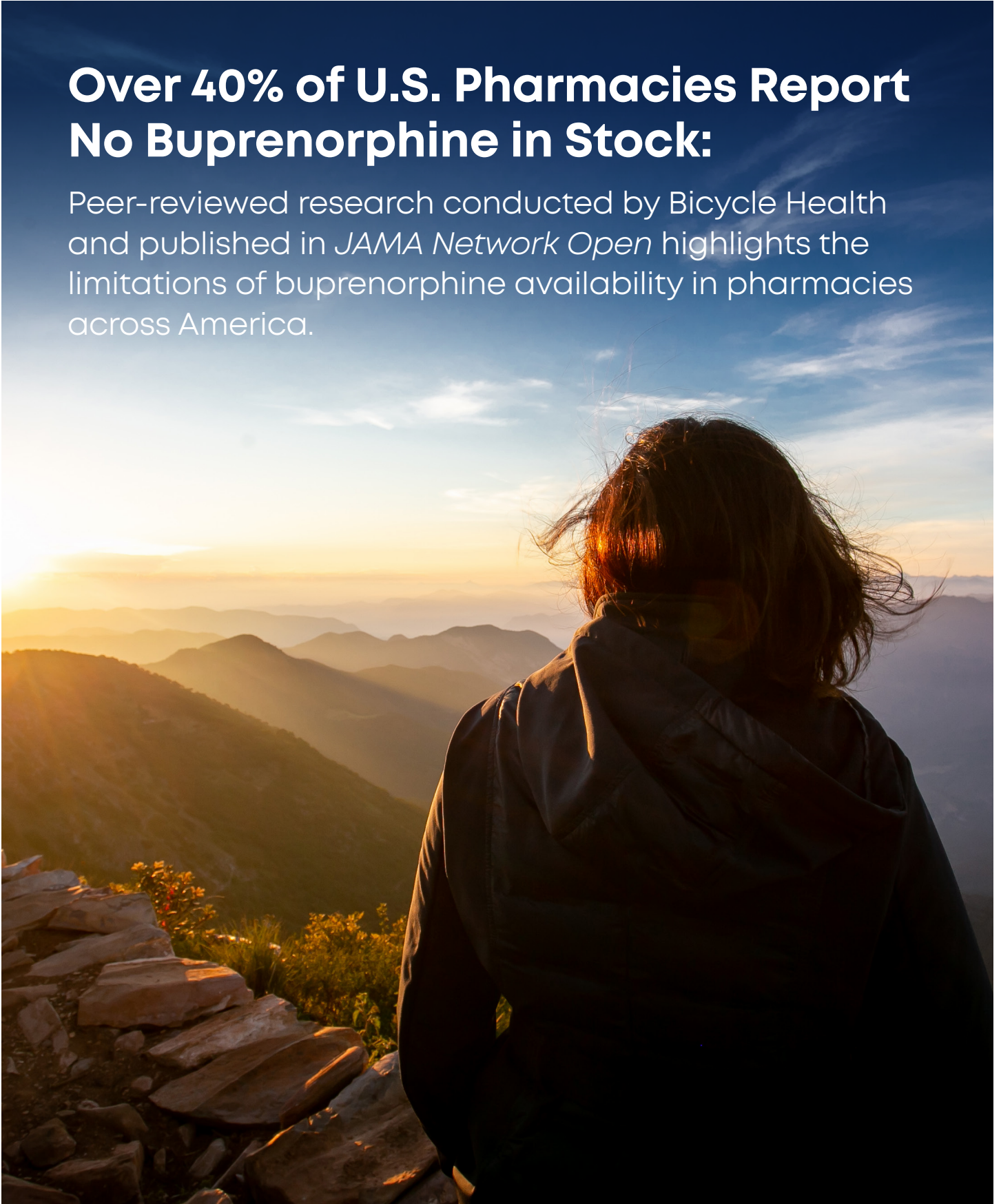


Over 40% of U.S. Pharmacies Report No Buprenorphine in Stock:

Peer-reviewed research conducted by Bicycle Health and published in *JAMA Network Open* highlights the limitations of buprenorphine availability in pharmacies across America.



Executive Summary



Medication for opioid use disorder (MOUD) with buprenorphine is one of the most effective ways to treat opioid use disorder (1, 2). For the vast majority of patients, the use of telemedicine improves adherence with MOUD treatment (3, 4, 5), and the rates of buprenorphine diversion and buprenorphine-associated deaths declined when access to buprenorphine was expanded during the pandemic (6, 7, 8, 9).

Deaths from opioid-related overdose have remained at epidemic levels for more than a decade without a clear solution in reach. But, as evidenced by published research, adherence to MOUD saves patient lives and reduces ED visits, non-fatal drug overdoses, and healthcare costs.

Two of those studies are highlighted here:

- A 2019 study in the *Journal of Substance Use and Addiction Treatment* found that, at six months, **only 3.6% of individuals who were adherent to MOUD experienced a nonfatal drug-related overdose** in the ED, compared to 13.2% of individuals who were non-adherent. (1)
- A 2013 study in the *Journal of Substance Use and Addiction Treatment* found that patients who were adherent to MOUD treatment saw their **total one-year healthcare costs decrease by 42 percent** (\$28,458 vs. \$49,051) when compared to non-adherent members. (2)

Suboxone, an FDA-approved medication that combines buprenorphine (a partial opioid agonist) and naloxone (an opioid antagonist), is commonly prescribed by clinicians to prevent opioid withdrawal symptoms and prevent relapse for people with opioid use disorder (OUD).



Historical Restrictions on Buprenorphine Access

In spite of its efficacy, it historically has been extremely difficult for patients to access MOUD treatment with Suboxone because clinicians needed an “X-waiver” in order to be able to write a prescription for buprenorphine, in any formulation (including Suboxone), for OUD treatment.

The X-waiver refers to a special certification that was required of physicians in the United States to prescribe buprenorphine for the treatment of OUD in the Drug Addiction Treatment Act of 2000 (DATA 2000).

Congress passed DATA 2000 in an effort to allow office-based treatment with MOUD. However, the additional requirements burdened prescribers and may have increased stigma and the perceived risks associated with prescribing buprenorphine. In the intervening years, several legislative changes were enacted to expand its access.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded the patient limit for physicians with an X-waiver from 100 to 275 patients, and - for the first time - permitted nurse practitioners and physician assistants to prescribe buprenorphine. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or short hand—the SUPPORT for Patients and Communities Act (the “SUPPORT Act”) of 2018 removed more barriers for physicians, RNs and PAs who wanted to prescribe buprenorphine to qualified patients. Still, buprenorphine is considered a controlled substance by the DEA and thus required an in-person, face-to-face visit prior to its prescription as required by the Ryan Haight Act.

However, in 2020, under the COVID-19 Public Health Emergency, federal regulators eased access to MOUD by allowing clinicians to prescribe buprenorphine (Suboxone) for a patient via telehealth, without an in-person evaluation.

Finally, on December 29, 2022, the Consolidated Appropriations Act of 2023 eliminated the X-waiver completely. While progress has been made to increase access to buprenorphine, the DEA issued a “Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications” through November 11, 2023.

The DEA had proposed to roll back telehealth access to buprenorphine when the COVID public health emergency (PHE) ended on May 11, 2023 before they received **“a record 38,000 comments on its proposed telemedicine rules”**, which would have limited telehealth prescriptions for buprenorphine to 30 days unless followed by a subsequent in-person visit.

The Success of MOUD Treatment Via Telemedicine

For most patients, the COVID-19 Public Health Emergency's expanded access to buprenorphine via telemedicine was a massive success. Numerous studies published in peer-reviewed medical journals made it clear that access to buprenorphine via telemedicine is more patient-centered, improves compliance with MOUD treatment, and is safe.

- A March, 2023 study in *JAMA Psychiatry* found that telehealth expansion of MOUD provision during the COVID-19 pandemic was associated with **lower odds of fatal drug overdose among Medicare beneficiaries**. Telehealth provision of MOUD was associated with improved retention in care and reduced odds of medically treated overdose for Medicare beneficiaries. (3)
- A July, 2022 study in the *American Journal of Psychiatry* found that buprenorphine for patients treated in Veterans Affairs hospitals increased as care shifted to telehealth during COVID. (4)
- A 2021 study in *BMJ Innovations* found the **retention rate for insured telehealth patients at 90 days was 80% compared to an industry average of 44%** and that “no-show rate” for telehealth patients was 9.5%, compared with an average of 23%. (5)

MOUD Treatment Retention Rates	30 Day Retention	90 Day Retention
Bicycle Health — Insured Patient Retention	86%	80%
Bicycle Health — All Patient Retention	75%	59%
In-Person Industry Average (From review of insurance claims data)	69%	44%
Patient No-Show Rate	Industry Average 23%	Bicycle Health 9.5%
Patients who see a provider within 24 hours?	NA	70%
Patients who receive motivational interviewing?	NA	89%



“Buprenorphine is a critical tool in the fight against the opioid overdose epidemic, but to be safely and effectively administered to patients with OUD, **they must have consistent, timely, and convenient access**. This study highlights how medication availability still represents a major barrier to care for many of Bicycle Health’s patients – as well as others seeking MOUD treatment across the United States.”

— **Dr. Scott Weiner**, Director of Research, Bicycle Health

Pharmacies in Flux

In spite of the broad support for expanded access to buprenorphine by clinicians and many policymakers, retail pharmacies sometimes refuse to fill prescriptions for buprenorphine written by telemedicine providers. Shortly after Bicycle Health's virtual MOUD treatment program sprung to life in 2020, patients quickly began telling our clinicians that they were encountering barriers to filling their buprenorphine prescriptions at their local pharmacy.

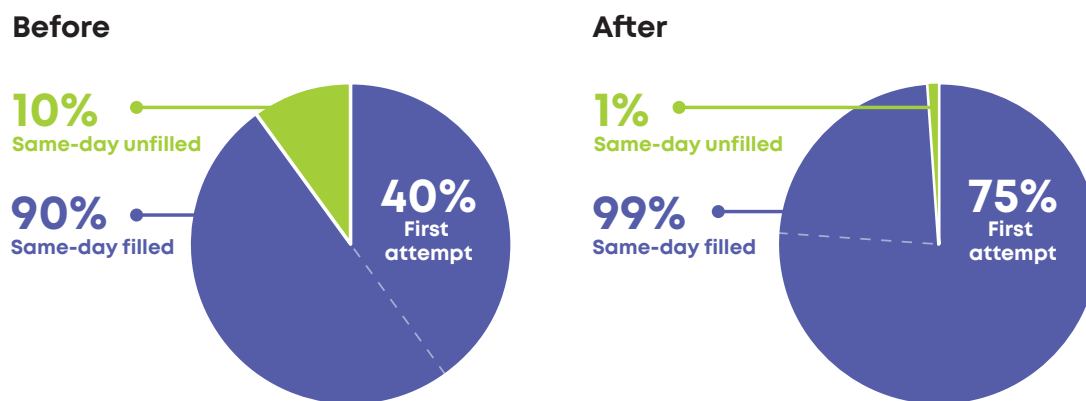
To address this issue for patients, Bicycle Health's clinical support staff would identify pharmacies that were geographically closest to our patients and call them to see if they had the medication in stock. Patient prescriptions were only sent to pharmacies that did have Suboxone, or comparable generics, in stock.

The results of these calls were tracked in Bicycle Health's Pharmacy Finder Tool, a database that allows our clinical support staff to identify pharmacies that are close to patients, can fill their buprenorphine (or Suboxone) prescriptions, accept the patient's insurance, and do not have a reported history of stigmatizing or declining service to patients.

The Pharmacy Finder helps clinical support staff find a pharmacy that will fill the medication for patients on the first attempt.

Pharmacy Finder improves success rates of pharmacy calls from 75% of the time, compared to 40% before the tool was implemented.

Figure 1. Success Rates of Bicycle Health's Pharmacy Finder Tool



Resistance to Buprenorphine Access Via Telemedicine

The reluctance among lawmakers and some regulators at the DEA to permanently expand access to buprenorphine via telemedicine centers around a fear of diversion: the misuse or over-prescribing of buprenorphine.

While the concern that buprenorphine diversion would worsen during the pandemic seems understandable, researchers proved those fears to be unfounded. Multiple studies have now shown that the rate of buprenorphine diversion went down once access was expanded through telemedicine.

- A January 2023 study in [JAMA Network Open](#) found that the percentage of **opioid-related deaths involving buprenorphine dropped from 3.6% to 2.1% from 2019 to 2021**, after the Ryan Haight Act was waived and telemedicine OUD care with no in-person requirement began. (6)
- The [same study](#) found that buprenorphine-involved deaths were more likely to involve other drugs (at least one), and less likely to involve illicitly manufactured fentanyl compared to other opioid-involved overdose deaths (50.2% vs. 85.3%). (7)
- A [2021 study covered in JAMA Network Open](#), found that, when buprenorphine is misused, people use it to treat withdrawal symptoms, not to get high. Researchers found that hydrocodone and oxycodone were far more commonly misused than buprenorphine, and that when buprenorphine was misused, patients were self-medicating their withdrawal symptoms, not getting high. (8)
- [Rubel, et al. 2023](#) additionally found the primary reported motivation for use of diverted buprenorphine was **lack of access to legitimate treatment for OUD**. The rate of use of diverted buprenorphine was highest by far in the population of patients with OUD not receiving MOUD. (9)

Buprenorphine Remains Difficult to Access

On May 26, 2023, Bicycle Health's Director of Research, Dr. Scott G. Weiner, MD, MPH and Chief Medical Officer, Brian Clear, MD published [a research letter in JAMA Network Open](#) in partnership with Dima M. Qato, PharmD, MPH, PhD; and Jeremy Samuel Faust, MD, MS.

The researchers conducted a cross-sectional study using data from Bicycle Health's Pharmacy Finder tool to examine the accessibility of buprenorphine at local pharmacies and identify regions and specific pharmacy chains where patients with opioid use disorder (OUD) might encounter difficulties in obtaining buprenorphine prescriptions.

Figure 2. Pharmacy Availability of Buprenorphine for Opioid Use Disorder Treatment in the US

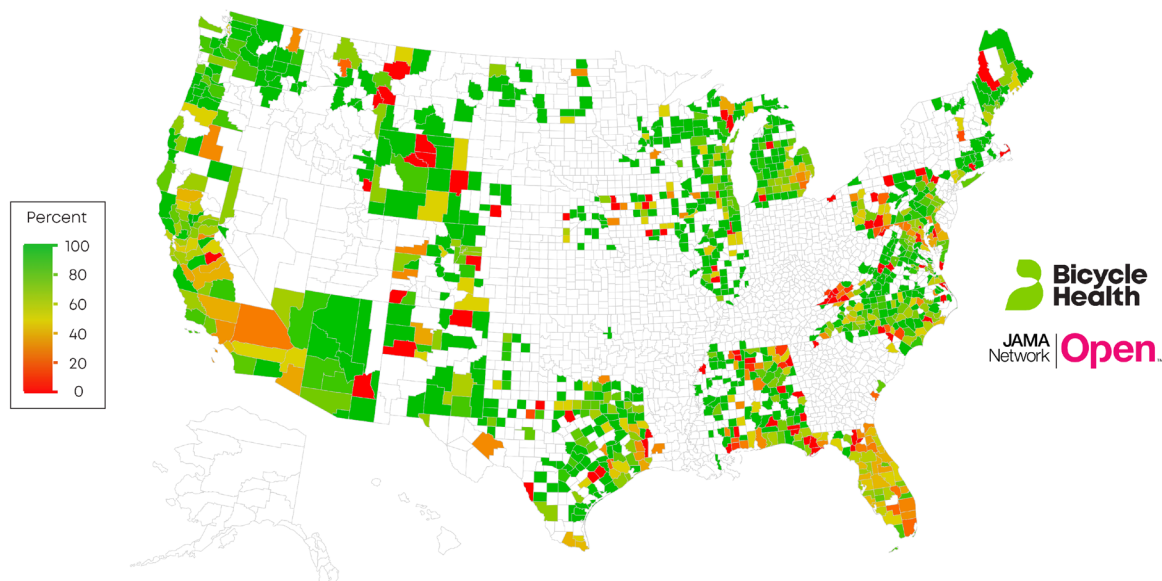


Figure: Availability of buprenorphine in the US by county.

*First stock check call to US pharmacies in 2022 by Bicycle Health medical staff.

**County availability indicates the percentage of pharmacies reporting stock over total pharmacies called in that county.

A JAMA Network Open study: jamanetwork.com/journals/jamanetworkopen/fullarticle/2805329

Findings

The researchers retrospectively analyzed data collected throughout 2022 from Bicycle Health's Pharmacy Finder, which records interactions with pharmacies.

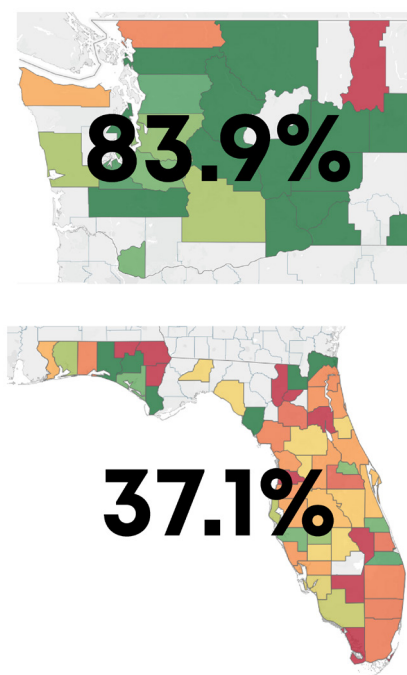
Bicycle Health's clinical support staff (CSS) ask new patients to specify their preferred pharmacy. Then, Bicycle Health's CSS team used a standardized script to inquire about the availability of different strengths and forms (tablet or film) of Suboxone (buprenorphine/naloxone) at the patient's preferred pharmacy.

Pharmacy responses were categorized as either "yes" or "no" depending on whether at least one formulation was available. Only the initial call made in 2022 was considered since Bicycle Health staff rarely made follow-up calls to pharmacies that previously reported not stocking Suboxone.

In total, 5,283 different pharmacies were contacted on behalf of 3,779 patients, out of which 3,058 (57.9%) confirmed having stock. National and regional chains were more likely to have stock compared to independent pharmacies, and there was variation across states, with availability ranging from 37.1% in Florida to 83.9% in Washington state.

Among the selected national and regional retail pharmacy brands, buprenorphine availability ranged from a low of 31.2% at Publix to 82.5% at H-E-B in certain states.

Figure 3. Pharmacy Availability of Buprenorphine for Opioid Use Disorder in Washington and Florida



Key findings from the research include:

- Pharmacy chains were more likely to have buprenorphine stock, with **61.6% of chain pharmacies** reporting availability vs. **45.3% of independent pharmacies**.
- Despite being more likely to have buprenorphine stock, there was still significant variability across chain pharmacy locations, based on chains where more than 40 locations reported stock.
- Over the course of this study, Bicycle Health made the most buprenorphine stock inquiries on behalf of patients to **CVS and Walgreens** locations. Buprenorphine availability was reported **59.7% and 70.3%** of the time, respectively.
- Buprenorphine availability varied widely across the 32 states included in this study. Of states with more than 100 pharmacies queried, **Florida locations were least likely to have stock (37.1%)** and Washington State locations were most likely to have stock (83.9%).
- Over the course of this study, Bicycle Health made the most buprenorphine stock inquiries on behalf of patients in Florida and California. Buprenorphine availability was reported 37.1% and 46.8% of the time, respectively.

Discussion

Implications of this large-scale study are profound. This study demonstrates the limitations in buprenorphine availability at retail pharmacies at the time of a patient's need.

In all, **only 57.9% of pharmacies reported having Suboxone in stock at the time of request**, with substantial differences observed among states and pharmacy chains in the US.

Without clear guidance and easing of policies from lawmakers and the DEA, access to buprenorphine will remain constrained. Limitations on access to medication via telemedicine can only serve to worsen the nation's opioid epidemic and prevent those newly diagnosed from accessing care.

Conclusion

The stigma associated with opioid use, the cost of in-person treatment options, and the lack of absence of telehealth treatment programs prior to the COVID public health emergency have all been consistent impediments in efforts to expand access to MOUD treatment with buprenorphine. As the Drug Enforcement Administration (DEA) looks to outline the regulations for prescribing via telehealth and continues setting stocking limits for buprenorphine, understanding the role these drugs play in addressing opioid use disorder is an important consideration. **Bicycle Health's evidence-based, clinically proven virtual care model is helping to increase access to these life-saving medications and address the opioid overdose epidemic head-on.**

Bicycle Health is committed to working alongside America's leading pharmacies, policymakers, and regulators to ensure patients across this country can safely and conveniently access the medications they need to maintain a healthy recovery.



“At Bicycle Health, we talk a lot about **defiant hope**, which is essentially the need to stay upbeat and hopeful, even when it feels like we cannot help enough people, or that too few people care about our patients. Seeing this research published in JAMA is a ‘defiant hope day’ for me, because it means this issue will get the attention it deserves.”

— **Ankit Gupta**, Founder and CEO, Bicycle Health



“This data helps illustrate a major gap in our ability to care for patients with OUD, but **the good news is it's a problem with a clear solution**. We've already had a positive response and commitment to improve stock rates from pharmacies.”

— **Dr. Brian Clear**, Chief Medical Officer, Bicycle Health

Endnotes

- [1] ["A comparison of adherence, outcomes, and costs among opioid use disorder Medicaid patients treated with buprenorphine and methadone: A view from the payer perspective," JSAT, Rapid Communication Volume 104, P15-21](#)
- [2] ["Relationship Between Buprenorphine Adherence and Health Service Utilization and Costs Among Opioid Dependent Patients," JSAT, Regular Article Volume 46, P456-462](#)
- [3] Jones, Christopher and Shoff, Carla, ["Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic," JAMA, JAMA Psychiatry. 2023;80\(5\):508-514. doi:10.1001/jamapsychiatry.2023.0310](#)
- [4] Zhang, Len, ["Impact of COVID-19 Telehealth Policy Changes on Buprenorphine Treatment for Opioid Use Disorder," The American Journal of Psychiatry](#)
- [5] Rollston R, Gallogly W, Hoffman L, et al Collaborative, ["Patient-centred care model that provides tech-enabled treatment of opioid use disorder via telehealth," BMJ Innovations 2022; 8:117-122.](#)
- [6] ["Overdose deaths involving buprenorphine did not proportionally increase with new flexibilities in prescribing" NIH, News Release, 20 Jan. 2023](#)
- [7] Han B, Jones CM, Einstein EB, Compton WM. ["Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US." JAMA Netw Open. 2021;4\(10\):e2129409. doi:10.1001/jamanetworkopen.2021.29409](#)
- [8] Stephanie K. Rubel, Matthew Eisenstat, Jessica Wolff, Michael Calevski & Sasha Mital (2023) [Scope of, Motivations for, and Outcomes Associated with Buprenorphine Diversion in the United States: A Scoping Review, Substance Use & Misuse, 58:5, 685-697, DOI: 10.1080/10826084.2023.2177972](#)
- [9] 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](#)