Bureau of Justice Assistance (BJA)
Comprehensive Opioid, Stimulant, and Substance Abuse Program (COSSAP)

Naloxone Distribution and Regulations

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Training and technical assistance providers at RTI International hear about many different experiences around the process of obtaining naloxone, the opioid antagonist that can reverse an opioid-related overdose. While some states report a relatively easy process, others report difficulty accessing naloxone. However, states have recognized that the best distribution channel is one that considers the naloxone needs and priorities of individual communities. For example, in North Carolina, the Department of Health and Human Services provides funding to individual local management entities and managed care organizations to facilitate regional distribution.

Types of Naloxone

Naloxone was initially approved by the U.S. Food and Drug Administration (FDA) in 1971 for use as an injection.[1] Intramuscular naloxone is drawn into a syringe from a vial and then injected into the person experiencing an overdose, usually in the thigh. One nasal spray version of naloxone, Narcan, was approved by the FDA in 2015, though other methods of nasal naloxone had been introduced prior.[2] In 2022, there were also three generic 4-milligram (mg) naloxone nasal sprays (from Teva, Sandoz, and Padagis) and one branded 8-mg nasal spray (Kloxxado® by Hikma). Nasal naloxone comes in a pre-measured dose, and the packaging resembles that of a nasal allergy spray. The device is inserted into the nose, and a plunger releases the medication.

Evidence Base for Naloxone

Over time, naloxone in all its forms has proved to be a safe and effective way to reverse opioid-related overdoses.[3, 4, 5] Naloxone reverses overdoses by attaching to opioid receptors in the brain and effectively blocking the effects of the opioid.[6] As such, naloxone has no effect on a person who does not have opioids in their system. In addition, people cannot become immune to naloxone, and having access to the lifesaving drug does not encourage or enable people to use opioids.[7] Despite the relative ease of use, efficacy, and safety of naloxone, research suggests that naloxone saturation has not been reached in any state.[8] This warrants rapid action, as there were an estimated 100,306 drug overdose deaths between

April 2020 and April 2021—a 28.5 percent increase from the year prior.[9]

Variation in State Efforts to Facilitate Naloxone Distribution

In the past, harm reduction programs with a prescribing physician could order naloxone from a distributor or the manufacturer. In some states and localities, a "standing order" was passed that essentially allowed the dispensing or distribution of naloxone to those who met specific criteria. However, programs that did not have a prescription and locations without a standing order were left to obtain naloxone in alternative ways. Sometimes this meant they would have to go through the state or a larger agency to order naloxone, but this often limited their naloxone options and supply pool and placed unnecessary barriers on distribution. While the barriers themselves—such as mandatory trainings for citizens—cause unnecessary delays, the time required to decipher the laws and limitations poses an obstacle as well.

Many states offer a bulk purchasing option that allows agencies in need of naloxone to buy it at a discounted rate. A two-pack Narcan kit used to cost around $75 through these state options, and a 0.4 mg/milliliter vial of naloxone usually cost around $30.[10] More recently, with the generic version of Narcan coming to market, a two-pack costs closer to $50. However, people who use drugs often prefer intramuscular naloxone because it is titratable and thus can be customized to decrease one's chances of being sent into immediate withdrawal from a naloxone revival. Intramuscular naloxone is the more affordable option, and multiple double-blind studies suggest that it takes effect faster than Narcan and is less likely to require multiple doses. Despite these advantages, nasal naloxone is still often preferred by the public.[11, 12, 13] Nasal sprays do not carry the stigma associated with syringes and fear, though unfounded, of bloodborne disease,[14] and the simplicity of the nasal spray dispenser may feel safer or less complicated than syringes.

Regardless of preference, naloxone is often still cost-prohibitive for many harm reduction groups despite state discounts. Harm reduction groups are forced to prioritize naloxone distribution to active drug users over individuals looking for naloxone "just in case," limiting the overall saturation of naloxone in a community.

Emerging Distribution Models: Case Study

Recent challenges in accessing naloxone have highlighted the precarious supply and problems that come with relying mostly on one manufacturer. This was evidenced by the April 2021 manufacturing and supply chain issues related to a manufacturing interruption at a Pfizer injectable facility that affected many injectables, including naloxone.[15] To ensure a more sustained and cost-effective solution that could mitigate future shortages, organizations in states such as Michigan, Minnesota, and North Carolina started to acquire, or expanded their acquisition of, intramuscular naloxone from Remedy Alliance (formerly known as the Opioid Safety and Naloxone Network Buyers Club), which struck a deal with a pharmaceutical company for exclusive access to its own line of naloxone at a discounted rate. This materialized in fall 2021, and the final contact was signed on June 3, 2022.[16]

Through this partnership, Remedy Alliance purchases naloxone in bulk and distributes it to harm reduction organizations, thus passing along the cost savings and ease of access. Remedy Alliance works with more than 150 groups to get naloxone in the hands of people who use drugs. As of September 22, 2022, the FDA described exemption and exclusion for harm reduction suppliers from certain requirements of the Drug Supply Chain Security Act for naloxone distribution, which further supports this new naloxone distribution

model.[17] For example, the Missouri Institute of Mental Health at the University of Missouri–St. Louis established protocols that allow for syringe service programs to obtain Remedy Alliance naloxone which is purchased by the state government.

Conclusion

As harm reduction needs continue to evolve, it is important to remember that responses and capacities may vary by state. However, the need for naloxone is universal. Staying up to date on current trends and federal regulations is an important way to provide the best response to the needs of each community. Finally, this awareness provides an opportunity for information sharing and state collaboration in building a response to the substance use crisis.

Endnotes

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13. Neale, J., et al., 2022, "Understanding Preferences for Type of Take-home Naloxone Device: International Qualitative Analysis of the Views of People Who Use Opioids," *Drugs: Education, Prevention and Policy* 29(2): 109–120.

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15. See note 10 above, Medrano, "The Pfizer Naloxone Shortage Ends, Leaving Us With Just the Regular One."

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