

Over-the-Counter Naloxone Policy Statement

POSITION:

ASTHO supports making over-the-counter (OTC) naloxone available as one component of a broader strategy to increase access to naloxone.

BACKGROUND:

More than 750,000 people in the United States died from an opioid-related overdose from 1999 -2021.¹ These trends have continued to worsen, driven by the increased presence of fentanyl in the illicit drug supply. Naloxone, an FDA-approved life-saving medication that can be used to reverse opioid overdoses and prevent overdose deaths, is an essential part of public health efforts. All states and Puerto Rico have implemented naloxone access laws to make it available without a patient-specific prescription. However, the mechanisms by which people can get it—and protections for administering it—are inconsistent² and can cause fear and uncertainty about accessing or administering it.

Summary of Recommendations

- Ensure that naloxone is affordable for those who may witness or experience an overdose.
- Address the stigma associated with substance use and naloxone to ensure that people who need naloxone feel safe accessing it.
- Identify ways to continue to engage people who need naloxone in available community programs and services.
- Evaluate how OTC naloxone affects availability, community access, overdose reversals, and cost.

Naloxone can be delivered by intranasal spray or intramuscular injection and works by reversing or blocking the effects of opioids. It does not cause harm if no opioids are present, and there is no evidence of related significant adverse events.³ The recent increase of fentanyl in the drug supply has raised concerns that a single naloxone dose may not be enough to counteract the potent synthetic opioid.⁴ Naloxone is often administered by first responders or bystanders, the latter of which are present in more than one-third of overdose deaths. Some models predict that equipping more people who are likely to witness an overdose with naloxone would reduce overdose deaths by 21%.⁵

On February 15, 2023, an FDA advisory panel voted unanimously to recommend that Narcan, a naloxone nasal spray manufactured by Emergent BioSolutions, be sold and distributed without a prescription. FDA will make a final determination on whether to approve the OTC nasal spray for use; doing so has the potential to make it available to more people who need it. However, it is one of many complementary strategies that can increase access to the life-saving drug. People who use drugs may continue to face significant barriers to accessing naloxone including cost, stigma, and availability.⁶

RECOMMENDATIONS/EVIDENCE-BASE

1. **Ensure that naloxone is affordable for those who may witness or experience an overdose.** Cost is the most reported challenge to accessing naloxone.⁷ People who use drugs are more likely to be uninsured or underinsured and face higher out-of-pocket costs for naloxone.⁸ The intranasal formulation that would be made available over the counter is currently more expensive than intramuscular versions, and more than one dose may be required to reverse a fentanyl overdose.

Public health efforts should ensure equitable access to naloxone and could include (1) continuing to offer it at no cost to those at risk of overdose through overdose education and naloxone distribution (OEND) programs, (2) continuing insurance formulary inclusion of non-OTC naloxone, (3) extending insurance coverage to OTC naloxone, and (4) using federal grants or opioid settlement funds to subsidize naloxone.⁹

2. **Address the stigma associated with substance use and naloxone to ensure that people who need naloxone feel safe accessing it.** Studies have shown that people who use drugs may experience stigma in healthcare settings, including pharmacies.¹⁰ Stigma can result in people not seeking care and may deter them from accessing OTC naloxone. Strategies for addressing stigma include using person-first language (e.g., “person with a substance use disorder” vs. “addict”), offering stigma reduction training,¹¹ and involving people with lived substance use experience in the education implementation process.¹²

3. **Identify ways to continue to engage people who need naloxone in available community programs and services.** Naloxone is distributed to lay-people through OEND programs, community distribution activities, pharmacies, and innovative methods such as public health vending machines. OEND programs, which are offered by states and territories, community-based organizations, and harm reduction organizations, have been shown to increase the reversal of potentially fatal overdoses,¹³ improve knowledge and attitudes about naloxone, and effectively reduce overdose mortality.¹⁴

OEND programs effectively reach people who need naloxone and reduce overdose mortality. Importantly, these programs connect with people and may refer them to additional services. Some experts have suggested that OTC naloxone may limit opportunities for people who use drugs to engage in harm reduction, treatment, and recovery services. This limitation could be addressed by continuing or increasing support for OEND and educating pharmacy staff and people accessing naloxone about resources that are available in the community.

4. **Evaluate how OTC naloxone affects availability, community access, overdose reversals, and cost.** Public health agencies have set up reporting systems to track how frequently naloxone is used to reverse overdoses and should consider how reversals using OTC naloxone might be monitored. Research should additionally review how OTC naloxone affects the cost, availability, and accessibility of all forms of naloxone. Approval of OTC naloxone would represent a major change in the overdose prevention landscape and should be studied to determine its impact.

APPROVAL DATES

Community Health and Prevention Policy Committee Review: February 16, 2023 (*statement reviewed, not formally approved, due to expedited process*)

Board of Directors Approval: March 6, 2023

Policy Expires: March 31, 2026

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

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- ¹ CDC. “Opioid Data Analysis and Resources.” Available at <https://www.cdc.gov/opioids/data/analysis-resources.html>. Accessed 2-16-2023
- ² LAPP. “Naloxone Access: Summary of State Laws.” Available at <http://legislativeanalysis.org/wp-content/uploads/2023/02/Naloxone-Access-Summary-of-State-Laws.pdf>. Accessed 2-16-2023
- ³ NIDA. “Naloxone for Opioid Overdose: Life-Saving Science.” Available at <https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science#:~:text=How%20Does%20Naloxone%20Work%3F,or%20through%20a%20nasal%20spray>. Accessed 2-16-2023
- ⁴ SAMHSA. “Opioid Overdose Prevention Toolkit.” Available at <https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf>
- ⁵ NIDA. “Naloxone for Opioid Overdose: Life-Saving Science.” Available at <https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science#:~:text=How%20Does%20Naloxone%20Work%3F,or%20through%20a%20nasal%20spray>. Accessed 2-16-2023
- ⁶ Evoy KE, Hill LG, Davis CS. Considering the Potential Benefits of Over-the-Counter Naloxone. *Integr Pharm Res Pract.* 2021;10:13-21. Published 2021 Feb 15. doi:10.2147/IPRP.S244709
- ⁷ Ibid <https://pubmed.ncbi.nlm.nih.gov/32146134/>
- ⁸ Peet ED, Powell D, Pacula RL. Trends in Out-of-Pocket Costs for Naloxone by Drug Brand and Payer in the US, 2010-2018. *JAMA Health Forum.* 2022;3(8): e222663. doi:10.1001/jamahealthforum.2022.2663
- ⁹ Evoy KE, Hill LG, Davis CS. Considering the Potential Benefits of Over-the-Counter Naloxone. *Integr Pharm Res Pract.* 2021;10:13-21. Published 2021 Feb 15. doi:10.2147/IPRP.S244709
- ¹⁰ Sisson ML, McMahan KB, Chichester KR, Galbraith JW, Cropsey KL. Attitudes and availability: A comparison of naloxone dispensing across chain and independent pharmacies in rural and urban areas in Alabama. *Int J Drug Policy.* 2019;74:229-235. doi:10.1016/j.drugpo.2019.09.021
- ¹¹ CDC. “Stigma Reduction.” Available at <https://www.cdc.gov/drugoverdose/od2a/case-studies/stigma-reduction.html>. Accessed 2-16-2023
- ¹² Kohrt BA, Jordans MJD, Turner EL, et al. Collaboration With People With Lived Experience of Mental Illness to Reduce Stigma and Improve Primary Care Services: A Pilot Cluster Randomized Clinical Trial. *JAMA Netw Open.* 2021;4(11):e2131475. Published 2021 Nov 1. doi:10.1001/jamanetworkopen.2021.31475
- ¹³ NIDA. “Naloxone for Opioid Overdose: Life-Saving Science.” Available at <https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science#:~:text=How%20Does%20Naloxone%20Work%3F,or%20through%20a%20nasal%20spray>. Accessed 2-16-2023
- ¹⁴ Razaghizad A, Windle SB, Filion KB, et al. The Effect of Overdose Education and Naloxone Distribution: An Umbrella Review of Systematic Reviews. *Am J Public Health.* 2021;111(8):1516-1517. doi:10.2105/AJPH.2021.306306a