

# Legal Strategies to Require Pharmacies to Stock Buprenorphine in Pennsylvania

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Stephen and Sandra Sheller have again increased their support for Temple Law School's Sheller Center for Social Justice with a \$700,000 gift, bringing their total contribution to the Center and related

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**NEWS**  
**Jefferson Health Establishes the Stephen and Sandra Sheller Consult and Bridge Program**  
Providing Person-Centered Care for People with Substance Use Disorder



MAY 2, 2024

This program establishes an innovative primary care model that provides comprehensive, relationship-based care across outpatient, hospital, ER, and addiction treatment settings

PHILADELPHIA — Today, Jefferson Health announced the opening of the Stephen and Sandra Sheller Consult and Bridge Program. The Bridge Program is an ecosystem of coordinated, high-quality care for people with severe substance use disorder. In this model, a single interdisciplinary care team provides comprehensive services for the Bridge patients across community, hospital, emergency department, and psychiatry settings. In addition to the full spectrum of health needs, the program's staff assists patients

# Objectives

1. Describe the problem
2. Detail legal theories
3. Next steps for advocacy

# The Problem

Many Philadelphia pharmacies do not stock buprenorphine

# The importance of readily accessible buprenorphine

Buprenorphine is:

- one of only three medications for the treatment of OUD
  - methadone is much more stringently regulated<sup>1</sup>
  - naltrexone requires complete withdrawal prior to initiation<sup>1</sup>
- effective in reducing withdrawal symptoms<sup>1, 2</sup>

1. Shulman M, Wai JM, Nunes EV. Buprenorphine Treatment for Opioid Use Disorder: An Overview. *CNS Drugs*. 2019;33(6):567-580. doi:10.1007/s40263-019-00637-z

2. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder, Manchur M, Leshner AI, eds. *Medications for Opioid Use Disorder Save Lives*. Washington (DC): National Academies Press (US); March 30, 2019.

# The importance of readily accessible buprenorphine

Delays, denials, or unavailability of buprenorphine can:

- produce feelings of frustration and stigma<sup>1</sup>
- result in withdrawal and cravings, which can result in a return to the use of substances in the illicit drug supply<sup>2</sup>

1. Textor L, Ventricelli D, Aronowitz SV. 'Red flags' and 'red tape': Telehealth and pharmacy-level barriers to buprenorphine in the United States. *Int J Drug Policy*. 2022;105:103703.
2. Jakubowski A, Fox A. Defining low-threshold buprenorphine treatment. *J Addict Med*. 2020;14:95–98.

# Aronowitz et al. 2024

## Survey of 351 pharmacies (83%) in Philadelphia

- **68%** regularly stock buprenorphine
- **2%** would order it when a prescription is sent
- **26%** said that they do not stock or order buprenorphine
- **5%** were unsure

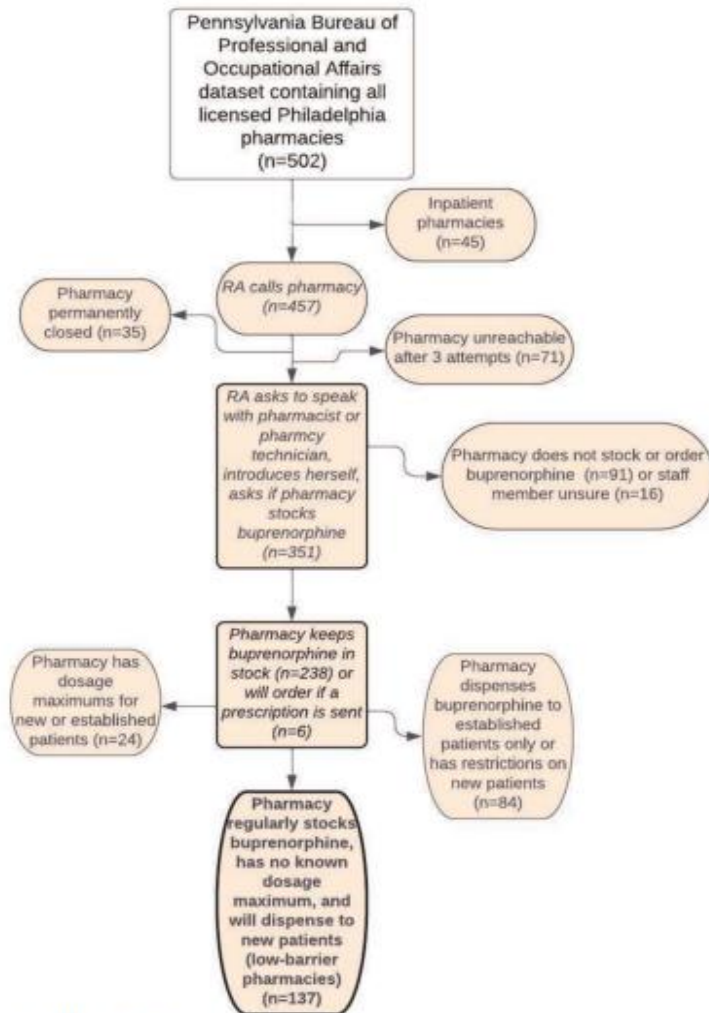


FIGURE 1. Pharmacy data collection flow diagram.

# Aronowitz et al. 2024

Only 137 (39%) of pharmacies were deemed “easier access” which  
1) regularly stock buprenorphine, 2) dispense to new patients, and 3) have  
no dosage maximums

Zip codes with predominantly White residents had more “easier access”  
pharmacies than those with predominantly Black residents

- 9 zip codes in Philadelphia had no “easier access” pharmacies
- 3 had only one, all areas with predominantly Black residents



# Messmer et al. 2024

Barrier	Number of Respondents (n)
→ Time delay in filling prescription	16
Lack of transportation to community pharmacy	15
Experiencing opioid withdrawal and unable to go to pharmacy	14
Lack of identification to pick-up prescription	10
→ No buprenorphine in stock at the community pharmacy	9
Stigma experienced by the patient	7
No pharmacy nearby	4
→ Pharmacist refused to fill prescription	1
Other (lack of money, pharmacy hours)	2

Of the **30** patients of a mobile medical clinic in Chicago who had received buprenorphine from a community pharmacy, **25 (83.3%)** reported experiencing a barrier to access

# Why are pharmacies reluctant to stock bupe?

Drug Enforcement Agency (DEA) licenses pharmacies to dispense controlled substances<sup>1</sup>

- Pharmacists have a duty to ensure prescriptions are issued for a legitimate medical purpose
- “**Red flags**” include cash payment, traveling long distances to a pharmacy, patients new to the pharmacy<sup>2</sup>
  - Red flags are not codified, nor is there complete guidance from an official DEA document.
- Pharmacists face **removal of licensure**<sup>3</sup>

1. Laura Stanley, Policymaking through Adjudication: DEA's Red Flags, George Washington University Regulatory Studies Center (Aug. 13, 2022), <https://regulatorystudies.columbian.gwu.edu/policymaking-through-adjudication-dea-red-flags>.

2. Textor L, Ventricelli D, Aronowitz SV. 'Red flags' and 'red tape': Telehealth and pharmacy-level barriers to buprenorphine in the United States. *Int J Drug Policy*. 2022;105:103703.

3. Qato DM, Watanabe JH, Clark KJ. Federal and State Pharmacy Regulations and Dispensing Barriers to Buprenorphine Access at Retail Pharmacies in the US. *JAMA Health Forum*. 2022;3(8):e222839. doi:10.1001/jamahealthforum.2022.2839

# The Legal Landscape

# The Role of Pharmacies

- Pharmacy practice is regulated in Pennsylvania (and other states) by a Pharmacy Board
- The Pennsylvania Pharmacy Act created the Board of Pharmacy, an empowered it to license pharmacists, oversee disciplinary actions, and promulgate regulations governing practice.
- (Pharmacies and the pharmacy board have played important roles in SUD policy; e.g., pharmacies in PA and elsewhere once required prescriptions for syringes)



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# The “shall maintain a supply . . . adequate . . .” argument

- The PA Pharmacy Board regulations state that: “A pharmacy shall maintain a supply of drugs . . . adequate to meet the needs of the health professions and the patients it is intended to serve.”
- Shall is not defined in the act, however, the Rules of Construction of the Pennsylvania Consolidated Statutes state, “words and phrases shall be construed according to rules of grammar and according to their common and approved usage . . .” and “general words shall be construed to take their meanings and be restricted by preceding particular words.” 49 Pa. Code § 27.14.
- The word, “shall” could be interpreted as mandatory or directory, but it is generally regarded as an imperative word. There is no case law with relevant statutory interpretation nor does it appear that the PA Pharmacy Board has ever enforced 49 Pa. Code § 27.14.

# The Privity Argument

- Another cause argument is that failure of pharmacies to carry Buprenorphine is a breach of their contract with Medicaid or medical assistance.
- The Pennsylvania Administrative Code for Human Services defines a “Provider” as, “[a] medical facility which signs an agreement with the department to participate in the MA program, including, but not limited to . . . Pharmacies . . .”
- PA Administrative Code also states, “the MA Program provides payment for medically necessary pharmaceutical services furnished directly to eligible recipients by pharmacies enrolled as providers in the program.”
- Together these provisions suggest that there is privity of contract between MA-participating pharmacies and Medicaid.

# The Privity Argument

- Under 55 Pa. Code § 1121.42, “pharmacies shall...conform to accepted standards of practice and quality of service when dispensing prescriptions to MA recipients. It shall be considered contrary to accepted standards of practice for a pharmacy to differentiate between MA recipients and the general public...”
- 55 Pa. Code § 1101.21 defines “**medically necessary**” as “a service, item, procedure, or level of care that is (i) compensable under the MA program (ii) necessary to the proper treatment or management of an illness, injury, or disability (iii) prescribed, provided or ordered by an appropriate licensed practitioner in accordance with accepted standards of practice.”
- However, the rules do not explicitly say pharmacies must dispense all medications to MA recipients, it can be argued that not carrying Buprenorphine and turning patients away when they come to fill the prescription is against the accepted standards of practice of pharmacy. The focus of most of the rules in the section relate to fraud.

# The Negligence Argument

- There is not a strong common law tradition of requiring private entities to carry certain products.
- In 2010, the U.S. Fourth Circuit of Appeals held that pharmacies do not have a legal duty to stock medication. The Plaintiff had a heart condition which required him to take multiple medications concurrently, one of which Rite Aid was unable to fill, leading to alleged injury.
- The court noted, “given the number of medications that exist, such a duty would be physically impossible for most pharmacies.” A state judge reached the same conclusion: “they do not have a duty to have available every drug that someone might request.” The case further explained that none of the provisions in federal law on the regulations of pharmacies set forth a duty of a retail pharmacy to have certain medication in stock at all times.



# Next Steps

# Pass New Legislation

Example: **Section 9-637** of the Philadelphia Code mandates opioid antidote (naloxone) availability<sup>1</sup>

- All retail pharmacies **must carry enough stock** of naloxone or opioid antidotes to fill at least two requests
- Each violation amounts to a **\$250 fine**

## Advantages:

Most direct approach  
Enforceable

## Disadvantages:

Time-consuming  
Resource-intensive  
Outcome not guaranteed

1. The Philadelphia Code § 9-637

# Ask the PA Attorney General to Investigate

**AG's Health Care Section**: helps Pennsylvanians secure the treatment they need, protects the public from unfair health care business practices, and helps shape Pennsylvania health care policies in favor of consumers<sup>1</sup>

- Office of the Attorney General can take **legal action against a pharmacy** after receiving a complaint via their website

## Advantages:

- Ease of filing complaint
- Consumer-led

## Disadvantages:

- Inefficient to address widespread phenomenon
- Onus on individuals to act

1. *Healthcare Matters*, Pennsylvania Attorney General, (Apr. 16, 2024), <https://www.attorneygeneral.gov/protect-yourself/healthcare-matters/>.

# Lobby the Pharmacy Board

Example: **39 Pa.B. 5312** of the Pennsylvania Pharmacy Rules and Regulations amended previous rulemaking to allow pharmacists to sell syringes to people without a prescription.

## Advantages:

The rulemaking process solicits evidence creating a record of need

The Pharmacy Board is accessible through public outreach

The change could occur quickly

## Disadvantages:

Unclear what the politics of this are for the Board

# Questions and Thanks!

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