



## HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

# Legality of Expired Naloxone in Oregon

## 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 Oregon law permits the distribution and administration of such naloxone. It concludes that, while regulations prohibit 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 harm reduction organizations. 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>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 Oregon Law

In recognition of the continuing epidemic of opioid-related harm and the importance of naloxone in addressing it, the Oregon legislature has modified state law to increase access to the medication in several ways. Perhaps the most important provision reads:

“Notwithstanding any other provision of law, a pharmacy, a health care professional or a pharmacist with prescription and dispensing privileges or any other person designated by the State Board of Pharmacy by rule may distribute and administer naloxone and distribute the necessary medical supplies to administer the naloxone. The pharmacy, health care professional or pharmacist may also distribute multiple kits to social service agencies... or to other persons who work with individuals who have experienced an opiate overdose. The social services agencies or other persons may redistribute the kits to individuals likely to experience an opiate overdose or to family members of the individuals.”<sup>10</sup>

The law further provides that any person who acts in good faith and without wanton misconduct is immune from civil liability for any act or omission committed during the distribution of naloxone and related supplies, as well as the administration of naloxone as authorized by the law.<sup>11</sup> A separate law permits pharmacists to prescribe naloxone as well as supplies necessary for its administration to both individuals and entities.<sup>12</sup> Finally, any person who lawfully obtains naloxone “may possess, distribute or administer it for the purpose of reversing opiate overdose.”<sup>13</sup>

Oregon Board of Pharmacy (Board) regulations that govern the operation of pharmacies require that all prescriptions be labeled with certain information, including the expiration date “after which the patient should not use the drug or medicine,” and prohibit the dispensing of drugs beyond that date.<sup>14</sup> The same restriction applies to prescription medications dispensed by non-pharmacist practitioners.<sup>15</sup> Violations of these requirements can result in a civil penalty not to exceed \$1,000 per violation for an individual or \$10,000 for a drug outlet.<sup>16</sup>

Other regulations govern expired medications in specific locations. For example, regulations governing outdoor youth programs require that all expired medications be returned to the base of operations and disposed of so they are not available to children at the program,<sup>17</sup> while those pertaining to host homes for children with intellectual or developmental disabilities require that expired medications be disposed of within 10 calendar days of their expiration.<sup>18</sup> Regulations governing residential care agencies likewise forbid expired medications from being maintained in the facility;<sup>19</sup> nearly identical language applies to therapeutic boarding schools,<sup>20</sup> academic boarding schools,<sup>21</sup> and foster care agencies.<sup>22</sup>

## Legal Analysis

Oregon law does not contain a general prohibition on the distribution or use of expired medications. However, specific regulations governing various entities do prohibit their distribution or use in specific circumstances. Most notably, a Board rule forbidding the dispensing of expired drugs applies to ambulatory and residential drug outlets (such as retail pharmacies).<sup>23</sup> While the Board is permitted to waive “any requirements” of the rule

forbidding the dispensing of expired medications from certain pharmacies “[u]pon written request and for good cause,”<sup>24</sup> it does not appear to have done so in the case of naloxone.

However, there is an argument that this prohibition does not apply in the case of naloxone. The naloxone law permits “a health care professional or a pharmacist with prescription and dispensing privileges or any other person designated by the State Board of Pharmacy by rule” to distribute naloxone and other necessary medical supplies and to administer naloxone in an emergency “[n]otwithstanding any other provision of law.” It is plausible for this language to be read to permit the distribution of naloxone from pharmacies covered by the prohibition on dispensing expired medications (i.e. “notwithstanding” that law). This could be clarified by the Board explicitly waiving that prohibition in the case of naloxone, as permitted by the rule.

Regardless, the prohibition does not apply to the distribution of naloxone by social services agencies and other individuals permitted to distribute naloxone under the law, unless they fall into one of the groups to which specific prohibitions on the handling of expired medications apply.<sup>25</sup> Further, any person who acts in good faith and without wanton misconduct is immune from civil liability for the distribution and administration of naloxone as permitted by the law. “Wanton” misconduct is a high standard, which generally requires that a person intentionally act “in disregard of a risk known to him or so obvious that he must be taken to have been aware of it, and so great as to make it highly probable that harm would follow.”<sup>26</sup>

While there are no relevant cases exactly on point, 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 such naloxone would be deemed to be in good faith and without wanton misconduct in the case of suspected opioid overdose.

## Conclusion

Oregon has modified state law to increase access to naloxone. While it is possible that Pharmacy Board regulations prohibit the dispensing of expired naloxone from retail pharmacies, those restrictions do not appear to apply to expired naloxone distributed from harm reduction organizations and similar entities. It is also likely that individuals who administer and distribute expired naloxone would be provided with civil immunity for those actions.

## SUPPORTERS



Robert Wood Johnson Foundation

**Support for the Network provided by the Robert Wood Johnson Foundation. The views expressed in this document do not necessarily reflect the views of the Foundation.**

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**January 2022**

- <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> 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> Pruyun 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> Or. Rev. Stat. § 689.681(2).
- <sup>11</sup> Or. Rev. Stat. § 689.681(3).
- <sup>12</sup> Or. Rev. Stat. § 689.682. See also Or. Admin. R. § 855-019-0460 (rules regulating pharmacist naloxone prescription). The Oregon Health Authority maintains a list of pharmacies at which naloxone is available without prior prescription at <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/pharmacies-distributing-naloxone.pdf>.
- <sup>13</sup> Or. Admin. R. 855-019-0460(7).
- <sup>14</sup> Or. Admin. R. § 855-041-1130(1)(j). The date must be “the same as that on the original container unless, in the pharmacist’s professional judgment, a shorter expiration date is warranted.” *Id.*
- <sup>15</sup> Or. Admin. R. § 855-043-0005(8). Somewhat interestingly, it does not apply to charitable pharmacies. See Or. Admin. R. § 855-044-0060(1)(i).
- <sup>16</sup> Or. Rev. Stat. § 689.832(1). The person to whom a notice of violation is addressed has ten days to apply to the Pharmacy Board for a hearing. *Id.* at (4).
- <sup>17</sup> Or. Admin. R. § 413-215-0961(15)(c).
- <sup>18</sup> The same requirement applies to discontinued, expired, and recalled medications, as well as the prescription medications of children who have died. Or. Admin. R. § 411-348-0120(3)(i).
- <sup>19</sup> Or. Admin. R. § 413-215-0551(7)(a).
- <sup>20</sup> Or. Admin. R. § 413-215-0651(7)(a).
- <sup>21</sup> Or. Admin. R. § 413-215-0251(4)(a).
- <sup>22</sup> Or. Admin. R. § 413-215-0381(5)(a). This is not intended to be a comprehensive list; it is likely that similar language appears in regulations governing other facilities as well.
- <sup>23</sup> See generally Or. Admin. R. § 855-041-1001 *et seq.* (regulations governing ambulatory and residential drug outlets).
- <sup>24</sup> Or. Admin. R. § 855-041-1130(1)(l). The rule pertaining to other practitioners does not contain a provision permitting it to be waived. See Or. Admin. R. § 855-043-0005.
- <sup>25</sup> “Social services agency” includes, but is not limited to, homeless shelters and crisis centers. Or. Rev. Stat. § 689.684(1).
- <sup>26</sup> See *State v. Gutierrez-Medina*, 442 P.2d 183 at 189 (2019) (quoting *Falls v. Mortensen*, 295 P.2d 182 (1956)).