

HARM REDUCTION & OVERDOSE PREVENTION Fact Sheet

Legality of Dispensing Expired Naloxone in California

Background


Drug overdose is a nationwide epidemic that claimed the lives of over 93,000 people in the United States in 2020.¹ 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.² 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.³

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.⁴ 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 2021.⁵

This fact sheet briefly discusses the efficacy of expired naloxone and examines whether California law permits the distribution and administration of such naloxone. We conclude that, while regulations prohibit many health-related organizations from distributing expired medications, no laws prohibit 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 that distribute naloxone pursuant to a prescription, regardless of its expiration date. Finally, we find that the same immunity attaches to individuals who administer expired naloxone so long as they act in good faith and with reasonable care, which is likely the case when naloxone is administered to an individual believed to be experiencing an opioid-related overdose.

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.⁶ 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.⁷

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.⁸

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.”⁹

Summary of Relevant California Law

California legislators have taken several steps to increase access to naloxone. First, California law permits licensed health care providers otherwise authorized to prescribe an opioid antagonist such as naloxone, if acting with reasonable care, to prescribe, dispense, or distribute the opioid antagonist to a person at risk of overdose as well as anyone in a position to assist such a person.¹⁰ These individuals are permitted to prescribe naloxone via standing orders in addition to traditional, patient-specific prescriptions.¹¹

In addition to dispensing under a traditional or standing order prescription, pharmacists are also permitted to furnish naloxone to patients “in accordance with standardized procedures or protocols” so long as they complete a one hour training.¹² The protocol requires the naloxone to be labeled with an expiration date but is silent as to the furnishing of expired naloxone.¹³ Pharmacies, wholesalers, and manufacturers are also permitted to furnish opioid antagonists to law enforcement agencies so long as the naloxone is for the use of trained agency employees.¹⁴

California law provides extremely broad immunity to individuals and organizations that increase access to naloxone. First, a licensed health care provider who acts with reasonable care “shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution” for issuing either a patient-specific prescription for naloxone or a naloxone standing order.¹⁵ Second, any person who possesses or distributes an opioid antagonist pursuant to a prescription or standing order “shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution.”¹⁶ Finally, a person not otherwise authorized to administer an opioid antagonist is provided the same protection so long as they act with reasonable care, in good faith, and are not compensated for administering the naloxone.¹⁷

Finally, California law contains numerous provisions related to expired and out of date medications. For example, drug manufacturers are required to destroy or bring into compliance drugs that are “outdated” or “deteriorated.”¹⁸ Similarly, county-established programs that distribute surplus medications are forbidden from dispensing expired medications,¹⁹ and law enforcement agencies are required to destroy expired opioid antagonists that they received from a pharmacy, wholesaler, or manufacturer.²⁰ Regulations governing primary care clinics, correctional treatment centers, acute care hospitals and other similar locations forbid those facilities from stocking medications that are past their expiration dates and from keeping deteriorated drugs available for use.²¹ While it is not strictly prohibited by law, the California Board of Pharmacy has taken the position that retail pharmacies cannot dispense expired prescription medications.²²

Legal Analysis

California law imposes several restrictions on the distribution, dispensing, and use of expired medications, including naloxone. However, all of these restrictions apply only to specific entities such as manufacturers,

hospitals, pharmacies, and certain law enforcement agencies. There are no regulations prohibiting the distribution of expired naloxone from harm reduction organizations and similar outlets.

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.²³ Even if this was not the case, California’s naloxone access law is clear: so long as a person possess or distributes naloxone pursuant to a prescription, including a standing order, they are immune from civil, criminal, and professional liability for that possession or distribution “[n]otwithstanding any other law.”²⁴ The naloxone access law does not differentiate between expired and non-expired naloxone, and therefore applies to both.²⁵

Similarly, “[n]otwithstanding any other law, a person not otherwise licensed to administer an opioid antagonist” is immune from criminal, civil, and professional liability so long as they act in good faith and with reasonable care.²⁶ 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 such naloxone would be deemed to be a reasonable action to take in the case of suspected opioid overdose.

Conclusion

California law is explicitly designed to increase access to naloxone for the reversal of opioid overdose. So long as a person acts pursuant to a prescription order or standing order, they are provided with immunity for possession, distribution, and administration of 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 and distributed without penalty and administered without legal penalty so long as the administrator acts with reasonable care.

SUPPORTERS



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- ¹ 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 October 15, 2021.
- ² 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.
- ³ 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.
- ⁴ 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/>.
- ⁵ See Kornfeld M. Affordable naloxone is running out, creating a perfect storm for more overdose deaths, activists say. *Washington Post.* August 11, 2021.
- ⁶ Prunyn 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.
- ⁷ The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
- ⁸ 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).
- ⁹ 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.
- ¹⁰ Cal. Civ. Code § 1714.22(b).
- ¹¹ Cal. Civ. Code § 1714.22(c). Individuals who obtain an opioid antagonist under a standing order are required to receive training from an opioid prevention and treatment training program. Cal. Civ. Code § 1714.22(d).
- ¹² Cal. Bus. & Prof. Code § 4052.01.
- ¹³ See Cal. Code Regs. tit. 16, § 1746.3.
- ¹⁴ Cal. Bus. & Prof. Code § 4119.9.
- ¹⁵ Cal. Civ. Code § 1714.22(e).
- ¹⁶ Cal. Civ. Code § 1714.22(f).
- ¹⁷ Cal. Civ. Code § 1714.22(f). If the person received naloxone under a standing order, the immunity applies only if they received training from an opioid prevention and treatment training program. *Id.*
- ¹⁸ See Cal. Code Regs. tit. 17, § 10377.4; Cal. Code Regs. tit. 17, § 10377.6(b)(3). Neither term is defined.
- ¹⁹ Cal. Health & Safety Code § 150204(h)(i)(1).
- ²⁰ Cal. Bus. & Prof. Code § 4119.9(b).
- ²¹ See e.g. Cal. Code Regs. tit. 22, § 70263(q)(9) (acute care hospitals); Cal. Code Regs. tit. 22, § 75037(b) (primary care clinics); Cal. Code Regs. tit. 22, § 79651(k) (correctional treatment centers).
- ²² See California Board of Pharmacy, Expiration dates – Compliance Guidelines (July 2001), available at https://www.pharmacy.ca.gov/publications/01_jul_script.pdf.
- ²³ “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).
- ²⁴ Cal. Civ. Code § 1714.22(d).
- ²⁵ “Distribution” is not defined but appears to apply broadly to both the large-scale provision of naloxone and the provision of naloxone to a specific person at risk of overdose or a person in a position to assist such an individual. For instance, the law permits a licensed health care provider authorized by law to prescribe an opioid antagonist to “prescribe and subsequently dispense or distribute” an opioid antagonist to a person at risk of overdose or another person. Cal. Civ. Code § 1714.22(b). It also permits those individuals to issue “standing orders for the distribution of an opioid antagonist” to those individuals. Cal. Civ. Code § 1714.22(c).
- ²⁶ Cal. Civ. Code § 1714.22(f). If the person received naloxone under a standing order, the immunity applies only if they received training from an opioid prevention and treatment training program. *Id.*