



# The Expanded Role of Pharmacists and Innovations to Improve Access to Treatment

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# Agenda

1. National landscape of pharmacist provided medication for opioid use disorder (MOUD)
2. Policy barriers to MOUD
  1. Education and training requirements for pharmacists
  2. Coverage of pharmacists' services
3. Case study of the impact of pharmacist provided MOUD

# Pharmacists

*Experts trained to optimize medications and improve health*



3<sup>rd</sup> largest profession



2<sup>nd</sup> most training behind physicians



Highly accessible



# The impact of pharmacist-provided care

- **Case study: Vaccines during the public health emergency**
  - From 2/20 – 9/22, pharmacists and their teammates:
    - conducted >42 million COVID-19 tests
    - **provided >270 million vaccinations within community pharmacy programs alone**
    - provided >50 million influenza and other vaccinations per year
  - **Pharmacists accounted for >50% of COVID-19 vaccinations in the United States**
  - Using conservative estimates, pandemic interventions by pharmacists and teammates averted
    - >1 million deaths,
    - **>8 million hospitalizations**
    - **\$450 billion in health care costs**

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SCIENCE AND PRACTICE



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**FEATURE**

**Essential services: Quantifying the contributions of America's pharmacists in COVID-19 clinical interventions**

John D. Grabenstein\*

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**ARTICLE INFO**

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**ABSTRACT**

*Background:* As the COVID-19 pandemic spread across the United States, America's pharmacists and their teammates expanded their clinical services to help their communities from every practice setting: community and ambulatory care, inpatient, long-term care, academia, public health, and many others.

*Objectives:* The objective of the study is to begin to quantify contributions of U.S. pharmacists in providing clinical interventions that mitigate and control the pandemic. These interventions span the gamut of diagnosis, prevention, treatment, and support, intervening patient by patient with vaccines, diagnostic tests, convalescent plasma, monoclonal antibodies, antiviral medications, and supportive therapies.

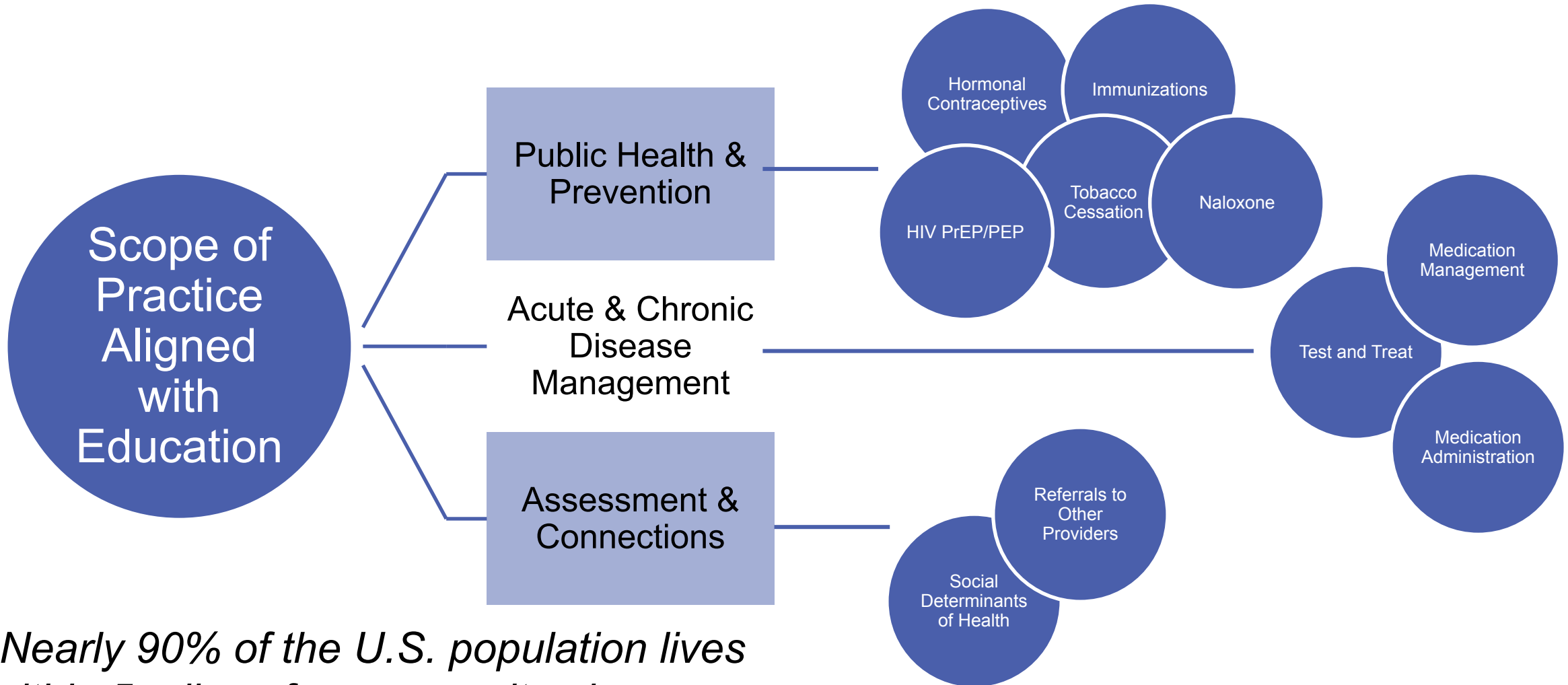
*Methods:* Review of published literature, relevant web pages, and queries to national and state professional pharmacy associations and government agencies.

*Results:* From February 2020 through September 2022, pharmacists and their teammates conducted >42 million COVID-19 tests, provided >270 million vaccinations (including 8.1 million COVID-19 vaccinations for long-term care residents) within community pharmacy programs alone, and provided >50 million influenza and other vaccinations per year. Pharmacists plausibly accounted for >50% of COVID-19 vaccinations in the United States. Pharmacists prescribed, dispensed, and administered an uncounted number of antibody products and antiviral medications, including care for 5.4 million inpatients and innumerable outpatients. Using conservative estimates, pandemic interventions by pharmacists and teammates averted >1 million deaths, >8 million hospitalizations, and \$450 billion in health care costs.

*Conclusions:* Pharmacists and their teammates contributed to America's health and recovery during the COVID-19 pandemic by providing >350 million clinical interventions to >150 million people in the form of testing, parenteral antibodies, vaccinations, antiviral therapies, and inpatient care. The number of lives touched and people cared for by pharmacists continues to rise.

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# Pharmacist Authorities to Meet Care and Health Equity Needs\*



*Nearly 90% of the U.S. population lives within 5 miles of a community pharmacy.*

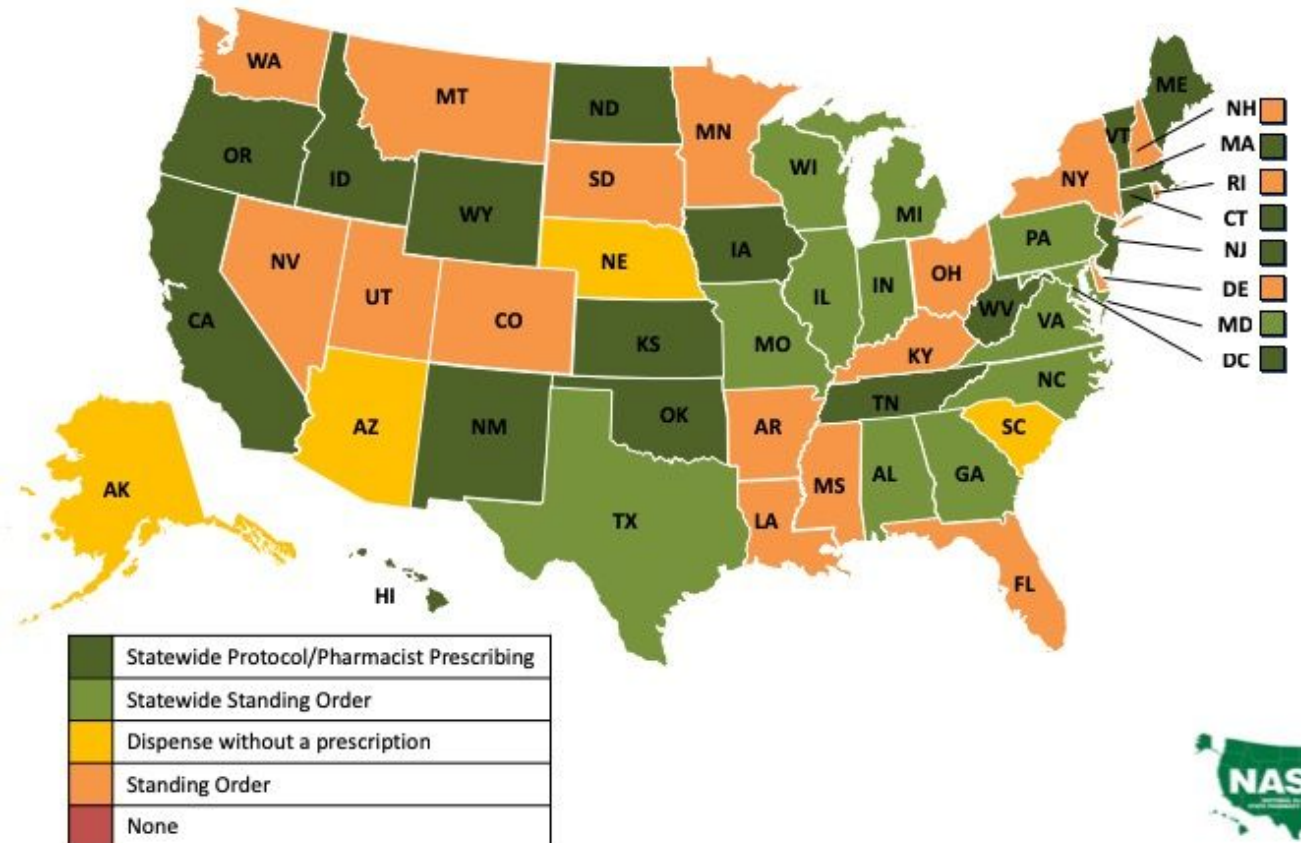
\*Varies by state

# Access to opioid antagonists

- Pharmacists in every state and DC have some expanded authority to furnish naloxone or opioid antagonists without a prescription

## Naloxone Access in Community Pharmacies

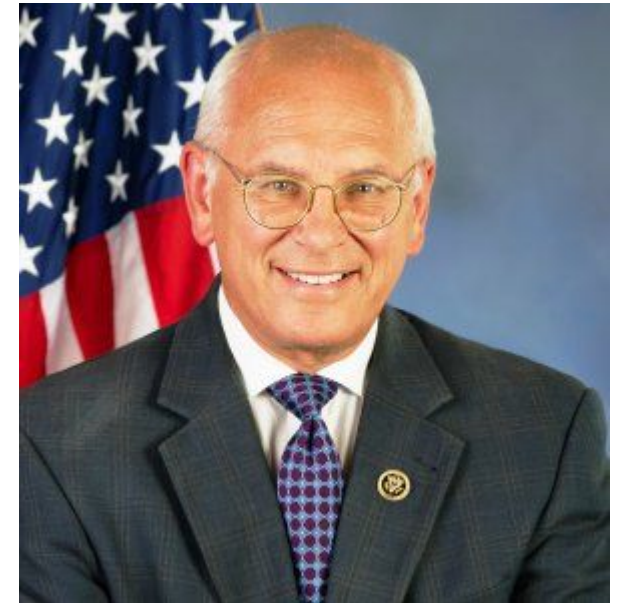
Based on data collected by NASPA (updated January 2019)



# Win – MAT Act becomes law!

## Mainstreaming Addiction Treatment Act

- Increases access to buprenorphine for substance use disorder and opioid use disorder
- Removes requirement that certain health care practitioners apply for a waiver to prescribe buprenorphine
- Currently, 11 states permit pharmacists to prescribe controlled substances

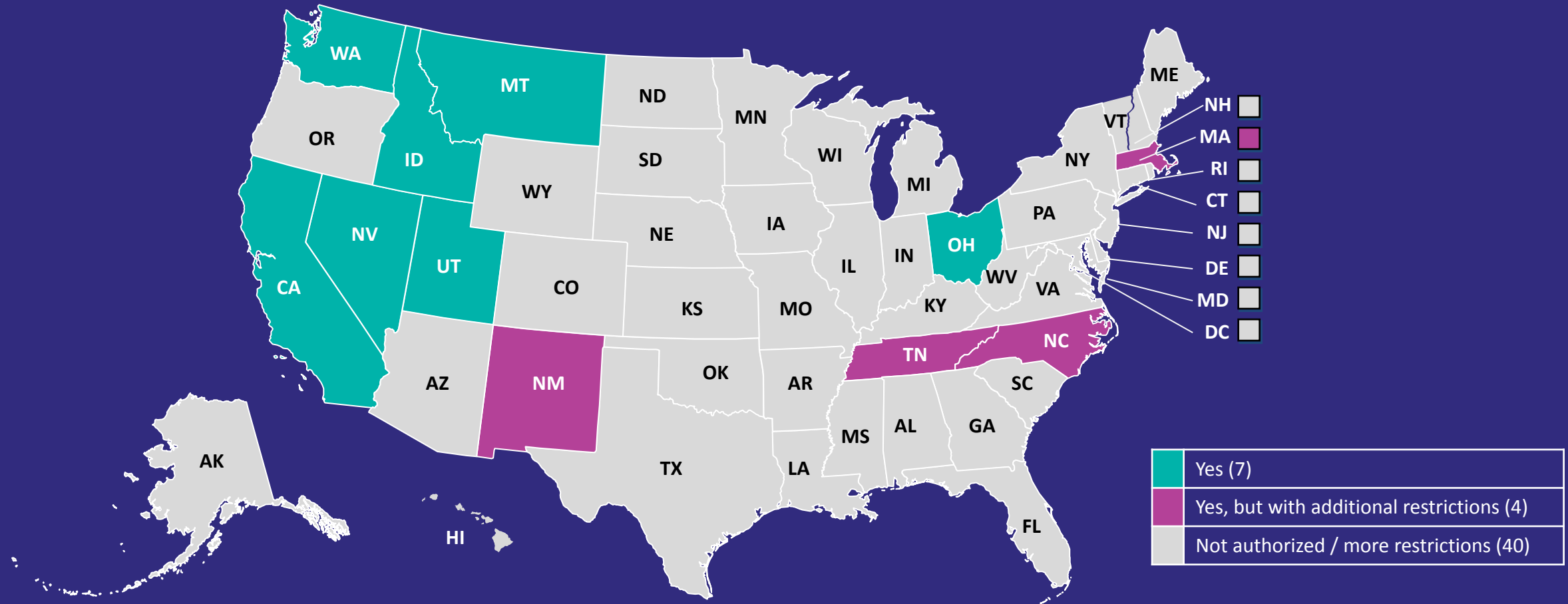


Congressman Paul  
Tonko (NY-20)

Image Source: Bloomberg Government



# Can pharmacists furnish MOUD via prescriptive authority, statewide protocol, or collaborative arrangement?

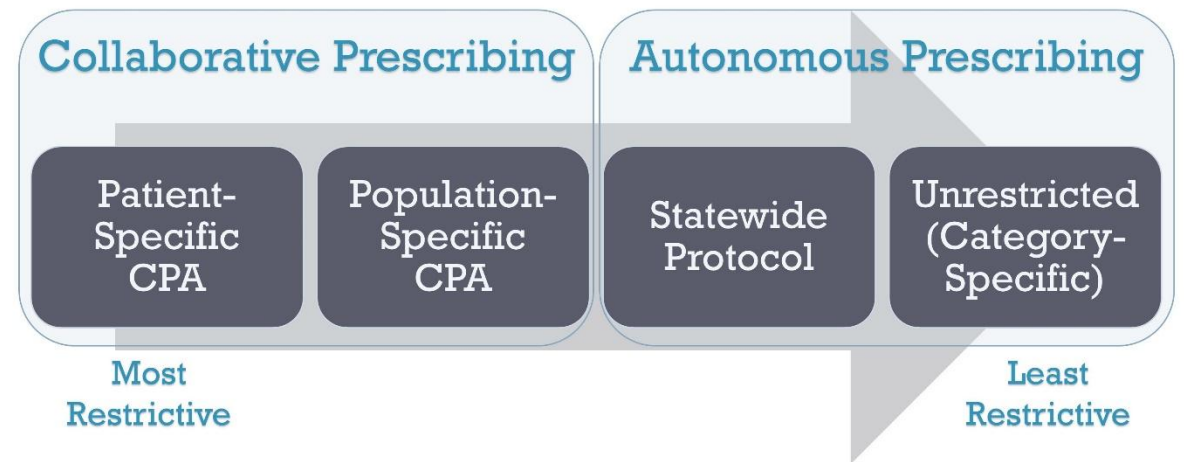




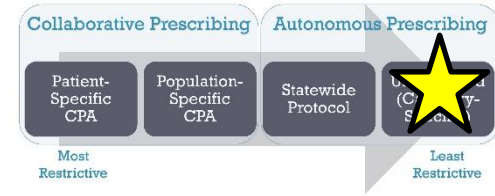
# Pharmacist provided MOUD

- Commonly provided via a collaborative practice agreement
- Recent trend is provided via statewide protocol or independent prescriptive authority
- Confirmed by review by DEA Diversion Control Division Mid-Level Practitioners Authorization by State

## Continuum of Pharmacist Prescriptive Authority



# State example: Idaho



## 350. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.

In accordance with Section 54-1705, Idaho Code, a pharmacist may independently prescribe provided the following general requirements are met by the pharmacist:

1. **Education.** Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained.
2. **Patient-Prescriber Relationship.** Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code.
3. **Patient Assessment.** Obtain adequate information about the patient’s health status to make appropriate decisions based on the applicable standard of care and the best available evidence.
4. **Collaboration with Other Health Care Professionals.** Recognize the limits of the pharmacist’s own knowledge and experience and consult with and refer to other health care professionals as appropriate.
5. **Documentation.** Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan.
6. **Prescribing Exemption.** The general requirements set forth in this section do not apply to collaborative pharmacy practice agreements, devices, and nonprescription drugs.

# State example: Nevada



**Sec. 12.3. Chapter 639 of NRS is hereby amended by adding thereto a new section to read:**

1. To the extent authorized by federal law, a pharmacist who registers with the Board to engage in the activity authorized by this section may, in accordance with the requirements of the protocol prescribed pursuant to subsection 2:

(a) Assess a patient to determine whether:

(1) The patient has an opioid use disorder; and

(2) Medication-assisted treatment would be appropriate for the patient;

(b) Counsel and provide information to the patient concerning evidence-based treatment for opioid use disorders, including, without limitation, medication-assisted treatment; and

(c) Prescribe and dispense a drug for medication-assisted treatment.

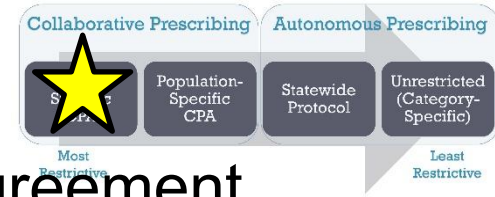
2. The Board shall adopt regulations:

(a) Prescribing the requirements to register with the Board to engage in the activity authorized by this section; and

(b) Establishing a protocol for the actions authorized by this section.

3. As used in this section, “medication-assisted treatment” means treatment for an opioid use disorder using medication approved by the United States Food and Drug Administration for that purpose.

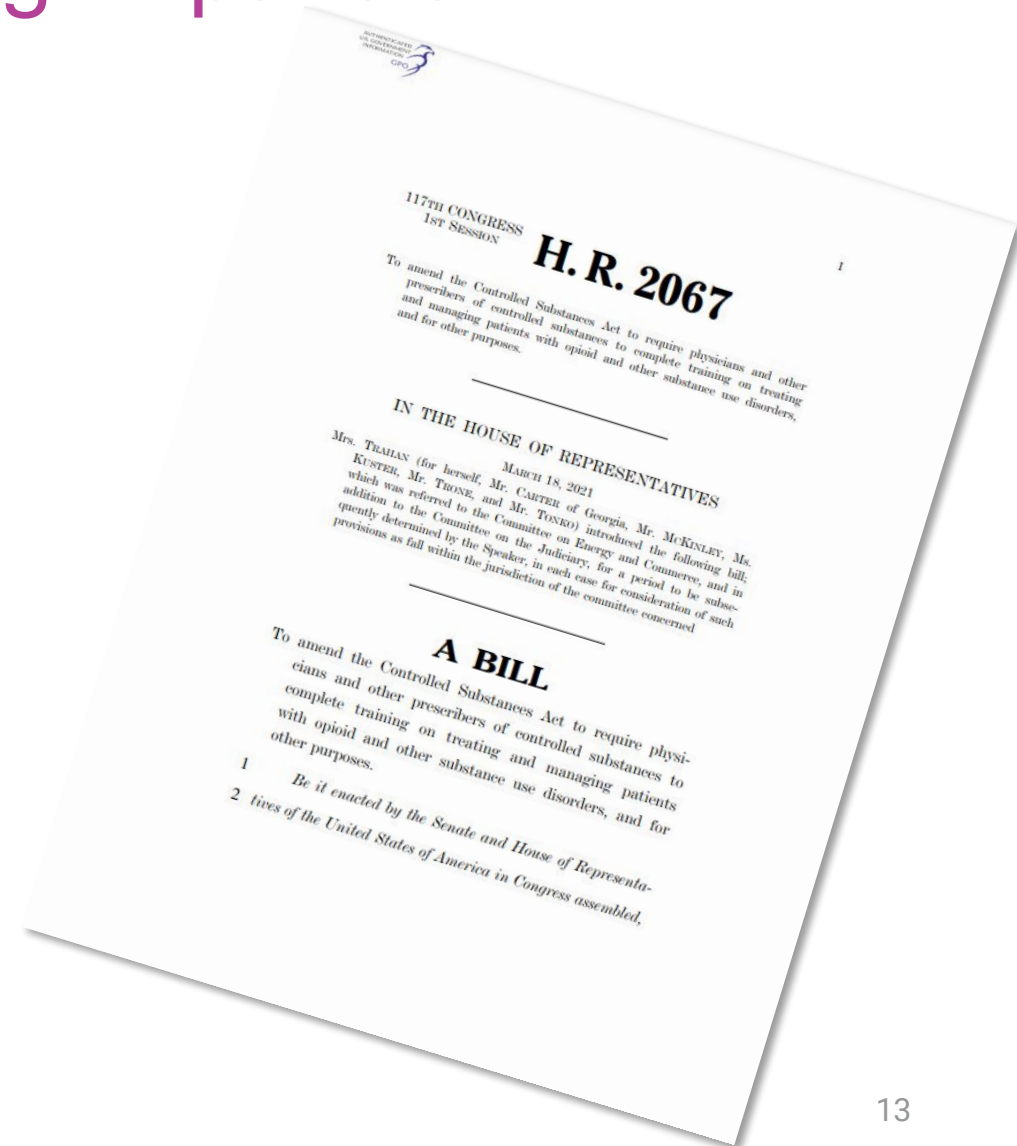
# State example: Ohio



- Authority to prescribe controlled substances included in consult agreement (collaborative practice agreement) section of code
- Collaborating prescriber: physician, physician assistant, clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner
- Allows for multiple prescribers and pharmacists
- Requires past prescriber-patient relationship
- “A pharmacist, as part of an opioid treatment program licensed by the state, may administer controlled substance narcotics pursuant to a consult agreement in accordance with this division of the Administrative Code for the maintenance or detoxification treatment of opioid addiction.”

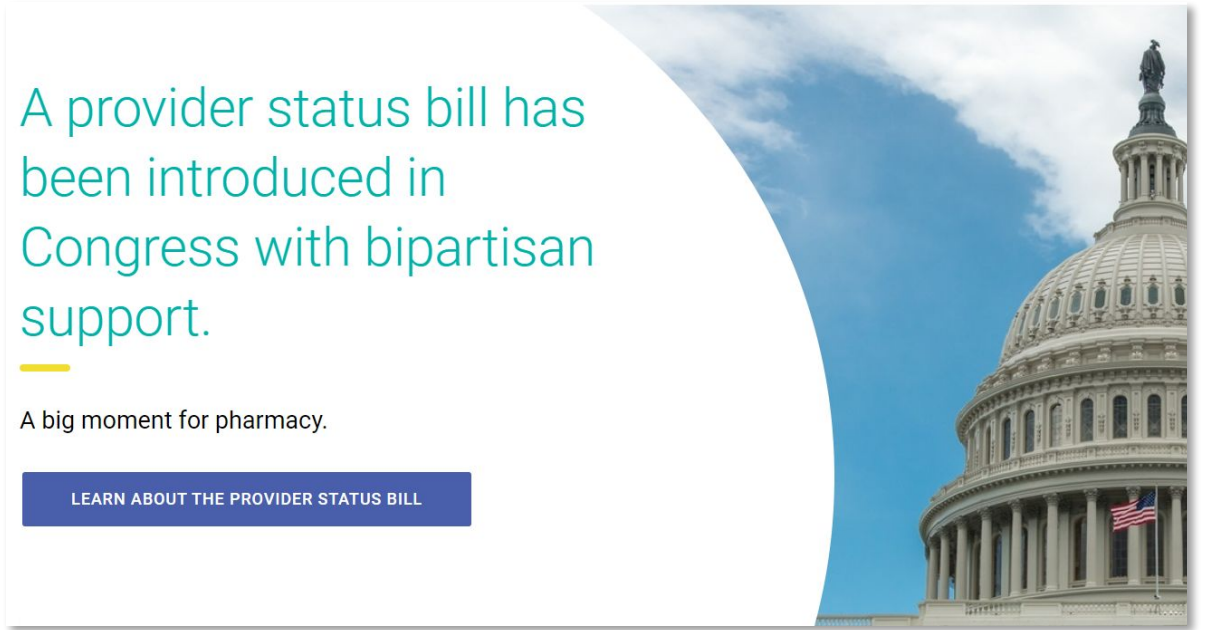
# The Medication Access and Training Expansion (MATE) Act

- Included in omnibus spending bill with the MAT Act at the end of 2022
- Went into effect June 2023
- Requires providers to complete a one time eight hours of training on the treatment and management of patients with opioid or other substance use disorders
- Only groups approved by DEA/SAMHSA may provide training
  - No continuing pharmacy education (CPE) provider approved



# Historical gaps in coverage of pharmacists' services

- Different than nearly all other health care professionals, pharmacists' services have historically not been covered under the medical benefit by health plans
- Services provided by pharmacists are distinct from the dispensing of medications



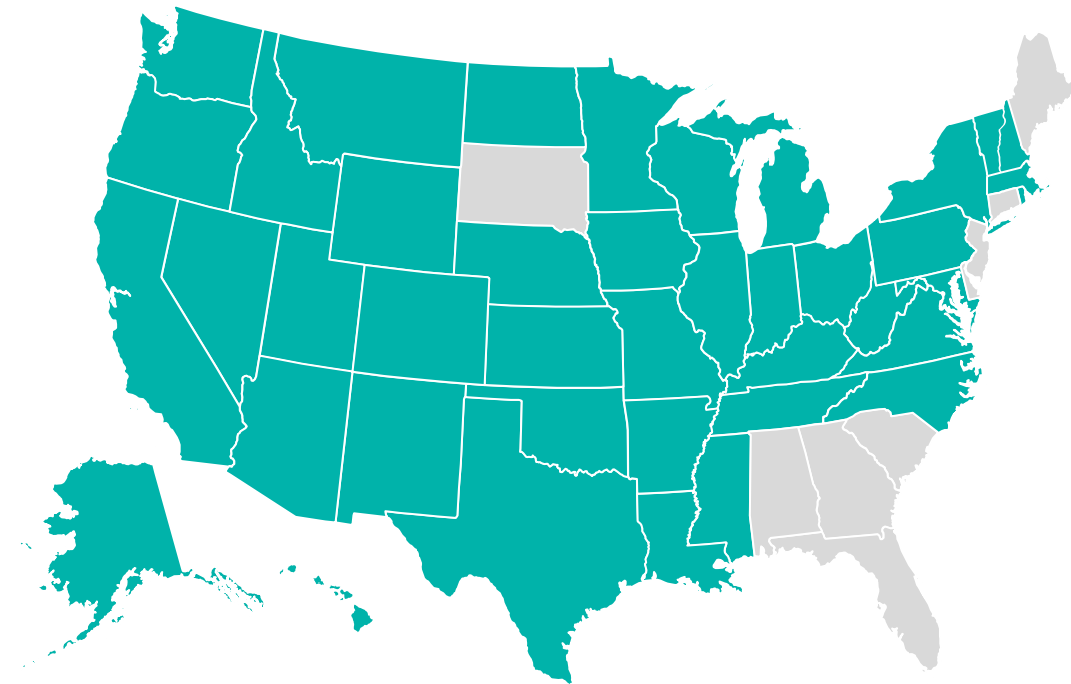
A provider status bill has been introduced in Congress with bipartisan support.

A big moment for pharmacy.

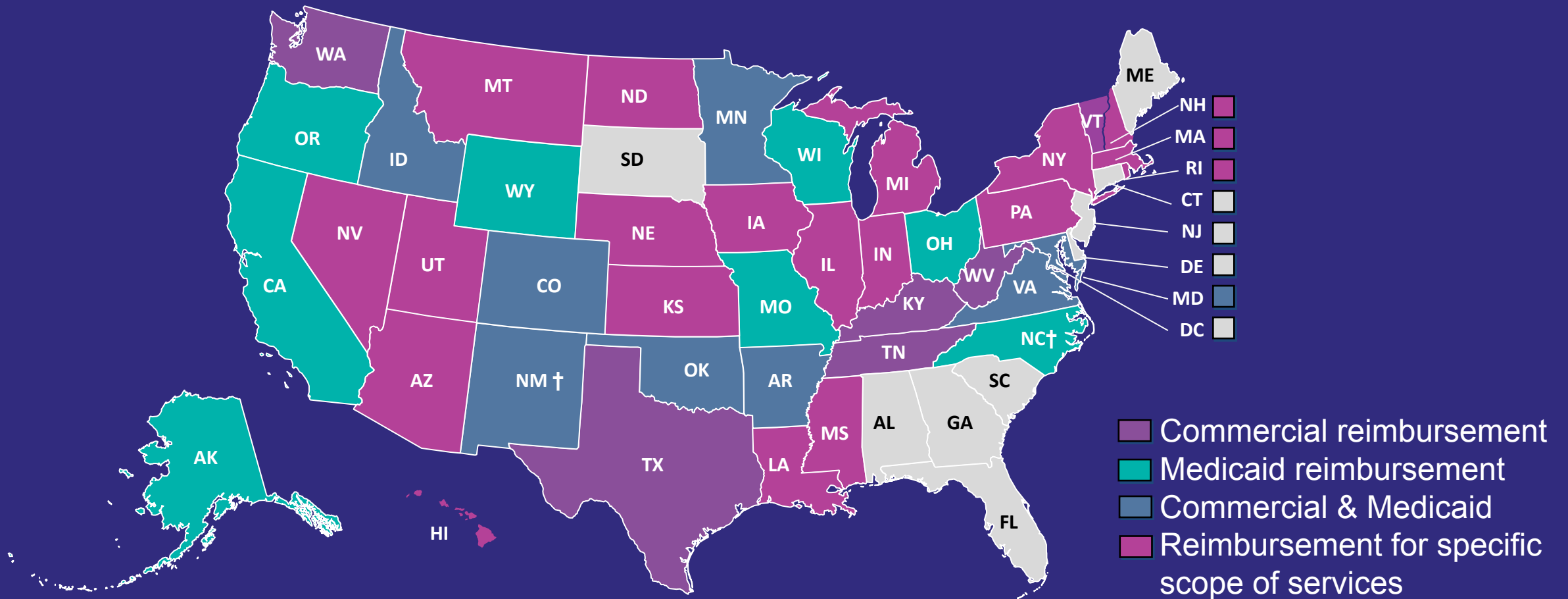
[LEARN ABOUT THE PROVIDER STATUS BILL](#)

# Trends in payment for pharmacists' services in the states

- Payment for services under Medicaid and commercial health plans
  - State medical assistance programs submitting state plan amendments to add pharmacists as **other licensed practitioners**
- Integrating pharmacists into established models in the **medical benefit**
  - CMS 1500 claim form
  - Billing HCPCS codes: **Commonly 99202-99205 & 99211-99215**
- Variability in scope of reimbursable services



# Payment for Pharmacists' Services in the States\*



\*Examples of states where pharmacists are receiving reimbursement for a broad or narrow scope of their patient care services. Not intended to be a comprehensive representation.

†Pharmacist reimbursement for a broad scope of services is limited to the requirement of being an advanced practice pharmacist.



# PHARMACY-BASED BUPRENORPHINE INDUCTION: A CARE MODEL FOR THE UNDERSERVED

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**October 2023**

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Clinical Research

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# Pharmacist's Oath (6/2021-pre sent)

<https://www.pharmacist.com/Publications/Transitions/oath-of-a-pharmacist-changing-times#:~:text=Oath%20of%20a%20Pharmacist%3A%20Final%20revised%20draft%20Revised%3A.service%20to%20others%20through%20the%20profession%20of%20pharmacy.>

I will apply my knowledge and experience to advance health equity to assure optimal outcomes for all patients.

I will accept the responsibility to improve my professional knowledge, expertise, and self-awareness.

I will champion diversity and inclusion, respect the perspectives of others, and mitigate my personal biases.

# Pharmacists are Primary Care & Public Health Providers

## Public Health

- Immunizations
- Medication therapy management
- Linkage to specialist care
- Patient & community education
- **Medications for opioid use disorder (MOUD)**

## Community Harm Reduction

- Naloxone
- Non-prescription syringes access
- Treatment as Prevention (HIV, HCV)
- Point-of care testing (HIV, COVID-19)
- **Medications for opioid use disorder (MOUD)**

# Opioid Agonist Therapies

(OAT):

*Methadone &  
Buprenorphine*

## Significantly reduce:

- Non-medical use of opioids
- Opioid overdose death
- All-cause death
- Risk of bloodborne infection transmission
- Criminal legal system involvement
- Healthcare usage

## OAT:

- Is safe
- Increases treatment retention
- Improves patients' quality of life and social functioning
- Costs less than treatment without medication

# OAT limitations

## **Only 1/3 of people with OUD receive ANY form of treatment**

- Fewest receive medication for OUD treatment **~1 out of 9 (13%)**
- Pharmacists cannot dispense methadone for OUD in US
- Pharmacists not permitted to prescribe buprenorphine without state DEA authority outside of CPA

## **Barriers and Inequities**

- Geography (e.g., Rural)
- Insurance (e.g., Medicaid)
- Structural and systemic racism
- Social distancing

## **COVID-19 – More Overdoses**

- Decreases access to opioids
- Unsafe supply
- Substance co-use
- Less tolerance
- Less nonprescribed buprenorphine access

# American Pharmacists Assoc. (APhA) House of Delegates Actions

## 2021

1. APhA supports the use of evidence-based **medicine as first-line treatment for opioid use disorder** for patients, including healthcare professionals, in and out of the workplace, **for as long as needed to treat their disease.**
2. APhA encourages pharmacies to maintain an inventory of medications used in treatment of opioid use disorder, **to ensure access for patients.**
3. APhA encourages pharmacists and payers to ensure patients have **equitable access to, and coverage for, at least one medication from each class of medications** used in the treatment of opioid use disorder.

## 2022

APhA advocates for pharmacists' **independent prescriptive authority** of medications indicated for opioid use disorders (MOUDs) and other substance use disorders to expand patient access to treatment.

# 2022 White House Office of National Drug Control Policy: National Drug Control Policy (Pharmacy Notes)

- Regulators should consider **allowing methadone dispensing from pharmacies** as is done in the United Kingdom [and Canada] because of their greater accessibility in most communities relative to OTPs
- Pilot methadone programs in federal prisons to leverage telemedicine and bureau of prison **pharmacists**.
- Train nurses, psychologists, **pharmacists** and social workers to care for people with substance use disorders.

# When Did Pharmacy-Based Methadone Occur in the US: 1966-1976

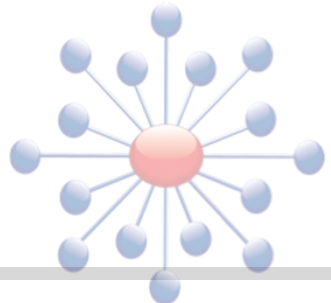
“Community pharmacy dispensing of methadone [for OUD] is a useful means of operating a methadone treatment program.”

Methadone could be marketed and distributed through retail pharmacies like any other schedule II narcotic.  
**Bowden CL, Maddux JF, Esquivel M. Am J Drug Alcohol Abuse. 1976;3(2):243-54.**

## *History of Changes*

- 1972: *APhA v. Weinberger*: FDA can't impose post-approval controls on methadone
- 1974: Case upheld in US Court of Appeals
- 1976 FDA changed regulations: Methadone can be dispensed for analgesia only

Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A, editors. Federal Regulation of Methadone Treatment. Washington (DC): National Academies Press (US); 1995. 5, Federal Regulation of Methadone Treatment. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK232105/>





MARCH 06, 2023

# SENS. MARKEY, PAUL AND REPS. NORCROSS, BACON INTRODUCE MODERNIZING OPIOID TREATMENT ACCESS ACT TO REACH MORE AMERICANS SUFFERING FROM OPIOID USE DISORDER AS ANNUAL OVERDOSES SURPASS 100,000 ACROSS U.S.

[Bill Text \(PDF\)](#)

Washington (March 6, 2023) - Senators Edward J. Markey (D-Mass.), Chair of the Health, Education, Labor and Pensions (HELP) Subcommittee on Primary Health and Retirement Security, and Rand Paul (R-Ky.) and Representatives Donald Norcross (NJ-01) and Don Bacon (NE-02) introduced their bipartisan and bicameral *Modernizing Opioid Treatment Access Act*. The legislation will improve patients' ability to access medication treatment for Opioid Use Disorder (OUD) by modernizing outdated rules, empowering board-certified physicians to prescribe methadone to patients, and allowing U.S. pharmacies to dispense methadone.

# Low-Barrier Buprenorphine is Successful

“Provide care that is **evidence-based**, emphasizes **harm reduction**, has a low barrier to entry, and is **longitudinal**.”



When we shift our focus to providing individualized care that incorporates patient-centered outcomes, we can better help our patients with OUD achieve **remission and lead improved lives.**”

## Stateline

# Addiction Treatment May Be Coming to a Pharmacy Near You

STATELINE ARTICLE

February 24, 2023

By: [Christine Vestal](#)

Read time: 5 min

## Genoa Pharmacist Andrew Terranova, URI PharmD:

“My experience with patients,” Terranova said, “showed me that many people seeking treatment face **homelessness, stigma, judgment and economic barriers** every day. So, coming into a pharmacy and being greeted by a pharmacist who wants to sit down with you and talk about being healthy was very much appreciated.”

Overall, Terranova said he and the other pharmacists at his pharmacy found the Brown University program rewarding. “**The improvement we saw and our interactions with patients, and to feel their gratefulness for getting help in a way and manner they weren’t used to, was extremely rewarding,**” he said.

“I’d be more than willing to jump in and keep helping addiction patients if the program were to ramp up,” he said. “**We’d all be willing to participate again and continue what we started.**”

## Stateline

# Addiction Treatment May Be Coming to a Pharmacy Near You

STATELINE ARTICLE

February 24, 2023

By: [Christine Vestal](#)

Read time: 5 min

## Study Investigator Jody Rich, MD:

“What we have in this epidemic is a workforce issue,” Rich said. “We don’t have enough bodies prescribing buprenorphine. **Physicians have had more than 20 years to go ahead and prescribe it for their patients with opioid use disorder and the vast majority have said, ‘No thank you.’**”

“Pharmacists are the most highly trained and **underappreciated health professionals** we have, and they are in the trenches,” Rich said. “They see what’s going on out there. We need them now and apparently, they’re up for the task.”

# Pharmacist Training and communications

American Society for Addiction Medicine (ASAM) Treatment of Opioid Use Disorder Course, *adapted for pharmacists*

Clinical documentation  
Urine/oral swab testing and test interpretation  
Motivational interviewing  
Harm reduction, *considerations for post-release from incarceration*  
Stigma reduction / communications

**7 pharmacists trained May 2018**

**9 pharmacists trained Nov 2018**

**5 pharmacists trained 2019-2021**

## Ongoing supports & detailing

- Weekly phone-based meetings, clinician check-ins
  - Academic detailing of sites by lead pharmacist
    - Emailed newsletters

# MATPharm Adaptations during COVID-19 Pandemic

**COVID-19 adaptations:** Pharmacy innovations to address need for on-demand withdrawal supports and ready access to buprenorphine induction

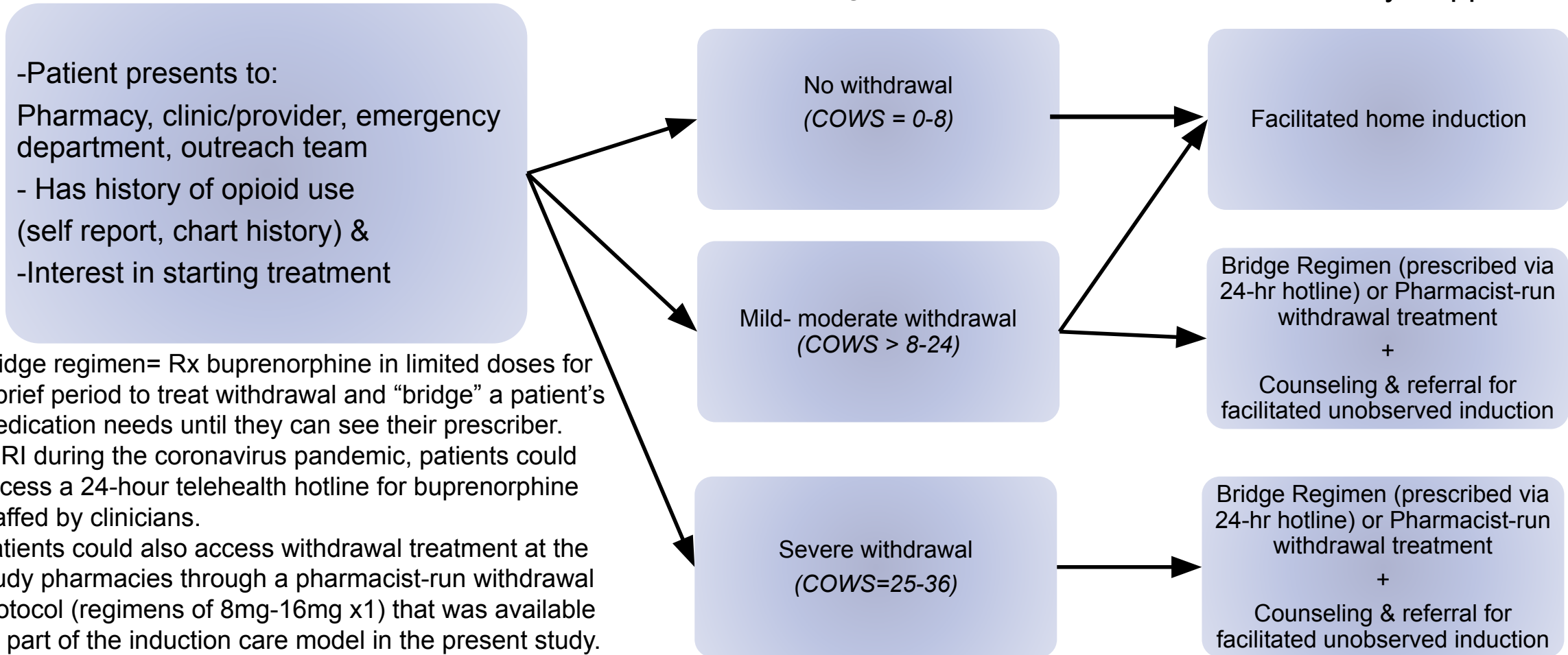
## Withdrawal Treatment

- Patient assessed by pharmacist
- Patient dispensed 24hr of medication
- Dosage dependent on severity of withdrawal symptoms

## BNX Induction

- Patient assessed by pharmacist
- Pharmacist speaks to provider to verify induction
- Patient begins treatment

# MATPharm Eligible: Any Opioid Hx, 18+ years old, On treatment or Interest in MOUD



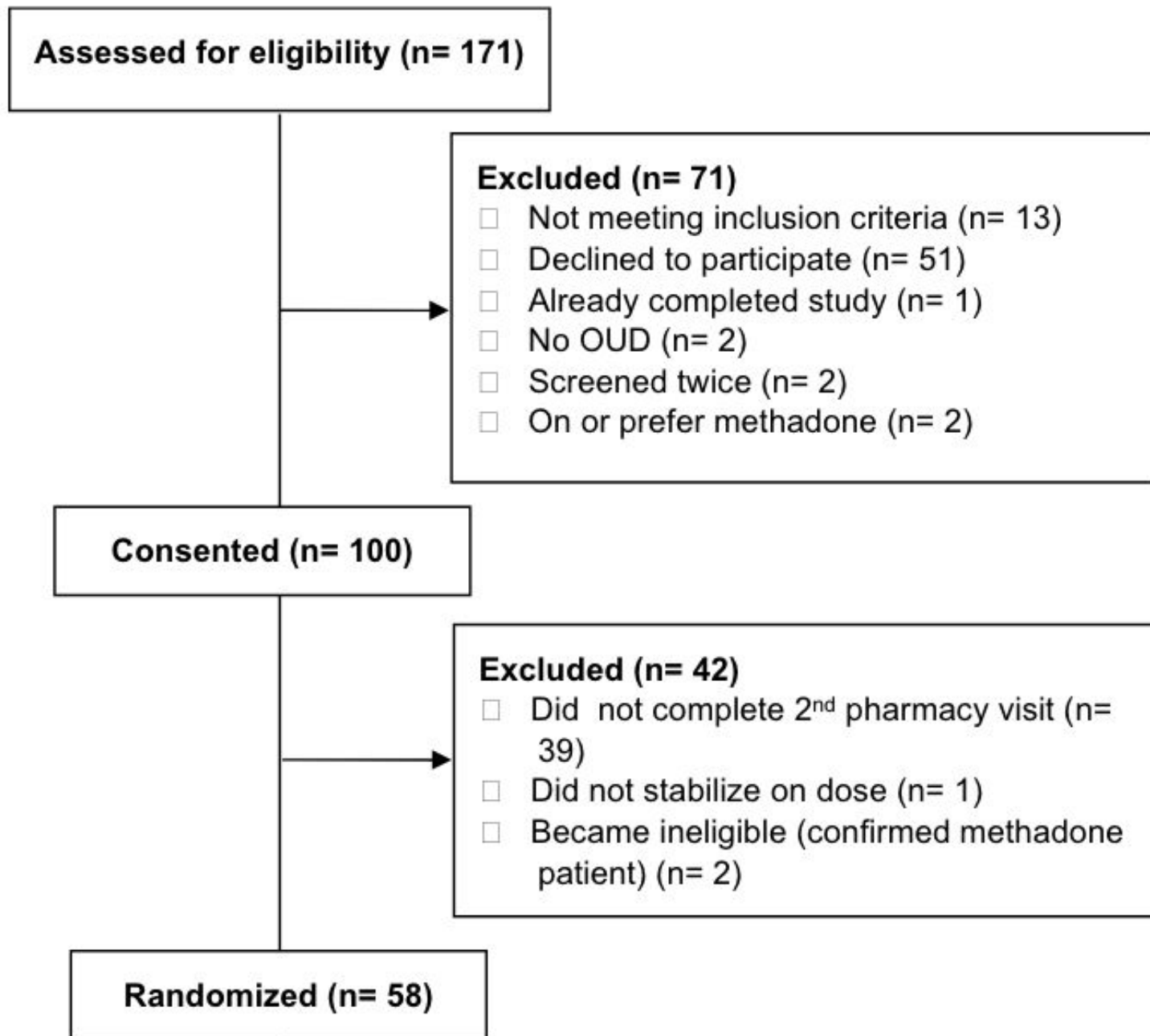
Bridge regimen= Rx buprenorphine in limited doses for a brief period to treat withdrawal and “bridge” a patient’s medication needs until they can see their prescriber. In RI during the coronavirus pandemic, patients could access a 24-hour telehealth hotline for buprenorphine staffed by clinicians. Patients could also access withdrawal treatment at the study pharmacies through a pharmacist-run withdrawal protocol (regimens of 8mg-16mg x1) that was available as part of the induction care model in the present study.

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.

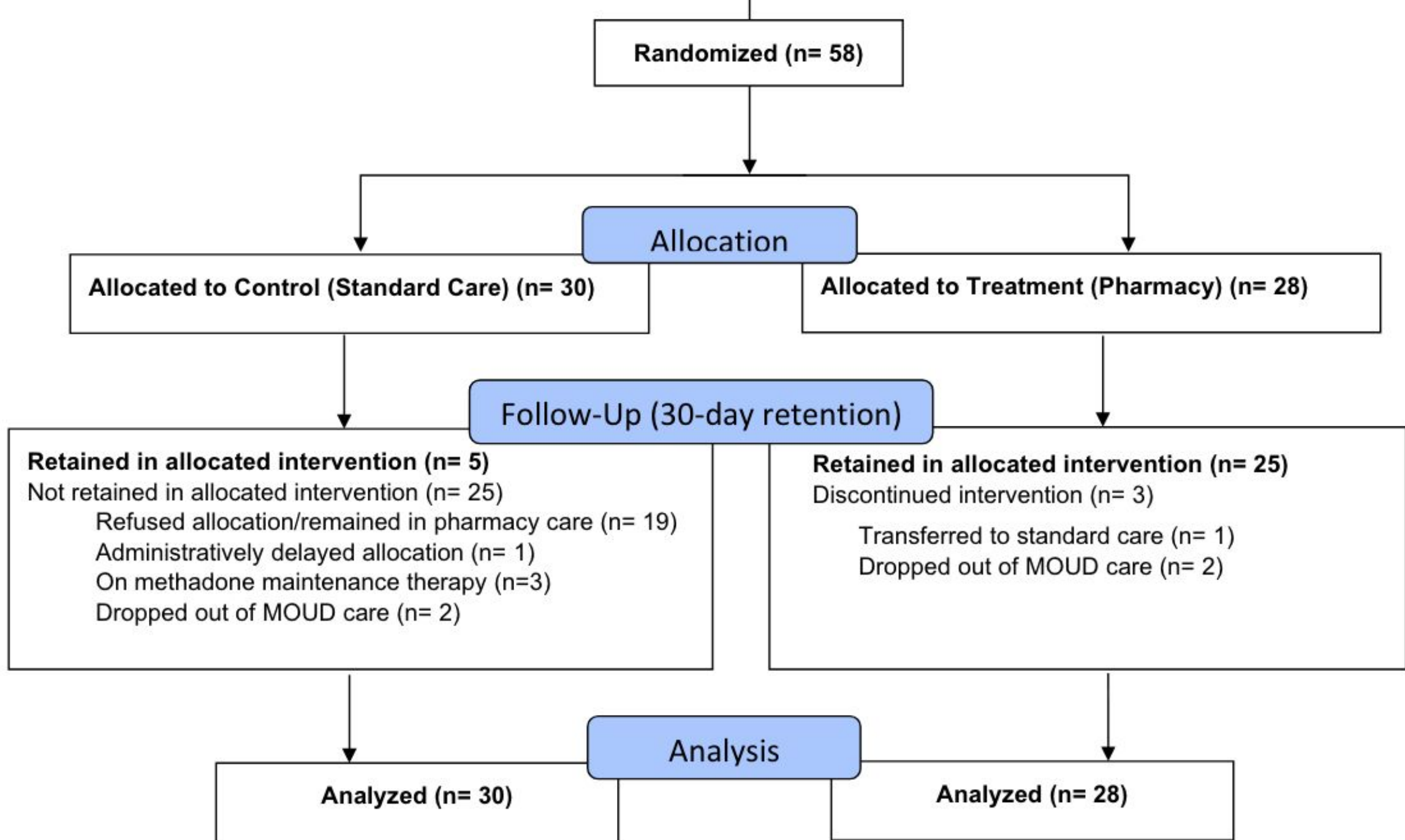
COWS: Clinical opiate withdrawal scale (scores 0 to 36)  
Treatment=medication treatment with Rx buprenorphine

Figure S2: CONSORT Diagram

Enrollment







# MATPharm: Pharmacy care has high induction rate, engagement comparable to usual care, less drop-out, no safety concerns

**Induction success rate: 58% stabilized ( $\geq 2$  pharmacy visits)**

**Primary outcomes: Initial engagement with community MAT ( $\geq 1$  visit in first 30 days post stabilization)**

- 89% pharmacy care, 17% usual care

**Drop out of care\***

- 6 pharmacy care (10%), 16 usual care (27%)

**Treatment crossovers\***

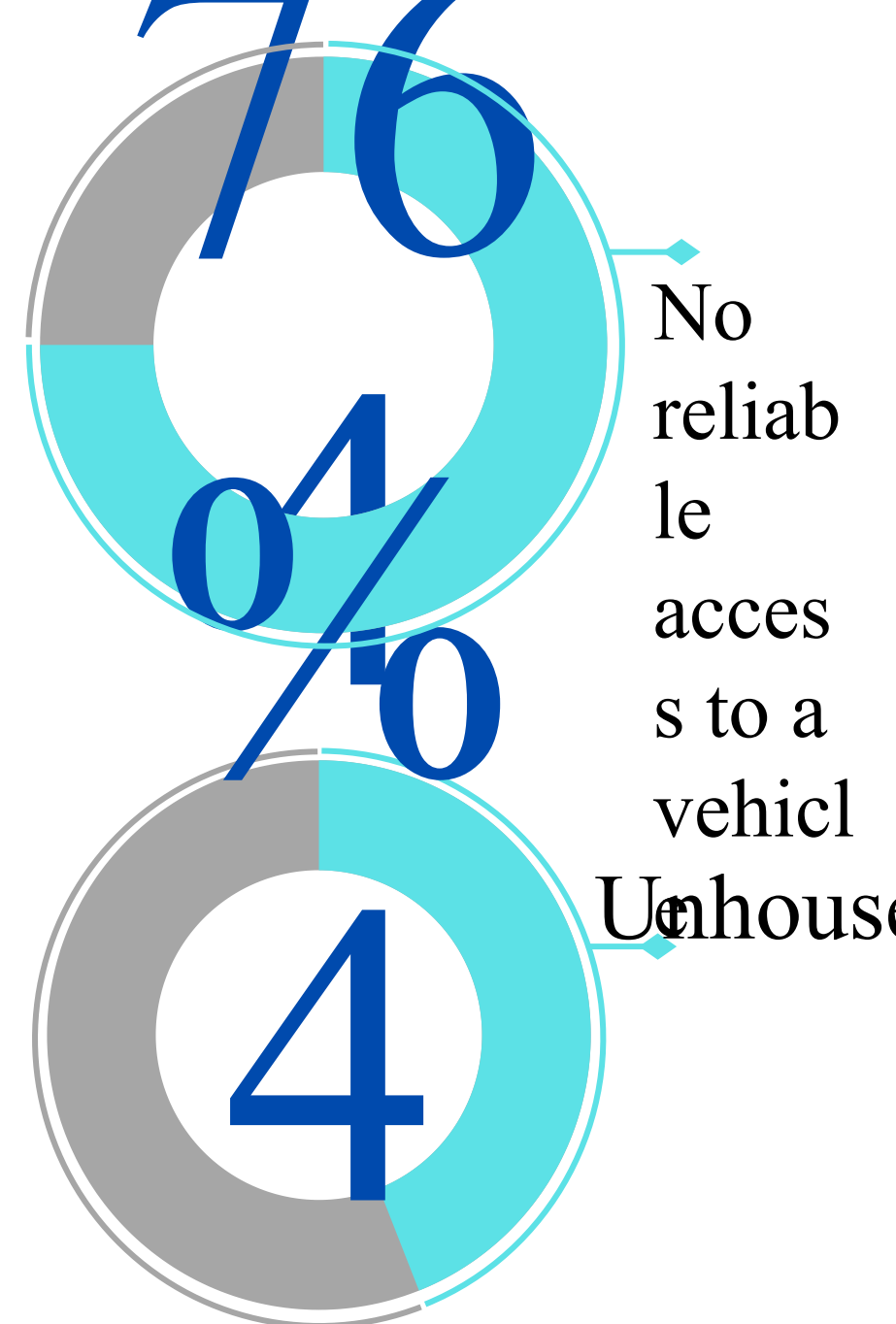
- 7 Pharmacy Inducted patients randomized to usual care refused to leave pharmacy care
- 5 Pharmacy Inducted patients randomized to usual care took 4-8 weeks to transfer to usual care provider

\*active, ongoing follow up

**Safety concerns\***: 0 deaths, 0 unanticipated severe adverse events, +36 dispensed naloxone

# Pharmacy induction promotes racial and economic equity and access to care

Rhode Island state	Induction patients
<b>White: 80.5%</b>	<b>White: 66%</b>
<b>19.5% BIPOC:</b>  Black or African American: 6.77% Other race: 5.47% Asian: 3.40% Two or more races: 3.33% Native American: 0.50% Native Hawaiian or Pacific Islander: 0.08%	<b>34% BIPOC:</b>  Black or African American: 12% Other race: 11% Asian: 0%, Two or more races: 8%, Native American: 3%, Native Hawaiian or Pacific Islander: 0%
<b>15% Hispanic</b>	<b>15% Hispanic</b>



# Key Self-Reported Demographics (n=100)

- Recruitment
    - 39% Outreach
    - 35% Word of mouth
  - 36% unemployed
  - 20% disabled
  - 49% 1+ lifetime overdose
  - 70% illicit drugs other than opioids
    - 25% >2 substances
    - 35% cocaine/crack
  - 44% reported any Rx use
  - 91% previous buprenorphine use
    - Rx (71%), non-Rx (69%), or both (49%)
  - 80% COWS 0-8 at induction (mild withdrawal)
  - 92% starting dose was  $\geq$  16 mg
- ## END OF STUDY (90 days)
- 334 visits, 14 touchpoints
  - 50% of all pharmacies, 75% at one pharmacy
  - 43% used study transportation
  - 31% received a phone
  - 46% required payment assistance

# POSITIVE EXPERIENCES RECEIVING CARE AT THE PHARMACY

“I felt comfortable to bring my babies to the pharmacy for my visits.”

“I never felt embarrassed going there....”

“The hours were perfect for me.”

“It was even better than I thought it would be. It was quick, easy, clean. People were so nice. Not out of my way at all. A very easy thing to do.”

“It's very convenient. People are happy and look like they like to be there. It was a nice environment.”

“It was the same thing: no surprises; on schedule, easy to do; that's exactly what I wanted. I was excited to go to the pharmacy.”

“I met with [the pharmacist]. I don't get to sit down and talk to someone like I do at the pharmacy, when I'm at the OTP.”

“[The study pharmacy] was more courteous, friendly and more personable than just going to [a large retail chain pharmacy] to pick up medication. I didn't have to stand in line and have people in my personal space.”

# Factors Affecting CPA Implementation Success

## Geographic / Systemic

- Health Workforce Shortage Areas
- Waivered provider density
- Addiction training programs
- Addiction consult services
- Research centers / CTN
- Patient referral sources, e.g. Syringe service programs, outreach
- Medicaid expansion
- **Provider status / payment for services**
- **State buprenorphine rules**

## CPA

- **State DEA recognition**
- **Perform, interpret, bill for lab tests**
- Type and # of clinician (MD, NP, PA)
- Number of pharmacists / technician roles
- Who can sign prescription
- Other professionals (peers, social workers)
- Locations allowed (community, hospital)
- Permit initiation of therapy
- Medication administration / FDA REMS
- Controlled substances permitted
- Training/education requirements

# Conclusions: Induction

Patients inducted in the pharmacy attain **stabilization comparable** to community-based usual care.

Transitions imposed by studies, systems, and stigma disrupt engagement in care. **Patients started in the pharmacy should maintain care in the pharmacy.**

Pharmacy based induction promotes **racial and economic equity** in medication treatment access.

Research is needed to identify the **combination and level of peer, social, and material supports** needed to optimize rates of induction to maintenance.

## Preserving dignity through expanded and sustained access to buprenorphine

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**Pharmacists, prescribing clinicians, and other treatment advocates** are called to act by implementation solutions that directly improve and sustain access to **high quality [behavioral healthcare]**, including:

- Education
- Regulatory changes
- Scope of practice expansion
- Payment reform

“Medication first” advocates need to go beyond hurdles to stocking, dispensing, insurance limitations, and communication **and implement solutions that directly expand equitable access to addiction care.**

**All pharmacists** should advocate for permanent changes to their state collaborative practice and telehealth policies to permit collaborative controlled substance initiation and maintenance



# Summary

- Pharmacist prescribed medications are expanding across the country
- 11 states currently allow pharmacists to prescribe MOUD
- Policy barriers include training requirements and payment for pharmacists' services
- Collaborative community pharmacy addiction practice provides superior care for underserved patients
- All treatment expansion advocates can reform policy to increase access to methadone and buprenorphine



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