Naloxone Access

APRIL 2022

INTRODUCTION

The United States is currently in the midst of an unprecedented drug epidemic. Just under 106,000 Americans died from a fatal drug overdose between November 2020 and October 2021.¹ This is the highest number of drug overdose deaths ever recorded.² Opioids are a major contributor to the drug overdose epidemic.³ Many opioid overdose deaths could be prevented with the timely administration of naloxone, an emergency opioid antagonist medication that is approved by the Food and Drug Administration (FDA) to reverse an opioid overdose.⁴ Approximately 60 percent of the 106,000 deaths mentioned above are linked to illicitly manufactured fentanyl.⁵ When someone shows signs of an opioid overdose, the timely administration of naloxone can play a huge role in stopping the overdose until the person can receive medical intervention.⁶ Research indicates that overdose deaths decrease when emergency opioid antagonists and overdose education are made available to community members.⁷ This fact sheet provides readers with an overview of what naloxone is and a brief overview of naloxone access laws in the United States.



HOW NALOXONE WORKS

Naloxone is an emergency opioid antagonist that works by reversing the effects of an opioid.⁸ Specifically, naloxone prevents decreased breathing which typically happens when someone overdoses on an opioid and must be given when someone shows the first sign of an overdose.⁹ Naloxone can be administered in three ways: (1) intramuscular (in the muscle) injection; (2) subcutaneous (under the skin) injection; or (3) by internasal spray (in the nose).¹⁰ Naloxone only works in the body for 30 to 90 minutes before its effects can wear off, which can cause the user to stop breathing again.¹¹ However, some types of opioids remain inside the body much longer than that, so an additional dose or doses of naloxone may be needed to continue to prevent an overdose.¹² In addition, the overdose victim must receive appropriate medical attention as soon as possible so that he or she can receive adequate treatment after the initial dose of naloxone.13

Currently, naloxone is only approved for use by prescription.¹⁴ However, many clinicians and policymakers are increasingly calling for naloxone to be classified as an over-the-counter (OTC) drug so that the life-saving abilities of this opioid antagonist are made more widely available to the public.¹⁵ In September 2019, the FDA published a statement on continued efforts to increase the availability of all forms of naloxone. In this statement, Acting Commissioner Norman Sharpless, M.D. stated:

> Addressing opioid overdose continues to be one of the most urgent public health priorities for the U.S. government and making potentially lifesaving treatments more readily available is one of the top ways we can address this crisis. . . [t]he FDA is working with other federal, state and local officials as well as health care providers, patients and communities across the country to increase availability of all forms of naloxone and combat the toll to communities, individuals and the economy

resulting from opioid abuse and addiction. . . [m]aking naloxone more widely available in every pharmacy as an approved over-the-counter (OTC) product would also be an important public health advancement – one we have been working on at the FDA.¹⁶

CURRENT STATUS OF NALOXONE ACCESS LAWS

Naloxone access laws delineate how someone may legally access naloxone in a particular state or jurisdiction. This includes which individuals can prescribe, dispense, or administer naloxone and what forms of civil or criminal immunity are provided, if any, for the use of the opioid reversal drug.¹⁷ All 50 states and the District of Columbia have some form of naloxone access law.¹⁸ Almost all allow physicians, pharmacists, advanced practitioner nurses, individuals at risk of an opioid overdose, and the family and friends of those individuals to administer naloxone.¹⁹ However, state law varies significantly on who is provided immunity for an act or omission performed in good faith related to prescribing or administering naloxone. As of March 2022, 39 states and the District of Columbia provide criminal immunity for dispensing naloxone to a layperson.²⁰ Fortyfive states and the District of Columbia provide civil immunity for dispensing naloxone to a layperson.²¹ Lastly, 38 states provide immunity from professional sanctions for dispensing naloxone.22

Despite the varying breadth of naloxone access laws, the Centers for Disease Control and

Prevention (CDC) reported that not enough naloxone is getting into the hands of those who need it most.²³ The CDC found that rural counties were three times more likely to be a low-dispensing county compared to a metropolitan county. Further, the CDC found that there were disparities in how pharmacies dispensed naloxone, even when state law allowed for uniform pharmacy dispensation.²⁴ In an effort to encourage access to naloxone, the Office of National Drug Control Policy (ONDCP), Executive Office of the President, in collaboration with LAPPA, recently released the *Model* Expanded Access to Emergency Opioid Antagonists Act to provide legislators and policymakers with a legislative template for the expansion of naloxone access laws.²⁵ In addition, there are many local efforts to find innovative ways to get naloxone into the hands of the people who need it most. For example, in Carter County, Tennessee, the county health department is partnering with a drug prevention organization, the Carter County Drug Prevention Coalition, to provide voluntary training to children on the administration of naloxone.²⁶ While the idea of children as young as six years old learning how to administer an emergency opioid antagonist might seem unconventional, Jilian Reece, drug prevention educator and director of the coalition notes "... I'd rather a kid should go through the trauma of giving Narcan than see their parent die."27

CONCLUSION

Naloxone is a lifesaving emergency opioid antagonist. The benefits of expanding access to naloxone are significant. These include saving the lives of a recordbreaking number of individuals suffering from opioid use disorder and experiencing an opioid overdose.

¹F.B. Ahmad, et al., *Provisional Drug Overdose Death Counts*, NAT'L CTR. HEALTH STATISTICS (March 16, 2022), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm. ² Id.

³ Opioid Overdose, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN. (accessed April 1, 2022), https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/opioid-overdose.

⁴ *What is Naloxone*, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN. (accessed April 1, 2022), https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naloxone.

⁵ 2022 A Critical Year to Address Worsening Drug Overdose Crisis, AMERICAN MED. ASS'N. (Jan. 11, 2022), <u>https://www.ama-assn.org/about/leadership/2022-critical-year-address-worsening-drug-overdose-crisis</u> citing to *Provisional Drug Overdose Death Counts*, NAT'L CTR.HEALTH STAT. (updated Mar. 16, 2022), <u>https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard</u>. ⁶ SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN., *supra* note 3.

⁷ U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose, U.S. DEP'T OF HEALTH & HUM. SERVICES (April 5, 2018), https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html, citing to Alexander Y. Walley et al., Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis, BMJ 2013;346:f174.

⁸ What is Naloxone?, NAT'L INST. DRUG ABUSE, (updated Jan. 2022), https://nida.nih.gov/publications/drugfacts/naloxone. ⁹ Id.

¹⁰ *Id*.

¹¹ Id. See also Naloxone for Opioid Overdose: Life-Saving Science, NAT'L INST. DRUG ABUSE (updated June 2021), https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science.

 12 Id.

¹³ Id.

¹⁴ Id.

¹⁵ Kirk E. Evoy, Lucas G. Hill, & Corey S. Davis, Considering the Potential Benefits of Over-the-Counter Naloxone, INTEGRATED PHARMACY RSCH. AND PRAC., Feb. 15, 2021, at 2.

¹⁶ Statement on Continued Efforts to Increase Availability of all Forms of Naloxone to Help Reduce Opioid Overdose Deaths, U.S. FOOD AND DRUG ADMIN.(released Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continuedefforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.

¹⁷ Naloxone Access: 50 State Summary, LEGIS. ANALYSIS PUB. POL'Y ASS'N, 3 (accessed Mar. 2022), https://legislativeanalysis.org/wpcontent/uploads/2021/05/Naloxone-Access-Summary-of-State-Laws-Final.pdf.

¹⁸ Id.

¹⁹ *Id.* at 4.

²⁰ Latest Research: Modest Progress On State Laws To Promote Naloxone And Syringe Access, TEMPLE UNIV. CTR. PUB. HEALTH LAW RSCH. (updated March 10, 2022), https://phlr.org/news/2022/3/latest-research-modest-progress-state-laws-promote-naloxoneand-syringe-access.

 21 Id.

²² Id.

²³ Still Not Enough Naloxone Where Its's Most Needed, CTR. DISEASE CONTROL PREVENTION (released Aug. 6, 2019), https://www.cdc.gov/media/releases/2019/p0806-naloxone.html.

²⁴ Id.

²⁵ White House Releases State Model Law to Help Make Access to Naloxone Consistent Across the Country, OFF. NAT'L DRUG CONTROL POL'Y (released Nov. 17, 2021), https://www.whitehouse.gov/ondcp/briefing-room/2021/11/17/white-house-releases-statemodel-law-to-help-make-access-to-naloxone-consistent-across-the-country/.

²⁶ It's Like A Little Squirt Gun: 'Children As Young As 5 Are Learning To Administer Narcan To Combat Tennessee's Opioid Crisis, INSIDER (published Feb. 25, 2020), https://www.insider.com/kids-learn-to-administer-narcan-to-combat-tennessees-opioid-crisis-2020- $\frac{2}{27}$. *Id.*

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include law enforcement/community engagement, naloxone laws, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

For more information about LAPPA, please visit: https://legislativeanalysis.org/.

© Legislative Analysis and Public Policy Association - This project is funded by a grant from the Office of National Drug Control Policy. Neither the Office of National Drug Control Policy, nor any other federal instrumentality operate, control, or are responsible for, or necessarily endorse this project.