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Optimizing Naloxone Access Through Group Purchasing

By Stacey McKenna

As the United States continues to grapple with the ongoing overdose crisis, it is increasingly important that policymakers look to effective harm reduction tools that can save lives right now.

Executive Summary

Last year, the United States saw more than 100,000 overdose deaths—the majority of which involved synthetic opioids such as fentanyl. Many of those deaths could have been prevented if the people most likely to experience or witness an overdose—people who use drugs—had better access to the overdose reversal medication naloxone.

Harm reduction organizations have been key distributors of naloxone since the mid-1990s, despite considerable barriers related to cost and naloxone's prescription status. Grassroots buyers clubs emerged to help overcome these challenges, and even as they have evolved over the past decade, group purchasing remains a cornerstone of naloxone procurement for harm reduction organizations. Nonetheless, most legislative and regulatory efforts, while well intentioned, have overlooked this aspect of naloxone access, leaving much room for improvement.

In this paper, we integrate a review of the scientific literature with findings from a survey of harm reduction organizations and interviews with several individuals

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familiar with harm reduction and naloxone group purchasing to describe the emergence of naloxone group purchasing, explain its role in facilitating naloxone access, and discuss how policy can improve this important resource.

Introduction

During the 12-month period ending in February 2023, almost 110,000 people died of a drug overdose in the United States. In line with recent years, more than two-thirds of these deaths involved fentanyl or related synthetic opioids. The opioid overdose reversal medication, naloxone, has become an essential tool in combatting this crisis, but policymakers can do more to ensure it gets into the hands of the people who need it most.

Local, state and federal governments in the United States have already engaged in some promising steps toward preventing overdose fatalities by expanding funding to harm reduction organizations and moving to permit harm reduction tools such as fentanyl test strips.³ However, when it comes to naloxone, even well-intentioned policy efforts do not go far enough. For example, much legislation has emphasized improving overdose preparedness among the non-drug-using general public (via pharmacy access) and professional first responders (such as law enforcement officers or school nurses).⁴ But on-the-ground experts emphasize that we must prioritize naloxone access among people who use drugs, as these individuals are the most likely front-line overdose responders.⁵

Key to accomplishing this is improving the ability of harm reduction organizations, which represent an essential source of naloxone access and training for people who use drugs, to procure and distribute large quantities of naloxone. One important way to improve such targeted community-based access is by considering how policy affects the group purchasing schemes upon which these organizations rely to make the most of their often-limited human and economic resources. However, there has been little new policy aimed at improving harm reduction organizations' ability to purchase and distribute the life-saving medication.

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F.B. Ahmad et al., "Provisional Drug Overdose Death Counts," National Center for Health Statistics, Aug. 16, 2023. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

^{2.} Mbabazi Kariisa et al., "Illicitly Manufactured Fentanyl-Involved Overdose Deaths with Detected Xylazine – United States, January 2019-June 2022," *Morbidity and Mortality Weekly Report* 72:26 (June 30, 2023), pp. 721-727. https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a4.htm#:~:text=In%202022%2C%20 provisional%20data%20indicated,(IMFs)%20(1).

^{3. &}quot;HHS Distributes \$47.8 Million in Grant Funding for Programs Expanding Access to Medications for Opioid Use Disorder, Addressing Other Facets of Overdose and Substance Use," Substance Abuse and Mental Health Services Administration, July 19, 2023. https://www.samhsa.gov/newsroom/press-announcements/20230719/hhs-distributes-grant-funding-programs-expanding-access-medications-opioid-use-disorder; Samantha Hendrickson, "Lifesaving fentanyl test strips still illegal in some states under '70s-era war on drugs law," abcNEWS, June 8, 2023. https://abcnews.go.com/US/wireStory/alive-states-legalize-fentanyl-test-strips-combat-surging-99922442#:~ttext=lt%20has%20joined%20at%20least,of%20helping%20prevent%20drug%20overdoses; "Legal Mapping of Harm Reduction Laws and Overdose Prevention Center Legislation," Association of State and Territorial Health Officials, July 31, 2023. https://www.astho.org/globalassets/report/legal-mapping-of-harm-reduction-laws-and-overdose-prevention-center-legislation.pdf.

^{4.} Stacey McKenna, "Why Naloxone Access Policy Should Prioritize People Who Use Drugs," R Street Explainer, May 2023. https://www.rstreet.org/wp-content/uploads/2023/05/naloxone-prioritize-PWUD-05-23-FINAL.pdf.

^{5.} Janet Weiner et al., "Expanding Access to Naloxone: A Review of Distribution Strategies," Penn Leonard Davis Institute of Health Economics Brief: Opioid Epidemic, May 29, 2019. https://ldi.upenn.edu/our-work/research-updates/expanding-access-to-naloxone-a-review-of-distribution-strategies.

Maya Doe-Simkins et al., "Naloxone Buyers Club: Overlooked Critical Public Health Infrastructure for Preventing Overdose Deaths," medRxiv Preprint, Nov. 16, 2021. https://www.medrxiv.org/content/10.1101/2021.11.14.21266221v2; Don C. Des Jarlais et al., "Expansion of Syringe Service Programs in the United States, 2015-2018," American Journal of Public Health 110:4 (March 11, 2020). https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2019.305515.

^{7.} Weiner et al. https://ldi.upenn.edu/our-work/research-updates/expanding-access-to-naloxone-a-review-of-distribution-strategies.



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This paper draws on a literature review, a short survey of 119 harm reduction organizations, and targeted interviews with representatives of several organizations engaged in harm reduction and familiar with the group purchasing of naloxone to explore three key aspects of this issue:

- The importance of harm reduction organizations in the distribution of naloxone, and the emergence of naloxone group purchasing.
- The current group purchasing landscape and how it affects naloxone access for people who use drugs.
- The ways in which policy could improve the potential of group purchasing to further enhance naloxone access among people who use drugs.

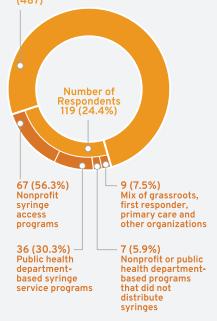
Based on informal conversations with on-the-ground harm reductionists, we postulated that a significant proportion of harm reduction organizations—likely the vast majority—accessed naloxone via larger group purchasing resources. However, in our review of the research, we were unable to confirm this suspicion in the literature. Therefore, we conducted a survey of harm reduction organizations to elucidate where and how they procure naloxone.

We created a brief, five-question survey in Google Forms and identified potential participants through the North American Syringe Exchange Network's (NASEN) online listing of organizations that provide naloxone as well as word-of-mouth recommendations. After cross-checking our sources to minimize potential duplicates, we reached out to 508 organizations from mid- to late-July, sending the survey via email and, rarely, website contact forms. Messages sent to 21 of these organizations "bounced," and our attempts to reach alternative contacts were unsuccessful, leaving 487 organizations that likely received the message and survey link. We sent one to two follow-up emails to organizations that did not open the original messages. Organizations were asked to complete the survey by mid-August 2023.

Out of the 487 organizations we contacted, 119 (24.4 percent) responded. Thirty six of the 119 responding organizations (30.3 percent) were public health department-based syringe service programs, 67 (56.3 percent) operated as nonprofit syringe access programs and 7 (5.9 percent) were nonprofit or public health department-based programs that did not distribute syringes. The remaining nine organizations included a mix of grassroots, first responder, primary care, federal and tribal syringe service programs; substance use disorder treatment programs; a nonprofit HIV/AIDS service organization; and a nonprofit harm reduction collective.

The Survey About the Participants

Number of Organizations Contacted (487)



The Emergence of Naloxone Group Purchasing

In 1971, the U.S. Food and Drug Administration (FDA) approved naloxone for the reversal of opioid overdoses.⁸ As an opioid antagonist, the drug binds to but does not activate the same receptors in the brain that attract heroin, fentanyl and other opioids.⁹ In doing so, naloxone removes activating opioids from the

^{8. &}quot;Naloxone facts and formulations," Commonwealth of Massachusetts, 2023. https://www.mass.gov/info-details/naloxone-facts-and-formulations?_gl=1*bce37r*_ga*MTQxOTkzNDc0My4xNjk2NTY0MTg0*_ga_MCLPEGW7WM*MTY5NjU2NTE2Ny4xLjAuMTY5NjU2NTE2Ny4wLjAuMA.

^{9. &}quot;Lifesaving Naloxone," Centers for Disease Control and Prevention, April 21, 2023. https://www.cdc.gov/stopoverdose/naloxone/index.html#:~:text=Naloxone%20 quickly%20reverses%20an%20overdose,opioids%20like%20fentanyl%20are%20involved.



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receptors or prevents them from attaching in the first place. The medication typically restores respiration within two to three minutes.¹⁰

Naloxone's early formulation was as an injectable medication, and the FDA's original approval and guidelines made it a prescription drug that was intended to be administered by medical professionals only. However, harm reductionists quickly recognized the drug's value outside of medical settings, and, in 1996, community-based organizations such as syringe service programs (SSPs) began distributing naloxone directly to people who use drugs, often operating in legal gray areas to do so. 12

In the early days of community-based naloxone distribution, laypeople received and administered the same injectable formulations they might find in an emergency department or on an ambulance. About a decade in, that began to change as well-resourced programs introduced improvised atomizers that allowed people to spray the injectable medication into the nose.¹³ According to one longtime grassroots harm reductionist:

I'm from Massachusetts, and when we were first doing naloxone distribution in Massachusetts before 2006 [or] 2007, it was all injectable that we would get from Chicago and give out illegally or whatever. Underground. And then, when the city of Boston, and then the state of Massachsetts subsequently took on doing naloxone distribution and paying for it and rolling it out statewide, they went with the adapted nasal product.¹⁴

In the mid 2010s, novel naloxone products that were designed specifically for "layperson" use came onto the market, including purpose-designed, concentrated intranasal and autoinjector options (though the latter has been discontinued). Now, both injectable and intranasal naloxone products are currently available in the United States in brand name and generic versions. In the last several years, additional high-dose products have been approved and made their way onto the market as well. In 2023, the FDA approved three intranasal naloxone products for over-the-counter (OTC) retail sales in an attempt to reduce barriers to purchasing the medication.

The Emergence of Naloxone Group Purchasing

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^{10.} Ibid.

^{11.} Kolbe and Fins, p. 643. https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/abs/birth-of-naloxone-an-intellectual-history-of-an-ambivalent-opioid/488D6075073599B12A2EFCDF6AE7F7BA.

^{12.} Eliza Wheeler et al., "Opioid Overdose Prevention Programs Providing Naloxone for Laypersons – United States, 2014," Morbidity and Mortality Weekly Report 64:23 (June 19, 2015), pp. 631-635. https://pubmed.ncbi.nlm.nih.gov/26086633.

^{13.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{14.} Ibid

^{15.} Laura Kolbe and Joseph J. Fins, "The Birth of Naloxone: An Intellectual History of an Ambivalent Opioid," Cambridge Quarterly of Healthcare Ethics 30:4 (October 2021), p. 643. https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/abs/birth-of-naloxone-an-intellectual-history-of-an-ambivalent-opioid/488D6075073599B12A2EFCDF6AE7F7BA.; Evan D. Peet et al., "Trends in Out-of-Pocket Costs for Naloxone by Drug Brand and Payer in the US, 2010-2018," JAMA Health Forum 3:8 (Aug. 19, 2022). https://jamanetwork.com/journals/jama-health-forum/fullarticle/2795473.

^{16. &}quot;Naloxone DrugFacts," National Institute on Drug Abuse, January 2022. https://nida.nih.gov/publications/drugfacts/naloxone.

^{17. &}quot;FDA Approves Higher Dosage of Naloxone Nasal Spray to Treat Opioid Overdose," U.S. Food & Drug Administration, April 30, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose.

^{18. &}quot;FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product," U.S. Food & Drug Administration, July 28, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product#:":text=FDA%20Approves%20Second%20Over%2Dthe%2DCounter%20 Naloxone%20Nasal%20Spray%20Product,-Share&text=Today%2C%20the%20U.S.%20Food%20and,known%20or%20suspected%20opioid%20overdose; "Padagis Announces the First Generic Over-the-Counter Approval of a Naloxone Nasal Spray Product," PR Newswire, July 19, 2023. https://www.prnewswire.com/news-releases/padagis-announces-the-first-generic-over-the-counter-approval-of-a-naloxone-nasal-spray-product-301881159.html.



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In the nearly 30 years that harm reduction organizations have been delivering naloxone to people who use drugs, it has become increasingly clear that these individuals, as well as their friends and family members, serve as essential overdose first responders. They are frequently present at the scene of an overdose, and studies find that they act as rescuers in the vast majority of successful reversals—up to 87 percent.¹⁹

Harm reduction organizations are the most effective way to get this lifesaving resource into the hands of lay first responders. Accessing naloxone at harm reduction organizations allows people to overcome significant pharmacy barriers, most notably cost and stigma.²⁰ Furthermore, it typically connects individuals with additional health-protective services, including counseling; testing for sexually transmitted infections; food and housing support; and, in some cases, a warm handoff to treatment if available and desired.²¹

Between the mid-1990s and 2014 (before fentanyl had become so common in the country's illicit opioid supply), harm reduction programs had distributed naloxone to more than 150,000 individuals—primarily people who use drugs—who in turn reversed more than 26,000 overdoses.²² In 2021, 7.7 million doses of naloxone were distributed outside of "retail pharmacies and traditional health care facilities," whereas only 2.64 million doses were distributed through pharmacies.²³

But, in order for these community-based organizations to continue offering life-saving overdose resources, they must first access large quantities of naloxone, which is an expensive, labor-heavy proposition that many harm reduction organizations struggle to manage independently.²⁴ As a result, in the last decade, naloxone group purchasing has become a key strategy in facilitating access.²⁵

Group Purchasing and Naloxone Access

Harm reduction organizations have long had to work together to overcome barriers related to operating in legal gray areas and with limited resources. In 2012, such efforts gave rise to the Opioid Safety and Naloxone Network (OSNN) Buyers Club.²⁶ In its first decade of operation, the OSNN Buyers Club primarily facilitated the process of bulk naloxone purchasing by negotiating prices with manufacturers while leaving the actual account set-up and purchasing

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87% of successful reversals.

^{19.} Alexander Y. Walley et al., "Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis," *British Medical Journal* 346:f174 (Jan. 31, 2013). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4688551.

^{20.} Kristin E. Schneider et al., "The role of overdose reversal training in knowing where to get naloxone: Implications for improving naloxone access among people who use drugs," Substance Abuse 42:4 (Oct. 1, 2021). https://journals.sagepub.com/doi/10.1080/08897077.2021.1875103; Kristin E. Schneider et al., "Practica implications of naloxone knowledge among suburban people who use opioids," Harm Reduction Journal 18:47 (April 28, 2021). https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00466-8.

^{21. &}quot;Syringe Services Programs (SSPs)," Centers for Disease Control and Prevention, Aug. 21, 2023. https://www.cdc.gov/ssp/index.html.

^{22.} Ibid

^{23. &}quot;Summary Report: Naloxone Economic View," Reagan-Udall Foundation, March 2023, p. 10. https://reaganudall.org/sites/default/files/2023-03/Naloxone%20 Report%20FINAL%203.8.23.pdf.

^{24.} Author interview with Eliza Wheeler (Zoom), July 27, 2023; Author interview with Tim Semantor (Zoom), Aug. 9, 2023.

^{25.} Ibid

^{26.} Maya Doe-Simkins et al., "Remedy Alliance: How an informal buyers club solved a naloxone access problem for harm reduction programs," Harm Reduction International Conference, 2023. https://hr23.hri.global/abstract/973/print#:~:text=In%20the%20United%20States%20since,shortage%20for%20the%20Buyers%20 Club.



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to individual organizations.²⁷ In 2019, they connected 110 harm reduction organizations across the country with manufacturers that provided those organizations with more than 1 million doses of injectable naloxone that were in turn distributed directly to people who use drugs.²⁸

In 2021, the OSNN Buyers Club changed their model, incorporating as an organization in the hopes that it would give them greater "legitimacy and bargaining power" with manufacturers and federal agencies. ²⁹ Today, the group operates as Remedy Alliance/For the People and acts as a need-based naloxone wholesaler that works with nearly 200 harm reduction programs, many of which were "previously unable to acquire their own autonomous supply." Remedy Alliance offers naloxone on a multi-tiered sliding scale: Some organizations pay a standard below-market price, while others pay "cost" or receive the medication for free. ³¹ In 2023, 64 percent of the more than 1.6 million doses of naloxone that Remedy Alliance distributed were sold at-cost, and 13 percent were given to organizations for free. ³²

Though Remedy Alliance remains the primary buyers club for harm reduction organizations, it is not the only one. Smaller harm reduction collectives have sprouted in a number of states. And, in recent years, as government funding for naloxone purchasing has increased, state health departments have also become group purchasers, typically providing naloxone to harm reduction organizations for free.³³

Indeed, of the 119 harm reduction organizations that responded to our survey on naloxone procurement, 90 (75.6 percent) reported that they currently receive naloxone through a city, state or county government program, and 5 (4.2 percent) reported receiving the medication from a federal agency such as Veterans Affairs or Indian Health Services. In addition, 38 organizations (31.9 percent) reported obtaining naloxone from a buyers club (such as Remedy Alliance or NASEN), and 20 (16.8 percent) said they work directly with pharmacies, manufacturers or distributors. Organizations reported a number of additional sources, including nonprofit clearinghouses, universities, and donations from other organizations or local foundations. It is noteworthy that although many organizations access naloxone from multiple sources, 72 of our survey respondents (60.5 percent) reported that they received the medication from just one type of source, most often a public health department.



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^{27.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{28.} Ibid.

^{29.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{30. &}quot;Annual Report," Remedy Alliance/For The People, Aug. 31, 2023, p. 45. https://cdr.lib.unc.edu/concern/parent/t722hm45f/file_sets/x346df49k.

^{31.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{32. &}quot;Annual Report," p. 8. https://cdr.lib.unc.edu/concern/parent/t722hm45f/file_sets/x346df49k.

^{33.} Robert M. Bohler et al., "The policy landscape for naloxone distribution in four states high impacted by fatal opioid overdoses," *Drug and Alcohol Dependence Reports* 6:100126 (Dec. 5, 2022). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9838196.



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In the remainder of this section, we draw further on our survey and interview findings to highlight two key ways group purchasing is essential to ensuring that SSPs and other harm reduction organizations maintain access to naloxone: product cost and prescription status.

Keeping Product Cost Down

Harm reduction programming is considered among the most effective and cost-effective public health interventions worldwide.³⁴ Organizations such as SSPs are key distributors of naloxone to people who use drugs, and, to eliminate a variety of barriers—cost and stigma chief among them—that make the medication difficult for some individuals to access at the pharmacy, they typically provide the medication free-of-charge to their participants.³⁵ To offer this life-saving service, harm reduction programs must cover the expense of naloxone themselves. However, these organizations are often drastically under-resourced, with median annual budgets falling 46 percent or more below minimum recommendations and staff capacity stretched thin.³⁶

Thus, medication cost can be prohibitive to maintaining adequate supply, especially when naloxone must be purchased in large quantities. And although injectable and intranasal naloxone are both highly effective at reversing opioid overdoses, product prices differ considerably depending on the route of administration and formulation.³⁷ The estimated 2023 "public interest" prices for intranasal products range from \$36 to \$48 for a two-dose kit, compared to \$3.20 to \$7.60 for injectable alternatives.³⁸

Group purchasing helps overcome these challenges, as their collective bargaining power allows them to negotiate lower prices. Among our survey participants, only a small proportion (6.7 percent) reported paying for their entire supply, slightly more than half of respondents (51.3 percent) said they receive all of their naloxone for free, and the remainder indicated that they pay for some and receive some for free. The access to affordable and no-cost naloxone is an essential tool for harm reduction organizations who must prioritize how to spend their limited funds.³⁹

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Working Around Prescription-Only Status

Until relatively recently, harm reductionists' work of acquiring and distributing naloxone took place in a legal grey area because the medication was designated

^{34.} David P. Wilson et al., "The cost-effectiveness of harm reduction," *International Journal of Drug Policy* 26:1 (Feb. 1, 2015), pp. S5-S11. https://www.sciencedirect.com/science/article/pii/S0955395914003119; Gideon Lasco et al., "The Global State of Harm Reduction 2022," Harm Reduction International, 2022. https://hri.global/wp-content/uploads/2022/11/HRI_GSHR-2022_Full-Report_Final.pdf.

^{35.} Schneider et al., "The role of overdose reversal training in knowing where to get naloxone: Implications for improving naloxone access among people who use drugs." https://journals.sagepub.com/doi/10.1080/08897077.2021.1875103; Schneider et al., "Practical implications of naloxone knowledge among suburban people who use opioids." https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00466-8.

^{36.} Barrot H. Lambdin et al., "Impact of the California Harm Reduction Initiative," RTI International (Jan. 30, 2023). https://www.rti.org/insights/impact-of-california-harm-reduction-initiative; Eyasu H. Teshale et al., "Estimated cost of comprehensive syringe service program in the United States," PLoS One 14:4 (April 26, 2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6485753.

^{37. &}quot;What Is the Price to Save a Life?" Remedy Alliance For the People, last accessed Aug. 27, 2023. https://cdr.lib.unc.edu/images/5h73q586k%2Ffiles%2Faae9d3a0-35a0-4f11-81b8-3154416b6ff9%2Ffcr:versions%2Fversion3/full/2027,/0/default.jpg.

^{38.} Ibid.

^{39.} Author interview with Tim Semantor (Zoom), Aug. 9, 2023.



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for prescription use only. As of 2023, all states have some laws—such as standing orders or pharmacist prescribing permissions—that make it easier for individuals to purchase the medication at a pharmacy.⁴⁰ However, the specifics of these laws, and the extent to which they allow harm reduction organizations to purchase large quantities of naloxone and distribute it to laypeople (versus simply administering on-site in case of an emergency) varies considerably.⁴¹

Group purchasing and distribution by public health departments, buyers clubs and others reduced some of these barriers. As one interviewee shared, as recently as 2019, when Remedy Alliance was still the Naloxone Buyers Club and operating primarily as a price negotiator, naloxone's prescription status created a problem, especially for small organizations,

Each program ... had to meet certain requirements for receiving prescription medications. They had to have a [Drug Enforcement Administration] license on file for their program, and a doctor's medical license that was in the state that they were operating in. They had to have a commercial address. This was a huge barrier for most harm reduction programs.⁴²

When health departments or collectives act as group purchasers, they are often able to use their state's standing order to access naloxone on behalf of harm reduction organizations. For example, in Washington, the state standing order explicitly allows "pharmacies and other entities" to dispense the medication. Similarly, in Colorado, Senate Bill 15-053 authorizes the Colorado Department of Public Health and Environment's chief medical officer to issue standing orders enabling harm reduction organizations to procure and distribute naloxone. Other organizations, such as Remedy Alliance, have used the FDA's public health emergency exemptions to work around the prescription-related restrictions.

In rare cases, group purchasers may still be hamstrung by naloxone's prescription status. In Wyoming, for example, the Department of Health purchases naloxone for organizations. However, those organizations must furnish their own standing order and are permitted to administer the naloxone only in the case of an onsite overdose, not distribute it directly to at-risk individuals to take home. In Florida, harm reduction organizations with a standing order can access intranasal naloxone for take-home distribution at no cost through the state's Department of Children and Families, but current policy requires that the medication be shipped from the state's central pharmacy to a local pharmacy licensed to dispense the medication.



As of 2023, all states have some laws that make it easier for individuals to purchase naloxone at a pharmacy. However, the specifics of these laws, and the extent to which they allow harm reduction organizations to purchase large quantities of naloxone and distribute it to laypeople varies considerably.

^{40.} Amy Judd Lieberman et al., "Harm Reduction and Overdose Prevention: 50-State Survey," The Network for Public Health Law, 2020. https://www.networkforphl.org/wp-content/uploads/2020/12/50-State-Survey-Harm-Reduction-Laws-in-the-United-States-final.pdf.

^{41.} Ibid.

^{42.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{43. &}quot;Washington State Statewide Standing Order to Dispense Naloxone HCI," Washington State Department of Health, Jan. 12, 2023.https://doh.wa.gov/sites/default/files/legacy/Documents/Pubs/150-127-StatewideStandingOrderToDispenseNaloxone.pdf.

^{44. &}quot;Naloxone standing orders," Colorado Department of Public Health & Environment, last accessed Aug. 29, 2023. https://cdphe.colorado.gov/prevention-and-wellness/injury-prevention/overdose-prevention/naloxone-standing-orders.

^{45.} Kastalia Medrano, "FDA Exempts Harm Reduction From Biggest Naloxone Access Restrictions," Filter, Sept. 26, 2022. https://filtermag.org/fda-naloxone-exemption-harm-reduction.

^{46.} Author interview with Shifa Hamid and Erica Mathews (Zoom), July 13, 2023.

^{47.} Author interview with Tim Semantor (Zoom), Aug. 9, 2023.



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Advancing Consumer Choice

Because harm reduction organizations receive much of their naloxone for free or a discount price, they are heavily dependent on product decisions made by group purchasers. At present, group purchasing preferences vary by group. For example, some state health departments exclusively purchase and distribute intranasal formulations, whereas Remedy Alliance has historically purchased injectable and adapted intranasal products.⁴⁸

In 2021, health systems, public health organizations, and harm reduction programs received and distributed an estimated 9 million intranasal naloxone doses, compared to about 5 million doses of injectable naloxone. ⁴⁹ This may be because, in recent years, the intranasal product has become the preferred option of many state and local government group purchasers. ⁵⁰ For example, Florida's Department of Children and Families and Wyoming's Department of Health purchase and distribute only intranasal naloxone. ⁵¹ Conversely, Colorado and Washington purchase both intranasal and injectable formulations, while the Washington State Department of Health's standing order explicitly excludes high-dose naloxone. ⁵² Meanwhile, in their first year of operation (August 2022 to August 2023), Remedy Alliance distributed more than 1.6 million doses of generic injectable naloxone and plans in the near future to distribute intranasal naloxone for the first time, thanks to receiving 200,000 donated doses. ⁵³

This year's approval of intranasal naloxone products for OTC status may also influence the specific products that will be available through harm reduction organizations as well as on pharmacy shelves.⁵⁴ None of the group purchasing organizations we interviewed were concerned that the OTC status of the intranasal medication would lead to an increase in their out-of-pocket costs because, unlike retail consumers, they are not dependent on insurance cost-sharing. In fact, it is possible that having multiple products on the market may lead to more competition, driving costs down. Furthermore, some interviewees speculated that OTC status might improve naloxone access in jurisdictions where procurement and distribution of the medication by harm reduction organizations continues to be hindered by weak naloxone access laws.⁵⁵

Understanding the preferences of people who use drugs and others who are likely to witness an overdose can help group purchasers make the best use of



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^{48.} Author interview with Shifa Hamid and Erica Mathews (Zoom), July 13, 2023; Author interview with Tim Semantor (Zoom), Aug. 9, 2023; Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{49. &}quot;Summary Report: Naloxone Economic View," p. 10. https://reaganudall.org/sites/default/files/2023-03/Naloxone%20Report%20FINAL%203.8.23.pdf.

^{50.} Author interview with Eliza Wheeler, (Zoom), July 27, 2023.

^{51.} Author interview with Shifa Hamid and Erica Mathews (Zoom), July 13, 2023; Author interview with Tim Semantor (Zoom), Aug. 9, 2023.

^{52.} Author interview with Chelsie Porter (Zoom), Aug. 16, 2023; Author interview with Jericho Dorsey and Andres Guerrero (Zoom), July 19, 2023.

^{53. &}quot;Annual Report," p. 2. https://cdr.lib.unc.edu/concern/parent/t722hm45f/file_sets/x346df49k; "Partnership to Save Lives: Harm Reduction Therapeutics to donate 200,000 RiVive™ naloxone doses to Remedy Alliance for free distribution," Remedy Alliance/For The People, Aug. 9, 2023. https://remedyallianceftp.org/blogs/news/partnership-to-save-lives-harm-reduction-therapeutics-to-donate-200-000-rivive%E2%84%A2-naloxone-doses-to-remedy-alliance-for-free-distribution.

^{54. &}quot;FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product." https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product#:~:text=FDA%20Approves%20Second%20Over%2Dthe%2DCounter%20Naloxone%20Nasal%20Spray%20Product,-Share&text=Today%2C%20the%20U.S.%20Food%20and,known%20Suspected%20opioid%20overdose; "Padagis Announces the First Generic Over-the-Counter Approval of a Naloxone Nasal Spray Product.". https://www.prnewswire.com/news-releases/padagis-announces-the-first-generic-over-the-counter-approval-of-a-naloxone-nasal-spray-product-301881159.html.

^{55.} Author interview with Shifa Hamid and Erica Mathews (Zoom), July 13, 2023; Author interview with Tim Semantor (Zoom), Aug. 9, 2023.



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their funds and have the biggest impact on the overdose crisis. It is essential that people have access not only to overdose reversal medications that are effective, but to products that they can and will use.

Although there is little large-scale research on the naloxone preferences of people who use drugs, qualitative studies and conversations with harm reductionists on the ground help provide some insight. Studies from the United States and Australia suggest that people tend to prefer products they see as easy to use with little risk of error, especially given the high-stress situation of responding to an overdose. For some, especially those who do not have a medical background or have never injected drugs themselves, this means preassembled intranasal naloxone products. However, others, like those who are familiar with needles or those who use opioids regularly, often prefer injectable naloxone. Another benefit of the injectable (or adapted nasal) naloxone is the ability to titrate the dose, which reduces the risk of putting the recipient into sudden withdrawal. For

Of note, people who use opioids and grassroots harm reductionists express resistance to the new high-dose naloxone formulations. One Florida-based harm reductionist explained in an interview that although distributing the new 5 and 8 milligram products in contexts where individuals are less likely to be opioid dependent (such as large music festivals) is probably harmless, these products are not ideal for individuals who use opioids regularly. When administered to people who are opioid dependent, high-dose naloxone often causes severe withdrawal, which comes with health risks of its own and may foment distrust in the medical system and harm reduction itself. Rather, he suggested, "It's better to titrate two 4 milligram doses than [give] one 8 [milligram dose]."

Furthermore, people's particular naloxone preferences are likely highly individualized and, in some cases, complex. For example, one representative of a group purchasing organization explained in an interview that the people served by their participating programs often request multiple forms of naloxone to be prepared for a variety of situations: While they may want the adapted or purpose-built intranasal devices for "randoms and newbies and people [they] don't know," they often keep the injectable for themselves, friends and others whose habits are familiar.⁶¹

In addition, although some people do initially prefer intranasal naloxone over injectable, training can help overcome this barrier. Indeed, a representative from a national, mail-based harm reduction organization explained, "We have had thousands of people who have reported getting naloxone from us for the first



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^{56.} Joanne Neale et al., "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 (Feb. 22, 2021), pp. 109-120. https://www.tandfonline.com/doi/full/10.1080/09687637.2021.1872499.

^{57.} Ibid.; Author interview with Tim Semantor (Zoom), Aug. 9, 2023; Author interview with Eliza Wheeler (Zoom), July 27, 2023.

^{58.} Author interview with Tim Semantor (Zoom), Aug. 9, 2023.

^{59.} Author interview with Tim Semantor (Zoom), Aug. 9, 2023; Shane Darke et al., "Yes, people can die from opiate withdrawal," *Addiction* 112:2 (February 2017), pp. 199-200. https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.13512.

^{60.} Author interview with Tim Semantor (Zoom), Aug. 9, 2023.

^{61.} Author interview with Eliza Wheeler (Zoom), July 27, 2023.



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time. We sent them IM [intramuscular] naloxone, they received training from us and they successfully reversed an overdose."⁶²

Ultimately, most of the harm reductionists we spoke with advocated for organizations to supply multiple products whenever possible to give participants "options, and to present those options neutrally and let people figure it out for themselves." Naloxone buyers groups should consider the importance of providing various administration routes, as they directly impact the products that lay users have access to and have the ability to significantly influence the options provided.

Improving Naloxone Access in a Group Purchasing-Dominated Landscape

Clearly, group purchasing of naloxone is a fundamental and essential tool in combatting the ongoing overdose crisis in the United States. Nonetheless, policy does not yet do enough to optimize access to this life-saving medication among the people who are most likely to experience, witness or reverse an overdose. In this section, we offer targeted policy suggestions to help improve group purchasing of naloxone for distribution by harm reduction organizations to better meet these needs.

Refining Naloxone Access Laws

Although the OTC status of intranasal naloxone products will reduce legal and prescription barriers to specific products, naloxone access laws remain an important way to ensure access to injectable formulations. States should ensure that their naloxone access laws:

- Extend to naloxone purchase and distribution by harm reduction organizations and others who provide take-home doses of naloxone to laypeople.
- Allow their health departments to purchase naloxone for organizations that distribute take-home doses.
- Remove unnecessary barriers to naloxone procurement by harm reduction organizations, such as requiring a commercial address or pharmacy partner.

Fostering Sustainable Funding

For most organizations working to supply naloxone, funding is a vital factor in making the various forms of the product accessible to those most in need:

Policy should encourage group purchasers and distributors—especially those
using state bulk funds—to prioritize funding grassroots and nonprofit harm
reduction organizations that directly engage with and distribute to people who
use drugs over for-profit entities or those that simply keep doses "on hand"
for use. This primarily means SSPs and other harm reduction organizations
but could also include organizations serving unhoused people, as well as first
responder leave-behind and hospital take-home programs.



Group purchasing of naloxone is a fundamental and essential tool in combatting the ongoing overdose crisis in the United States. Nonetheless, policy does not yet do enough to optimize access to this life-saving medication and we offer three policy suggestions to improve group purchasing.

Policy Suggestion



Policy Suggestion



^{62.} Interview with Jamie Favaro (Phone), Aug. 8, 2023.



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- States should earmark portions of their opioid settlement dollars to support naloxone purchase and distribution, ensuring a sustainable fund to address this public health emergency.
- Federal and state law and funding regulations can optimize uptake by
 permitting group purchasing organizations such as public health departments
 to procure and distribute intranasal and injectable formulations in line with
 product preference and budget limitations.

Facilitating Broader OTC Product Approval

Beyond reducing legal and prescriptions barriers, OTC approval can put naloxone directly into the hands of those who need it, when they need it:

- The FDA can promote competition by considering and approving, as appropriate, a broader range of OTC naloxone nasal sprays.
- Lawmakers and the FDA should consider establishing a pathway that would remove the prescription status of injectable naloxone purchased by health departments or approved wholesalers and distributed to harm reduction organizations.

Conclusion

As the United States continues to grapple with the ongoing overdose crisis, it is increasingly important that policymakers look to effective harm reduction tools that can save lives right now. Naloxone has been approved for the reversal of opioid overdoses for more than 50 years. Since the 1990s, harm reduction organizations have been distributing this life-saving medication to the very people who are most likely to witness and reverse an overdose: people who use drugs. However, they continue to face barriers related to naloxone's cost and prescription status, and policy has not yet caught up with the on-the-ground reality.

In the past decade, buyers clubs and other group purchasing efforts have been organized to facilitate this process, both easing the cost of naloxone for harm reduction organizations and helping navigate often complex legal environments. Prudent policy will improve group purchasing of these medications. We can enhance naloxone access laws; provide smart, sustainable funding for these programs; promote competition; and remove unnecessary prescription barriers, all of which will safeguard access to this lifesaving medication.

Policy Suggestion





With prudent policy, we can enhance naloxone access laws; provide smart, sustainable funding for these programs; promote competition; and remove unnecessary prescription barriers, all of which will safeguard access to this lifesaving medication.

About the Author

Stacey McKenna is a medical anthropologist and resident senior fellow in Integrated Harm Reduction at the R Street Institute. Her research and writing focuses on the ways that policy affects drug use, related risks, and people who use drugs' right to protect their health.