



HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

Legality of Expired Naloxone in Tennessee

Background

Drug overdose is a nationwide epidemic. In 2021 alone, it claimed the lives of nearly 108,000 people in the United States.¹ Opioids, either by themselves or in combination with other drugs or alcohol, were responsible for approximately 75% of these deaths. However, many of these approximately 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 successfully increased access to naloxone, few explicitly address the legality of distributing and administering the lifesaving medication past its expiration date, despite its proven efficacy and safety.⁴ As many governmental and non-governmental organizations increasingly have stocks of such expired naloxone, it is important to determine the legality of distributing it. This determination is especially pressing due to an unprecedented shortage of injectable naloxone, which has been plaguing the country since early 2021.⁵

This factsheet discusses whether Tennessee laws forbid the prescription, dispensing, distribution, possession, or administration of expired naloxone. It also discusses whether taking such actions might impact a medical professional's risk of criminal, civil, or administrative liability for prescribing or dispensing expired naloxone, or a layperson's criminal or civil immunity for distributing or administering it.

In summary, Tennessee law forbids the possession, sale, or distribution of "out-of-date" prescription medications, including naloxone. However, Tennessee's naloxone access law provides civil and administrative immunity for distribution and administration of naloxone, which would likely apply to expired naloxone to the same extent it applies to non-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 had expiration dates as early as the 1990s—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 high-variability



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 this study noted that the data suggest “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 Tennessee Law

Tennessee’s naloxone law, which was most recently amended effective July 1, 2022, increases access to naloxone in several ways.¹⁰ First, licensed healthcare practitioners acting in good faith and exercising reasonable care may prescribe naloxone or another opioid antagonist, directly or by standing order, to a person at risk of overdose or to a family member, friend, or other person in a position to assist a person experiencing an overdose.¹¹ Licensed healthcare practitioners can also prescribe opioid antagonists to an organization or other entity for the purpose of that organization or entity distributing the drug to someone at risk of overdose or to family members, friends, or other people in a position to assist in the event of an overdose.¹² Further, the Department of Health’s chief medical officer may implement a statewide collaborative pharmacy practice agreement allowing pharmacists who have completed a training program to dispense an opioid antagonist to individuals who do not otherwise have a prescription for it.¹³

Both individuals and entities acting under a standing order may receive and store naloxone or another opioid antagonist.¹⁴ They may also provide an opioid antagonist, directly or indirectly, to individuals at risk of overdose or their family, friends, or others in a position to assist in the event of an overdose, so long as the provision is done at no cost to the recipient.¹⁵ First responders acting under a standing order may also receive, store, and provide an opioid antagonist to a person at risk of overdose or a person in a position to assist in the event of an overdose.¹⁶ Individuals may administer opioid antagonists to others if they have a good faith belief that the other person is experiencing an overdose and they exercise reasonable care in administration.¹⁷

Civil immunity and immunity from disciplinary action is provided to licensed healthcare providers who administer, prescribe, dispense, or issue standing orders for opioid antagonists in the absence of gross negligence or willful misconduct.¹⁸ These immunities are also provided to pharmacists acting under the collaborative practice agreement and the chief medical officer who implemented the agreement, so long as they act without gross negligence or willful misconduct.¹⁹ Civil immunity is also provided to individuals or entities providing or administering opioid antagonists in the absence of gross negligence or willful misconduct.²⁰

Though not specific to naloxone, Tennessee law forbids the possession, sale, or distribution of “out of date, old [or] deteriorated” drugs.²¹ Violation of this law is a class C misdemeanor.²² Per regulations governing the practice of pharmacy, the “owner or pharmacist in charge of a pharmacy practice site shall immediately return



or destroy all outdated” prescription drugs.²³ Prohibitions regarding expired drugs also appear in regulations governing charitable clinic pharmacies,²⁴ juvenile detention centers,²⁵ child care centers,²⁶ assisted care living facilities,²⁷ adult care homes,²⁸ and the prescription drug donation program.²⁹ Pharmacy regulations impose civil penalties of up to one thousand dollars for violations of these prohibitions.³⁰

Legal Analysis

Tennessee law forbids the possession, sale, or distribution of outdated prescription medications, although, due to a quirk in how the law was written, this prohibition does not appear to apply to state and local health departments.³¹

Tennessee’s naloxone access law does not directly provide protection from criminal penalties such as those imposed for a violation of this law. For licensed healthcare practitioners or pharmacists who dispense naloxone under the statewide collaborative practice agreement, there appears to be no protection other than the aforementioned civil and administrative immunity. However, Tennessee law regarding “individual[s] or entit[ies] acting under a standing order” states that, “[n]otwithstanding any other law,” so long as they are providing naloxone at no cost to the recipient, those individuals and entities may receive, store, and provide naloxone. The language of the statute does not track exactly to the language of the statute prohibiting the possession and distribution of expired medications, and it is possible that the naloxone access law would preempt the restriction on providing out of date medications.

If this prohibition was found to apply, it would not void the civil and administrative immunity provided by the naloxone access laws. Because the efficacy and safety of expired naloxone is backed by solid evidence, and because of the urgency needed to stop the overdose death crisis through mass distribution of naloxone, distributing expired naloxone would likely not rise to the level of gross negligence or willful misconduct.³² Administration of expired naloxone by anyone using reasonable care and having a good faith belief that the recipient of treatment was experiencing an overdose would also be provided civil immunity to the same extent as provided for non-expired naloxone.³³

Conclusion

Tennessee law prohibits the possession and distribution of out-of-date prescription medication, although this prohibition likely does not apply to health departments. There is no immunity from criminal penalties for the possession or distribution of expired medication for prescribers or pharmacists acting under a protocol, but there may be for individuals and entities who operate under a standing order. However, civil and administrative immunity for the distribution of expired naloxone should apply to the same extent that it applies to non-expired naloxone.

SUPPORTERS

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- ¹ NAT'L CTR. FOR HEALTH STAT., PROVISIONAL DRUG OVERDOSE DEATH COUNTS (2022), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last visited May 12, 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. James Chamberlain et al., *A comprehensive review of naloxone for the emergency physician*, 12 AM J EMERG MED. 650, 660 (1994).
- 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 Meryl Kornfield, *Affordable naloxone is running out, creating a perfect storm for more overdose deaths, activists say*. WASH. POST. (August 11, 2021, 7:00 AM), <https://www.washingtonpost.com/health/2021/08/11/naloxone-demand/>.
- ⁶ Schuyler Pruyn et al., *Quality Assessment of Expired Naloxone Products from First-Responders' Supplies*, in 23 PREHOSP EMERG CARE 647, 653 (2019).
- ⁷ The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- ⁸ Mohammad F. Hossain et al., *Chemical stability of naloxone products beyond their labeled expiration dates*, 18 J OPIOID MANAG. 39, 46 (2022).
- ⁹ See Dulcie Lai et al., *The effects of heat and freeze-thaw cycling on naloxone stability*, 16 HARM REDUCT J. 17 (2019) (finding stability across temperatures reported between -20 and 80 degrees Celsius); Bart Johansen et al., *Effect of extreme temperatures on drugs for prehospital ACLS*, 11 AM J EMERG MED. 450, 452 (1993) (finding stable results).
- ¹⁰ While the naloxone access law uses the term "opioid antagonist," that term is defined as "naloxone hydrochloride which is approved by the federal food and drug administration for the treatment of a drug overdose." TENN. CODE ANN. § 63-1-152(a). We therefore use the term "naloxone" in the fact sheet when referring to that law.
- ¹¹ TENN. CODE ANN. § 63-1-152(b). The law defines "opioid antagonist" as "a formulation of naloxone hydrochloride or another similarly acting and equally safe drug approved by the United States food and drug administration for the treatment of a drug-related overdose." TENN. CODE ANN. § 63-1-152(a)(2).
- ¹² TENN. CODE ANN. § 63-1-152(b).
- ¹³ TENN. CODE ANN. § 63-1-157.
- ¹⁴ TENN. CODE ANN. § 63-1-152(c)(1).
- ¹⁵ TENN. CODE ANN. § 63-1-152(c)(2).
- ¹⁶ TENN. CODE ANN. § 63-1-152(i).
- ¹⁷ TENN. CODE ANN. § 63-1-152(d).
- ¹⁸ TENN. CODE ANN. § 63-1-152(f); (g).
- ¹⁹ TENN. CODE ANN. § 63-1-157(6); (7).
- ²⁰ TENN. CODE ANN. § 63-1-152(f)(2).
- ²¹ "Any drug or device that is misbranded, out of date, old, deteriorated, not kept under proper refrigeration as required, or that has been exposed to fire, heat, smoke, water, flood or windstorm damage is deemed to be adulterated, and the possession, sale or distribution of those drugs or devices is prohibited." TENN. CODE ANN. § 53-10-106(a)(1).
- ²² "Any person, firm or corporation possessing, selling, bartering or giving away any drug in violation of this part or violating any other provision of this part commits a Class C misdemeanor." TENN. CODE ANN. § 53-10-108.
- ²³ TENN. COMP. R. & REGS. 1140-03-11.
- ²⁴ TENN. COMP. R. & REGS. 1140-12-.06; TENN. COMP. R. & REGS. 1140-12-.05(1)(a)(6).
- ²⁵ TENN. COMP. R. & REGS. 0250-04-08-.06(7); (9).
- ²⁶ TENN. COMP. R. & REGS. 1240-04-01-.12(13)(a)(2).
- ²⁷ TENN. COMP. R. & REGS. 1200-08-25-.07.
- ²⁸ TENN. COMP. R. & REGS. 1200-08-36-.06(4)(f).
- ²⁹ TENN. COMP. R. & REGS. 1140-17-.06; TENN. CODE ANN. § 63-10-507.
- ³⁰ TENN. COMP. R. & REGS. 1140-08-.01.
- ³¹ The law that forbids the possession, sale, or distribution of out of date drugs does not appear to apply to "the department of health and local health departments, which shall be subject to § 63-10-405." TENN. CODE ANN. § 53-10-102(b). The referenced section, § 63-10-405, seems unrelated – but § 63-10-205, which does appear to relate to the health department's authority to distribute certain drugs, was previously numbered 63-10-405. Our hypothesis is that § 53-10-102 was not amended to reflect the numbering change, and that health departments are subject to the provisions of § 63-10-205 instead. Therefore, if health departments were to distribute expired naloxone, they may not be in violation of § 53-10-106. The exact details of how and what medications a health department is authorized to distribute are unclear, as the statute instructs the commissioner of health to promulgate regulations and those regulations do not currently exist. Until February 19, 2017, there was a regulation listing medications that were allowed to be distributed by health departments (naloxone did not appear on that list, although it did include "Emergency Agents"). TN ADC 1140-01-.15 That regulation has been repealed, and there does not appear to be any other current law regarding health department medication distribution.
- ³² Tennessee law does not equate the breaking of a law with willful misconduct per se. *Bohlen-Huse Coal & Ice Co. v. McDaniel*, 148 Tenn. 628 (1924) (operating a motor truck without license required by city ordinance is not willful misconduct). Worker's compensation cases have determined three elements for "willful misconduct": an intention to do an act, a purposeful violation of orders, and element of perverseness. *Rogers v. Kroger Co.*, 832 S.W.2d 538 (Tenn. 1992). Further, willful misconduct requires a "knowledge that serious injury to another will probably result, or with a wanton and reckless disregard of the possible results." 8 Tenn. Prac. Pattern Jury Instr. T.P.I.-Civil 3.30 (2021 ed.) Because of the strong evidence for the efficacy of expired naloxone and naloxone's lack of any effect other than stopping an opioid overdose, distributing or administering expired naloxone would



likely not be considered “perverse” or done with “knowledge that serious injury to another will probably result.” It is also unlikely a court would find that distributing or administering expired naloxone would be a “negligent act done with utter lack of concern for the safety of others, or one done with such a reckless disregard for the rights of others that a conscious indifference to consequences can be implied,” to meet the criteria for gross negligence.

Ruff v. Memphis Light Gas & Water Div., 619 S.W.2d 526 (Tenn. App. 1981).

³³ TENN. CODE ANN. § 63-1-152(g).