



## HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

# Legality of Dispensing and Administering Expired Naloxone in Colorado

## Background

Drug overdose is a continuing epidemic that claimed the lives of over 67,000 Americans in 2018.<sup>1</sup> Opioids, both prescription painkillers and illegal drugs such as heroin and illicitly manufactured fentanyl, were responsible for approximately 70% of these deaths.<sup>2</sup> Many of the people killed by opioids would be alive today if they had quickly received the medication naloxone and, where needed, other emergency care.<sup>3</sup> 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>4</sup>

While these laws take a number of approaches to increase access to this life-saving medication, none explicitly address the legality of dispensing naloxone that is past its expiration date. As many governmental and non-governmental organizations will increasingly have stocks of such expired naloxone, which has a listed shelf life of only one to two years, it is important to determine whether distribution or use of that naloxone is permissible under existing law. This factsheet discusses whether Colorado laws forbid the prescription, dispensing, distribution, possession, or administration of expired naloxone and whether such actions impact the risk of civil liability for medical professionals who prescribe or dispense naloxone or laypeople who distribute or administer it.

In summary, Colorado does not prohibit the prescribing, possession, or use of expired naloxone obtained via a valid individual prescription or standing order. Colorado does prohibit pharmacists from dispensing expired medications, including naloxone; however, the naloxone access law explicitly provides that dispensing naloxone as permitted by that law does not constitute unprofessional conduct.



## **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 such study, 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>5</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>6</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 tested at 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>7</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>8</sup>

## **Summary of Relevant Colorado Law**

Colorado's naloxone access law provides a number of protections for those who act to increase access to opioid antagonists. First, prescribers may prescribe or dispense, and pharmacists may dispense, an opioid antagonist to a person at risk of overdose, a third party who may be in a position to reverse an overdose, and persons working or volunteering with a harm reduction organization<sup>9</sup>, a law enforcement agency or first responder, a school district, school, or employee or agent of a school, and non-private entities who make defibrillators or AEDs (collectively referred to here as “Community Organizations”).<sup>10</sup> Community Organizations may also possess opioid antagonists, administer them in the event of an opioid overdose, and furnish them to both persons at risk of overdose and third parties.<sup>11</sup>

While prescribers, pharmacists, and Community Organizations are “strongly encouraged” to educate persons receiving naloxone on its use, including risk factors for overdose, recognizing an overdose, calling emergency medical services, and rescue breathing, no such training is required.<sup>12</sup> Community Organizations are also encouraged, but not required, to train their employees and volunteers.<sup>13</sup>

Colorado law provides civil and criminal immunity to prescribers, pharmacists, and Community Organizations acting in good faith for the furnishing, administering, or subsequent use of an opioid antagonist.<sup>14</sup> This civil and criminal immunity is absolute so long as the relevant individual acted under the authority provided under the statute. Additionally, it is not unprofessional conduct for prescribers and pharmacists to prescribe or dispense naloxone in good faith as permitted by the law.<sup>15</sup>

“Opioid antagonist” is defined in Colorado law as “naloxone hydrochloride or any similarly acting drug that is not a controlled substance and that is approved by the federal food and drug administration for the treatment of a drug overdose.”<sup>16</sup> Though not specific to expired naloxone, Colorado law does establish some limitations on pharmacists regarding the dispensing of expired drugs. Specifically, a provision of Colorado's State Board of Pharmacy regulations states that “[n]o drug or device shall be dispensed which will be outdated prior to utilization by the consumer, based on the practitioner's directions for use.”<sup>17</sup> It is not clear what specific penalty might be imposed for a violation of this regulation, but the State Board of Pharmacy has the ability to deny,

suspend, or revoke licenses, certifications, or registrations for unprofessional conduct, which includes violation of “[t]he lawful rules of the board”<sup>18</sup>

## Legal Analysis

By regulation, pharmacists in Colorado are generally not permitted to dispense expired medications, or medications that will expire before the patient uses them according to the prescriber’s instructions. However, the naloxone access law is clear that any pharmacist who dispenses naloxone in good faith as permitted by that law does not “engage...in unprofessional conduct”<sup>19</sup> for purposes of the law that forbids violation of “the lawful rules of the board.”<sup>20</sup> Dispensing of naloxone as permitted by the law is therefore not unprofessional conduct and not sanctionable by the Board. Nothing in the law limits this protection to naloxone that is not expired.

The regulation prohibiting dispensing of expired drugs applies only to persons licensed by the State Board of Pharmacy and does not apply to Community Organizations. Therefore, furnishing of expired naloxone by Community Organizations carries the same liability risk as furnishing non-expired naloxone. As noted above, such organizations are provided with complete criminal and civil immunity for such furnishing so long as they act in good faith and in compliance with the naloxone access law.

## Conclusion

In summary, no Colorado law prohibits the possession of expired naloxone acquired via a valid prescription or standing order. Pharmacists are generally prohibited from dispensing expired medications or medications that will expire prior to the patient’s use, based on the prescriber’s orders. However, this regulation is superseded by the naloxone access law, which states that pharmacists who dispense naloxone per its terms are not engaging in unprofessional conduct.

Additionally, there appears to be no prohibition on Community Organizations furnishing naloxone that is past its expiration date or will likely be past its expiration date at the time it is used. The Colorado law that provides criminal and civil immunity to prescribers for the prescription or dispensing of naloxone, to pharmacists for the dispensing of naloxone, and to Community Organizations for the possession or furnishing of naloxone, applies regardless of the medication’s expiration status, so long as the person providing the naloxone acts in good faith.

## SUPPORTERS



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## References

- <sup>1</sup> N. Wilson, et al., *Drug and Opioid-Involved Overdose Deaths - United States, 2017-2018*, 69 MMWR MORB MORTAL WKLY REP (2020).
- <sup>2</sup> *Id.*
- <sup>3</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 J. M. Chamberlain & B. L. Klein, *A comprehensive review of naloxone for the emergency physician*, 12 AM J EMERG MED (1994).
- <sup>4</sup> For a comprehensive list of state naloxone access laws, see NETWORK FOR PUBLIC HEALTH LAW, LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND GOOD SAMARITAN LAWS (2018), available at <http://www.networkforphl.org/wp-content/uploads/2020/01/legal-interventions-to-reduce-overdose.pdf>.
- <sup>5</sup> Schuyler Pruyn et al., *Quality Assessment of Expired Naloxone Products from First-Responders' Supplies*, 23 Prehospital Emergency Care 5, 647-653 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/30596290>
- <sup>6</sup> The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- <sup>7</sup> Charles Babcock, 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), <https://www.eventscribe.net/2018/PharmSci360/fsPopup.asp?efp=UUFSQIZZVFM1OTQ2&PosterID=165883&rnd=0.926461&mode=posterinfo>
- <sup>8</sup> Dulcie Lai et al., *The effects of heat and freeze-thaw cycling on naloxone stability*, Harm Reduction Journal 16, Article number 17 (2019), <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0288-4>. Similar results were obtained from a previous study, see R. Bart Johansen et al., *Effect of extreme temperatures on drugs for prehospital ACLS*. Am J Emerg Med. 1993;11:450–2.
- <sup>9</sup> “Harm Reduction Organization” is defined as “an organization that provides services, including medical care, counseling, homeless services, or drug treatment, to individuals at risk of experiencing an opiate-related drug overdose event or to the friends and family members of an at-risk individual.” Colo. Rev. Stat. Ann. § 12-30-110(7)(b).
- <sup>10</sup> This prescribing and dispensing may occur either directly or in accordance with standing orders and protocols. Colo. Rev. Stat. Ann. § 12-30-110(1)(a).
- <sup>11</sup> Colo. Rev. Stat. Ann. § 12-30-110(1)(b).
- <sup>12</sup> Colo. Rev. Stat. Ann. § 12-30-110(2)(a).
- <sup>13</sup> Colo. Rev. Stat. Ann. § 12-30-110(2)(b).
- <sup>14</sup> Colo. Rev. Stat. Ann. § 12-30-110(4); 13-21-108.7(3). For Community Organizations, this includes immunity even if the opioid antagonist was stolen.
- <sup>15</sup> Colo. Rev. Stat. Ann. § 12-30-110(3).
- <sup>16</sup> Colo. Rev. Stat. Ann. § 12-30-110(7)(5),
- <sup>17</sup> 3 Code Colo. Regs. § 719-1:3.00.40.
- <sup>18</sup> Colo. Rev. Stat. Ann. § 12-280-108(1)(c).
- <sup>19</sup> Colo. Rev. Stat. Ann. § 12-30-110(3).
- <sup>20</sup> Colo. Rev. Stat. Ann. § 12-280-126(c)(II).