

HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

Legality of Expired Naloxone in North Carolina

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 70% of these deaths. Many of those 70,000 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. 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 North Carolina law permits the distribution and administration of such naloxone. We conclude that, while North Carolina law limits or prohibits the use and distribution of expired medications by pharmacies, emergency medical services, and some other organizations, it is silent on the distribution of expired naloxone by harm reduction organizations and the administration of expired naloxone by laypersons. Further, we find that the criminal and civil immunity provided in the state naloxone's access law likely applies to the provision and use of 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 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 North Carolina Law

North Carolina has taken several steps to increase access to naloxone. First, North Carolina law permits practitioners, if acting in good faith and with reasonable care, to prescribe naloxone directly or by standing order to a person at risk of overdose or a family member, friend, or other person in a position to help a person at risk of overdose.¹⁰ The state health director may issue a statewide standing order for naloxone to be dispensed to those individuals,¹¹ and has done so.¹²

A practitioner acting in good faith and with reasonable care may also prescribe naloxone, directly or by standing order, to “any governmental or non-governmental organization” for that organization to distribute naloxone to a person at risk of overdose or another person at risk of experiencing an opiate-related overdose.¹³ Pharmacists may dispense naloxone to these individuals and organizations.¹⁴ Any person who lawfully obtains naloxone may administer it, using reasonable care, to someone they believe in good faith is experiencing an overdose.¹⁵

An organization that is permitted to obtain naloxone under the law is permitted to distribute that naloxone via a standing order so long as basic instruction and information on how to administer the medication is included.¹⁶ The state Division of Public Health has created a Naloxone Distribution Toolkit that includes best practices for such distribution as well as examples of standing orders for both dispensing to an individual and distribution by an organization.¹⁷ A practitioner who prescribes naloxone, a pharmacist who dispenses it, a person who administers it, the state health director who issues a standing order for it, and any agency or organization that distributes naloxone as authorized by the law are all immune from civil or criminal liability.¹⁸ Finally, North Carolina’s syringe services program (SSP) law requires that SSPs offer access to naloxone kits or referrals to programs that provide access to naloxone.¹⁹

North Carolina law does contain several provisions explicitly related to expired and out of date medications. For example, regulations governing adult care homes,²⁰ family care homes,²¹ nursing homes,²² and residential childcare facilities²³ require the disposal or return of expired drugs. Licensed EMS providers are required to have protocols in place that “assure that supplies and medications are not used beyond the expiration date.”²⁴ The state’s drug depository program, which permits the donation of unused drugs, supplies, and medical devices to uninsured and underinsured patients in the state, requires participating pharmacies or free clinics to only accept and dispense drugs that have not reached their expiration date.²⁵

The Board of Pharmacy has also promulgated several regulations related to expired drugs. For example, the pharmacist-manager of a pharmacy is required to “separate from the dispensing stock all drug products more than six months out of date.”²⁶ Each pharmacy in North Carolina must register every year with the Board, and

registered pharmacies must “develop and implement policies and procedures to ensure that all out-dated ... drugs ... are destroyed or disposed of so as to render them unusable.”²⁷ The label of dispensed prescription drugs is required to include the expiration date of the drug.²⁸

Legal Analysis

North Carolina law imposes several restrictions on the acquisition, distribution, storage, and use of expired medications, including naloxone. However, these restrictions apply only to specific entities such as pharmacies, EMS providers, and other regulated facilities. There are no laws prohibiting the distribution of expired naloxone from harm reduction organizations and similar outlets.

While there are no relevant cases on the question, due to the demonstrated negative consequences associated with opioid overdose and the strong evidence that naloxone, even when expired, reverses the effects of opioids, it is likely that the civil and criminal immunity provisions of the naloxone access law would apply to expired naloxone to the same extent that they apply to non-expired naloxone.²⁹ Further, it is likely that a person who received naloxone via prescription or standing order would be protected from civil and criminal liability for administering expired naloxone.

Conclusion

Certain regulated facilities in North Carolina, including pharmacies, are prohibited from using or dispensing expired medications, including naloxone. However, no law prevents harm reduction organizations from distributing expired naloxone to the same extent they are permitted to distribute non-expired naloxone, and laypeople who possess expired naloxone can likely administer it in the event of an overdose without fear of legal sanctions.

SUPPORTERS




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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, available at <https://www.washingtonpost.com/health/2021/08/11/naloxone-demand/>.
- 6 Pruy 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 N.C. Gen. Stat. § 90-12.7(b)(1).
- 11 N.C. Gen. Stat. § 90-12.7(b)(2).
- 12 North Carolina State Health Director's Standing Order for Naloxone, March 12, 2018, <https://naloxonesaves.org/wp-content/uploads/sites/19608/2019/01/2018-Standing-Order.pdf>.
- 13 N.C. Gen. Stat. § 90-12.7(b)(3).
- 14 N.C. Gen. Stat. § 90-12.7(c).
- 15 N.C. Gen. Stat. § 90-12.7(d).
- 16 N.C. Gen. Stat. § 90-12.7(c1).
- 17 See North Carolina Division of Public Health, Injury and Violence Prevention Branch, *North Carolina Naloxone Distribution Toolkit*, <https://www.ncdhhs.gov/media/8091/download>.
- 18 N.C. Gen. Stat. § 90-12.7(e).
- 19 N.C. Gen. Stat. § 90-113.27(b)(5).
- 20 "Medications, excluding controlled medications that are expired...shall be stored separately from actively used medications until disposed of." 10A N.C. Admin. Code 13F.1007(b). "Controlled substances that are expired, discontinued or no longer required for a resident shall be returned to the pharmacy within 90 days of the expiration or discontinuation of the controlled substance or following the death of the resident." 10A N.C. Admin. Code 13F.1008(c)
- 21 "Medications, excluding controlled medications that are expired...shall be stored separately from actively used medications until disposed of." 10A N.C. Admin. Code 13G.1007(b). "Controlled substances that are expired, discontinued or no longer required for a resident shall be returned to the pharmacy within 90 days of the expiration or discontinuation of the controlled substance or following the death of the resident." 10A N.C. Admin. Code 13G.1008(c)
- 22 "Drugs that are outdated, discontinued or deteriorated shall be removed from the facility within five days." 10A N.C. Admin. Code 13D.2605(a)(4).
- 23 "Expired or discontinued prescription medications shall be disposed of in accordance with Federal Drug Administration guidelines..." 10A N.C. Admin. Code 70I.0604(s).
- 24 10A N.C. Admin. Code 13P.0204(b)(7)(C).



²⁵ N.C. Gen. Stat. § 90-85.44(c)(3).

²⁶ 21 N.C. Admin. Code 46.2502(k).

²⁷ 21 N.C. Admin. Code 46.3001(a).

²⁸ 10A N.C. Admin. Code 27G.009(b)(3)(E).

²⁹ N.C. Gen. Stat. § 90-12.7(e)(5).