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HARM REDUCTION & OVERDOSE PREVENTION

Fact Sheet

Legality of Dispensing and Administering Expired Naloxone in Georgia

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 a number of approaches to increase access to this life-saving medication, none explicitly address potential legal issues associated with 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 Georgia 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, Georgia law likely does not prohibit the prescribing, possession, or use of expired naloxone obtained via a valid individual prescription or standing order. Georgia does, however, prohibit retail pharmacies and pharmacists from dispensing expired medications, including 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.[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 Georgia Law

Georgia's naloxone access law provides a number of protections for those who act to increase access to opioid antagonists. First, physicians may prescribe opioid antagonists "for use in accordance with a protocol…" and pharmacists may dispense an opioid antagonist pursuant to such a protocol to a person at risk of overdose as well as to a pain management clinic, first responder, harm reduction organization, family member, friend, or other person in a position to assist someone at risk of overdose (collectively "Third Parties").[9] A person acting in good faith and with reasonable care may administer that opioid antagonist in accordance with the protocol. Additionally, the state health officer is specifically authorized to prescribe opioid antagonists via standing order.[10] "Opioid antagonist" is defined in Georgia law as "any drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors and that is approved by the federal Food and Drug Administration for the treatment of an opioid related overdose."[11]

Georgia law provides civil, criminal, and professional licensing immunity to physicians and pharmacists acting in good faith and in compliance with the standard of care applicable to them for prescribing and dispensing an opioid antagonist.[12] The state health officer is also provided civil, criminal, and professional licensing immunity for the issuance of standing orders for naloxone so long as they act in good faith.[13] Further, any person acting in good faith and with reasonable care, other than a physician, who administers naloxone acquired via traditional prescription or standing order has civil, criminal, and professional licensing immunity.[14] This immunity is absolute so long as the relevant individual acted under the authority provided under the statute.

Though not specific to expired naloxone, Georgia law does establish some limitations on pharmacists regarding the dispensing of expired drugs. Specifically, a provision of Georgia's State Board of Pharmacy Retail Pharmacy regulations states that "…under no circumstances will any Pharmacy or Pharmacist permit any drug or device to be dispensed which bears a date of expiration which has been reached, or any drug or device which is in a deteriorated condition."[15] 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 revoke licenses or impose other disciplinary action deemed appropriate by the board.[16]

Legal Analysis

By regulation, retail pharmacies and pharmacists in Georgia are not permitted to dispense expired or deteriorated medications. No such restriction applies to other providers who are authorized by law to dispense medications. It is possible that physicians would be entitled to immunity for dispensing expired naloxone under the state naloxone access law, although it is not clear whether such dispensing would be in compliance with the standard of care applicable to those providers.

There is no law prohibiting the administration of expired naloxone to a person who is overdosing. Georgia law provides immunity to any person other than a physician who administers naloxone so long as they use reasonable care in doing so. In the state of Georgia, reasonable care is care that is commensurate with the reasonably foreseeable risk of harm.[17] While there are no dispositive cases, there is no evidence to suggest that the administration of expired naloxone would cause harm to a person who is overdosing. Thus, a court would likely find that any person other than a physician who administered expired naloxone to a person experiencing an overdose would be entitled to the immunity provided by the naloxone access law.

Conclusion

Under Georgia law, retail pharmacies and pharmacists are prohibited from dispensing expired medications or deteriorated drugs. However, no Georgia law prohibits the possession of expired naloxone acquired via a valid prescription or standing order. The Georgia law that provides criminal, civil, and professional sanctions immunity to physicians for the prescription or dispensing of naloxone, to pharmacists for the dispensing of naloxone, and to Third Parties for administering naloxone, applies regardless of the medication's expiration status so long as the person providing the naloxone acts in good faith and within the standard of care.

SUPPORTERS

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References

[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/wp-content/uploads/2020/01/legal-interventions-to-reduce-overdose.pdf.

[5] 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

[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] GA. CODE ANN § 26-4-116.2.

[10] GA. CODE ANN § 31-1-10.

[11] GA. CODE ANN § 26-4-116.2(a)(3); GA. CODE ANN § 31-11-55.1(a)(2).

[12] GA. CODE ANN § 26-4-116.2(e)(1); (2).

[13] GA. CODE ANN § 26-4-116.2(e)(3); GA. CODE ANN., § 31-1-10. Georgia's current standing order is available here: https://dph.georgia.gov/sites/dph.georgia.gov/files/ChronicDisease/Standing%20Order%20Naloxone%5B2%5D.pdf

[14] GA. CODE ANN § 26-4-116.2(e)(4).

[15] GA. COMP. R. & REGS. § 480-10-11.

[16] GA. CODE ANN § 43-1-19(a)(8); GA COMP. R. & REGS 480-5-.01; GA COMP. R. & REGS § 480-5-.03.

[17] *Hemphill v. Johnson*, 230 Ga. App. 478, 497 S.E.2d 16 (Ga. Ct. App. 1998); *Herron v. Hollis*, 248 Ga. App. 194, 546 S.E.2d 17 (Ga. Ct. App. 2001).