

HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

Legality of Expired Naloxone in Texas

Background

Drug overdose is a nationwide epidemic that claimed the lives of over 100,000 people in the United States in the past year alone.¹ Opioids, either alone or in combination with other drugs or alcohol, were responsible for approximately 75% of these deaths. Many of those 75,000 people would be alive today if they had been administered the opioid antagonist naloxone and, where needed, other emergency care.² In light of the ongoing crisis, all fifty states and the District of Columbia have modified their laws to increase access to naloxone, the standard first-line treatment for opioid overdose.³

While these laws have been successful in increasing access to this lifesaving medication, few explicitly address the legality of distributing and administering naloxone that is past its expiration date.⁴ As many governmental and non-governmental organizations increasingly have stocks of such expired naloxone, it is important to determine whether that naloxone may be distributed to individuals or organizations that are able to utilize it so that this potentially lifesaving medication does not go to waste. This is especially true considering the unprecedented shortage of injectable naloxone that has been plaguing the country since early 2021.⁵

This fact sheet briefly discusses the efficacy of expired naloxone and examines whether Texas law permits the distribution and administration of such naloxone. It concludes that, while regulations prohibit pharmacies and pharmacists from dispensing expired medications and require some facilities and organizations to quarantine or dispose of them, no laws prohibit the distribution of expired naloxone by harm reduction organizations. Further, the state's naloxone access law provides criminal, civil, and professional immunity to individuals who distribute and administer naloxone so long as they do so in good faith and with reasonable care, a standard that may often be met in the context of expired naloxone.

Efficacy of Expired Naloxone

Numerous studies have demonstrated that naloxone retains its potency long past its expiration date, even when kept in less-than-ideal conditions. In perhaps the most comprehensive study on the subject, expired naloxone samples – some which expired as early as the early 1990's - were obtained from fire departments, emergency medical services and law enforcement agencies.⁶ Upon testing, it was discovered that these samples, which had mostly been stored in ambulances, police cars, and similar environments, retained nearly all of their active ingredient even after nearly 30 years in storage. Only one sample, which was more than 25 years past its expiration date, had fallen to below 90% of its original strength.⁷

While that study was conducted with naloxone vials designed for injection with a needle and syringe, similar results have been obtained with Evzio, an auto-injector device, and Narcan, a nasal spray. Testing on several of these products that were at least one year past their listed expiration date revealed that they all retained greater than 100% of their labeled naloxone concentration. The researchers who conducted that study noted that the data suggests “extending the shelf life of these products” to “aid in avoiding the significant expense of replacing them every two years and also increase the availability” of naloxone in communities.⁸

Even extremes of heat and cold seem to do little to impact the efficacy of naloxone. In another study, ampoules of naloxone were cycled through repeated heating and cooling cycles for 28 days. These samples, which had been either repeatedly cooled to around -70 degrees Fahrenheit or heated to around 176 degrees Fahrenheit, “remained at comparable concentrations as ampoules stored at room temperature.”⁹

Summary of Relevant Texas Law

In recognition of the importance of naloxone in addressing opioid-related harm, Texas has taken several steps to increase access to the medication. Texas law permits prescribers to prescribe naloxone and other opioid antagonists, directly or by standing order, to a person at risk of experiencing an opioid-related drug overdose or to a family member, friend, or other person in a position to assist someone at risk of overdose.¹⁰

Pharmacists may dispense opioid antagonists under a valid prescription to the same categories of people.¹¹ Persons and organizations acting under a standing order may store and distribute opioid antagonists so long as they do not request or receive compensation for the storage or distribution.¹² Pharmacists can request a standing order for naloxone from the Texas Pharmacy Association after completing a one-hour training course.¹³

Any person is authorized to possess an opioid antagonist, regardless of whether they have a prescription for it.¹⁴ Any prescriber who prescribes (or does not prescribe) an opioid antagonist or a pharmacist who dispenses (or does not dispense) an opioid antagonist is immune from criminal and civil liability and professional sanctions for the act or omission, or for any eventual outcome from administering the opioid antagonist so long as they act in good faith and exercise reasonable care.¹⁵ Likewise, any person who, in good faith and with reasonable care, administers or does not administer naloxone to someone they believe is suffering an opioid-related overdose is not subject to criminal prosecution, professional sanction, or civil liability for the act or omission.¹⁶ Emergency services personnel are specifically authorized to administer naloxone where clinically indicated.¹⁷

There are no Texas laws specific to expired naloxone, but the state restricts the distribution of expired or out of date medications in several ways. Of most relevance, Class A, B, C, D, and F pharmacies are prohibited from dispensing any drug bearing an expiration date beyond that expiration date.¹⁸ The Board of Pharmacy considers the selling, purchasing, and trading of drugs (or offering to do so) beyond the manufacturer’s expiration date violations subject to administrative penalties¹⁹ and grounds for discipline on both a pharmacy’s license²⁰ and an individual pharmacist’s license.²¹ Assisted living facilities,²² foster homes,²³ nursing facilities,²⁴ day activity and health services facilities,²⁵ residential operations in general,²⁶ community residential facilities for those on parole,²⁷ and other community supervision facilities²⁸ all have rules governing when and how to quarantine or destroy expired medications. The state Prescription Drug Donation Program, which permits individuals to donate unused unit-dose prescription drugs to participating providers for redistribution, is not allowed to accept any expired medication.²⁹ However, medications can be dispensed from the program so long as the dispensing pharmacist “has determined they are of an acceptable integrity.”³⁰

Legal Analysis

Texas law imposes restrictions on the dispensing of expired medications, including naloxone, from pharmacies in Classes A-D and F. Further, several types of facilities are prohibited from distributing or using expired drugs. The state Prescription Drug Donation Program is not allowed to accept donated drugs that are past their

expiration date. However, as there is no prohibition on the distribution of expired medication by laypersons, the free distribution of naloxone outside of those circumstances by lay people is not generally prohibited.

Further, Texas's naloxone access law provides that "to the extent of a conflict between this subchapter and another law, this subchapter controls."³¹ The law defines "opioid antagonist" as "any drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors." As noted above, naloxone products fit that description long after the manufacturer's expiration date has passed. It is therefore likely that civil and criminal immunity provisions of the naloxone access law apply to expired naloxone to the same extent that they apply to non-expired naloxone, even for pharmacists and others prohibited by other laws from distributing expired medication.³²

Conclusion

Certain regulated facilities and programs in Texas are prohibited from accepting, storing, dispensing, and administering expired medications, including naloxone. However, the conflict of laws provision in the naloxone access law appears to extend liability protections for distributing expired naloxone to pharmacists and other distributors to the same extent that it provides liability protections for distributing non-expired naloxone.

The law explicitly allows lay people to engage in the non-sale distribution of naloxone via standing order and allows anyone to possess naloxone. Civil, criminal, and professional sanction immunities would likely apply to those who obtain expired naloxone from lay distributors to the same extent that they apply to non-expired naloxone. Further, these protections extend to anyone possessing naloxone, expired or otherwise, regardless of prescription status.³³ Finally, people who possess naloxone, expired or not, are permitted to administer it in the event of a suspected overdose.³⁴

SUPPORTERS



Robert Wood Johnson Foundation


Support for the Network provided by the Robert Wood Johnson Foundation. The views expressed in this document do not necessarily reflect the views of the Foundation.

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¹ National Center for Health Statistics. Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts. 2021; <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>. Accessed January 18, 2022.

² Opioid overdose is caused by excessive depression of the respiratory and central nervous systems. Naloxone, a κ - and δ , and μ -opioid receptor competitive antagonist, works by displacing opioids from these receptors, thereby reversing their depressant effect. See Chamberlain JM, Klein BL. A comprehensive review of naloxone for the emergency physician. *Am J Emerg Med.* 1994;12(6):650-660.

- ³ For a comprehensive list of state naloxone access laws, see Network for Public Health Law, Legal Interventions to Reduce Overdose Mortality: Naloxone Access Laws. <https://www.networkforphl.org/wp-content/uploads/2021/04/NAL-FINAL-4-12.pdf>.
- ⁴ Colorado is a notable exception. There, state law explicitly extends immunity protections to individuals who furnish or administer expired naloxone. See Colo. Rev. Stat. § 13-21-108.7(3)(a); Colo. Rev. Stat. § 18-1-712(2)(a). The Colorado Consortium for Prescription Drug Abuse Prevention has created an Expired Naloxone Program toolkit that walks agencies through the process of donating expired naloxone. See Colorado Consortium for Prescription Drug Abuse Prevention, Expired Naloxone Donation program, <https://corxconsortium.org/projects/expired-naloxone/>.
- ⁵ See Kornfeld M. Affordable naloxone is running out, creating a perfect storm for more overdose deaths, activists say. *Washington Post*. August 11, 2021.
- ⁶ Pruyn S, Frey J, Baker B, et al. Quality Assessment of Expired Naloxone Products from First-Responders' Supplies. *Prehosp Emerg Care*. 2019;23(5):647-653.
- ⁷ The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- ⁸ Mohammad Hossain, et al., Evaluation of Chemical Stability of Naloxone Products beyond Their Labeled Expiration Dates, American Association of Pharmaceutical Scientists presentation at PharmSci 360 Conference (November 6, 2018).
- ⁹ The study reported the temperatures in Celsius (-20 and 80 degrees Celsius). Lai D, Pham AT, Nekkar Rao PP, Beazely MA. The effects of heat and freeze-thaw cycling on naloxone stability. *Harm Reduct J*. 2019;16(1):17. Similar results were obtained from a previous study. See Johansen RB, Schafer NC, Brown PI. Effect of extreme temperatures on drugs for prehospital ACLS. *Am J Emerg Med*. 1993;11(5):450-452.
- ¹⁰ Tex. Health & Safety Code § 483.102(a).
- ¹¹ Tex. Health & Safety Code § 483.103(a).
- ¹² Tex. Health & Safety Code § 483.104.
- ¹³ Texas Pharmacy Association, Texas Pharmacist Naloxone Standing Order Application. Legality of drug checking equipment in the United States: A systematic legal analysis
- ¹⁴ Tex. Health & Safety Code § 483.105.
- ¹⁵ Tex. Health & Safety Code § 483.102(c); Tex. Health & Safety Code § 483.10(c).
- ¹⁶ Tex. Health & Safety Code § 483.106(a).
- ¹⁷ Tex. Health & Safety Code § 483.106(b).
- ¹⁸ Class A: "Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device." 22 Tex. Admin. Code § 291.33(f)(2)(A); Class B: "Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device." 22 Tex. Admin. Code § 291.54(f)(3); Class C: "Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug." 22 Tex. Admin. Code § 291.76(d)(5)(A)(v); Class D: "Any drug or device bearing an expiration date may not be provided, dispensed, or administered beyond the expiration date of the drug or device." 22 Tex. Admin. Code § 291.93(e)(2)(C); Class F: "Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug." 22 Tex. Admin. Code § 291.151(d)(5)(A)(v).
- ¹⁹ "The following violations by a pharmacist may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions...selling, purchasing, or trading, or offering to sell, purchase, or trade of misbranded prescription drugs or prescription drugs beyond the manufacturer's expiration date: \$1,000." 22 Tex. Admin. Code § 281.65(1)(T).
- ²⁰ Grounds for discipline for a pharmacy license: "...the pharmacy engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of...prescription drugs beyond the manufacturer's expiration date." 22 Tex. Admin. Code § 281.8(b)(4)(B).
- ²¹ Grounds for discipline for a pharmacist's license: "selling, purchasing, or trading, or offering to sell, purchase, or trade...prescription drugs beyond the manufacturer's expiration date." 22 Tex. Admin. Code § 281.7(a)(28)(B).
- ²² "Medications past expiration date or discontinued by physician order must be inventoried for disposition in accordance with state law." 26 Tex. Admin. Code § 553.589(8). "Medications no longer being used by the resident for the following reasons are to be kept separate from current medications and are to be disposed of by a registered pharmacist licensed in the State of Texas...medications that have passed the expiration date." 26 Tex. Admin. Code § 553.261(a)(6)(A)(iii).
- ²³ Foster homes must "remove medication on or before the expiration date and store it in a separate locked area until it is destroyed within 30 days." 26 Tex. Admin. Code § 749.1521(7).
- ²⁴ "Medications past an expiration date or discontinued by physician order must be inventoried for disposition in accordance with state law." 26 Tex. Admin. Code § 554.2108(d)(2)(F)(iii).

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- ²⁵ “A facility must keep medication that is no longer being used by an individual for the following reasons separate from current medications and ensure the medication is disposed of by a registered pharmacist licensed in the State of Texas...the expiration date of the medications has passed.” 26 Tex. Admin. Code § 559.62(f)(6)(A)(iii).
- ²⁶ “Discontinued medication, expired medication, and medication left at your operation must be inventoried and stored separately from current medications as directed by the administrator.” 26 Tex. Admin. Code § 748.2103(a); “When you have an accumulation of this medication, you must destroy the medication in accordance with state and federal law.” 26 Tex. Admin. Code § 748.2103(b); “remove medication on or before the expiration date and destroy it in a way that ensures that children do not have access to it.” 26 Tex. Admin. Code § 748.2101(7).
- ²⁷ “Medications that are discontinued, have expired dates or are no longer in use shall be stored in a separate locked container or drawer until destroyed.” 37 Tex. Admin. Code § 195.41(j)(6)(G).
- ²⁸ “Medications that are discontinued, have expired dates, or are no longer in use shall be stored in a separate locked container or drawer until destroyed.” 37 Tex. Admin. Code § 163.39(n)(7)(H).
- ²⁹ “The participating provider may accept a prescription drug only if all of the following requirements are met...the drug is not expired.” 25 Tex. Admin. Code § 95.4(b)(2)(D).
- ³⁰ “Donated drugs may be dispensed only if the drugs are prescribed by a health care professional for use by an eligible recipient and are dispensed by a licensed pharmacist who has determined that the drugs are of an acceptable integrity.” 25 Tex. Admin. Code § 95.6(a).
- ³¹ Tex. Health & Safety Code § 483.107.
- ³² Tex. Health & Safety Code Ann. § 483.107.
- ³³ Tex. Health & Safety Code § 483.105.
- ³⁴ Tex. Health & Safety Code § 483.106(a).