



## HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

# Legality of Expired Naloxone in Kansas

## 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

While these laws have been successful in increasing access to this lifesaving medication<sup>4</sup>, few explicitly address the legality of distributing and administering naloxone that is past its expiration date.<sup>5</sup> 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.<sup>6</sup>

This fact sheet briefly discusses the efficacy of expired naloxone and examines whether Kansas law permits the distribution and administration of such naloxone. It concludes that, while regulations prohibit certain pharmacies and certain health professionals from dispensing expired medications and require some organizations to dispose of them, no laws prohibit the distribution of expired naloxone by other authorized parties. Further, the state's naloxone access law provides civil immunity to individuals who distribute and administer naloxone so long as they do so in good faith and without wanton misconduct, 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.<sup>7</sup> 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.<sup>8</sup>

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.<sup>9</sup>

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.”<sup>10</sup>

## **Summary of Relevant Kansas Law**

In recognition of the importance of naloxone in reducing opioid related-harm, Kansas has taken several steps to increase access to the medication. First, Kansas law permits pharmacists to dispense naloxone under a statewide protocol to individuals believed to be at risk of experiencing an opioid-related overdose as well as family members, friends, caregivers, or others in a position to assist a person they believe in good faith to be experiencing an overdose.<sup>11</sup> First responders, scientists, and technicians operating under a first responder agency<sup>12</sup> and school nurses are permitted to possess, store, and administer naloxone so long as they receive certain training.<sup>13</sup>

Additionally, any person who receives naloxone as permitted by the law and administers that naloxone in good faith and with reasonable care to a person experiencing a suspected opioid overdose will not be subject to civil liability or criminal prosecution “unless personal injury results from the gross negligence or willful or wanton misconduct in the administration of the emergency opioid antagonist.”<sup>14</sup> Finally, first responder agency employees and contractors are protected from “disciplinary or other adverse action by a professional licensure entity or any professional review” for good faith administration of naloxone,<sup>15</sup> as are health care providers and pharmacists who prescribe or dispense naloxone in good faith and with reasonable care pursuant to the Kansas naloxone law.<sup>16</sup>

The Kansas Board of Pharmacy has issued a statewide opioid antagonist protocol that establishes requirements for licensed pharmacists to dispense naloxone.<sup>17</sup> Among other requirements, pharmacists dispensing naloxone must provide in-person counseling that includes information about procedures for administering naloxone, signs of overdose, and other educational content.<sup>18</sup>

Neither Kansas law nor the Kansas Board of Pharmacy explicitly bars pharmacies from dispensing expired or out-of-date medications. However, pharmacists dispensing naloxone must provide training to naloxone recipients about “proper storage, disposal, and expiration date of the emergency opioid antagonist dispensed.”<sup>19</sup> Kansas law does limit the acquisition, distribution, storage, and use of expired medications in other instances; for example, licensed nurses and medication aides are prohibited from administering expired medications in adult day care facilities.<sup>20</sup> The state’s drug donation program bars participating recipients, which can include indigent health care clinics, federally qualified health centers, or community mental health centers,<sup>21</sup> from accepting expired medications<sup>22</sup> and requires them to destroy expired medication in their possession.<sup>23</sup> Similarly, group homes, including emergency shelters, maternity homes, and residential care facilities,<sup>24</sup> are required to discard unused and expired medications.<sup>25</sup>

## **Legal Analysis**

Kansas law imposes some restrictions on the acquisition, distribution, storage, and use of expired medications by certain regulated entities including adult day care facilities,<sup>26</sup> donating and accepting entities participating in

Kansas' drug donation program,<sup>27</sup> and group homes.<sup>28</sup> While pharmacists are required to counsel patients and bystanders about the expiration date and proper disposal of naloxone they dispense, there are no laws prohibiting the possession or administration of expired naloxone outside of certain regulated facilities.<sup>29</sup> Outside of these specific situations, it is likely that 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.<sup>30</sup> These immunities likely extend to individuals who receive naloxone with a provider prescription, as well as to those who access naloxone through the pharmacy protocol.<sup>31</sup>

## Conclusion

Certain regulated facilities in Kansas are prohibited from storing, dispensing, and administering expired medications, including naloxone. Outside of these facilities, however, and provided the naloxone is obtained pursuant to the naloxone access law, it is likely that civil and criminal immunity provisions of the that law would apply to expired naloxone to the same extent that they apply to non-expired naloxone.

Given the established consequences of opioid overdose and the strong evidence that naloxone, even when expired, reverses the effects of opioids, most individuals who possess naloxone pursuant to the Kansas naloxone access law can likely administer it in the event of a suspected overdose without being subject to civil or criminal penalties.<sup>32</sup>

## SUPPORTERS



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<sup>1</sup> 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 November 18, 2021.

<sup>2</sup> Opioid overdose is caused by excessive depression of the respiratory and central nervous systems. Naloxone, a  $\kappa$ - and  $\delta$ , and  $\mu$ -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.

<sup>3</sup> For a comprehensive list of state naloxone access laws, see Network for Public Health Law, Legal Interventions to Reduce Overdose Mortality: Naloxone Access Laws. 2021; <https://www.networkforphl.org/wp-content/uploads/2021/04/NAL-FINAL-4-12.pdf>. Accessed October 16, 2021.

<sup>4</sup> Smart R, Pardo B, Davis CS. Systematic review of the emerging literature on the effectiveness of naloxone access laws in the United States. *Addiction.* 2021;116(1):6-17.

<sup>5</sup> 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/>.
- <sup>6</sup> See Kornfeld M. Affordable naloxone is running out, creating a perfect storm for more overdose deaths, activists say. *Washington Post*. August 11, 2021.
- <sup>7</sup> 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.
- <sup>8</sup> The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- <sup>9</sup> 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).
- <sup>10</sup> 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.
- <sup>11</sup> These individuals are referred to as "patients" and "bystanders". Kan. Stat. Ann. § 65-16,127(c).
- <sup>12</sup> First Responder Agencies electing to provide naloxone to their employees or volunteers must meet certain requirements, including procuring a physician medical director for the opioid antagonist program and ensuring that those with access to naloxone have experienced certain levels of training. Kan. Stat. Ann. § 65-16,127(e).
- <sup>13</sup> Kan. Stat. Ann. § 65-16,127(e). See also Kan. Admin. Regs. 68-7-23(a).
- <sup>14</sup> Kan. Stat. Ann. § 65-16,127(g)(2).
- <sup>15</sup> Kan. Stat. Ann. § 65-16,127(g)(3).
- <sup>16</sup> Kan. Stat. Ann. § 65-16,127(g)(1).
- <sup>17</sup> Kansas State Board of Pharmacy, *Protocol for Dispensing Naloxone to Individuals at Risk of Experiencing, Witnessing, or Responding to an Opioid-Related Overdose* (2017), <https://pharmacy.ks.gov/docs/librariesprovider10/Naloxone/naloxone-statewide-protocol---official.pdf>.
- <sup>18</sup> Kan. Stat. Ann. § 65-16,127(d); Kansas State Board of Pharmacy, *Protocol for Dispensing Naloxone to Individuals at Risk of Experiencing, Witnessing, or Responding to an Opioid-Related Overdose 7* (2017), <https://pharmacy.ks.gov/docs/librariesprovider10/Naloxone/naloxone-statewide-protocol---official.pdf> ("A pharmacist shall provide in-person counseling, training, and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, 1. Risk factors of opioid overdose; 2. Strategies to prevent opioid overdose; 3. Signs of opioid overdose; 4. Steps in responding to an overdose; 5. Information on naloxone, including possible adverse reactions; 6. Procedures for administering naloxone; 7. Proper storage, disposal, and expiration of the naloxone product dispensed; and 8. Information on where to obtain a referral for substance use disorder treatment.").
- <sup>19</sup> Kan. Admin. Regs. 68-7-23(d)(2)(G).
- <sup>20</sup> Kan. Admin. Regs. 26-43-205(h)(4).
- <sup>21</sup> Kan. Stat. Ann. § 65-1669(o).
- <sup>22</sup> Kan. Stat. Ann. § 65-1671(c).
- <sup>23</sup> Kan. Admin. Regs. 68-18-3(c). Additionally, wholesale distributors are required to have a quarantine area for storage of prescription-only drugs and devices that are outdated. Kan. Admin. Regs. 68-14-7(3).
- <sup>24</sup> Kan. Admin. Regs. 28-4-268(i).
- <sup>25</sup> Kan. Admin. Regs. 28-4-275.
- <sup>26</sup> Kan. Admin. Regs. 26-43-205(h)(4).
- <sup>27</sup> Kan. Stat. Ann. § 65-1671(c).
- <sup>28</sup> Kan. Admin. Regs. 28-4-275.
- <sup>29</sup> Kan. Admin. Regs. 68-7-23(d)(2)(G).
- <sup>30</sup> See Kan. Stat. Ann. § 65-16,127(g).
- <sup>31</sup> See Kan. Stat. Ann. § 65-16,127(g).
- <sup>32</sup> See Kan. Stat. Ann. § 65-16,127(g)(2).