LEGAL ACTION CENTER
Breaking Barriers. Defending Dignity.

Overcoming Barriers to Buprenorphine in Retail Pharmacies

EXECUTIVE SUMMARY

Buprenorphine is a highly effective, easy to use medication to treat opioid use disorder, and despite federal and New York State policy reforms to ease access in recent years, its use is still quite limited. One key reason for this is limited access at retail pharmacies. Buprenorphine is restricted or unavailable in retail pharmacies for many reasons, including a confusing array of real and perceived restrictions on selling it, a lack of guidance, and stigma. LAC spoke with buprenorphine prescribers who shared struggles finding pharmacies who carry buprenorphine or dealing with pharmacies that second-guess prescriptions or add unnecessary limitations on quantities or dosage. Federal action is needed to fully address these barriers, but in the meantime, New York State can and should issue guidance to pharmacists to clarify expectations on dispensing buprenorphine and provide education to alleviate stigma.

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Introduction

Buprenorphine is a highly effective medication to treat opioid use disorder (MOUD) that should be easily and widely available. Studies have consistently shown that the medication leads to reduced cravings, increased quality of life, and reduction in both nonfatal and fatal overdoses as well as a reduction in death from other health issues.[i] Despite this, nationwide, only about 20% of those who need access to MOUD receive it.[ii] Further, racial disparities in access to buprenorphine are stark, with lack of access most pronounced for Black individuals.[iii] The disparities in access continue even as

overdose rates have skyrocketed in Black communities in general and among Black men in particular.[iv]

Several federal and New York State policies have recently been enacted to attempt to alleviate barriers to buprenorphine. Unlike methadone, it can now be prescribed in office-based settings by any medical provider with a license to prescribe controlled substances after the 2023 Consolidated Appropriations Act eliminated the “x-waiver” that had required providers to obtain an additional waiver to prescribe buprenorphine and put a cap on the number of patients to which each provider could prescribe. In 2019, to alleviate delays in access to buprenorphine and other forms of MOUD, New York prohibited prior authorization of all FDA-approved forms of MOUD in Medicaid and New York-regulated commercial insurance to alleviate administrative delays to obtaining buprenorphine. This was enacted after clear evidence showed that insurance companies were routinely imposing prior authorization on MOUD prescriptions, causing delays in care and major administrative burdens for the small number of available buprenorphine providers in the state. Federal and New York State agencies continue to state they prioritize access to buprenorphine, yet there has been little if any increase in use.

The reasons for the limited use of buprenorphine are varied and include stigma among providers against treating patients with substance use disorder (SUD), as well as stigma among patients themselves who believe MOUD treatment just substitutes one substance with another. The lack of education about SUD among primary care providers creates another barrier to MOUD access.[v] Still, many states continue to limit access to buprenorphine in other ways.[vi]

One critical access barrier to buprenorphine is the difficulty patients face trying to fill prescriptions through retail pharmacies. With the expansion of office-based prescribing, retail pharmacies are a main source for obtaining buprenorphine prescriptions, as they are for almost all other medications. The Legal Action Center (LAC) reached out to pharmacists, providers, and patients to get first-hand accounts of the barriers faced by

patients who try—and too often fail—to get their buprenorphine prescription filled. The reasons pharmacists gave for not dispensing buprenorphine ranged from supplier shortages and wholesale-distributor order limitations to the perceived Drug Enforcement Agency's (DEA) cap on buprenorphine orders that pharmacists believe could result in liability or revocation of the pharmacy's license.[vii] Pharmacies often complain that they need more guidance or instruction about the various rules around controlled substance dispensing, and buprenorphine specifically. This issue brief examines some of the reasons for these barriers and offers recommendations for New York State policymakers to increase buprenorphine access at pharmacies statewide.

Pharmacy Barriers to Buprenorphine

The prescription opioid crisis of recent years was fueled in large part by inadequate oversight of the sale and distribution of these medications, but resulted in an overcorrection, leading to inadequate supply of and access barriers to not only buprenorphine but all opioids that people need for pain management.[1] Federal enforcement has cracked down on pharmacies, wholesalers, medical providers, and manufacturers in an effort to prevent another spike in prescription opioid overdoses. As a result, manufacturers are restricting their production of opioid-based products, wholesalers are limiting the amount they sell to pharmacies, and pharmacies are understocking and scrutinizing each prescription out of fear of canceled orders and the threat of both civil and criminal liability. However, unlike traditional opioids like oxycodone or fentanyl, buprenorphine access decreases diversion and risk of overdose death.[vii] And yet, buprenorphine is treated largely the same as other opioids in the monitoring and enforcement of anti-diversion measures.

To explore how some of these anti-diversion measures might be impacting consumers, the American Society of Addiction Medicine (ASAM) conducted a national survey of buprenorphine prescribers and released a report in 2022 detailing difficulties their patients faced receiving their prescriptions at pharmacies.

[1] https://www.hrw.org/news/2018/12/18/us-fears-prescribing-hurt-chronic-pain-patients#

ASAM's key findings included

- **45% of respondents said their most common obstacle was pharmacies declining to fill a prescription for buprenorphine;**
- **41% reported pharmacies had an inadequate stock of buprenorphine; and**
- **65% said their patients had to go to a different pharmacy to fill their prescription.**

LAC discussions with New York providers yielded remarkably similar responses. One upstate prescriber said that although she had patients that preferred to use the Walmart pharmacy, they almost always refused to fill prescriptions for buprenorphine. In New York City, prescribers described a process whereby they catalogued which pharmacies would always fill prescriptions for their patients and tried to steer their patients to those, even if they were otherwise inconvenient for those patients. Still other prescribers said they often cycled through a list of pharmacies because it wasn't clear if a particular pharmacy would accept new buprenorphine patients or if they had reached their "cap" for the month until they sent the prescription. Relatedly, recent data from the CDC shows that New York's rate of buprenorphine dispensing at retail pharmacies is only 4.2 per 100 as of 2023, which is lower than it was in 2019 and below the national average.[viii] Buprenorphine patient caps, refusals to stock, and other pharmacy issues all lead to low rates of pharmacy dispensing of buprenorphine.

Recent data from the CDC shows that New York's rate of buprenorphine dispensing at retail pharmacies is only 4.5 per 100 as of 2022, which is lower than it was in 2019, and low compared to other states as well as below the national average.

Despite a common understanding of the importance of MOUD, regulation of it has been applied in ways that are as arbitrary as they are unscientific. The Drug Enforcement Agency (DEA) is the federal body charged with enforcing the Controlled Substances Act (CSA) and engaging in oversight of all controlled substances. Because buprenorphine is

an opioid partial agonist and listed as a schedule III narcotic analgesic, it falls under DEA purview. The DEA has recently made statements confirming their strong support for ensuring ready access to MOUD and their commitment to ensuring an adequate supply. However, some of the most common reasons pharmacies cite for not dispensing buprenorphine are fear of DEA enforcement action and perceived DEA caps on buprenorphine orders that can result in liability or revocation of a pharmacy's license.[ix]

Suspicious Orders Report System (SORS)

The perception that the DEA has implemented a cap on buprenorphine orders continues to be a barrier to pharmacies carrying it. Pharmacies worry that filling "too many" buprenorphine prescriptions can risk enforcement action by the agency. Although the DEA has explicitly denied imposing a maximum number on what wholesalers can order and what pharmacies can distribute[x] and researchers have documented a lack of evidence of DEA-imposed limits,[xi] through the Suspicious Orders Reporting System (SORS), the DEA can take enforcement action against pharmacies who dispense a suspicious amount of buprenorphine.

A version of suspicious orders monitoring for controlled substances began as early as 1971, but the current SORS was established by regulations implementing amendments to the Controlled Substances Act (CSA) included in the 2018 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) with the purpose of preventing diversion of controlled substances.[xii] As an opioid itself, as well as a controlled substance, buprenorphine is included within this system. All DEA registrants, including pharmacies and wholesalers/distributors, must design and implement a system to monitor for suspicious orders and report orders deemed suspicious to the DEA.[2] A suspicious order "may include, but is not limited to an order of a controlled substance of an unusual size; an

[2] Provisions to require DEA registrants to engage in suspicious orders monitoring first appeared in regulation in 1971 but the 2019 SUPPORT Act created the centralized system used today. *See* https://www.federalregister.gov/d/2020-21302/p-72

order of a controlled substance deviating substantially from the normal pattern, and; orders of controlled substances of unusual frequency."[xiii] Determining what quantities of medication should be deemed "suspicious" is largely left to the discretion of the wholesalers who develop their monitoring systems per DEA requirements. These internal compliance programs are mandated by DEA regulations, but the DEA has not clearly specified what criteria these programs should look for in determining a "suspicious order" or, more specifically, how to treat a potential "suspicious order" of buprenorphine.[xiv] Without clear guidance, confusion among pharmacies persists.[xv]

The confusion surrounding and perception of caps on buprenorphine ordering and dispensing often lead to barriers in access to the medication. Pharmacies, unaware of what quantity will be flagged as suspicious by the wholesalers or DEA, may and often do impose their own internal restrictions on all controlled substances[xvi] or otherwise set very conservative limits on their own ordering, including of buprenorphine.[xvii] The ambiguity caused by the DEA and the discretionary policies created by pharmacies in response to wholesaler monitoring results in supply shortages of buprenorphine.

Opioid Settlement Monitoring Requirements

The recent $21 billion nationwide settlements with the three main U.S. pharmaceutical wholesalers – AmerisourceBergen, Cardinal Health, and McKesson – included specific injunctive relief requirements for each wholesaler to establish a Controlled Substance Monitoring Program ("CSMP") that includes a suspicious orders monitoring protocol similar to the SORS, sets a customer pharmacy threshold for ordering controlled substances, and compels wholesalers to submit reports to the states that were parties to the settlement. The wholesalers are responsible for implementing these programs and have the ability to terminate or suspend pharmacies' ability to order product.[xviii]

The definition of suspicious orders in the settlement agreement is the same as the CSA's definition for the SORS program: orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. The distributors are to monitor for suspicious orders and each wholesaler is also required to apply

specific metrics to identify “red flags” of suspicious orders which are specified in the agreement.

The distributors have implemented “data-driven systems” to detect suspicious orders from customer pharmacies and can terminate or suspend pharmacies’ ability to receive shipments based on suspicious orders. They must also report them to regulators in the settling states. These data-driven systems involve wholesalers creating algorithms, which flag, automatically cancel, and report certain orders.[xix] Reports have said that these algorithms use built-in quantitative thresholds and have resulted in “tens of thousands of drug orders [being] canceled” as wholesalers juggle—with no clear guidance from the DEA about how these compliance programs should be set up— what they perceive to be appropriate safeguards.[xx]

While wholesalers impose increasingly arbitrary limitations through their monitoring programs, the settlement agreements bar them from telling pharmacies what sorts of thresholds will trigger their systems.[xxi] Although the purpose of this is to also prevent bad acts by pharmacies, as with the SORs, the pharmacies may begin imposing their own discretionary limits—sometimes much lower than what might actually be considered suspicious—to avoid hitting the threshold and triggering an order cancellation or a report to regulatory authorities. This again creates barriers to access for patients.

Despite its clear therapeutic benefit, concerns about diversion have overridden the strong need for widespread access to buprenorphine.

The result is an unnecessary circumspection on a life-saving medication. In creating the CSRM, the settlement agreements categorize medications into “highly diverted controlled substances”—which does not include buprenorphine—and all other controlled substances. Some monitoring requirements in the agreements only apply to those medications categorized as “highly diverted controlled substances,” such as certain data collection about prescribers who regularly prescribe them. But otherwise, buprenorphine for the treatment of OUD is

included in suspicious order monitoring and order threshold setting that can lead to canceled orders. Despite its clear therapeutic benefit, concerns about diversion have overridden the strong need for widespread access to buprenorphine.

Pharmacies "Corresponding Responsibility"

Another barrier to access comes from the implementation of pharmacies' "corresponding responsibility." Per DEA regulations, pharmacists have a "corresponding responsibility" along with the prescriber to ensure controlled substances are properly prescribed and dispensed.[xxii] The prescription must be issued for a legitimate medical purpose. Consequently, a pharmacist may be prosecuted for knowingly and intentionally distributing controlled substances if they deliberately ignore a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose.[xxiii] However, yet again, the DEA does not provide clear guidance as to what a doubtful, questionable, or suspicious prescription looks like, what pharmacies are required to know before dispensing, or whether any exceptions for buprenorphine or other forms of MOUD exist. Instead, they must rely on "red flags" of questionable prescriptions that have been defined primarily through prior enforcement orders as well as more recently included in the national settlement agreements. According to one study, "Red flags can include patients paying in cash, patients driving long distances to obtain their prescriptions or doctors writing prescriptions for certain combinations of drugs."[xxiv] While settlement agreements define red flags more clearly, they are nonetheless still vague and include unusual formulation ordering, which includes ordering single-dose buprenorphine—a formulation used for pregnant patients and others who cannot tolerate naloxone—"out-of-area" patients receiving highly-diverted controlled substances, paying cash for controlled substances, and excessive ordering of controlled substances.

Because of a combination of stigma, fear of liability, and miseducation, too many pharmacies are treating each opioid prescription, including buprenorphine for OUD, as if the patient is abusing it.

Pharmacists occasionally create additional barriers when attempting to evaluate patients for red flags. In a recent secret shopper study in Tennessee, several pharmacies stated they would fill buprenorphine prescriptions only if certain conditions were met.[xxv] Pharmacists would only fill buprenorphine prescriptions from physicians known to the pharmacy or if they were local, or they would only fill the prescription if the individual provided proof of local address. In another study—also in Tennessee—communication between pharmacists and physicians prescribing buprenorphine was analyzed and several instances were identified wherein physicians felt the pharmacists were "overstepping" or even "practicing outside the scope of their expected roles and responsibilities—and subsequently encroaching on the roles of physicians…" in their questioning of the physician.[xxvi] Prescribing-physicians were asked whether the patient would be tapered off, what the reasons for the medication were, and whether the provider made sure the patient wasn't exhibiting drug-seeking behavior.[xxvii] Even after answering the questions, numerous pharmacists still limited the length of the prescription or straight out refused to dispense the medication. Because of a combination of stigma, fear of liability, and miseducation, too many pharmacies are treating each opioid prescription, including buprenorphine for OUD, as if the patient is abusing it. Regardless of the reason, dispensing shorter or smaller prescriptions than clinically needed makes it more difficult to continue taking buprenorphine as prescribed. When pharmacists question prescriptions, they do more than just determine the medical legitimacy of a prescription—they second-guess the physician's judgment altogether.[xxviii]

Pharmacists often have to navigate competing or nonexistent guidance regarding buprenorphine prescriptions. According to one medical provider LAC spoke to, pharmacists will often dispense a lower dose of buprenorphine to the patient than what was prescribed, potentially as a way to fulfill their corresponding responsibility. Unfortunately, when a pharmacist dispenses a lower dose than prescribed,

pharmacists open themselves up to claims of negligence in New York. New York courts have found that pharmacists can be held liable for negligence for failing to fill a prescription precisely as directed by the physician.[xxix] In one instance, the court found that a pharmacist who did fill the prescription as written was not negligent for failing to contact the patient's physician to inquire about the prescribed dose. Both of these outcomes are contrary to many pharmacists understanding of their corresponding responsibility which suggests they should be second-guessing physician's prescriptions for buprenorphine except without clarity on the criteria to do so. Physicians provide individualized treatment to each patient; it should never be the role of the pharmacist to determine what is a reasonable dose or prescription amount.[xxx] Rather, pharmacists should defer to the prescribing physician's training, experience, and knowledge of the patient's condition.[xxxi] Importantly, the court has refused to impose a duty to contact the prescribing physician if the dosage is inadequate for the patient, and portended that imposing a duty on pharmacists to police dosages would only lead pharmacists to second-guess every prescription a doctor orders to escape liability.[xxxii] This corresponding responsibility and a requirement for pharmacists to follow "red flags" put pharmacies in a tricky situation where they must navigate contradictory guidance and either go against a physician's prescription and risk claims of negligence or fill it as written and face enforcement action from the DEA or their wholesaler. In the end, this can be a reason to forgo stocking buprenorphine altogether.

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It is also arguable that pharmacies who limit or refuse to fill buprenorphine dosages are unlawfully stepping beyond their scope of practice. In New York, the scope of pharmacy is defined as "administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority, and collaborative drug therapy management...."[xxxiii] To practice beyond the scope would be considered ethical misconduct under New York regulations.[xxxiv] According to New York regulations, a pharmacist may refuse to provide medication but

must refer the patient elsewhere so the needs of the patient can be met in a timely manner. There is no evidence that pharmacists are referring buprenorphine prescriptions to other pharmacies to be filled and no providers we spoke to reported that this has happened. New York has yet to investigate or bring enforcement action against pharmacists that fail to fill buprenorphine prescriptions against their scope of practice. Consequently, fear of DEA or wholesaler actions is currently a bigger driver of pharmacist behavior than concerns about violating their professional requirements under New York law.

Barriers resulting from pharmacy "policing" of prescriptions are made worse by pharmacies' skepticism of telehealth. Providers in upstate New York told LAC that some pharmacies will not fill buprenorphine prescriptions that are written via telehealth despite the growing reliance on technology to bridge gaps in health care access in rural areas. Some large pharmacy chains have instituted similar policies nationwide.[xxxv] This remains true even though the DEA relaxed telehealth prescribing requirements during the COVID-19 public health emergency to permit prescriptions for buprenorphine without an in-person visit.

Buprenorphine Red Flags

The red flags that pharmacies rely on to indicate suspicious prescriptions or suspicious orders are in fact common behaviors and strategies employed to overcome pervasive stigma toward people with SUDs. For example, given the elimination of the x-waiver, any provider licensed to prescribe controlled substances can now prescribe buprenorphine.[xxxvi] However, so far there is little evidence that additional clinicians are beginning to prescribe buprenorphine and so access remains challenging.[xxxvii] In fact, many communities in New York still lack buprenorphine prescribers.[xxxviii] Once someone finds a prescriber, potentially far from where they live or via telehealth only, they still have the burden of locating a pharmacy willing to fill their prescription. One study found

that in New York City, it's more likely that there will be pharmacy deserts (neighborhoods with no pharmacies or pharmacies with limited hours) in Black and Latine neighborhoods.[xxxix] The problem of pharmacy deserts plagues New York's rural areas as well.[xl] Yet, traveling long distances (or out-of-state) to a pharmacy for buprenorphine is a red flag that can lead to enforcement action by the DEA.[3]

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Similarly, paying cash for prescriptions instead of using insurance is considered a red flag, but paying cash for buprenorphine treatment is a common and often required practice. Studies have consistently shown that buprenorphine prescribers regularly require upfront cash payment from patients with OUD, even for those insured by Medicaid or private insurance.[xli] In some cases, people might pay cash in an effort to limit disclosures of information about their SUD to their employers or family members with access to their insurance information.[4] An analysis of the prevalence and reasons for cash payment of buprenorphine should be informing the use of this red flag in prescription monitoring, but because there is no concrete way to differentiate buprenorphine from other opioids in red flags, this isn't done.

One court in West Virginia rejected the DEA's immediate suspension of a pharmacy's registration to dispense controlled substances for failure to show that the pharmacy was endangering the public's health and safety.[xlii] What had the pharmacy done? They had filled prescriptions for Subutex (a brand name of buprenorphine) for out-of-state patients. The DEA did not contend that the patient was diverting or abusing Subutex, just that the patient had traveled from out of state. The Court stated that the red flags that were relevant to opioids like out-of-area prescribers and patients and paying in cash should not apply to buprenorphine.[xliii] Unlike traditional opioids, buprenorphine

[3] The nationwide distributor settlement red flag is for "out-of-area" patients for highly diverted substances.

access decreases diversion and risk of overdose death.[xliv] Despite this, anti-diversion measures are applied the same to buprenorphine, with few exceptions that acknowledge the important role it plays in treatment.

Stigma and Discrimination

Stigma and discrimination toward people who use drugs and/or who have SUDs is longstanding and pervasive, including among health care professionals and pharmacists.[xlv] This stigma intersects with many other forms of stigma and discrimination including those related to race and ethnicity, class, and criminal legal system involvement.[xlvi] In fact, concerns about confidentiality, stigma and discrimination consistently rank among the barriers to treatment.[xlvii] For clients who are Black, the compounded stigma and racism along with the use of red flags lead to disproportionate barriers in access to care and higher rates of overdose than for white Americans.[xlviii] Addressing stigma is a complex undertaking that certainly requires education and culture shift, but it also warrants a better understanding of the perceived risk in working with patients with SUD and developing a risk tolerance.[xlix] Research has shown that in general, pharmacists' attitudes towards working with patients with SUD are positive, but education, training and understanding of the patient population are needed.[l]

Conclusion

For individuals who are ready and willing to use MOUD, the barriers to access are many. As retail pharmacies continue to grow as the primary source for MOUD prescriptions, the struggles to obtain buprenorphine will also grow unless changes are made. The varying systems that oversee buprenorphine dispensing need to acknowledge that its use is critical to stemming the overdose crisis, and the dangers of not doing so must be weighed against the more minimal risks of diversion. Education, training, and efforts to eradicate stigma and racism are necessary if buprenorphine access at retail pharmacies is to become a reality.

Recommendations for New York State to Reduce Barriers to Buprenorphine Access in Pharmacies

Although policy change at the federal level is necessary to fully alleviate barriers, New York State officials can do more to monitor how barriers are affecting buprenorphine access within the state, facilitate conversations among all parties to create common understanding, and distribute education and guidance to limit barriers.

- The New York State Board of Education, in collaboration with the Department of Health and OASAS, must conduct oversight of pharmacies to ensure pharmacists are not improperly limiting buprenorphine dosage amounts or daily doses against provider prescriptions and outside of their scope of practice. Additionally, state agencies or an independent third party can conduct secret shopper surveys of pharmacies in all areas of the state to determine whether they stock buprenorphine, accept new patients with buprenorphine prescriptions, do not improperly cap the number of buprenorphine patients they will accept monthly, and review data to determine whether refusals are occurring more frequently for Black and brown New Yorkers.
- The state should facilitate collaborative conversations between the DEA regional office, distributors operating in the state, and pharmacists to ensure adequate stocking of buprenorphine, an understanding about factors that may lead to DEA enforcement action, and an understanding among the DEA and distributors about common purchasing patterns among current buprenorphine patients. There should be a common understanding about the ability of pharmacies to request increases in thresholds.
- OASAS and DOH should issue guidance to pharmaceutical distributors operating in the state and pharmacies about how to evaluate common practices among buprenorphine patient and prescribing and purchasing patterns.

- The state should provide education to pharmacies about the importance of dispensing buprenorphine for treating OUD and the need to follow provider prescriptions, and address concerns about potential liability.
- New York should continue funding and expanding low-threshold buprenorphine providers, specifically in areas of the state with high overdose rates and high percentages of BIPOC individuals, and the State should reach out to pharmacies in these areas to ensure they are stocking buprenorphine and providing it appropriately to patients.

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[vii] *See* Molly Doernberg et al., *Demystifying buprenorphine misuse: Has fear of diversion gotten in the way of addressing the opioid crisis?* 40 Substance Abuse J. 148 (Apr. 22, 2019) available at https://www.tandfonline.com/doi/abs/10.1080/08897077.2019.1572052?journalCode=wsub20. *See* Michelle Lofwall and Sharon Walsh, *A Review of Buprenorphine Diversion and Misuse: The Current Evidence Base and Experiences from Around the World*, 8(5) J. Addiction Med. 315 (Sept.–Oct. 2014) ("[i]n the United States...the number of deaths involving sublingual buprenorphine products (including generics) that are specifically approved by the Food and Drug Administration for the indication of opioid

dependence treatment from 2002 to October of 2013 totaled 464."); Center for Disease Control, *Drug overdose deaths hit record numbers in 2014* , (Dec. 14, 2015) available at https://www.cdc.gov/media/releases/2015/p1218-drug-overdose.html ("[f]rom 2000 to 2014 nearly half a million Americans died from drug overdoses").

[viii] CDC Dispensing Rate Maps, last accessed January 2025, available at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/buprenorphine-dispensing-maps.html

[ix] American Society of Addiction Medication, *Reducing Barriers to Lifesaving Treatment: Report on the Findings from ASAM's Pharmacy Access Survey* (2022), https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/reports/asam-pharmacy-access-survey-report-final-11.7.22.pdf?sfvrsn=6da97680_3.

[x] U.S. Department of Justice & Drug Enforcement Agency, *Suspicious Orders (SORS) Q&A*, https://www.deadiversion.usdoj.gov/faq/sors_faq.htm; Bayla Ostrach, et al., *DEA disconnect leads to buprenorphine bottlenecks*, J. of Addiction Med. (2021).

[xi] *Id.*

[xii] *Suspicious Orders Report Systems*, DEA, available at: https://www.deadiversion.usdoj.gov/sors/sors.html.

[xiii] 21 U.S.C. 802(57).

[xiv] *Id.*

[xv] Aneri Pattani, *DEA takes aggressive stance toward pharmacies trying to dispense addiction medicine*, NPR (Nov. 8, 2021), https://www.npr.org/sections/health-shots/2021/11/08/1053579556/dea-suboxone-subutex-pharmacies-addiction.

[xvi] *See* Alyssa M. Peckham, et al., *Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic*, Am. J. Health Syst. Pharm. (Feb. 15, 2021) ("Buprenorphine ordering caps coupled with stigma, fear of unwarranted regulatory oversight, and gaps in education...lead[] to problematic gatekeeping. Examples of such gatekeeping may include a pharmacy restricting buprenorphine dispensing to existing patients, refusing to fill new buprenorphine prescriptions for large quantities, and in some instances refusing new patients all together.") (Internal quotes omitted).

[xvii] Krista Mahr & Ben Leonard, *Biden's next battle in his opioids fight: His own bureaucracy*, Politico (Mar. 8, 2023), https://www.politico.com/news/2023/03/08/bidens-opioids-bureaucracy-00085968.

[xviii] Distributor Settlement Agreement, March 25, 2022, available at: https://nationalopioidsettlement.com/distributor-janssen-settlements/.

[xix] Christina Jewett & Ellen Gabler, *Opioid Settlement Hinders Patient's Access to a Wide Array of Drugs*, The New York Times, https://www.nytimes.com/2023/03/13/us/drug-limits-adhd-depression.html.

[xx] *Id.*

[xxi] *Id. at xix*

[xxii] 21 C.F.R. § 1306.04(a).

[xxiii] *Id.*; 21 U.S.C. § 841(a)(1), § 842(a)(1).

[xxiv] Laura Stanley, Policymaking Through Adjudication: DEA's Red Flags, August 2022, available at: https://regulatorystudies.columbian.gwu.edu/policymaking-through-adjudication-dea-red-flags.

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[xxvi] Daniel J. Ventricell et al., *Communication Experiences of DATA-waivered Physicians with Community Pharmacists: A Qualitative Study*, Subst. Use Misuse (Oct. 8, 2019).

[xxvii] *Id.*

[xxviii] 21 C.F.R. § 1306.05(a) (a list of the factors pharmacists must consider in determining a valid prescription).

[xxix] Prison pharmacist was found negligent for failing to meet his duty of care by dispensing the medication as prescribed by the claimant's doctor. *France v. State of New York*, 132 Misc.2d 1031, 506 N.Y.S.2d 254 (N.Y. Ct. Cl. 1986).

[xxx] *Brumaghim v. Eckel*, 94 A.D.3d 1391, 1393, 944 N.Y.S.2d 329, 322 (3d Dept. 2012).

[xxxi] *Id.*

[xxxii] *Id.*

[xxxiii] 10 NYCRR Section 6801(1).
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