

HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

Legality of Expired Naloxone in Kentucky

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. 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 Kentucky law permits the distribution and administration of such naloxone. We conclude that, while Kentucky law limits or prohibits the use and distribution of expired medications by pharmacies 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 Kentucky Law

Kentucky has taken several steps to increase access to naloxone. Both pharmacists who dispense naloxone as well as physicians who prescribe it, either directly or by standing order, are immune from professional disciplinary action for any outcomes related to those actions.¹⁰ Pharmacists may request and receive a certification to initiate the dispensing of naloxone.¹¹ A physician may issue a protocol to certified pharmacists that includes (1) criteria for eligible persons or agencies, (2) identification of which naloxone products are authorized to be dispensed, (3) education to the person whom the naloxone is dispensed, (4) procedures for documentation of naloxone dispensation, and (5) length of time the protocol is in effect.¹²

Notwithstanding any law to the contrary, a pharmacist utilizing a protocol may dispense naloxone to any person or agency as part of a harm reduction program, regardless of who the ultimate user is, so long as the person or agency provides training on the mechanism and circumstances for the administration of naloxone.¹³

A Kentucky statute provides that a person or agency may receive a prescription for naloxone, possess naloxone and any equipment needed for its administration, and administer naloxone to individuals experiencing an apparent opiate-related overdose.¹⁴ Any person acting in good faith who administers naloxone received under this law is immune from criminal and civil liability, unless personal injury results from gross negligence or willful or wanton misconduct of the person administering the drug.¹⁵

Kentucky law does contain several provisions related to expired medications. For example, regulations prohibit reissuing patients’ expired medications in pharmacy services in hospitals¹⁶, prohibit expired medication in ambulance equipment kits¹⁷, and require nurses at residential hospice facilities to discard expired medication.¹⁸ Further, a statute requires that home health agencies have procedures for handling drugs that are beyond their expiration date.¹⁹

Legal Analysis

Kentucky law imposes several restrictions on the storage and distribution of expired medications, including naloxone. However, these restrictions apply only to specific entities such as hospitals 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.²⁰

Conclusion

Certain regulated facilities in Kentucky are prohibited from storing 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 February 16, 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 Pruyne 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.

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- 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 KY. Rev. Stat. §217.186(1)
- ¹¹ 201 ky. code regs. 2:360. The application for pharmacist certification for naloxone dispensing can be found at <https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20NALOXONE%20DISPENSING.pdf>.
- ¹² 201 KY. Code Regs. 2:360. An example of a sample protocol can be found at <https://pharmacy.ky.gov/Documents/Sample%20Naloxone%20Protocol%20and%20Education%20Sheets.pdf>
- ¹³ KY. Rev. Stat. §217.186(7).
- ¹⁴ KY. Rev. Stat. § 217.186(3).
- ¹⁵ KY. Rev. Stat. § 217.186(4).
- ¹⁶ 201 KY. Code Regs. 2:074(4)(10)(b).
- ¹⁷ 202 KY. Code Regs. 7:550(2)(6).
- ¹⁸ 902 KY. Code Regs. 20:380(4)(2)(3)(e).
- ¹⁹ KY. Rev. Stat. § 315.00(5)(f).
- ²⁰ KY. Rev. Stat. §217.186(4).