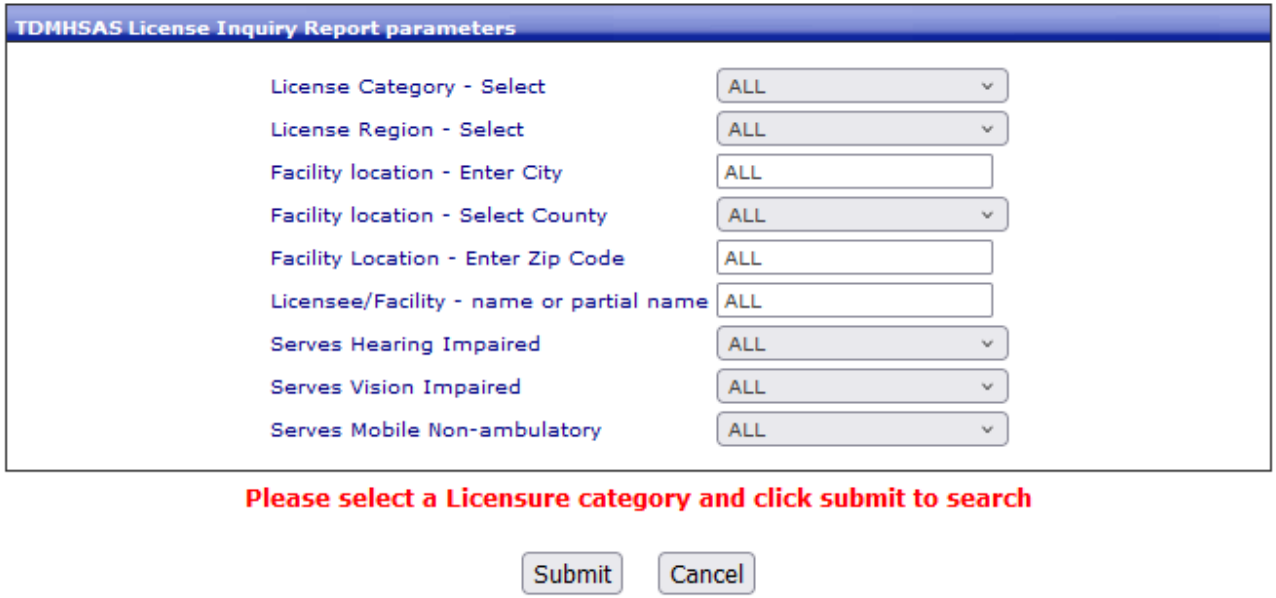
How do I find a Provider?



https://www.tn.gov/behavioral-health/licensing/find-a-licensed-facility-or-service.html

MOUD Utilization

How do I find a Provider?



https://www.tn.gov/behavioral-health/licensing/find-a-licensed-facility-or-service.html

MOUD Utilization

How many licensed providers (OBOTs and OTPs) are there?

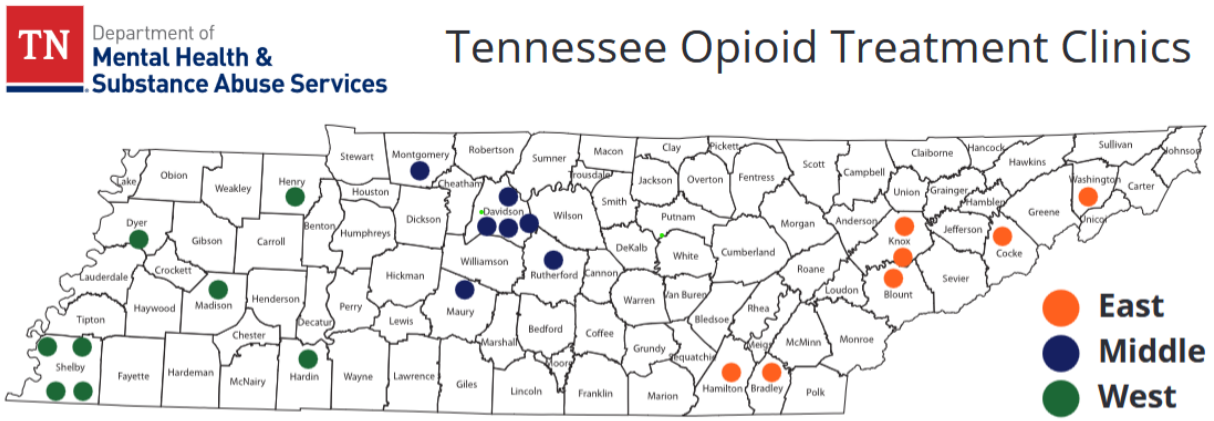
OBOTs

DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES - CURRENT LICENSES

License Category: Nonresidential Office-Based Opiate Treatment Facilities — January 17, 2025

191	Licenses
115	LicensEEs
191	Sites
	licensed categories (services)

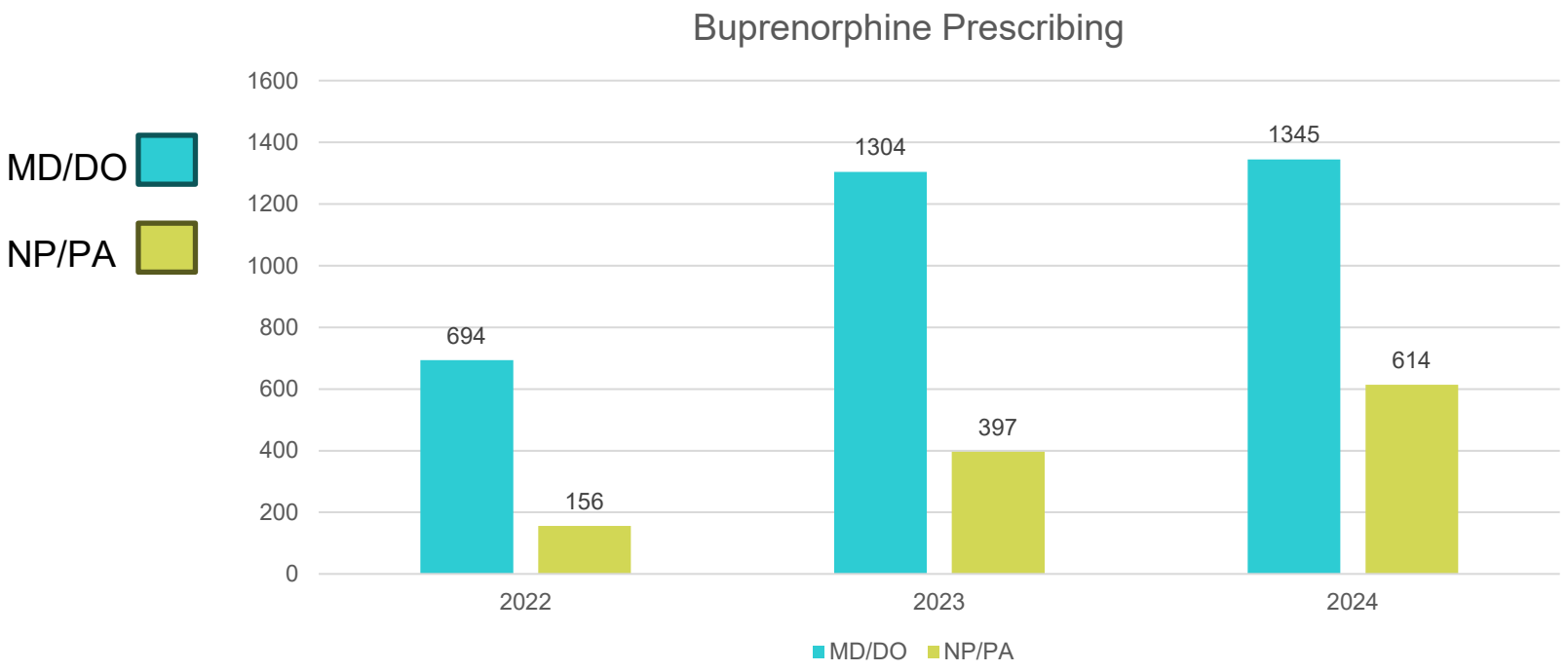
OTPs



https://www.tn.gov/behavioral-health/licensing/find-a-licensed-facility-or-service.html

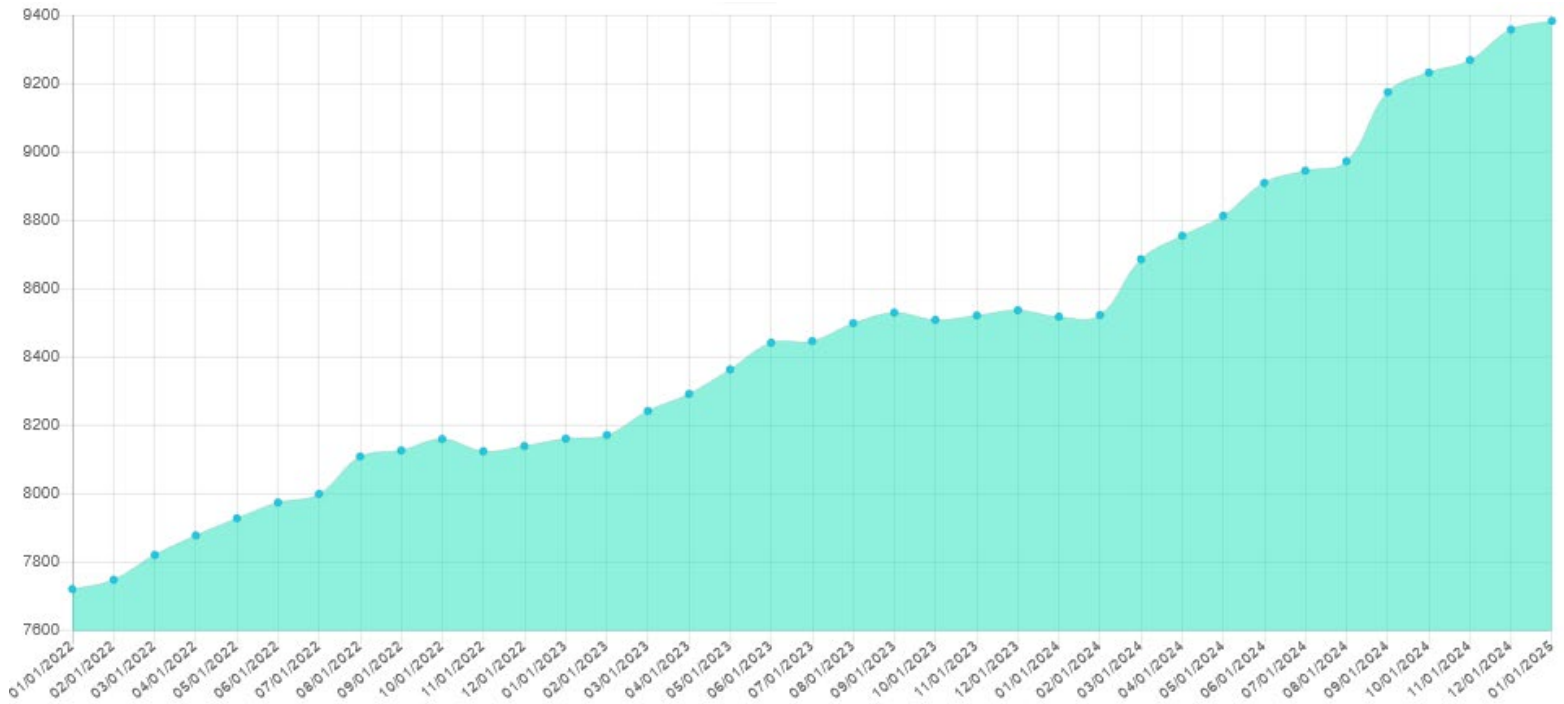
MOUD Utilization

- As of 7/2024, TN has approximately 1,960 active **prescribers of buprenorphine**, per the CSMD



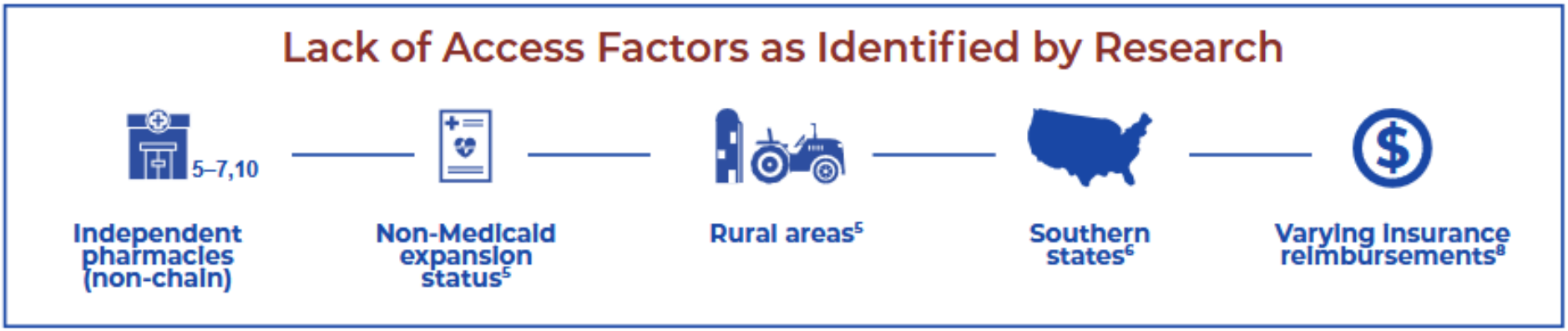
MOUD Utilization

- As of 01/2025, TN has approximately 1,960 active **patients receiving methadone** at an OTP, per the CSMD



Barriers to Access MOUD

Barriers to Accessing MOUD



- Barriers Identified by Roundtable Participants
  - Stigma
  - Patient Barriers
  - Classification in the Same Category as Other Opioids
  - Fear of Violating Rules
  - Pharmacies Losing Money on Every Prescription

Policy Priority Roundtable Summary Report – Improving Buprenorphine Access in Pharmacy Settings – SAMHSA
https://www.samhsa.gov/sites/default/files/policy-priority-roundtable-buprenorphine-access-pharmacies.pdf

NABP PhARM-OUD Guidance

NABP – PhARM-OUD Guidelines

The Pharmacy Access to Resources and Medication for Opioid Use Disorder (PhARM-OUD) Guideline

A Joint Consensus Practice Guideline from the National Association of Boards of Pharmacy and the National Community Pharmacists Association

NABP – PhARM-OUD Executive Summary

Recommendation 1 | Maintenance pharmacotherapy with buprenorphine

Pharmacists should maintain a sufficient supply of buprenorphine in their pharmacies and be willing to dispense buprenorphine to patients with OUD. Declining to dispense buprenorphine can lead to interruptions in OUD treatment, force patients into withdrawal, and increase risk of recurrent opioid use, and death.

Recommendation 2 | Potential indicators of misuse or diversion and prescription drug monitoring programs

Pharmacists should use their state's prescription drug monitoring program (PDMP), where operational and available, to make informed buprenorphine dispensing decisions. The information in the PDMP profile should be used as a supplement, rather than as a substitute for clinical judgement when reviewing a buprenorphine prescription.

Recommendation 3 | Early refills

Occasional requests to refill buprenorphine early are unlikely to indicate misuse of buprenorphine but may instead indicate that a patient has been asked to change their dose, lost or damaged a dosage unit, or is attempting to refill their medication in advance of a change in residence or insurance benefits. Before making a dispensing decision, pharmacists should discuss the context of the request with the patient, contact the prescriber, and document their rationale for dispensing or declining the prescription.

NABP – PhARM-OUD Executive Summary Continued

Recommendation 4 | Telehealth

Pharmacists should dispense buprenorphine prescriptions issued by virtual health, or telehealth, prescribers if the prescription is legitimate, and the pharmacist can fulfill their corresponding responsibility.

Recommendation 5 | Buprenorphine monoproduct

Current clinical evidence supports the efficacy of buprenorphine monoproduct for the treatment of OUD.

Recommendations 6 | Optimizing the safety and effectiveness of buprenorphine pharmacotherapy

Pharmacists and pharmacy technicians should do the following to optimize the quality of care for persons prescribed buprenorphine:

- Pharmacists should counsel patients on buprenorphine's potential adverse effects and encourage patients to report adverse events if they emerge.
- Pharmacists should offer to dispense naloxone to patients prescribed buprenorphine for the management of OUD.
- As with any medication, pharmacists should educate patients about the dangers of certain drug combinations (particularly full opioid agonists, benzodiazepines, and sedative hypnotics) and the risks associated with alcohol use while taking buprenorphine.
- Pharmacists should provide counseling on the safe storage and disposal of buprenorphine products.
- Pharmacy technicians can provide valuable support to the process of care. Where not otherwise prohibited by state law, technicians can improve the efficiency of care by extracting information from prescription monitoring programs, contacting prescribers, reminding patients to refill their prescriptions, and assisting with reimbursement issues.

NABP – PhARM-OUD Executive Summary Continued

Recommendations 7 | Care coordination and prescriber communication

Pharmacists can meet the comprehensive care needs of their patients and prevent interruptions in pharmacotherapy for OUD by doing the following:

- Extending the same level of medication therapy management, immunization, and point-of-care testing services to patients with OUD as they do to other patients.
- Implementing collaborative practice agreements that could potentially enable pharmacists to monitor buprenorphine pharmacotherapy, provide supportive care, and potentially create opportunities to bill for cognitive services provided.
- Promoting adherence to treatment for OUD by being willing and able to refer patients in treatment to local primary care, mental health, and peer support providers upon patient request.

- If a pharmacist needs to clarify a buprenorphine prescription for whatever reason, they should make every effort to promptly contact the prescriber through direct communication via phone, email, or pager rather than fax while following state and federal privacy rules.
- If pharmacists cannot promptly reach a prescriber to renew or clarify a buprenorphine prescription, they should consider dispensing a partial quantity of the prescription to prevent interruptions in care.

NABP – PhARM-OUD Executive Summary Continued

Recommendation 8 | Stigma toward persons with OUD

Pharmacists, pharmacy technicians, and all pharmacy staff should approach persons living with OUD with empathy, compassion, and support, recognizing and addressing how their biases may impact their ability to provide care and make appropriate, patient-centered decisions.

Recommendation 9 | Employer oversight

Pharmacy policies for buprenorphine dispensing should prioritize flexibility, allowing individual pharmacists to exercise their professional judgment when deciding whether to dispense a prescription for buprenorphine.

Ditch the Red Flags – Adopt the Yellow Flags

Tennessee Buprenorphine Guidelines

Tennessee Nonresidential Buprenorphine Treatment Guidelines

(Fall 2023 Update)

TN Department of Mental Health & Substance Abuse Services

TN Department of Health

https://www.tn.gov/content/dam/tn/mentalhealth/documents/Bupe_Treatment_Guidelines_Fall_2023.pdf

TN

Section III: Ongoing Treatment - E. PHARMACISTS

1. Pharmacists are crucial for ensuring safe and appropriate access to buprenorphine. Pharmacists and staff should be knowledgeable of buprenorphine in the treatment of OUD, using resources made available by APhA, ASHP, AAPP, or SAMHSA, for example.

2. Non-compounding and non-veterinarian community pharmacies that primarily dispense prescriptions for human patients, including other controlled substances, should make reasonable efforts to keep buprenorphine-containing products in stock.

3. Pharmacists shall attempt to collaborate with prescribers to resolve any concerns, such as distance from the provider, dose, or combination prescribing, before refusing to fill the prescription. For example, telehealth is increasing in prevalence, is a viable option for some patients, and may explain why some patients may be a considerable distance from their providers.

Section III: Ongoing Treatment - E. PHARMACISTS

4. Pharmacists should consider collaborating with the provider to gain insight into the patient's treatment plan in an effort to assist the patient in meeting their therapeutic goals. Some patients may not feel comfortable sharing the treatment plan in its entirety due to potentially sensitive information, therefore having the treatment plan should not preclude access to medication. Collaboration between the pharmacist, patient, and provider should be attempted to determine what can and will be shared to allow the pharmacist to actively participate and facilitate the patient's recovery and progress toward their therapeutic goals.

5. Pharmacists should also offer other healthcare services, such as vaccinations, disease screening, and providing resources, as appropriate.

Recent State and Federal Legislative Changes

State Legislative Updates

- **Nurse Practitioners (NPs) and Physician Assistants (PAs) prescribing Buprenorphine**

  NPs and PAs may only prescribe buprenorphine in certain clinical settings (licensed OBOTs, FQHCs/CMHCs, and teaching hospitals). Other limitations exist, such as maximum daily dose, number of patients treated at a time, and must accept TennCare.

- **Buprenorphine Prescribing and Telehealth**

  The prescribing of buprenorphine products by telehealth may only be conducted by a practitioner that is contracted with TennCare's BE-SMART network or on behalf of an OBOT, FQHC/CMHC, or a hospital.

State Legislative Updates

- **Methadone Reporting to the CSMD**

  Recent changes to federal privacy laws permit the reporting of methadone and buprenorphine dispensing to state PDMPs if required by the state. The Tennessee Department of Health has been authorized to promulgate rules to require OTPs to report controlled substance dispensing to the CSMD and will be required when those rules are effective.

State Legislative Updates

- **Possession of Xylazine**

  Except for veterinary use, it is a Class A misdemeanor to knowingly possess xylazine and Class C felony to knowingly manufacture, deliver, or sell xylazine, or to knowingly possess xylazine with intent to manufacture, deliver, or sell xylazine.

Federal legislative updates

- **Waiver Elimination (Mainstreaming Addiction Treatment (MAT) Act)**
  Section 1262 of the Consolidated Appropriations Act, 2023 (also known as Omnibus bill), removed the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications for OUD. Formerly known as the DATA waiver, or X-waiver.

- **Revision of 42 CFR Part 8**
  This final rule modifies and updates certain provisions of regulations related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of opioid use disorder with medications for OUD in OTPs.

Federal legislative updates

- **3-Day Rule**

  Practitioners may dispense up to a 3-day supply of a controlled substance to a person for the purpose of initiating maintenance treatment or detoxification while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended.

- **MOTAA?**

  The proposed Modernizing Opioid Treatment Access Act would allow extended telehealth flexibilities for initiating MOUD and allow practitioners at an OTP and other certain qualified practitioners to prescribe methadone for addiction to be filled at community pharmacies.

Federal legislative updates

****Just Announced****

- Buprenorphine and Telehealth Rules

  The DEA has recently announced the final rules for prescribing buprenorphine through telehealth. Buprenorphine may be prescribed by means of telehealth, including audio-only, for up to 6 months without an in-person examination or unless the practitioner meets the definition of “practice of telemedicine” as defined in 21 U.S.C. 802(54).

QUESTIONS?

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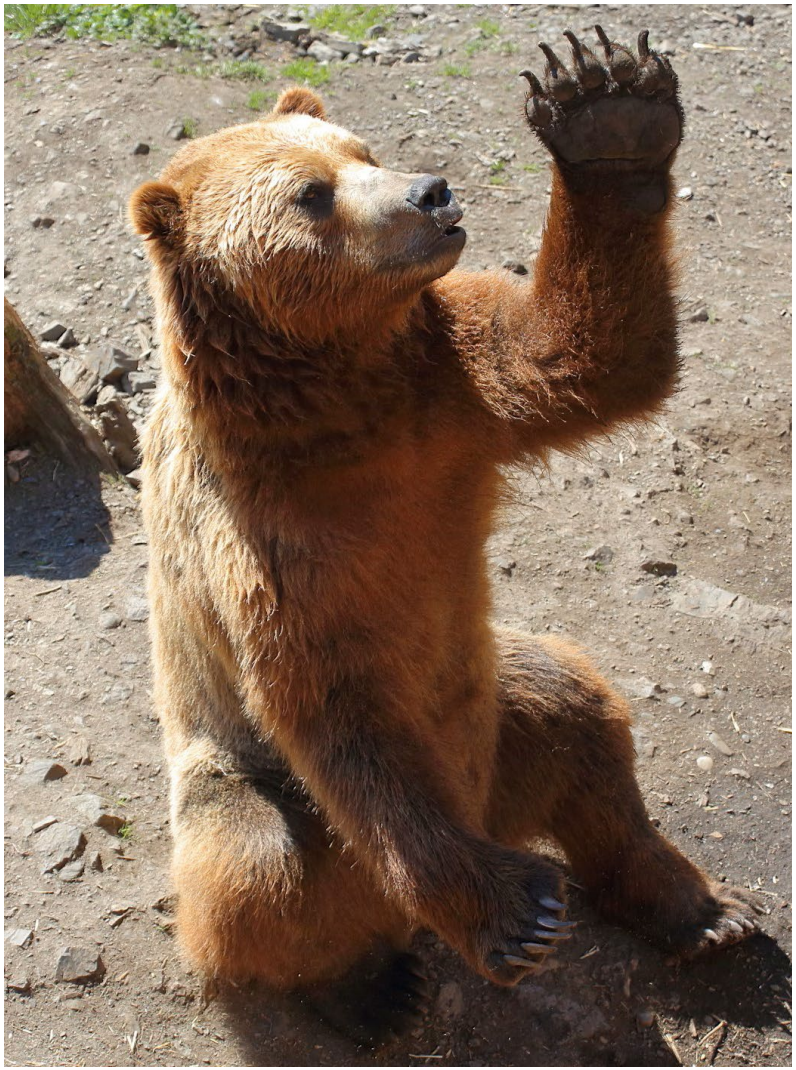
Work cell: (901) 356-1914



Resources

- **SAMHSA TIP 63:** https://store.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002
- **Federal OTP Guidelines:** https://store.samhsa.gov/product/federal-guidelines-opioid-treatment-programs-2024/pep24-02-011
- **NABP PhARM-OUD Guidelines:** https://nabp.pharmacy/wp-content/uploads/2024/09/PhARM-OUD-Guidance.pdf
- **SAMHSA's Improving Buprenorphine Access in Pharmacy Settings:** https://www.samhsa.gov/sites/default/files/policy-priority-roundtable-buprenorphine-access-pharmacies.pdf

Resources (Continued)

- **TN Department of Mental Health and Substance Abuse Services – MAT Webpage**: https://www.tn.gov/behavioral-health/substance-abuse-services/treatment---recovery/treatment---recovery/opioid-treatment-programs.html
- **National Academies' Medication-Assisted Treatment for Opioid Use Disorder:** https://www.nationalacademies.org/our-work/medication-assisted-treatment-for-opioid-use-disorder