

# Regulatory Strategies to Address the Opioid Epidemic

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# Current Regulatory Challenges in Addiction Medicine

## Telemedicine

- Flexibility of prescribing controlled substances (buprenorphine)
- Enhanced flexibility of take home methadone doses from opioid treatment programs
- Public Health Emergency set to expire on October 15; expecting HHS to extend for another 90 days
- Scrutiny around telemedicine prescribing brought into the spotlight
  - ADHD and stimulant prescribing
  - Published data related to buprenorphine and methadone telemedicine management has been positive

# Current Regulatory Challenges in Addiction Medicine

## Prescribing AND dispensing of buprenorphine

- Prescribers
  - Concerns about being raided for improper buprenorphine prescribing habits on both local and federal levels
  - Most waived prescribers are not prescribing near their limits
- Pharmacists
  - Stigma
  - Refusing to stock buprenorphine
  - Wholesaler/company established “par levels”

# Buprenorphine “Misuse” & Diversion

- Several studies have evaluated buprenorphine misuse and abuse
  - Estimated prevalence of approximately 25%<sup>1</sup>
- Most individuals that report non-medical use do so for at least one of the following reasons<sup>2</sup>
  - Avoid/mitigate withdrawal symptoms
  - Unable to access treatment
  - Maintain abstinence from other opioids

<sup>1</sup> Han B, et.al. Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US. *JAMA Netw Open*. 2021;4(10):e2129409.

<sup>2</sup> Howard D, et al. Buprenorphine in the United States: Motives for abuse, misuse, and diversion, *Journal of Substance Abuse Treatment*, Volume 104, 2019, Pages 148-157.

# DEA takes aggressive stance toward pharmacies trying to dispense addiction medicine

November 8, 2021 - 2:05 PM ET

ANERI PATTANI

FROM **KHN**



Suboxone and a similar medicine, Subutex, are both proven to help people with opioid addiction stay in recovery. Yet the Drug Enforcement Administration often makes it hard for pharmacies to dispense it.

George Frey/Bloomberg via Getty Images

<https://www.npr.org/sections/health-shots/2021/11/08/1053579556/dea-suboxone-subutex-pharmacies-addiction>

TREATMENTS

# It's The Go-To Drug To Treat Opioid Addiction. Why Won't More Pharmacies Stock It?

August 13, 2019 - 5:00 AM ET  
Heard on Morning Edition

NINA FELDMAN

FROM **WHYY**

5-Minute Listen + PLAYLIST Download Share Menu



A bus run by the organization Prevention Point parks at Kensington and Allegheny avenues in Philadelphia to offer harm-reduction services to drug users in the area. Louis Morano (center), who was visiting the Prevention Point bus for the second time, sits outside and waits to be seen by Dr. Ben Cocchiaro.

Brad Larson for WHYY

<https://www.npr.org/sections/health-shots/2019/08/13/741113454/its-the-go-to-drug-for-opioid-addiction-so-why-won-t-more-pharmacists-stock-it>

# Pharmacists' Attitudes Towards Dispensing Buprenorphine

- 80% had no negative complaints about patients filling a prescription for buprenorphine/naloxone
- 12.5% of respondents stated not wanting opiate-dependent patients in their pharmacies
- 75% were not concerned with buprenorphine/naloxone prescription forgery
- 80% did not believe that diversion was an issue

# Pharmacists' Attitudes Towards Dispensing Buprenorphine

- Telephonic “shopper survey” conducted in multiple US counties reporting higher than average opioid overdose rates
- Nearly 30% reported limitations on filling buprenorphine prescriptions
- One in five pharmacies would not fill buprenorphine prescriptions at all
- Limitations and refusal to fill was more common in independent pharmacies and those in the south

# Opportunities

- Administration of long-acting injectable formulations

In conclusion, CUSP asks that the DOJ take the following actions:

1. State in plain language that a DEA-registered practitioner who does not hold a DATA 2000 waiver may receive delivery of and administer an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment;
2. State in plain language that a pharmacist authorized under state law to implant or inject controlled medications may administer in such state an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment; and
3. Modify the time limit so that a practitioner who receives delivery of an implantable or injectable controlled medication prescribed to a patient for maintenance or detoxification treatment has 60 days after delivery to administer such medication.



Please contact us if you have questions or would like clarifications. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Michael C. Barnes".

Michael C. Barnes  
Chairman

# Pharmacists May Be Key to Expanding Bupe Access, NIDA Pilot Shows

- 71 patients managed by community pharmacists
  - Six physicians and six pharmacists
- 89% of patients remained in the six-month study
- 95.3% adhered to daily treatment regimen
- Proportion of negative drug screens was > 95%
- ZERO overdoses
- All patients stated that they would enroll again

# Opportunities

- National Association of Boards of Pharmacy (NABP) MAT initiative
  - Requesting removal of the DATA 2000 waiver to allow states to decide what clinicians can prescribe MAT
  - Allow pharmacists to obtain an individual controlled substance registration
  - Allowing pharmacist-provided MAT for patients diagnosed with OUD and allowing control at the state level would build on recent efforts of the state boards of pharmacy to combat the opioid crisis
  - Pharmacists could facilitate counseling and support services
  - Whether urban or rural, patients generally live within a few miles of a pharmacy, whereas provider locations are not as accessible