



## HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

# Legality of Dispensing and Administering Expired Naloxone in Illinois

## Background

Drug overdose is a continuing epidemic that claimed the lives of nearly 72,000 Americans in 2017.<sup>1</sup> Opioids, both prescription painkillers and illegal drugs such as heroin and illicitly manufactured fentanyl, were responsible for nearly 48,000 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> To attempt to increase access to naloxone, 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 steps 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 and is quite expensive to purchase, it is important to determine whether distribution or use of that naloxone is permissible under existing law.<sup>5</sup> This factsheet discusses whether Illinois laws forbids the prescription, dispensing, distribution, possession, or administration of expired naloxone and whether such actions negatively impact risk of civil liability.

In sum, Illinois law does not prohibit the prescription, dispensing, distribution, or administration of expired medications, nor is there a general prohibition on the possession of expired naloxone obtained via a valid prescription or a standing order. Numerous studies have shown that naloxone remains effective long past its expiration date, perhaps even decades, even when not stored at optimal conditions. Because Illinois law provides professional and criminal immunity for the prescribing, dispensing, and administration of naloxone in the absence of “willful and wanton misconduct,” those activities are likely covered for expired naloxone to the same extent they apply 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 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>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, similar results have been obtained with the products Evzio and Narcan. 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>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 Illinois Law

Illinois’ naloxone access law provides a number of protections for those who act to increase access to the medication. First, healthcare professionals acting in good faith are provided immunity from any violation of professional licensing statutes as well as criminal immunity for the prescribing or dispensing of an “opioid antagonist” to patients at risk of opioid overdose and persons who are not at risk of overdose but may be in a position to help another individual during an overdose.<sup>10</sup> In addition, pharmacists are protected from civil liability for administering or dispensing an opioid antagonist under a protocol or standing order so long as they do so “without fee or compensation in any way” and without willful and wanton misconduct.<sup>11</sup>

Unlike many states, Illinois has not enacted immunity protections for the distribution of naloxone by laypeople.<sup>12</sup> While Illinois law authorizes the Department of Public Health to “establish or authorize programs for prescribing, dispensing, or distributing opioid antagonists for the treatment of drug overdose,” no immunity is provided for laypeople who distribute naloxone in these programs.<sup>13</sup><sup>14</sup> The law does, however, provide immunity from civil liability, in addition to immunity from violations of professional licensing statutes and criminal prosecution, to laypeople who have received certain information and who administer an opioid antagonist to another person without fee in a good faith belief that the other person is experiencing an overdose.<sup>15</sup>

“Opioid antagonist” is defined in Illinois law as any drug that “binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone...”<sup>16</sup> Willful and wanton misconduct is not defined in the relevant statute, but the Illinois Supreme Court and Illinois legislature have defined reckless, willful, and wanton conduct in other contexts as conduct “committed with ‘utter indifference’ to or ‘conscious disregard’ for the safety of others, sometimes called a ‘reckless disregard’ for the safety of others.”<sup>17</sup> Further, relevant (but not controlling) case law defines it as an “injury that must have been intentional” or an act that was “committed under circumstances exhibiting a reckless disregard for the safety of others, such as a failure, after knowledge of impending danger, to exercise ordinary care to prevent it or a failure to discover the danger through recklessness or carelessness when it could have been discovered by the exercise of ordinary care.”<sup>18</sup>



## Legal Analysis

We found no laws that explicitly address the question of dispensing or administering expired naloxone to the general public.<sup>19</sup> Illinois' Drug Overdose Prevention Program guidelines require that Opioid Education and Naloxone Distribution Program Directors "routinely assess the expiration date of naloxone to ensure that naloxone with earlier expiration dates are distributed prior to naloxone with later expiration dates," but do not prohibit the distribution or dispensing of expired naloxone.<sup>20</sup> A search of case law in Illinois and related federal cases regarding the administration or distributing of expired drugs found no relevant decisions on the subject. There is therefore no prohibition on such activities.

The evidence also suggests that all otherwise applicable legal protections apply to expired naloxone to the same extent that they apply to non-expired naloxone. Naloxone that is past its expiration date is highly likely to be an "opioid antagonist" under Illinois law, as studies have repeatedly found that naloxone that is past its expiration date maintains much of its previous concentration and therefore would likely still bind to opioid receptors and block or inhibit the effects of opioids acting on those receptors, the requirements for a substance to qualify as an "opioid antagonist".<sup>21</sup> Further, the research evidence that naloxone remains an effective opioid antagonist long past its stated expiration date suggests that it would not be willful and wanton misconduct to supply or administer expired naloxone, as it does not appear to be reckless or careless to use naloxone after the product's expiration date.

## Conclusion

In summary, it is not illegal under Illinois law to prescribe, dispense, distribute or administer naloxone that is past its expiration date, nor is there any controlling federal law on the subject. There is also no law prohibiting the possession of expired naloxone acquired via a valid prescription or standing order. Further, an Illinois law that provides criminal and civil immunity to certain individuals for the prescription, dispensing, and administration of naloxone likely applies regardless of the medication's expiration status. There appears to be no legal reason to destroy expired naloxone or prevent it from being dispensed, distributed or administered in Illinois.

## SUPPORTERS



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<sup>1</sup> Holly Hedegaard, M.D., et al., Drug Overdose Deaths in the United States, 1999-2017, *available at* <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf> (last visited Jan. 12, 2019).

<sup>2</sup> Id.

<sup>3</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 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/\\_asset/qz5pvn/network-naloxone-10-4.pdf](http://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf).

<sup>5</sup> Davis CS, Carr D. *Naloxone Affordability Measures Needed*. Journal of the American Pharmacists Association 2017; 57(6): 740-741.

<sup>6</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>7</sup> The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.

<sup>8</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=UUFSQLZZVFM1OTQ2&PosterID=165883&rnd=0.926461&mode=posterinfo>

<sup>9</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>10</sup> 20 Ill. Comp. Stat. Ann. 301/5-23 (d)(1).

<sup>11</sup> 745 Ill. Comp. Stat. Ann. 49/36.

<sup>12</sup> Under the Illinois Pharmacy Practice Act, “distribute” means to “deliver, other than by dispensing, a prescription medication.” Ill. Admin. Code tit. 68, § 1330.10.

<sup>13</sup> 20 Ill. Comp. Stat. Ann. 301/5-23 (b)(1).

<sup>14</sup> “‘Dispense’ means to interpret, verify computer entry of, select the prescribed product for, prepare and/or deliver a prescription medication to an ultimate consumer or to a person authorized to receive the prescription medication by or pursuant to the lawful order of a practitioner, including the compounding, packaging and/or labeling necessary for delivery and any recommending, advising and counseling concerning the contents, therapeutic values, uses and any precautions, warnings and/or advice concerning consumption. Dispense does not mean the physical delivery to a patient or a patient’s representative in a home or institution by a designee of a pharmacist or by common carrier or the physical delivery of a drug or medical device to a patient or patient’s representative by a pharmacist’s designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open.” Ill. Admin. Code tit. 68, § 1330.10.

<sup>15</sup> The immunity from civil and criminal penalty applies only if the layperson acts without “willful or wanton misconduct.” 20 Ill. Comp. Stat. Ann. 301/5-23 (d)(2).

<sup>16</sup> 20 Ill. Comp. Stat. Ann. 301/5-23(d)(4).

<sup>17</sup> Grant Dixon III, *You Don’t Know It When You See It: Pleading Requirements for Willful and Wanton Conduct*, 27 DCBA Brief 24, 25 (2015), citing *Pfister v. Shusta*, 167 Ill.2d 417, 421 (1995); 745 Ill.Comp.Stat. § 10/1-210; *American National Bank & Trust Co. v. City of Chicago*, 192 Ill.2d 274, 285 (2000).

<sup>18</sup> *Henslee v. Provena Hosps.*, 369 F. Supp. 2d 970, 977-978 (N.D. Ill. 2005), defining the concept of “willful and wanton misconduct” within the EMS Act, 210 Ill. Comp. Stat. Ann. 50/3.150.

<sup>19</sup> There are some regulations that govern the disposal of expired medications in specific public health institutions, but they are applicable only in certain limited situations, none of which are applicable to the outpatient setting. These institutions include Community Living Facilities, Long-term Care Facilities, Veteran’s Homes, Facilities for the Developmentally Disabled, Skilled Nursing Care Facilities, Sheltered Care Facilities, Hospice Care Facilities, Assisted Living Facilities, and Supportive Residences. Ill. Admin. Code tit. 77, § 370.840; Ill. Admin. Code tit. 77, § 350.3760; Ill. Admin. Code tit. 77, § 340.1665; Ill. Adm. Code tit. 77, § 350.1450; Ill. Admin. Code tit. 77, § 300.1650; Ill. Admin. Code tit. 77, § 390.1450; Ill. Admin. Code tit. 77, § 280.4030; Ill. Admin. Code tit. 77, § 330.1510; Ill. Admin. Code tit. 77, § 295.5000; Ill. Admin. Code tit. 77, § 385.2150. Additionally, the Department of Corrections has a rule on inmates’ possession of expired medication; Rule 308 Ill. Admin. Code tit. 20, § 504 App. A.

<sup>20</sup> [https://www.dhs.state.il.us/OneNetLibrary/27896/documents/2018\\_DOPP\\_Guidelines\\_for\\_Implementation.pdf](https://www.dhs.state.il.us/OneNetLibrary/27896/documents/2018_DOPP_Guidelines_for_Implementation.pdf)

<sup>21</sup> See 20 Ill. Comp. Stat. Ann. 301/5-23(d)(4).