



## HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

# Legality of Dispensing Expired Naloxone in Washington

## Background

Drug overdose is a nationwide epidemic that claimed the lives of over 100,000 people in the United States in the most recent twelve-month period.<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, few explicitly address the legality of distributing and administering naloxone that is past its expiration date.<sup>4</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 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.<sup>5</sup>

This fact sheet briefly discusses the efficacy of expired naloxone and examines whether Washington law permits the distribution and administration of such naloxone. We conclude that, while state regulations do prohibit some activities related to expired drugs in some contexts, none apply to the distribution of expired naloxone by harm reduction organizations and similar entities. We further find that the state's naloxone access law provides absolute criminal, civil, and professional immunity to all individuals who prescribe, dispense, distribute, and administer naloxone as permitted by state law, so long as they act in good faith and with reasonable care.

## 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>6</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>7</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>8</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 -20 degrees Celsius or heated to 80 degrees Celsius, “remained at comparable concentrations as ampoules stored at room temperature.”<sup>9</sup>

## **Summary of Relevant Washington Law**

Washington legislators have taken several steps to increase access to naloxone. Washington law permits practitioners to prescribe, dispense, distribute, and deliver an opioid overdose reversal medication directly to a person at risk of overdose as well as by prescription, collaborative drug therapy agreement, standing order, or protocol to a first responder, family member, or anyone in a position to assist such a person.<sup>10</sup> The practitioner must inform the recipient that the person who experienced the overdose should be transported to a hospital or a first responder should be summoned after naloxone is administered.<sup>11</sup>

The state Secretary of Health is permitted to issue a standing order prescribing opioid overdose reversal medications such as naloxone to any person at risk of experiencing an opioid overdose or any person or entity in a position to assist such a person.<sup>12</sup> A statewide standing order that permits pharmacists to dispense naloxone and any “eligible entity” to possess, store, deliver, distribute, or administer it has been issued by a physician designated by the Secretary of Health.<sup>13</sup> “Eligible entities” are defined as a person at risk of experiencing an opioid-related overdose and any person or entity in a position to assist such a person.<sup>14</sup> Pharmacists must provide written instructions on the proper use of naloxone, including seeking immediate medical attention, when they dispense the medication.<sup>15</sup>

The naloxone access law permits any person to possess, store, distribute, or administer naloxone legally obtained via a traditional prescription or other process permitted by the law (such as via a standing order).<sup>16</sup> The law also provides extremely broad immunity to individuals and organizations that increase access to naloxone: Practitioners who prescribe, dispense, distribute, or deliver, pharmacists who dispense, and any person who possesses, stores, distributes, or administers naloxone are immune from civil and criminal liability and administrative action so long as they act in good faith and with reasonable care.<sup>17</sup> Otherwise applicable drug labeling requirements, including those related to the listing of expiration dates, do not apply to opioid overdose reversal medication distributed under the law.<sup>18</sup>

Washington law does contain some provisions related to expired and out of date medications. For example, childbirth centers are required to destroy expired drugs,<sup>19</sup> and expired drug samples offered by manufacturers must be disposed of or returned to the manufacturer.<sup>20</sup> Further, a state law that permits pharmacies to participate in a program that permits practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, and patients to donate prescription drugs and supplies for redistribution specifies that drugs donated to the program cannot be accepted by the pharmacy unless there is at least six months from the date of acceptance to the expiration date of the drug.<sup>21</sup> However, Washington law includes no general prohibitions on expired medication distribution generally or expired naloxone specifically.

## **Legal analysis**

While Washington law imposes some restrictions on expired medications, these restrictions apply only to specific entities and types of drugs. There are no regulations prohibiting the distribution of expired naloxone from harm reduction organizations and similar outlets. In particular, drugs donated to a harm reduction

organization would not generally be subject to the restrictions on acceptance of soon-to-be expired or expired drugs for donation. The law that containing that restriction only applies to donations to pharmacies<sup>22</sup>, and does not limit the distribution of expired drugs so long as they are accepted by the pharmacy six months prior to expiration.

Even where the distribution of expired naloxone is prohibited by statute or regulation, such prohibitions have no practical effect. As noted above, the state naloxone access law provides extremely broad protections explicitly designed to encourage the prescription, distribution, and administration of naloxone. Under general rules of statutory construction, a law specific to a particular situation, like the provision of naloxone, prevails over a law of general application, like one that applies to all medications.<sup>23</sup> Even if this was not the case, Washington's naloxone access law is clear: so long as a person obtained naloxone as permitted by the law, they are immune from civil, criminal, and professional liability for distributing it so long as they act in good faith and with reasonable care.<sup>24</sup> The law also exempts naloxone from otherwise applicable labeling requirements, including those regarding the listing of expiration dates.<sup>25</sup> The naloxone access law does not differentiate between expired and non-expired naloxone, and therefore applies to both.

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 administering expired naloxone would be deemed to be in good faith and a reasonable action to take in the case of suspected opioid overdose.

## Conclusion

Washington law is explicitly designed to increase access to naloxone for the reversal of opioid overdose. Once a person obtains naloxone legally, they are provided with immunity for possession, distribution, and administration of that naloxone. This immunity applies regardless of the expiration status of the naloxone. We therefore conclude that it is likely that expired naloxone may generally be possessed, distributed, and administered without penalty so long as the individuals performing those actions act in good faith and with reasonable care.

## 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.

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- <sup>2</sup> 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.
- <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> 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>5</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>6</sup> Pruyt 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>7</sup> The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- <sup>8</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>9</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>10</sup> Wash. Rev. Code Ann. § 69.41.095(1)(a). "Opioid overdose reversal medication" is defined as "...any drug used to reverse an opioid overdose that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors. It does not include intentional administration via the intravenous route." Wash. Rev. Code Ann. § 69.41.095(7)(b).
- <sup>11</sup> Wash. Rev. Code Ann. § 69.41.095(1)(b).
- <sup>12</sup> Wash. Rev. Code Ann. § 69.41.095(5).
- <sup>13</sup> Washington State Department of Health, *Standing Order to Dispense Naloxone*, signed February 1, 2021, <https://www.doh.wa.gov/Portals/1/Documents/Pubs/150-127-StatewideStandingOrderToDispenseNaloxone.pdf>.
- <sup>14</sup> *Id.*
- <sup>15</sup> Wash. Rev. Code Ann. § 69.41.095(2).
- <sup>16</sup> Wash. Rev. Code Ann. § 69.41.095(3).
- <sup>17</sup> Wash. Rev. Code Ann. § 69.41.095(4).
- <sup>18</sup> Wash. Rev. Code Ann. § 69.41.095(6).
- <sup>19</sup> Wash. Admin. Code 246-329-150(5)(c).
- <sup>20</sup> Wash. Rev. Code Ann. 69.45.040(5).
- <sup>21</sup> Wash. Rev. Code Ann. § 69.70.050(1)(b).
- <sup>22</sup> Wash. Rev. Code Ann. § 60.70.020(1).
- <sup>23</sup> "Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976), citing *Morton v. Mancari*, 417 U.S. 535, 550-551 (1974).
- <sup>24</sup> Wash. Rev. Code Ann. § 69.41.095(3).
- <sup>25</sup> Wash. Rev. Code Ann. § 69.41.095(6).