Closing the Loop: Transitions of Care for Persons with Opioid Use Disorder

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PhARM Program

Learning Objectives

- Identify the risks of untreated opioid use disorder or disruptions in treatment
- Review barriers to buprenorphine access in community pharmacies and consensus, evidence-based solutions.
- Create a plan to initiate and continue pharmacotherapy for opioid use disorder during transitions between the health system and community settings

Disclaimers and Disclosures

Dr. Varisco receives funding from the Texas Targeted Opioid Response, a public health initiative operated by the Texas Health and Human Services Commission through federal funding from the Substance Abuse and Mental Health Services Administration grant award number 1H79TI087739-01.

The views expressed do not reflect the official policies of the Department of Health and Human Services or Texas Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. or Texas Government.

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Part 1: Understanding the Risks of Untreated OUD

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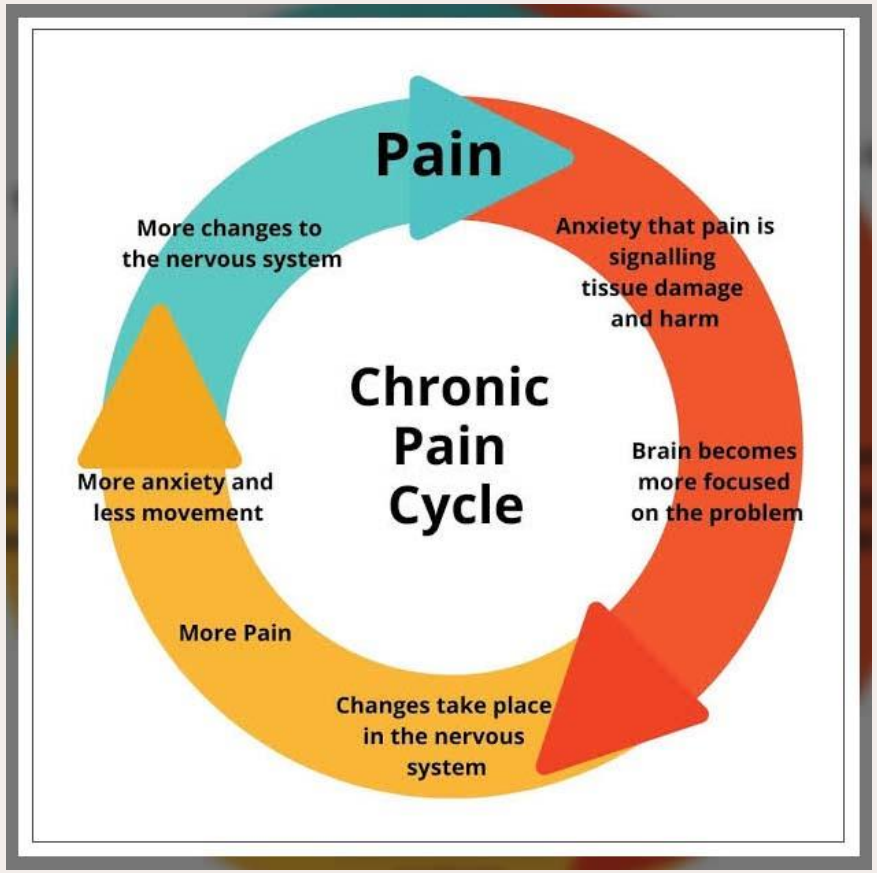
A Nation in Pain



20.9% of US adults (51.6 million persons) living with chronic pain

6.9% of US adults (17.1 million persons) living with high-impact chronic pain

$560 billion in lost productivity annually

Rikard SM, Strahan AE, Schmit KM, Guy GP Jr.. Chronic Pain Among Adults — United States, 2019–2021. MMWR Morb Mortal Wkly Rep 2023;72:379–385. DOI: http://dx.doi.org/10.15585/mmwr.mm7215a1.

Why are we all in pain?

Multimorbidity:	• Odds of chronic pain are 1.4-3.9 times higher in patients with six or more chronic conditions
Mental Health Conditions:	• 30-56% of people with chronic pain have co-occurring depression
Metabolic Syndrome:	• Patients who are overweight or obese are 1.5-2.2 times more likely to experience chronic pain than those who are not.

Dominick CH, Blyth FM, Nicholas MK. Unpacking the burden: understanding the relationships between chronic pain and comorbidity in the general population. Pain. 2012 Feb;153(2):293-304. doi: 10.1016/j.pain.2011.09.018. Epub 2011 Nov 8. PMID: 22071318.

Wright, L. J., Schur, E., Noonan, C., Ahumada, S., Buchwald, D., & Afari, N. (2010). Chronic pain, overweight, and obesity: findings from a community-based twin registry. The Journal of Pain, 11(7), 628-635.

Five Sentences to the Fifth Vital Sign:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

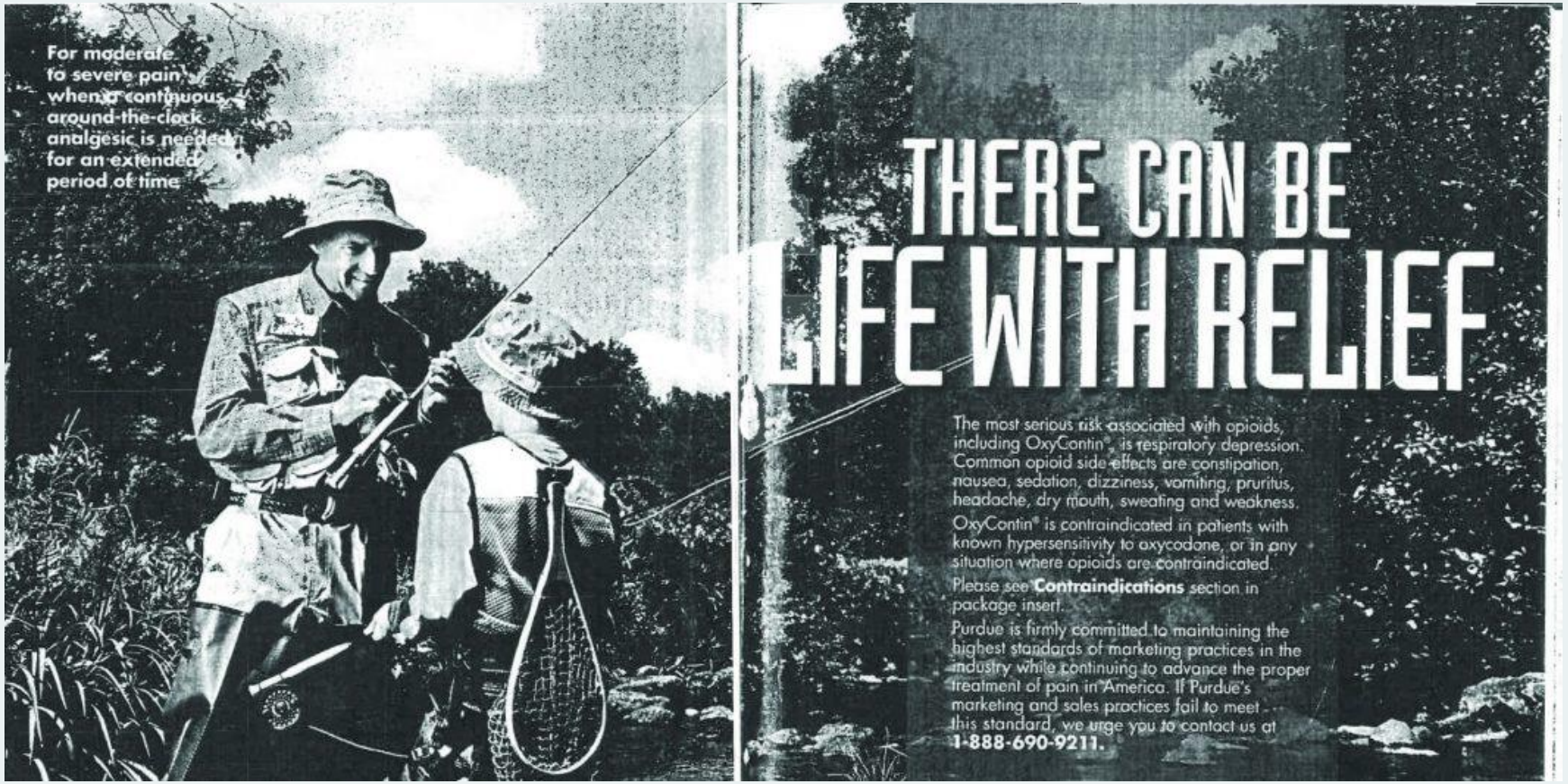
To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Waltham, MA 02154 Boston University Medical Center

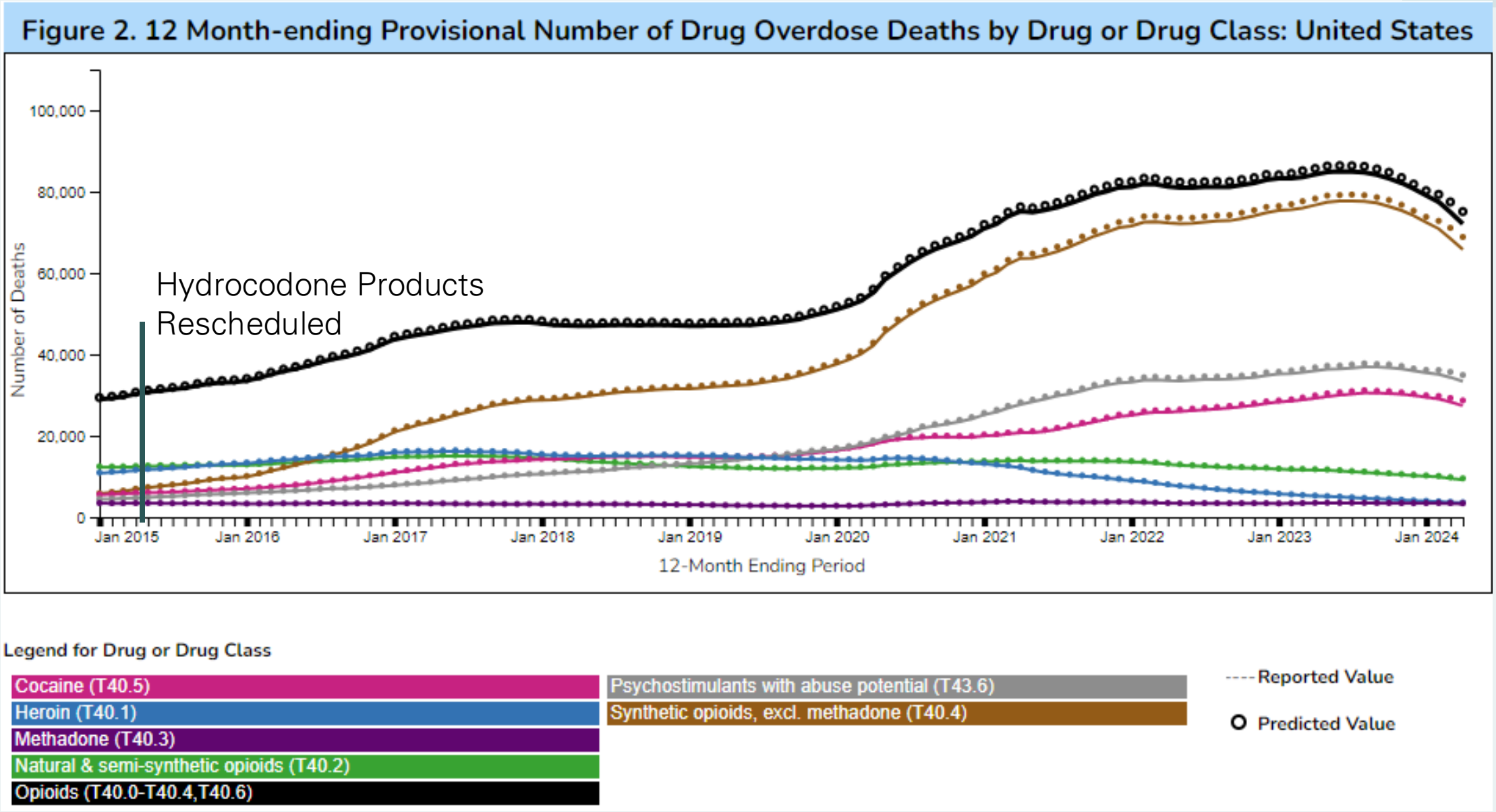
1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

Porter J, Jick H. Addiction rare in patients treated with narcotics. N Engl J Med. 1980 Jan 10;302(2):123. doi: 10.1056/nejm198001103020221. PMID: 7350425.

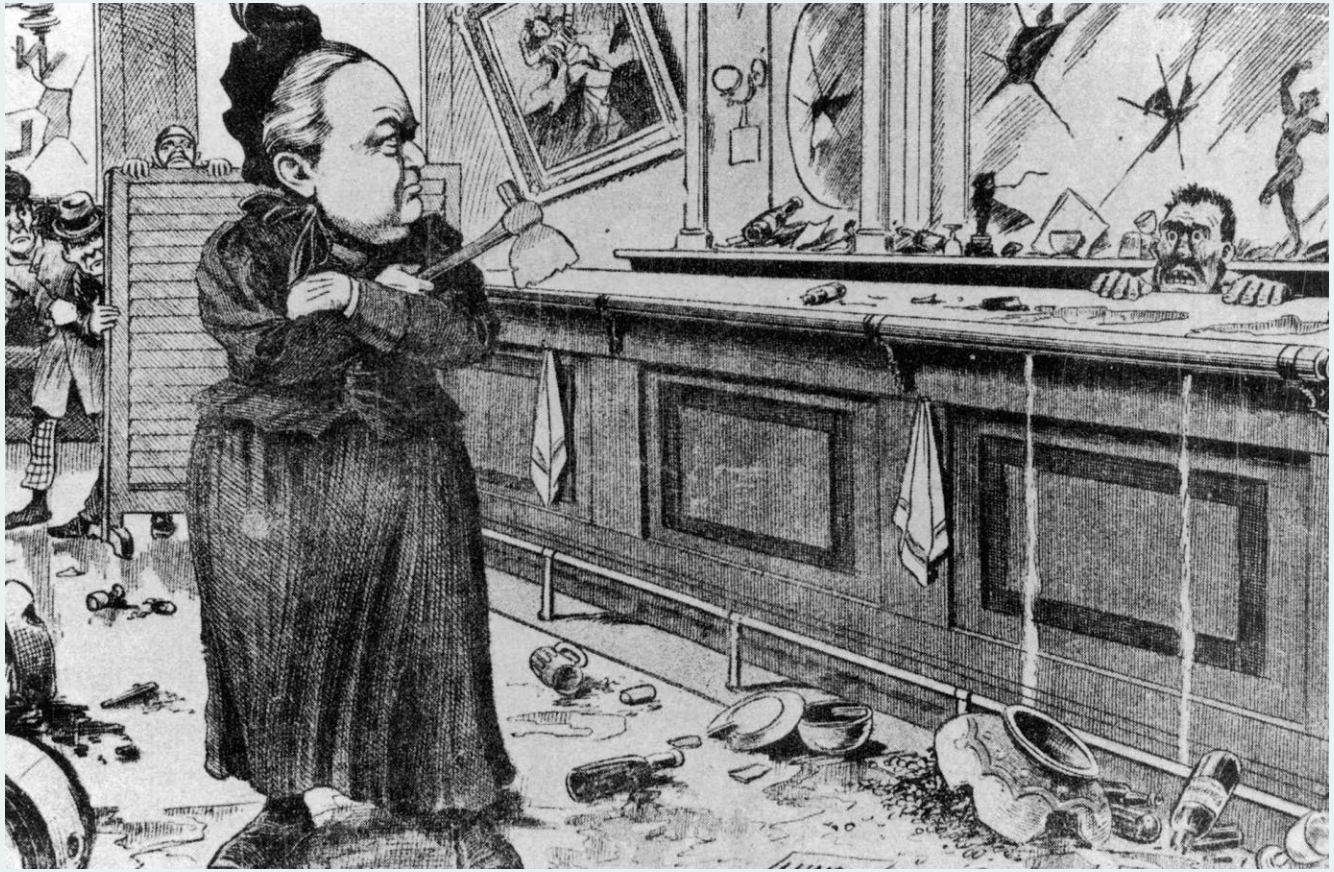
We know where that went:



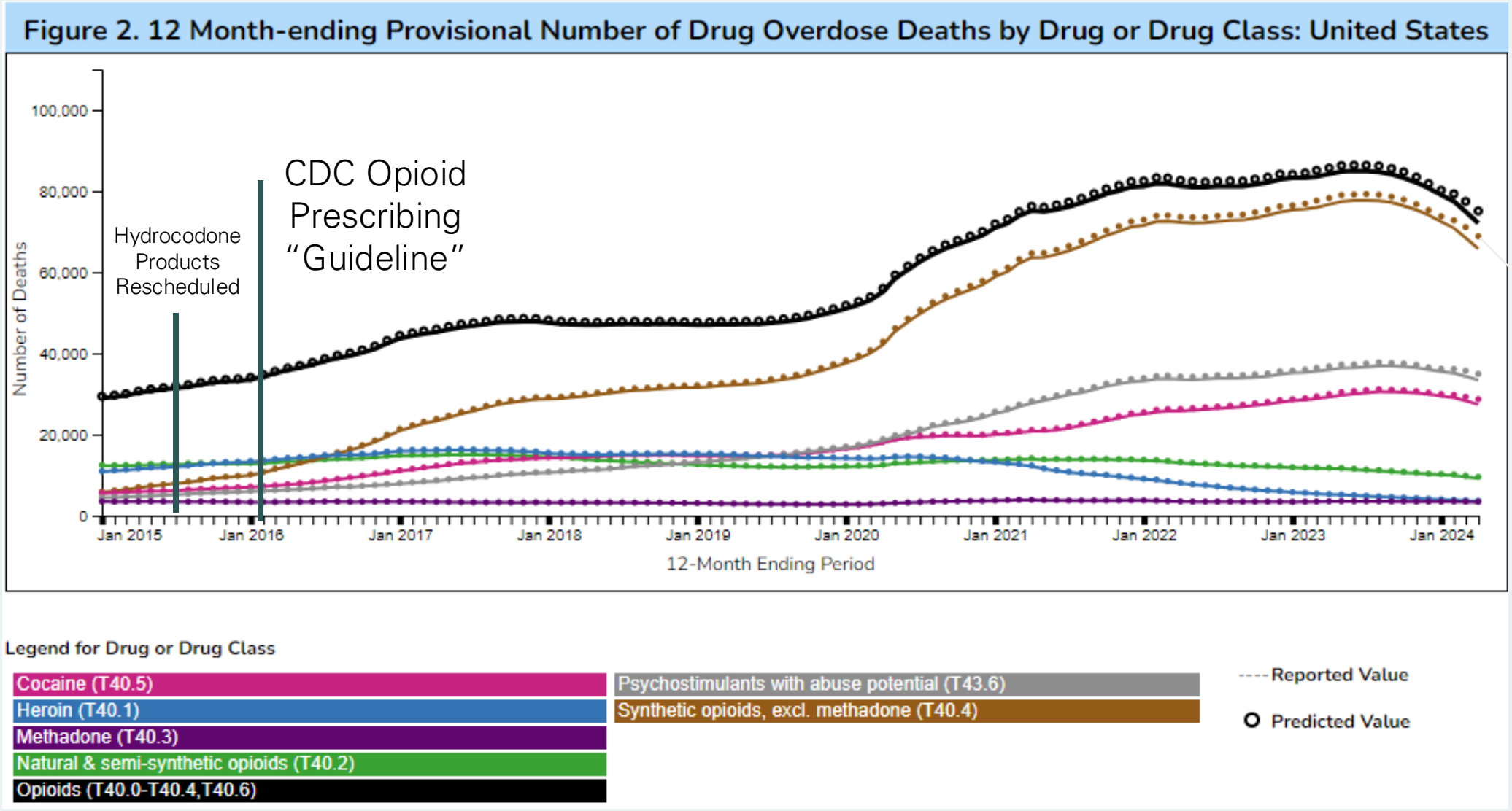
The US Opioid Overdose Crisis:



Prohibition!



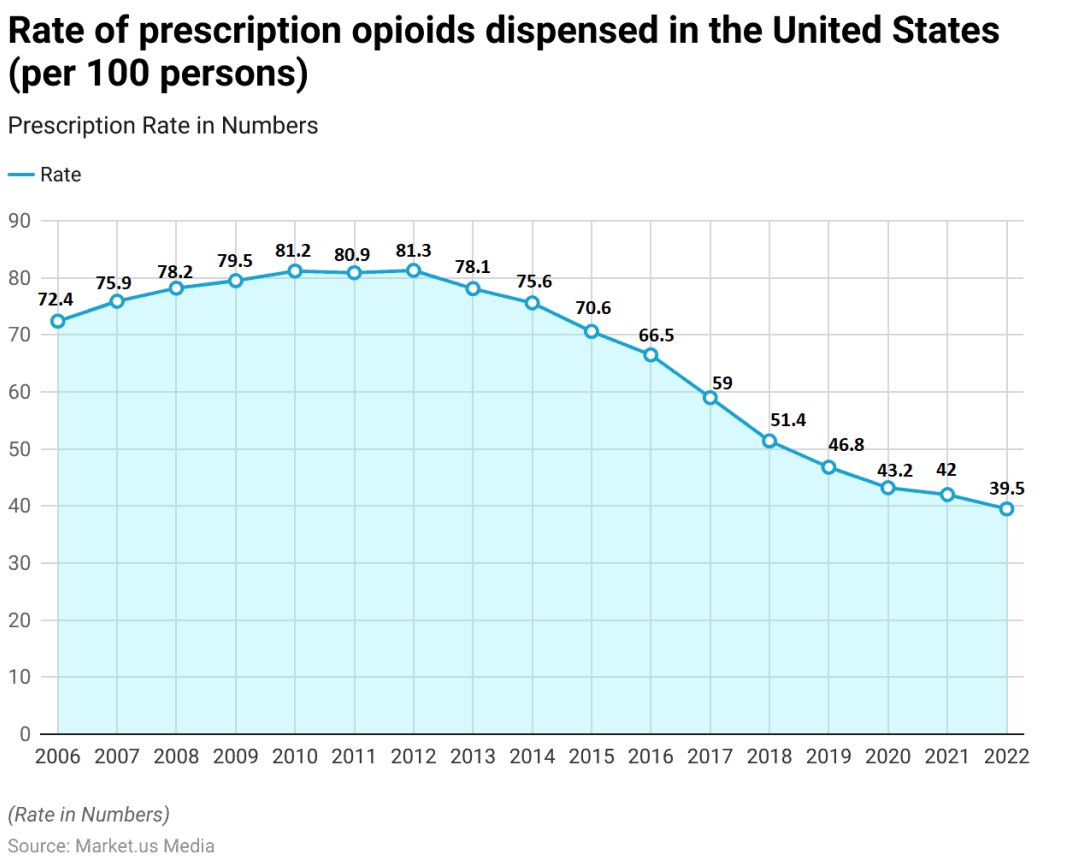
The US Opioid Overdose Crisis:



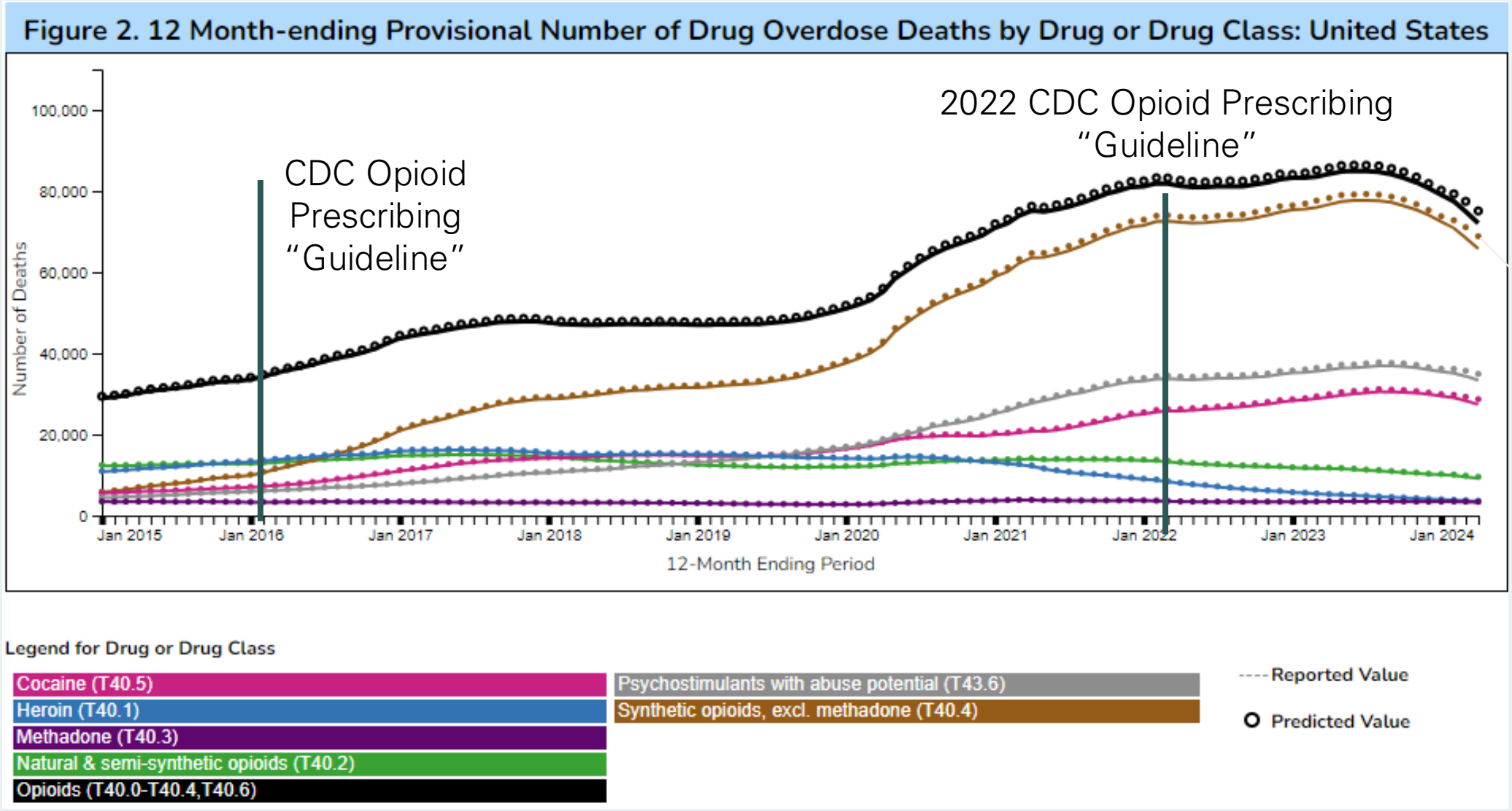
2016 Centers for Disease Control and Prevention (CDC) Prescribing Guidelines:

Risk mitigation strategies were recommended without evidence:	• Recommendation: "When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy." • "The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain"
Limits on duration of treatment:	• "Three days or less will often be sufficient; more than seven days will rarely be needed."
Ambiguous recommendations:	• "Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently."

Changes in Opioid Dispensing



The US Opioid Overdose Crisis:



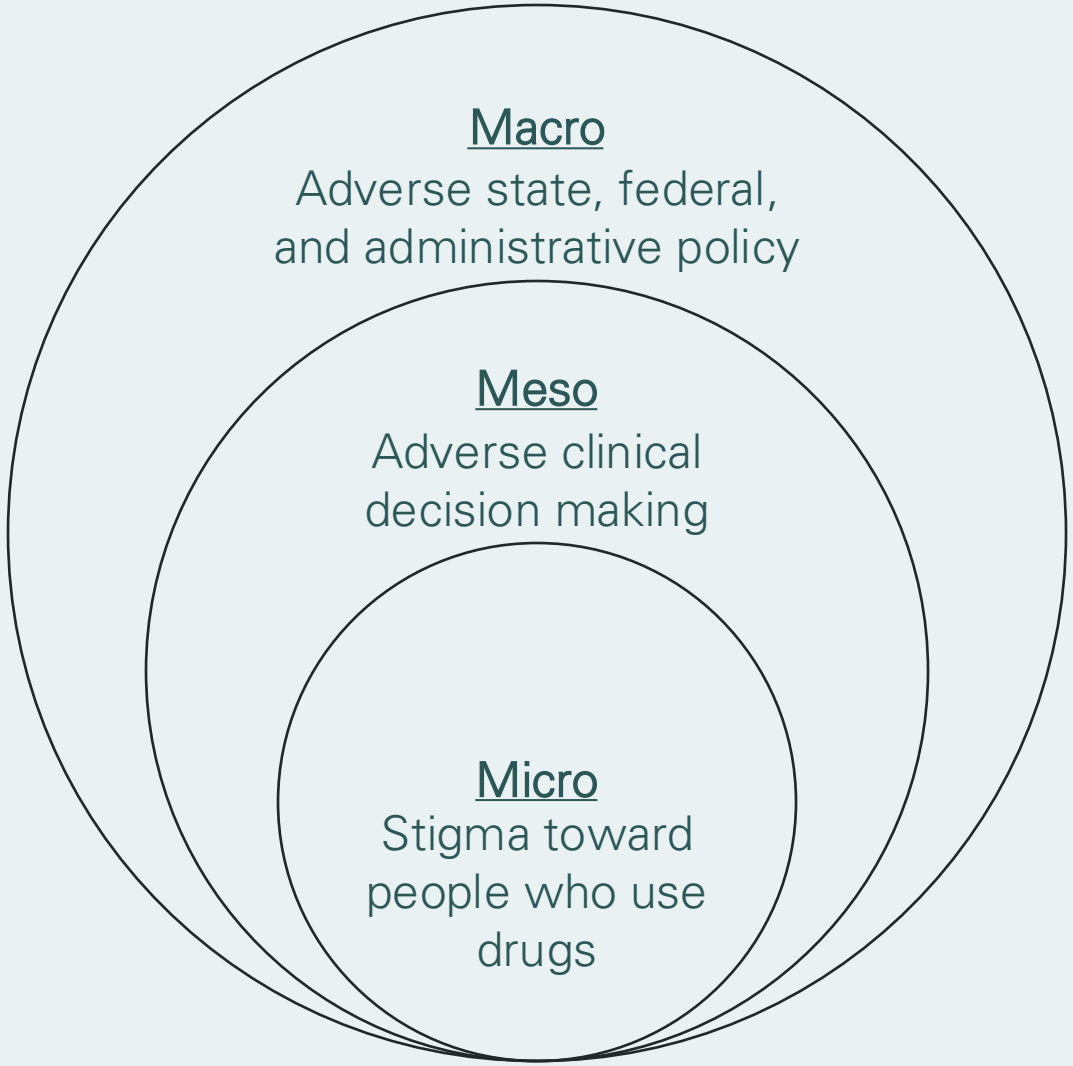
Codifying the Guidelines:

"Although not the intent of the 2016 CDC Opioid Prescribing Guideline, design and implementation of new laws, regulations, and policies also appeared to reflect its recommendations."

CDC Clinical Practice Guideline for Prescribing Opioids for Pain, 2022

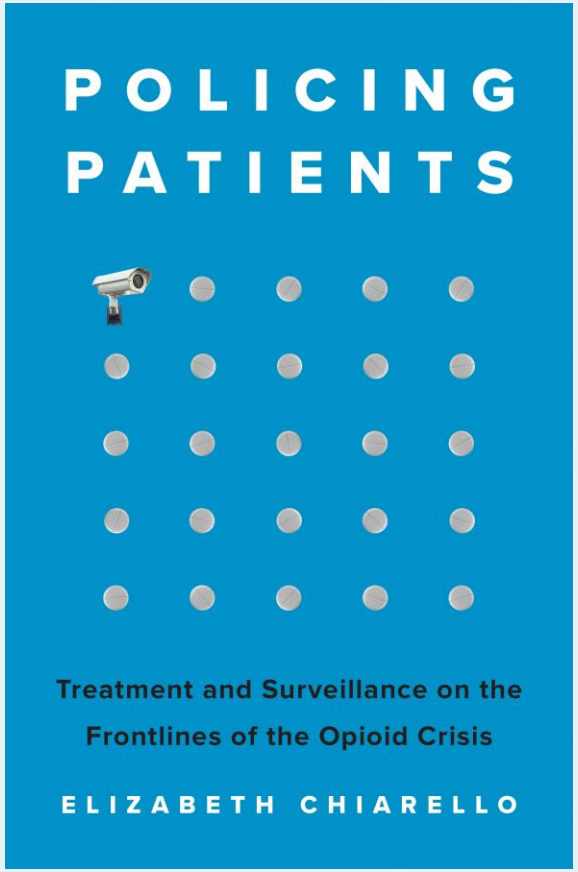
Tipping the Scales

Understanding the Risk Environment:

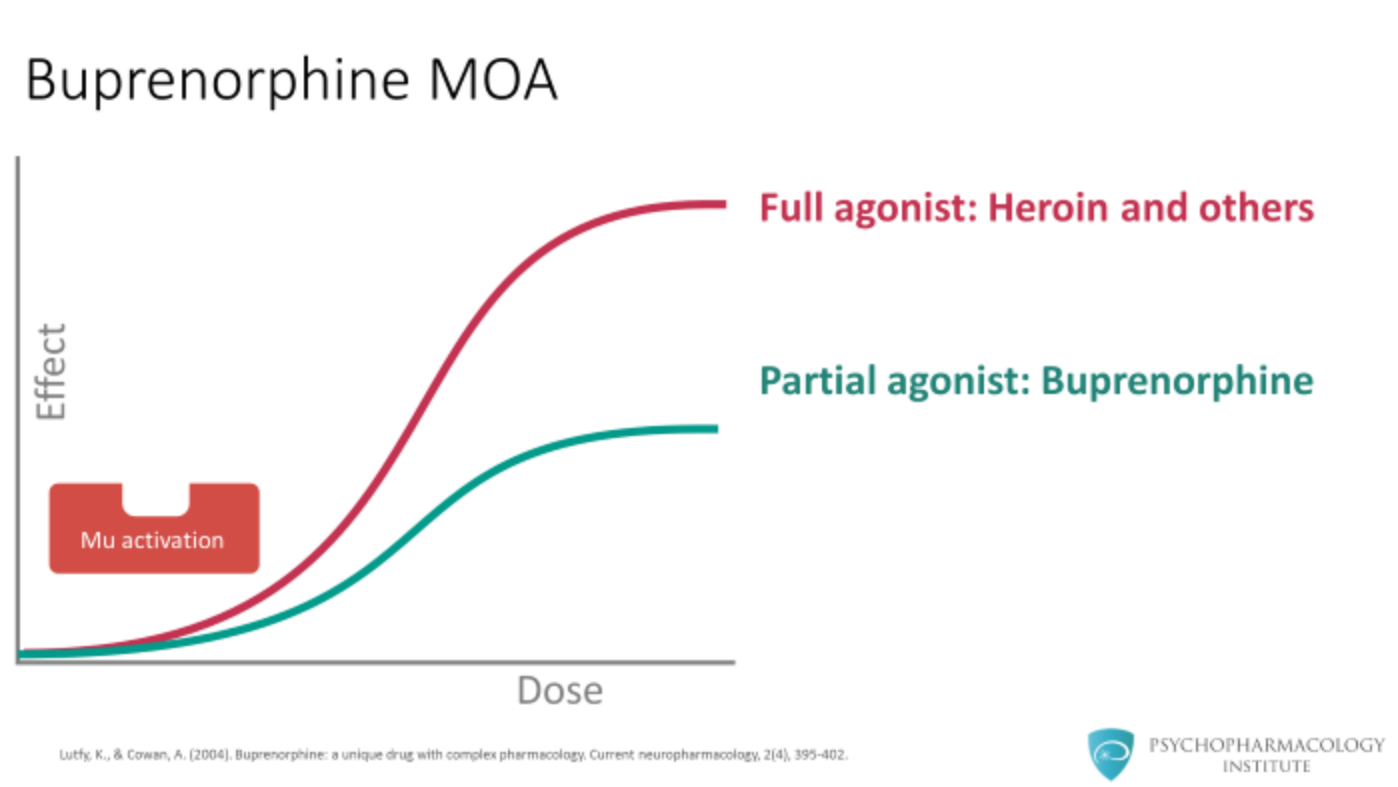


Adapted from Figure 1 in: Cooper HL, Cloud DH, Freeman PR, et al. Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky. *Int J Drug Policy*. Mar 26 2020:102701. doi:10.1016/j.drugpo.2020.102701

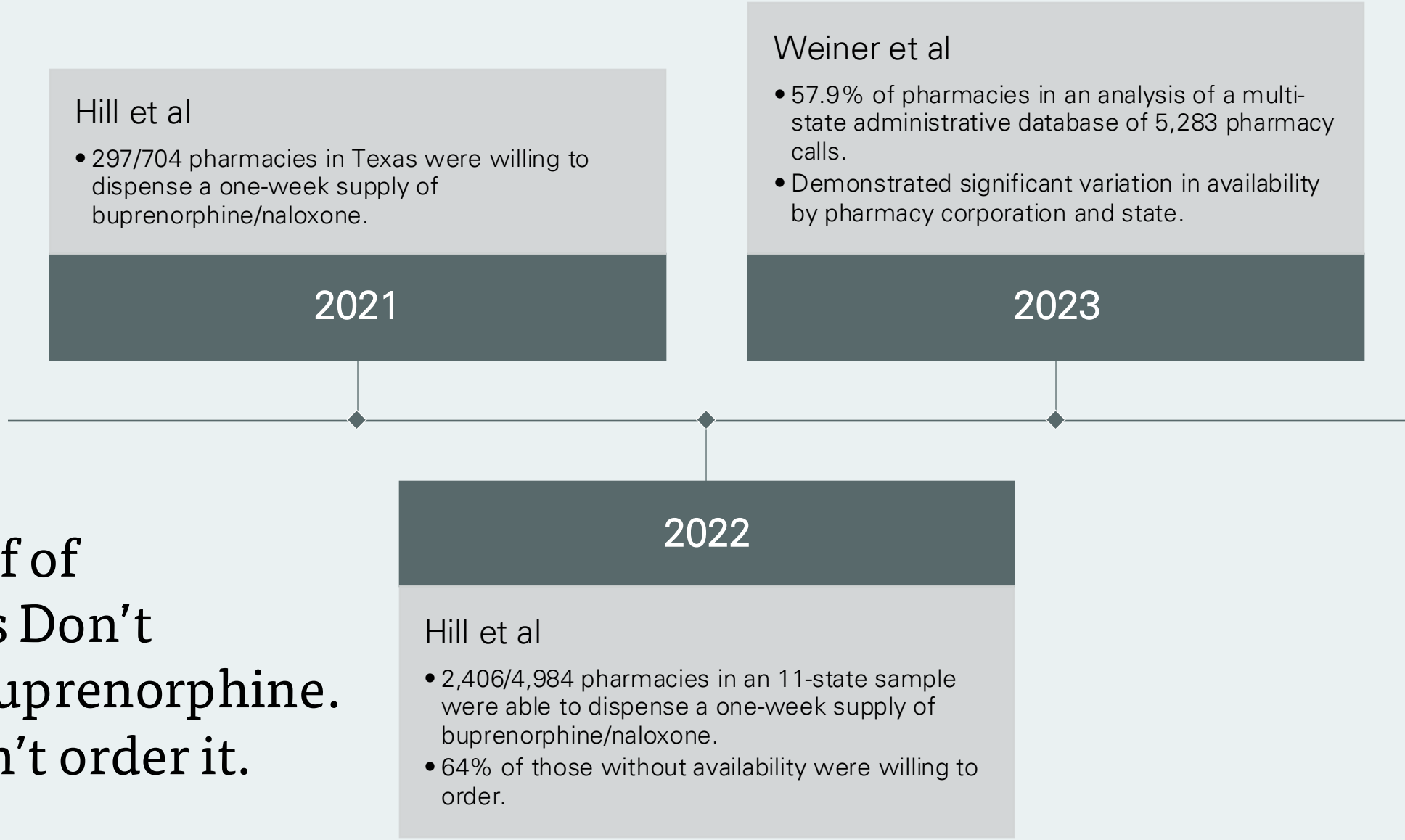
There's a whole book on this!



The Actual Solution



TLDR: Half of Pharmacies Don't Dispense Buprenorphine. A third won't order it.



Is oversight a good thing?

TABLE 4 Predictors of pharmacist and physician prescription monitoring program query identified through hierarchical logistic regression in a sample of opioid prescriptions from the Texas prescription monitoring program

	Pharmacist		Prescriber	
	aOR	95% CI	aOR	95% CI
Medication[a]				
Codeine	1.00	Ref.	1.00	Ref.
Tramadol	1.15	1.14–1.16	1.26	1.23–1.28
Oxycodone	4.51	4.42–4.60	1.96	1.90–2.01
Hydrocodone	2.53	2.50–2.56	1.98	1.95–2.02
Buprenorphine	1.40	1.35–1.45	2.24	2.15–2.35
Fentanyl	1.96	1.88–2.05	1.61	1.53–1.70
Morphine	2.00	1.93–2.07	1.62	1.56–1.69
Other opioid	4.36	4.22–4.51	1.75	1.68–1.83

Thornton JD, Varisco TJ, Downs CG. Factors associated with the use of the prescription monitoring program by prescribers and pharmacists in Texas. https://doi.org/10.1002/pds.5198. *Pharmacoepidemiology and drug safety*. 2021/01/17 2021;n/a(n/a)doi:https://doi.org/10.1002/pds.5198

Texas-a public health leader

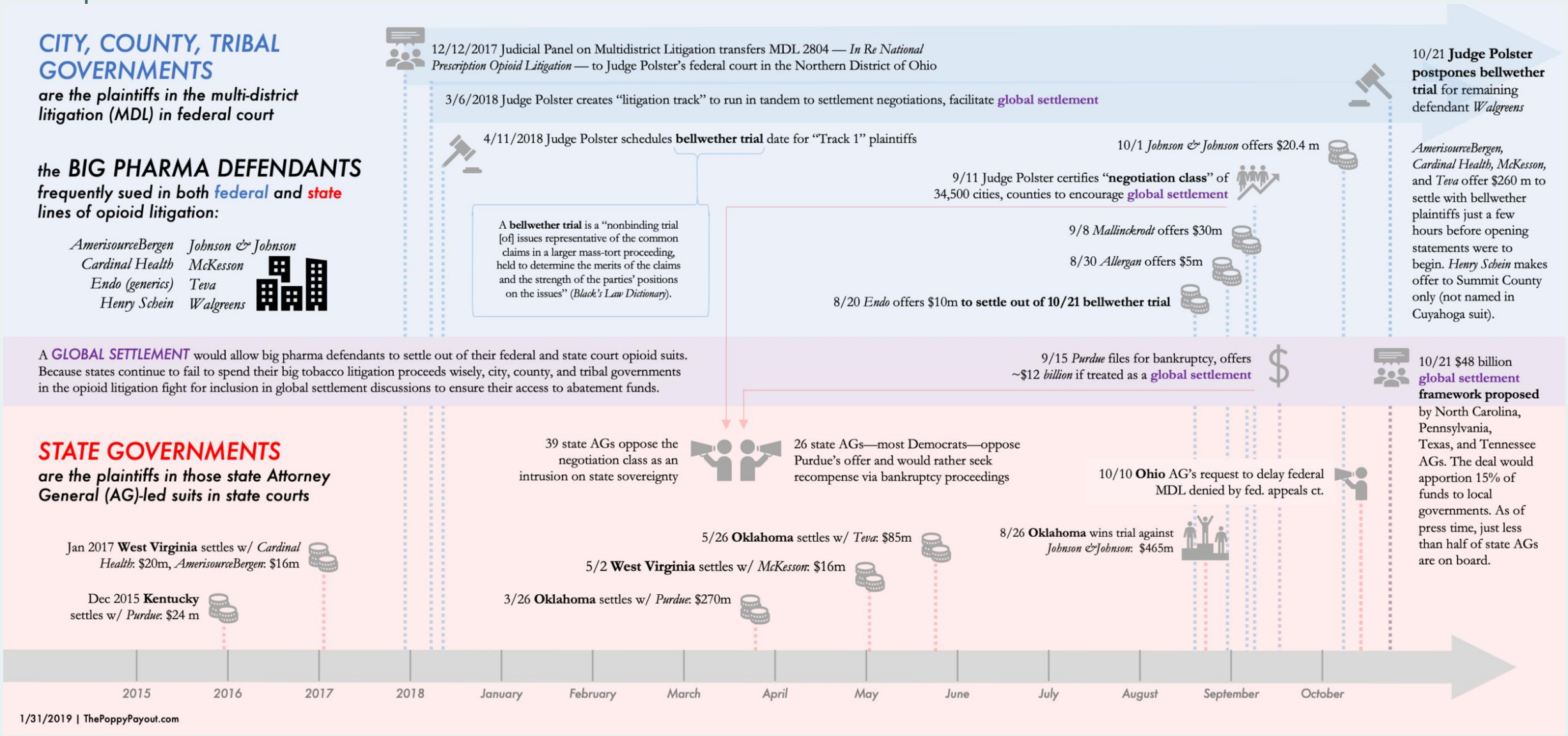
Table 2. Availability of Buprenorphine at Retail Pharmacies by Parent Organization and Select States, 2022

	Pharmacies reporting stock, No./total No. called (%)					
Parent organization	Overall	California	Florida	Michigan	North Carolina	Texas
CVS	750/1256 (59.7)	119/230 (51.7)	74/196 (37.8)	34/102 (33.3)	109/136 (80.2)	108/153 (70.6)
Walgreens	820/1167 (70.3)	63/10		65/96 (67.7)	91/113 (80.5)	94/130 (72.3)
Walmart	206/354 (58.2)	12/37		10/15 (66.7)	33/45 (73.3)	27/48 (56.3)
Rite-Aid	197/337 (58.5)	43/92		51/91 (56.0)	NA	NA
Publix	57/183 (31.2)	NA		NA	7/13 (53.9)	NA
Safeway	92/132 (69.7)	12/22		NA	NA	NA
Kroger	50/90 (55.6)	NA		10/30 (33.3)	NA	25/36 (69.4)
Meijer	33/50 (66.0)	NA		29/43 (67.4)	NA	NA
Costco	31/47 (66.0)	8/12		NA	NA	NA
H-E-B	33/40 (82.5)	NA		NA	NA	33/40 (82.5)
Harris	19/34 (55.9)	NA		NA	12/22 (54.6)	NA
Sav-On	18/31 (58.1)	3/10		NA	NA	NA
Brookshires	16/29 (55.2)	NA		NA	NA	16/28 (57.1)
Ralphs	4/14 (28.6)	3/13		NA	NA	NA
Vons	3/13 (23.1)	3/13		NA	NA	NA
Other	729/1506 (48.1)	64/16		84/159 (52.8)	60/132 (45.5)	48/89 (53.9)

Abbreviation: NA, not applicable.

Weiner SG, Qato DM, Faust JS, Clear B. Pharmacy Availability of Buprenorphine for Opioid Use Disorder Treatment in the US. JAMA Netw Open. 2023;6(5):e2316089. doi:10.1001/jamanetworkopen.2023.16089

Decision Making at the Wrong Bench:



Decision Making at the Wrong Bench:

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 ordering Highly Diverted Controlled Substances.

2. **Ordering ratio of Highly Diverted Controlled Substance base codes or drug families to non-Controlled Substances:** Analyze the ratio of the order volume of each Highly Diverted Controlled Substance base code or drug family to the total order volume of all non-Controlled Substances to identify Customers with significant rates of ordering each Highly Diverted Controlled Substance base code or drug family.

3. **Excessive ordering growth of Controlled Substances:** Analyze significant increases in the ordering volume of Controlled Substances using criteria to identify customers that exhibit percentage growth of Controlled Substances substantially in excess of the percentage growth of non-Controlled Substances.

4. **Unusual formulation ordering:** Analyze ordering of Highly Diverted Controlled Substances to identify customers with significant ordering of high-risk formulations. High-risk formulations include, but are not limited (*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.

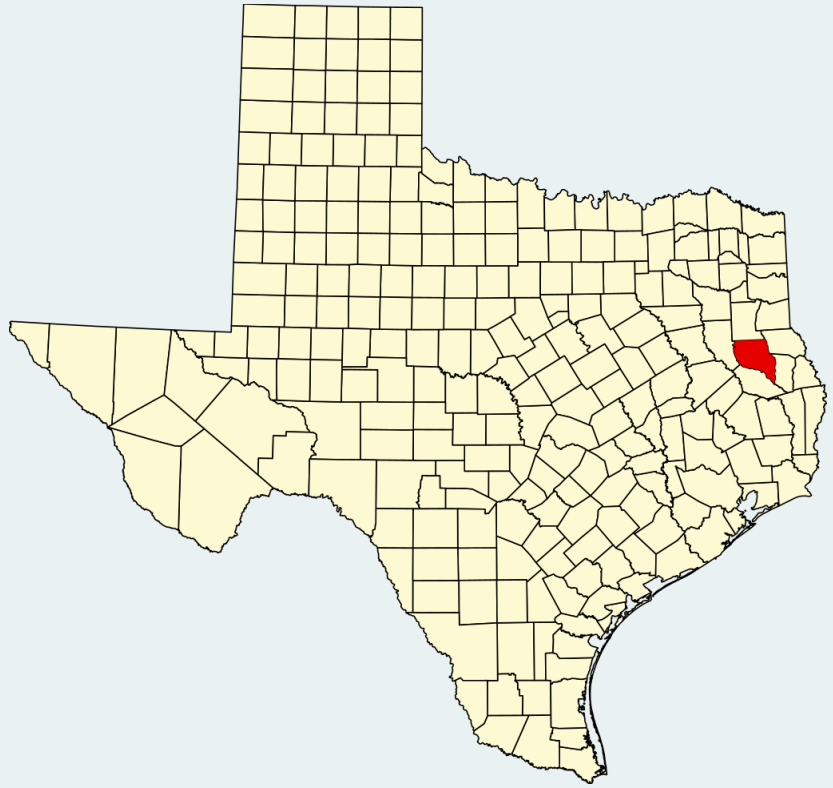
Nobody messes with HEB…

"I'm always looking at my narcotic-only profiles, and of course, being a hospice pharmacy, I know my fentanyl is higher. The state board [of pharmacy] will even look and check and see that it's hospice prescriptions so I know I'm given a little leeway. Your wholesaler does not care but at least the board does. So we stopped dispensing any type of Suboxone."

-Independent Pharmacist | Nacogdoches, Texas

Fun Facts About Nacogdoches County:

- Population: 64,653
  - 32,147 residing in Nacogdoches
  - 23.3% of families below the poverty line
- Land Area: 35 mi^2
- Community pharmacies in the county: 9
  - Independent community pharmacies in the county: 2



Varisco TJ, Bratberg J, Hill LG, et al. Consensus Recommendations to Improve Buprenorphine Distribution: Results from the PhARM-OUD Expert Panel. *Manuscript under review.*

Stigma makes denying care more convenient than providing care.

"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?"

-Independent community pharmacist, Texas

Let's check the guidelines!

“Any pharmacy can fill a prescription for sublingual or buccal [buprenorphine] formulations”

-SAMHSA, TIP 63

What went wrong?

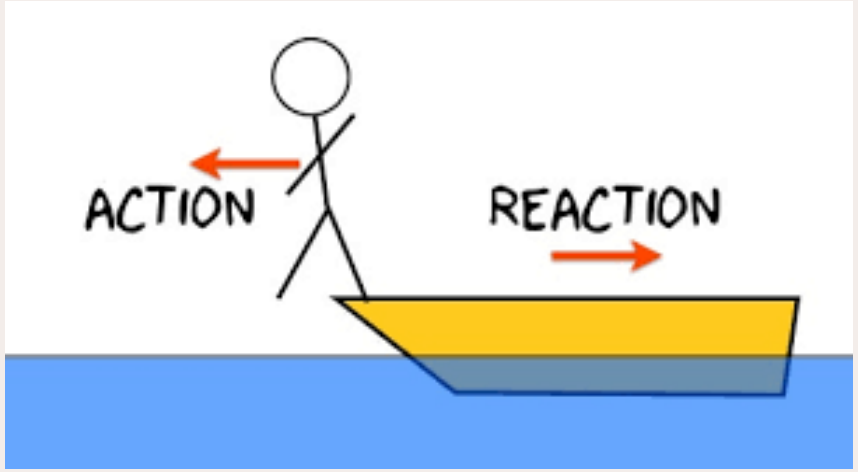
Decades of letting one party control the conversation:

- Pharmaceutical manufacturers (1995-2015)
- Enforcement and legal entities (2015-2020)

Limited patient and provider input

Lack of evaluation:

- Untested assumptions
- Newton's third law



Part 2: Developing the PhARM-OUD Guidelines

The University of Texas at Austin
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Stakeholder engaged research

Research that involves individuals, organizations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavor.

Must traverse the entire contimuum of care:

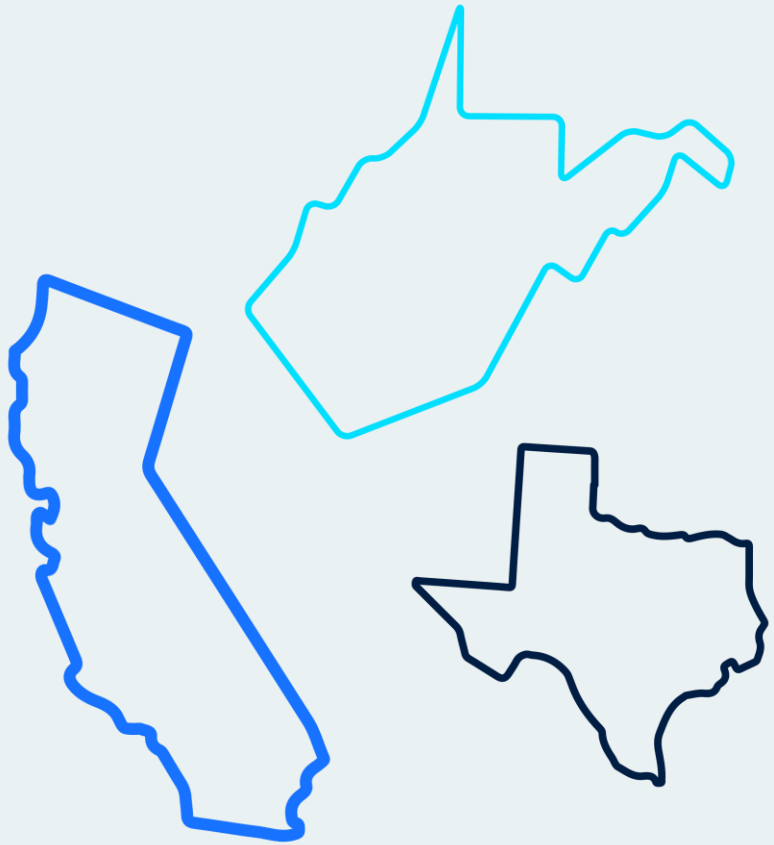
- Patients
- Prescribers
- Pharmacists
- Distributors
- Regulators

Integrates experience and evidence

Deverka PA, Lavallee DC, Desai PJ, Esmail LC, Ramsey SD, Veenstra DL, et al. Stakeholder participation in comparative effectiveness research: defining a framework for effective engagement. J Comp Eff Res. 2012;1(2):181–94

Setting the Scope

- Focus group with pharmacists in Texas, California, and West Virginia:
  - Disparate policy, practice, and need environments
  - Prioritized “bench” pharmacists
- Moderator guide grounded in the Theory of Planned Behavior:
  - Clarified purpose of interviews
  - Intended to identify barriers to dispensing and adaptive practices
  - Facilitated open discussion as much as possible



More than stigma and time constraints:

Stigma:

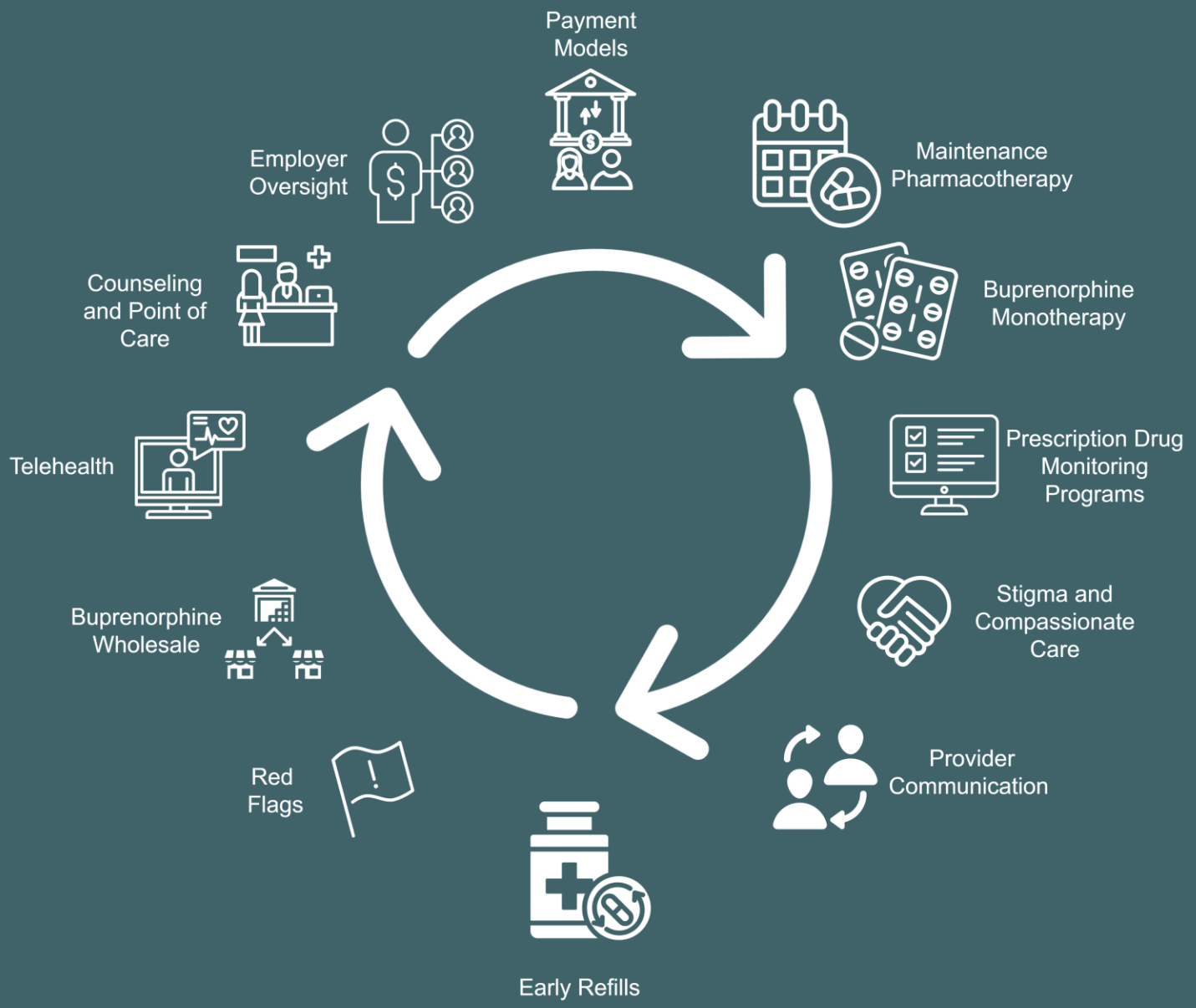
"Nobody will sell insulin needles unless you have an injectable prescription at that pharmacy, and there's no law against it. The problem is that at the first pharmacy that does it, there will be people going to get needles and a 17-year old girl will be ringing up all these people and ***you know and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

Enforcement:

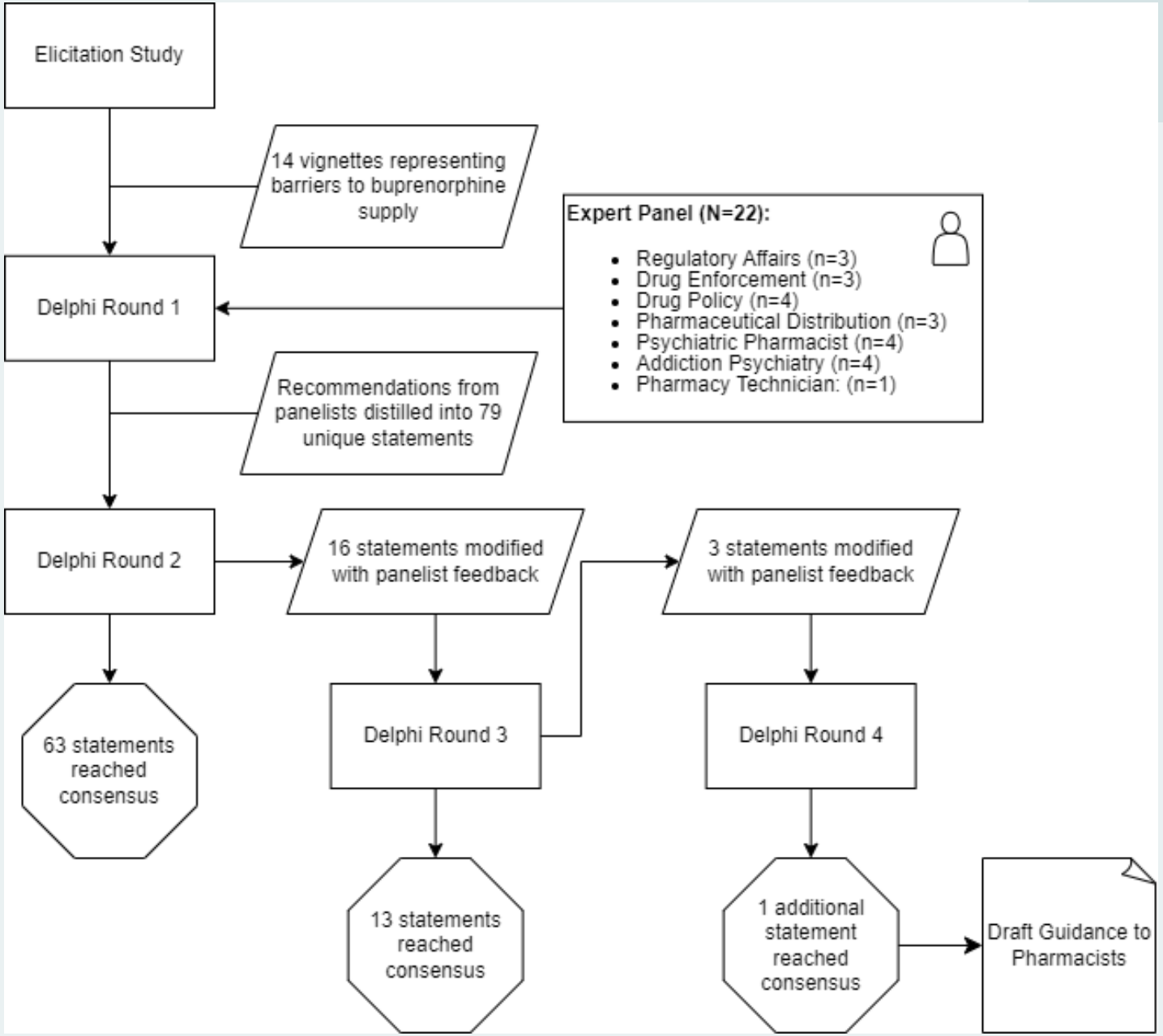
"You know, ***I recently had a visit from the DEA****, just a random inspection, and that [buprenorphine] was one of the key drugs they were interested in looking at"*

Wholesale Restrictions

"If we dispense a hundred prescriptions, 20 of them can be controlled substances. ***One we hit that quota, game over.*** *You can order whatever you want. They won't ship anything."*


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

The Delphi Study:



NABP
National Association of Boards of Pharmacy

Comment Period Open for Draft Guideline to Improve Access to Medication for Opioid Use Disorder in Community Pharmacies

The National Association of Boards of Pharmacy (NABP) is collaborating with the University of Houston (UH) College of Pharmacy, the National Community Pharmacists Association, and other stakeholders to create a multiagency, multi-stakeholder evidence-based consensus guideline to advance pharmacists' willingness to dispense buprenorphine for the treatment of opioid use disorder (OUD). The draft guideline is posted on the NABP website for public comment until May 31, 2024.

The project, "Creation of a Multi-Stakeholder Practice Guideline to Improve Access to Medication for Opioid Use Disorder in Community Pharmacies," is funded by the Foundation for Opioid Response Efforts. The central objective of this initiative is to generate consensus- and evidence-based solutions to regulatory and administrative barriers that are unique to the pharmacy profession's access to buprenorphine supplies and pharmacist's dispensing of the medication. In addition, the initiative is intended to address gaps in prevailing OUD treatment guidelines from the American Society of Addiction Medicine and the Substance Abuse and Mental Health Services Administration.

As part of the project, focus groups with pharmacists in three states met in September and October 2023 to identify attitudinal, environmental, and social barriers to buprenorphine dispensing. UH then recruited a panel of 23 experts in addiction medicine, law enforcement, and pharmacy to address pharmacists' barriers to dispensing through the creation of a consensus practice guideline.

After the close of the public comment period, NABP will convene a panel of 10 to 20 experts who were not involved in the initial guideline creation process for a one-day workshop at NABP Headquarters in Mount Prospect, IL. The panel will review the aggregated comments and discuss potential changes to the guideline document. When finalized later this summer, the guideline will be disseminated nationwide.

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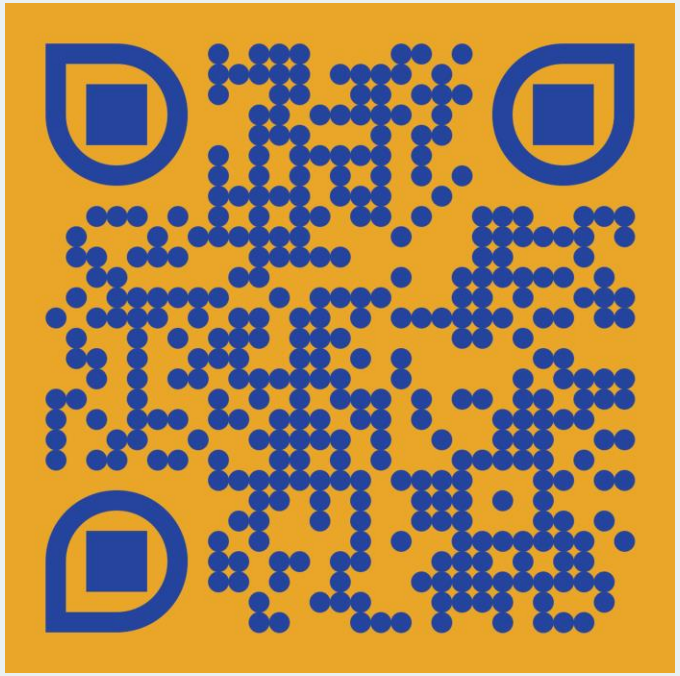


The Recommendations:

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

Newton's Third Law:

Theme	Example Quote
Awareness of Thresholds	*We ran a report. We know now. So the percentage is that we have to dispense 20% of our total prescriptions, so for example, if we dispense a hundred prescriptions, 20 of them can be controlled substances. One we hit that quota, game over. You can order whatever you want. They won't ship anything.*
Buprenorphine Rationing	*So now you've got your patients, your regular customers who live in town, who, you know, have cancer or whatever and you got to ensure that you've got medication for them and that's why we try to limit sometime these out of town prescriptions because we gotta make sure we have it for our regular customers.*
Care Interruptions	*And then one of my sister stores actually was cut off for a month. They had hit their limit.... They're literally sharing a corner with a treatment facility and there's another one about 10 minutes from where they are So once they were out, they were out.*
Payer Limitations	*I don't know, it's nothing bad, but it's always made me kind of raise my eyebrow that our state Medicaid will only pay for name brand for Suboxone films unless they get something from the provider…, but I've always felt like that was a little odd, which I'm going to assume is due to some contractual things with pharmaceutical providers, but that I always thought was odd, kind of restricting what we can offer to patients."*
Enforcement	*You know, I recently had a visit from the DEA, just a random inspection, and that [buprenorphine] was one of the key drugs they were interested in looking at and you know if they're going to be coming and you know if that's what they're interested in then that's not what I want to be dispensing obviously..*

Recommendations to Distributors:

Use one distributor	Buprenorphine orders should be concentrated with one distributor rather than multiple.
Don't let thresholds dictate decisions	Pharmacists should not decline to dispense buprenorphine based on speculative concerns about potential distributor-controlled substance purchasing restrictions.
DEA must provide concrete guidance to distributors	The Drug Enforcement Administration (DEA) should provide guidance to pharmaceutical distributors to ensure that Suspicious Order Reporting Systems (SORS) do not interfere with a pharmacy's ability to dispense buprenorphine.
Distributors should revise thresholds	Pharmaceutical distributors should urgently revise the parameters of their buprenorphine SORS with or without input from DEA.
Buprenorphine thresholds should be set independently of other substances	SORS should be designed by distributors to monitor buprenorphine orders in isolation from other controlled substances.
Approve threshold change requests quickly	Pharmaceutical distributors should clarify procedures for threshold change requests and ensure that threshold change requests are urgently approved for buprenorphine orders.

Part 3: Follow the Process

The University of Texas at Austin
PhARM Program

What we know:

- Less than 60% of pharmacies stock buprenorphine
- Interruptions in care increase risk of mortality
- Fewer than 60% of patients will complete 180 days of agonist pharmacotherapy.

What we don’t know:

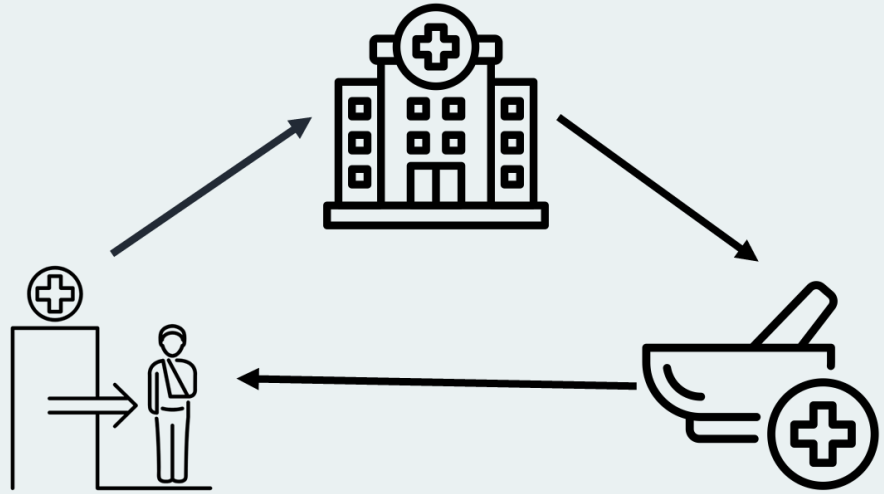
- How can we enhance collaborative care?
- How can we effectively enhance the perceived value of providing care to persons with OUD?
- What strategies can we use to improve the efficiency of transitions of care?

How does your health system manage transitions of care for people with OUD?

1) What are the barriers?

2) Who are the key players?

3) How do you promote continuity after discharge?

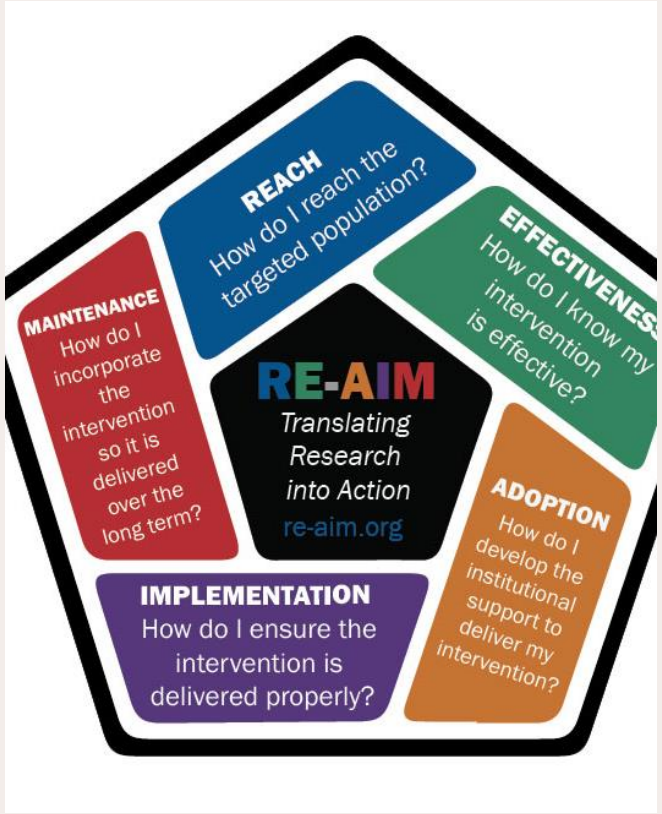


Pitfalls:

- Lack of interconnected systems
- Stigma
- Fear of regulation
- Absence of clinical champions
- Figuring out where to start

The Study:

- Participatory design with three health systems
- Inpatient, outpatient, pharmacy, administration, and administration
- Central objective:
  - Identify opportunities to improve transitions of care for persons with OUD
- Design:
  - Monthly meetings with clinical subject matter experts
  - Monthly implementation meetings with health system participants
  - Participatory draft of an implementation toolkit to guide transitions of care

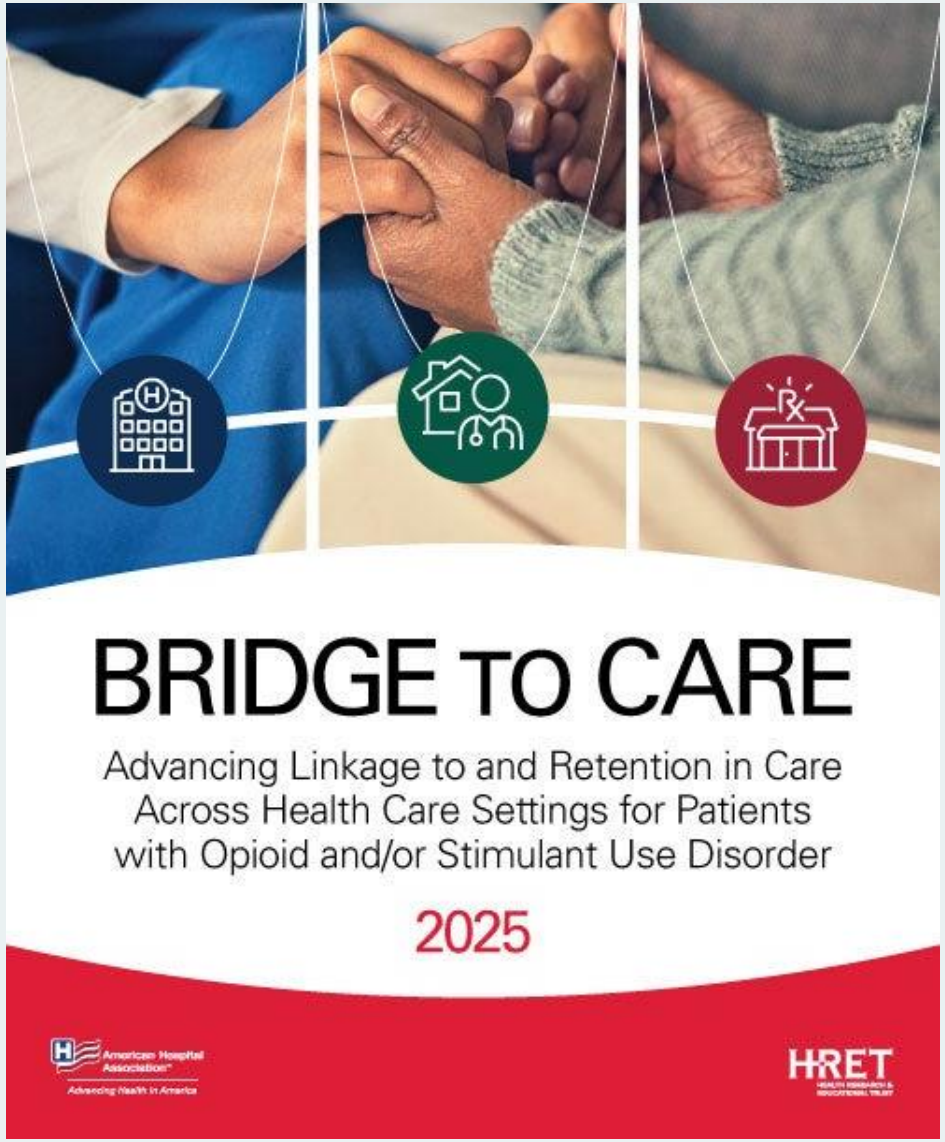


The Participants:

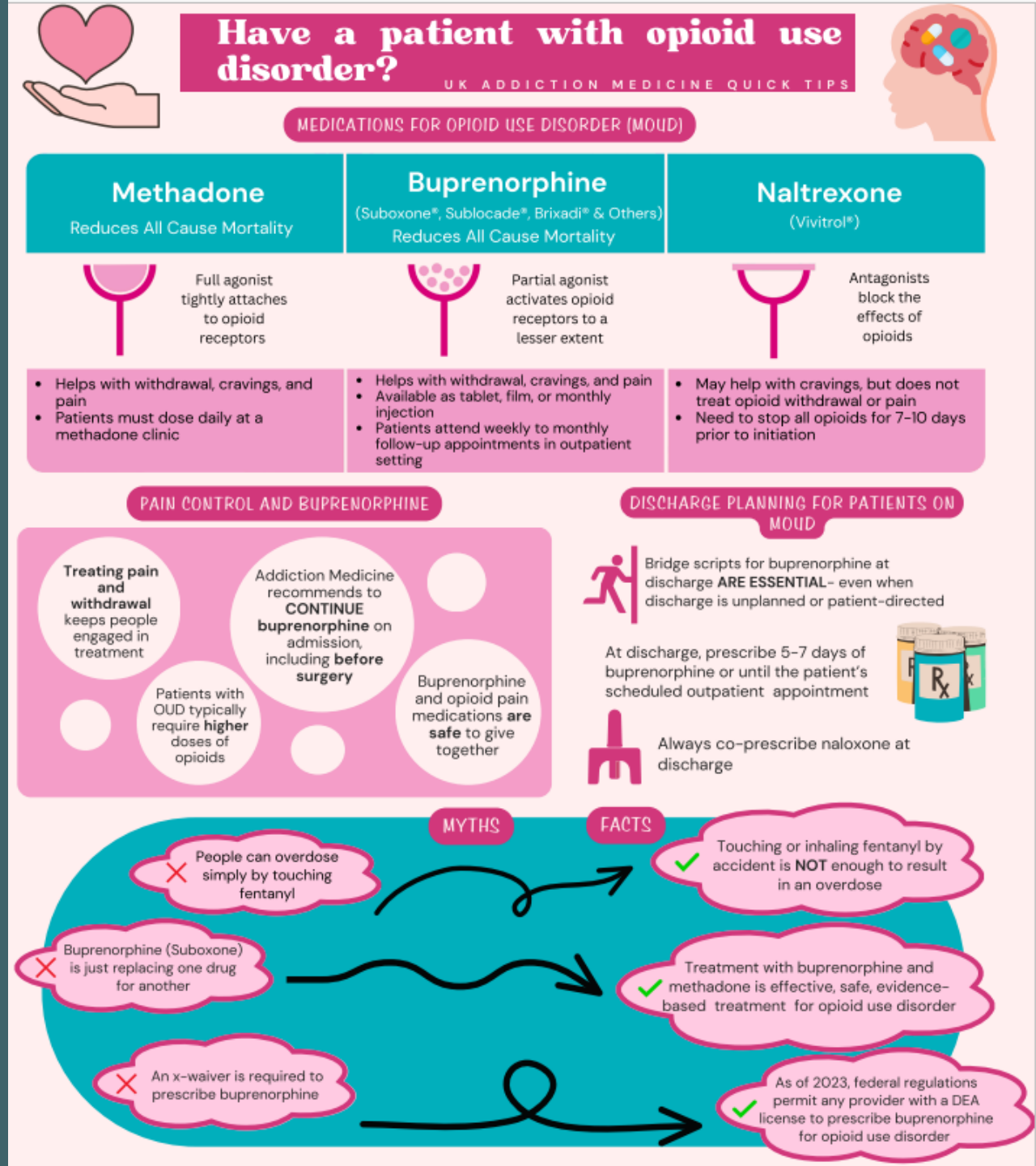
- Established, advanced SUD programs
- Expanded access models for methadone and tele-buprenorphine
- Desire to improve acceptance of SUD care through clinical champions

- Established inpatient SUD service line
- Excellent EMR tools
- Desire to improve transitions from the ED and to the community

- Nascent SUD service line
- Interested in a whole person approach
- Peer-centric model with a need for value demonstration and clinical champions


BRIDGE TO CARE
Advancing Linkage to and Retention in Care
Across Health Care Settings for Patients
with Opioid and/or Stimulant Use Disorder
2025
HRET

Better than anything a professor has ever made:



Recommendations

Plan	Be proacting with discharge planning and coordinate with community pharmacies prior to discharge
Coordinate	Leverage hospital pharmacists to coordinate warm handoffs to their community counterparts
Verify	Ensure that buprenorphine prescriptions are complete and that the prescriber can be easily contacted
Champion	Leverage opportunities to engage hospital leadership to discuss and evaluate policies that interfere with continuity of SUD care after admission

Use the 72 Hour Rule

BRIEF REPORT

CME/MOC

Dispensing Methadone at Hospital Discharge: One Hospital's Approach to Implementing the "72-hour Rule" Change

Emily Skogrand, PharmD, Jackie Sharpe, PharmD, and Honora Englander, MD

"practitioners . . . are allowed to **dispense** not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both)."-21 CFR 1306.07(b)

1. Build relationships between pharmacy champions and leadership
2. Develop policies for methadone dispensing
3. Develop a communication workflow between providers and dispensing pharmacists
4. Develop an EMR documentation strategy
5. Engage Opioid Treatment Programs early

Pragmatic Solutions:

INNOVATION IN PRACTICE: SUPPORTING NEEDED IDENTIFICATION FOR PATIENTS AT OHSU

Problem:

Lack of suitable ID may delay patient access to treatment as programs may require identification documents, which patients may lack – particularly those experiencing homelessness. This requirement was causing disruptions in linkage and connection to ongoing care.

Implementation:

Providers contacted area program clinicians to explain the problem. Together, they found a practical temporizing avenue: hospital clinicians take a "headshot" photo which they upload into the electronic record and print, making sure patients have a copy at hospital DC. This has the patient's name, DOB and medical record number and can serve to verify identity for ongoing care.

Takeaways:

Partnering across settings can allow hospital and community teams to recognize potential ways to overcome barriers in linkage and retention in care.

A seat at the table:

Potential individuals to include in the conversation: clinical champion(s), hospital pharmacists, community pharmacists, pharmacy trainees, pharmacy technicians, addiction consult, and/or physicians and advanced practice providers who provide clinical care to patients with OUD/StUD, social workers, peer supporters	
How can hospital-based pharmacists better provide support to clinicians when they have questions about MOUD?	
How can the hospital pharmacy team support identification and documentation of MOUD in the EHR?	
What additional training may be helpful for the hospital-based pharmacy team?	
How can pharmacists support effective peer-to-peer communication between inpatient pharmacy staff and their community counterparts?	
What strategies can pharmacists use to reduce the stigma of OUD and StUD among pharmacy teams?	

"**Treat every prescription as a transition in care**. Utilize hospital-based pharmacists to educate patients and their community pharmacy counterparts about the importance of successful treatment continuation."

Assessment Questions

The 72-hour rule allows providers to ___a three-day supply of methadone for the emergency treatment of opioid withdrawal.

A. Dispense
B. Prescribe
C. Provide
D. A or B

Which of the following accurately describes the effects of hydrocodone rescheduling on opioid prescribing and mortality?

A. Opioid prescriptions decreased and overdose deaths decreased.

B. Opioid prescriptions increased and overdose deaths decreased.

C. Opioid prescriptions decreased and overdose deaths increased.

D. Opioid prescriptions decreased and overdose deaths decreased.

Which of the following is **not** a reason that community pharmacies do not stock medication for opioid use disorder?

A. Fear of enforcement

B. Stigma toward persons who use drugs

C. Prioritizing other medications over buprenorphine

D. Drug shortages

Claim Codes

- Pharmacists:

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