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HARM REDUCTION AND OVERDOSE PREVENTION

Fact Sheet

Legality of Dispensing and Administering Expired Naloxone in the District of Columbia

Background

Drug overdose is a continuing epidemic that claimed the lives of over 67,000 Americans in 2018.[1] Opioids, both prescription painkillers and illegal drugs such as heroin and illicitly manufactured fentanyl, were responsible for approximately 70% of these deaths.[2] 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.[3] 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.[4]

While these laws take several 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 District of Columbia 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.

We conclude that District of Columbia law does not prohibit the possession or use of expired naloxone obtained via a valid individual prescription or standing order. The District of Columbia also does not expressly prohibit the prescribing, dispensing, or distributing of expired naloxone by either pharmacists or recognized community organizations. Though District of Columbia law prohibits pharmacies from dispensing expired “deteriorating drugs”, this prohibition arguably does not extend to naloxone given naloxone’s long-term potency and effectiveness, and does not prevent non-pharmacy community organizations from distributing 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.[5] 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.[6]

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.[7] 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." [8]

Summary of Relevant District of Columbia Law

The District of Columbia's naloxone access law guarantees a series of protections for those who act to increase access to opioid antagonists. First, health professionals acting in good faith may prescribe, dispense, or distribute an opioid antagonist to a person at risk of overdose, a third party who may be in a position to reverse an overdose, and to persons working or volunteering with a community organization.[9] Community organization employees and volunteers may dispense or distribute an opioid antagonist to both persons at risk of overdose and third parties.[10]

Health professionals are not required to complete any additional training to engage in those activities. However, community organization employees and volunteers must complete Department of Health training prior to distributing opioid antagonists. This training includes how to screen a patient for being at risk of an opioid-related overdose, how opioid antagonists operate to stop overdose, when and how to properly administer an opioid antagonist, when administration is contraindicated, and precautions and potential adverse reactions related to opioid antagonist administration.[11] Opioid antagonist recipients must also receive training that includes the importance of seeking medical care after opioid-related overdose and information on how to access "substance abuse treatment services".[12]

District of Columbia law provides civil and criminal immunity to both health professionals and community organization employees and volunteers for any injuries that might arise from the use of an opioid antagonist, regardless of whether the opioid antagonist is administered by or to the person to whom it was prescribed or distributed.[13] All crimes are covered by this immunity umbrella, and civil liability protections apply unless the actions of the health professional or community organization constitute recklessness, gross negligence, or intentional misconduct.[14]

"Opioid antagonist" is defined in District of Columbia law as "a drug, such as Naloxone, that binds to the opioid receptors with higher affinity than agonists but does not activate the receptors, effectively blocking the receptor, preventing the human body from making use of opiates and endorphins."[15] "Recklessness" is understood in District of Columbia case law as "misconduct requiring a conscious choice of a course of action,

either with knowledge of the serious danger to others involved in it or with knowledge of facts that would disclose this danger to any reasonable person."[16] Additional case law recognizes gross negligence as "such an extreme deviation from the ordinary standard of care as to support a finding of wanton, willful and reckless disregard or conscious indifference for the rights and safety of others . . . This standard implies that the actor has engaged in conduct so extreme as to imply some sort of bad faith."[17]

Though not specific to expired naloxone, District of Columbia law does establish some limitations on pharmacies regarding the dispensing of expired drugs. Specifically, a provision of DC's pharmacy licensing law prohibits selling or dispensing any "drugs that may deteriorate" after the expiration date as labeled on the original container.[18] Furthermore, pharmacies are required to comply with the General Operating Standards per District of Columbia's municipal regulations, which prohibit pharmacies from storing expired drugs with currently dated products.[19] Violation of these prohibitions is a Class 1 Infraction, a civil penalty punishable by a $2,000.00 fine for the first offense.[20]

Legal Analysis

For pharmacies, the legality of dispensing expired naloxone hinges on whether naloxone is considered a "drug that may deteriorate." The plain language of the law seems to broadly encompass drugs that deteriorate to any extent, not just those that deteriorate in a way that renders them ineffective or dangerous. Interpreted this way, District of Columbia law would prohibit pharmacies from dispensing expired naloxone, and distribution of expired naloxone by pharmacies may be considered intentional misconduct if the violation of the law was done with knowledge that doing so is prohibited. However, the term "deteriorating drug" is not defined in the statute, nor does it appear to be a term of art in the pharmaceutical or medical community. This potential ambiguity coupled with the studies indicating naloxone's long-term potency and effectiveness could support arguments that naloxone should not be categorized as a "drug that may deteriorate," but this argument might not be persuasive were it to be tested.

This restriction, however, applies only to pharmacies. Community organizations and other non-pharmacy entities that are authorized to distribute naloxone are therefore not prohibited from dispensing expired naloxone. Because of the evidence that expired naloxone is likely as efficacious as non-expired naloxone, it is likely that expired naloxone carries similar liability risk for community organizations as non-expired naloxone.

Conclusion

The legality of distributing expired naloxone in the District depends on the entity doing the dispensing. It is likely that pharmacies are prohibited from dispensing or distributing expired naloxone if naloxone or other opioid antagonists are deemed to be "drugs that may deteriorate." However, it can be argued that naloxone should not be considered a deteriorating drug because of its long potency and effectiveness. If naloxone is not considered a deteriorating drug, there appears to be no legal prohibition on its distribution by pharmacies after expiration, provided it is stored separately from non-expired drugs.

It appears permissible under District of Columbia law to for community organizations to dispense or distribute naloxone that is past its expiration date. The District of Columbia law that provides criminal and civil immunity to health professionals and community organizations for the prescription, dispensing, and distribution of naloxone likely applies regardless of the medication's expiration status in the absence of reckless, grossly negligent, or intentional misconduct, and the distribution of expired naloxone, without more, likely does not meet that standard.

SUPPORTERS

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[1] N. Wilson, et al., *Drug and Opioid-Involved Overdose Deaths - United States, 2017-2018*, 69 MMWR MORB MORTAL WKLY REP (2020).
[2] *Id*.
[3] 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).
[4] 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.
[5] Schuyler Pruyn et al., *Quality Assessment of Expired Naloxone Products from First-Responders' Supplies*, 23 Prehosptial Emergency Care 5, 647-653 (2018), https://www.ncbi.nlm.nih.gov/pubmed/30596290
[6] The potency of that sample, which expired in May 1992, was approximately 89% of that when it was new.
[7] 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
[8] 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.
[9] D.C. Code § 7-404(b); Per D.C. Code § 7-404(d)(1)(A), a pharmacist may distribute and dispense, but not prescribe, an opioid antagonist pursuant to a written protocol or standing order.
[10] D.C. Code § 7-404(c).
[11] D.C. Code § 7-404(d)(3)(A-E).
[12] D.C. Code § 7-404(e)(1-6).
[13] D.C. Code § 7-404(f).
[14] D.C. Code § 7-404(f)(1).
[15] D.C. Code § 7-403(i)(2).
[16] *Mero v. City Segway Tours of Wash. DC, LLC*, 962 F. Supp. 2d 92, 100 (D.D.C. 2013), quoting *In re Romanksy*, 825 A.2d 311, 316 (D.C. 2003), quoting 57 Am. Jur. 2d Negligence § 302 (1989).
[17] *Mero v. City Segway Tours of Wash. DC, LLC*, 962 F. Supp. 2d 92, 100 (D.D.C. 2013), quoting *District of Columbia v. Walker*, 689 A.2d 40, 44-45 (D.C. 1997).
[18] DC Code § 47-2885.13(a).
[19] 22-B DCMR § 1901.6; *Morgan Pharmacy*, No. 2018-DOH-D101390 (November 2, 2018) (Final Order).
[20] 16 DCMR § 3618(c); 16 DCMR § 3201.