

Over the Counter Naloxone and the Puzzle of Overdose Reversal

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Faculty Disclosures

- Marta Sokolowska, PhD, has no financial relationships to disclose relating to the subject matter of this presentation
- Jonathan Woodruff, Esq., has no financial relationships to disclose relating to the subject matter of this presentation
- Yngvild Olsen, MD, MPH, has no financial relationships to disclose relating to the subject matter of this presentation
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Learning Objectives

- Discuss recent federal actions and activities to broaden access to naloxone and other opioid overdose reversal agents, including among high-risk populations and communities
- Discuss research efforts to examine optimal naloxone administration paradigms to maximize opioid overdose reversals and minimize long term sequelae
- Explain the overdose reversal agent market and how the combination of prescription and over-the-counter (OTC) products may confuse retailers about how to market OTC naloxone
- Discuss the elements of state overdose reversal agent laws and how OTC naloxone fits (or does not fit) within them
- Discuss OTC-related provisions in recently proposed federal and state bills
- Explain how federal grants can be used to support naloxone saturation efforts in states and communities

Over-the-Counter Naloxone and the Puzzle of Overdose Reversal: An FDA Perspective

Marta Sokolowska, PhD

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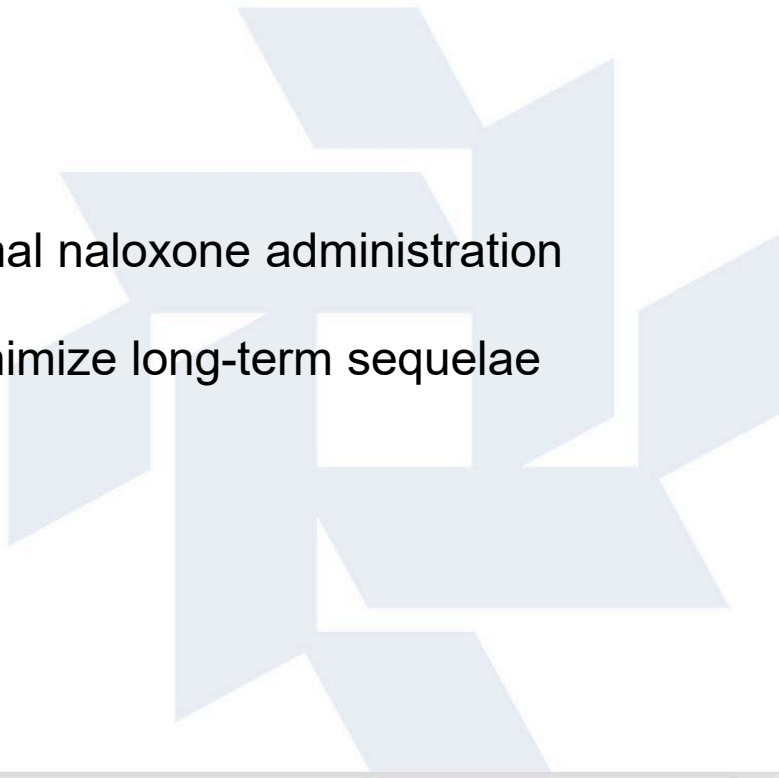
Disclaimer and Conflict of Interest Statement

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

I have no conflicts of interest to disclose.

Outline

- Recap of FDA's 2023 and 2024 actions and activities to broaden access to overdose reversal agents
- Summary of recent naloxone availability data
- Overview of research efforts to examine optimal naloxone administration paradigms
 - Goal: Maximize overdose reversal and minimize long-term sequelae



FDA's 2023 and 2024 Activities to Broaden Access to Overdose Reversal Agents



Broadening Access to Overdose Reversal Agents: March 2023 – Jan 2024

March 29, 2023

FDA NEWS RELEASE

FDA Approves First Over-the-Counter Naloxone Nasal Spray

Agency Continues to Take Critical Steps to Reduce Drug Overdose Deaths Being Driven Primarily by Illicit Opioids

July 18, 2023

Abbreviated New Drug Application (ANDA): 211951

~~Company: INGENUITY~~

The sANDA, submitted as "Prior Approval Supplement," provides for a change from

We have completed the review of this sANDA, as amended, and it is **approved**.

January 17, 2024

FDA announces shelf-life extension for naloxone nasal spray

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FDA Approves Prescription Nasal Spray to Reverse Opioid Overdose

Nalmefene Hydrochloride Product in Nasal Spray Form Provides Additional Tool for Harm Reduction Groups and First Responders

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FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product

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May 22, 2023

July 28, 2023

Impact of Naloxone Shelf-Life Extension

- Total market for naloxone nasal sprays¹
 - \$270M in 2022
 - \$282M in 2023
- A 3- to 4-year shelf-life extension of naloxone nasal sprays could result in significant cost savings to purchasers
 - \$100M+ over a 12-year period
- Savings could be substantially higher as naloxone coverage is much greater than what is captured in IQVIA²

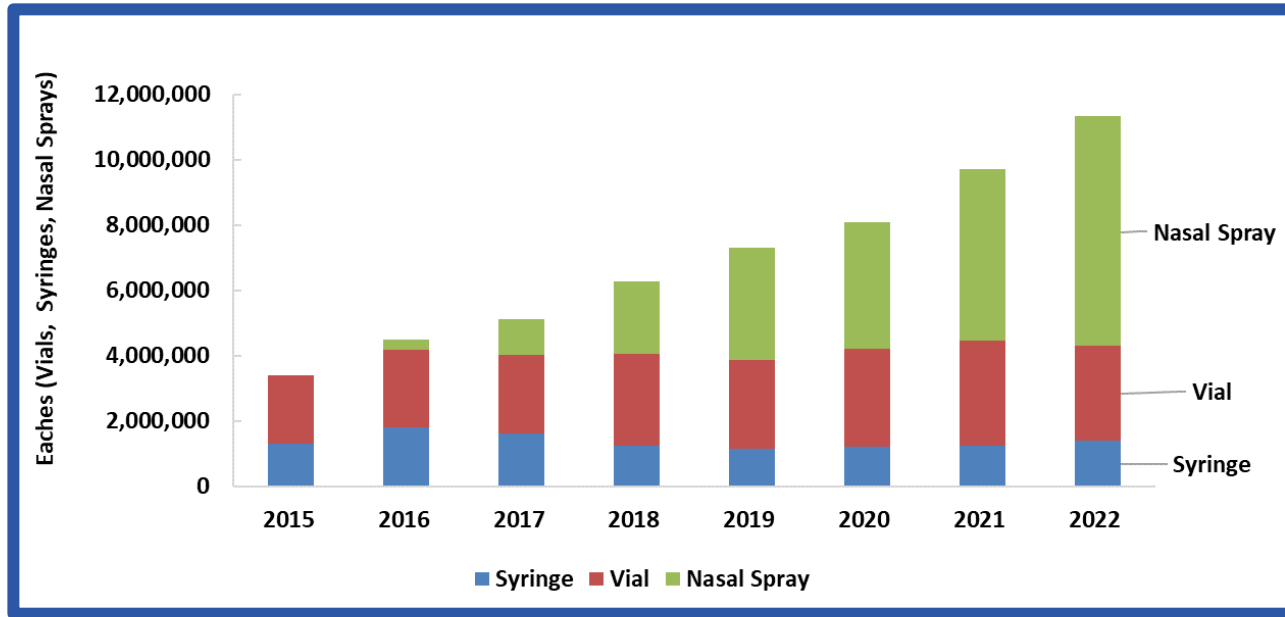
¹ IQVIA National Sales Perspectives, CY2022-CY2023, all naloxone nasal spray products

² <https://reaganudall.org/sites/default/files/2023-03/Naloxone%20Report%20FINAL%203.8.23.pdf>

Recent Naloxone Availability Data



Increases in Naloxone Availability

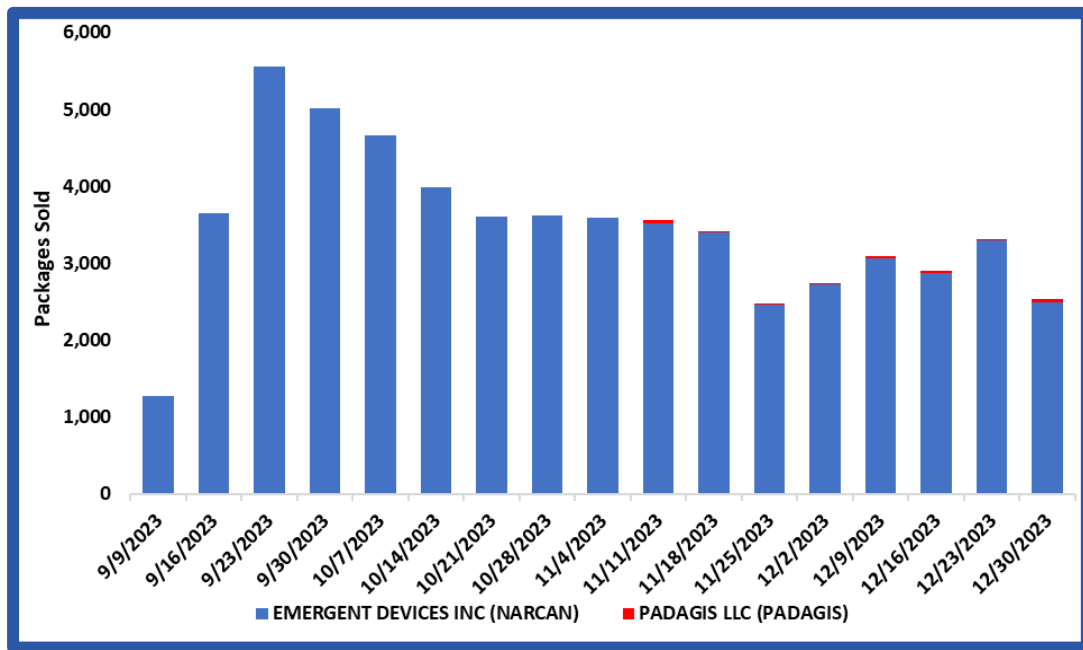


Nationally Estimated Number of Naloxone Units (Vials, Syringes, Nasal Sprays) Sold From Manufacturers to U.S. Channels of Distribution, Stratified by Product Formulation, Annually 2015 to 2022

Source: IQVIA National Sales Perspective™. Time period 2015 to 2022, extracted Oct 2023.

Distributed products do not provide a direct estimate of use. These data underestimate total naloxone availability as they do not capture direct sales or donations from manufacturers, for example to harm reduction organizations. These data may vary from previous/other analyses due to timing of data source updates and when data were retrieved from the tool.

OTC Naloxone In-Store Sales

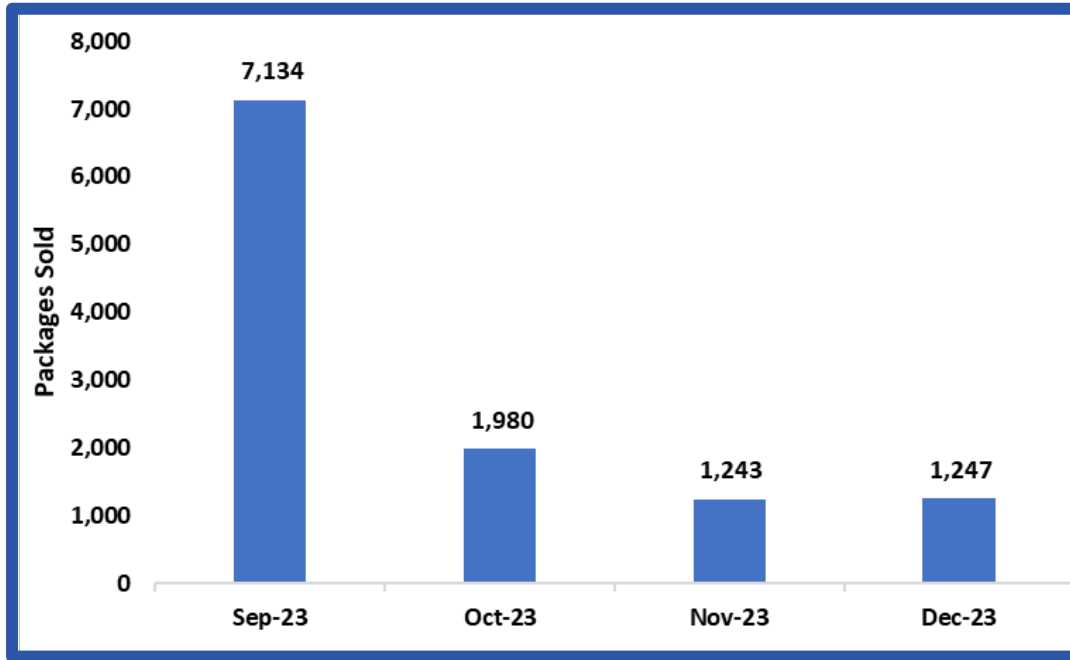


Estimated total of **59,015** packages* have been sold **in-store** from 9/3/23 through 12/30/23

Weekly estimated number of over-the-counter naloxone nasal spray packages (two sprays per package) sold from U.S. stores from September 3, 2023, through December 30, 2023. Source: IQVIA OTC Naloxone Reporting. Data provided 1/16/2023.

* Packages sold indicates number of boxes containing two nasal sprays and is a projected estimate based on amount of dollars in sales to consumers reported from in-store point-of-sales (POS) systems from U.S. retail stores.

OTC Naloxone Online Sales



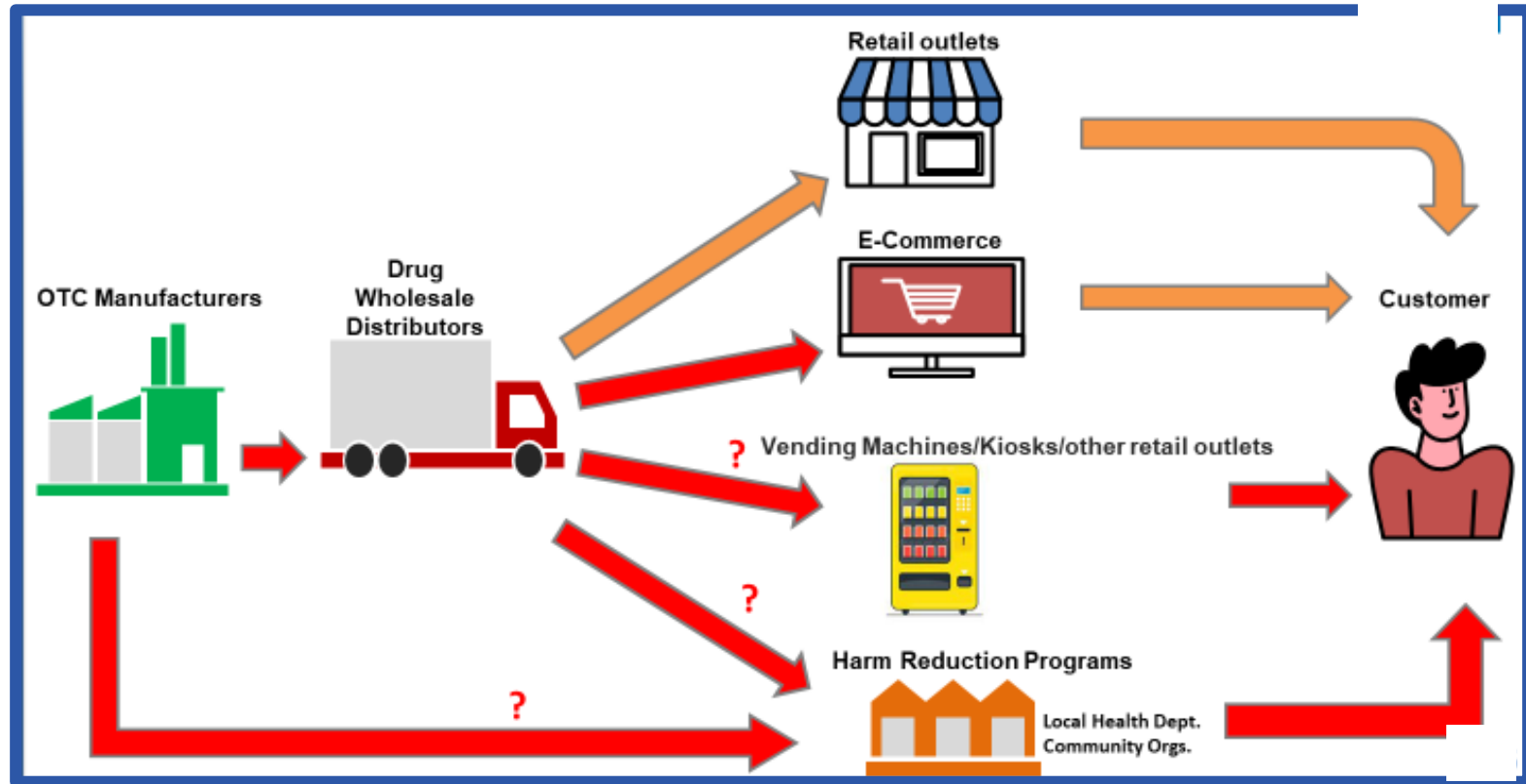
Estimated total of **11,605** packages* sold online from September through December 2023

Monthly estimated number of OTC naloxone nasal spray packages (two sprays per package) sold from U.S. online retailers, September 2023 to December 2023.

Source: IQVIA OTC Naloxone Reporting. Data provided 1/30/2024.

* Packages sold indicates number of boxes containing two nasal sprays. Packages calculated from dollars in sales reported from both electronic point of sale retailers and passive e-receipt collection from a panel of two million individuals, then divided by an estimated price of \$45 per package.

Data Gaps: Other Settings for OTC Naloxone



Rx and OTC Naloxone: Data Limitations

- Lack of visibility into harm reduction programs
 - Data on direct sales, donations, and use of products available through non-traditional settings (eg, harm reduction programs) not captured
- Incomplete coverage
 - OTC sales data on consumer purchases from Costco, Dollar Tree, 99 Cent, specialty stores, kiosks, convenience stores, vending machines, and other non-traditional settings not captured
- Limited data by geography
 - Sub-national data available for outpatient dispensing of Rx naloxone; however, these data account for a small proportion of total naloxone availability

Research Efforts to Examine Optimal Naloxone Administration Paradigms



Fatal Overdoses Workshop: Innovation Opportunities

- Titratable and selective OD reversal agents for a milder/more gradual reversal (eg, naloxone pen)
- Devices for automated OD detection/alert and assisted ventilation outside hospitals
- Pre-use agents to prevent respiratory depression or post-use respiratory stimulants
- Ideal naloxone dosing strategy in community setting vs hospital setting



Overdose Reversal: Unanswered Questions

Pharmacology in Emergency Medicine

DO HIGHER DOSES OF NALOXONE INCREASE THE RISK OF PULMONARY COMPLICATIONS?

Kirstin Acus, MD,* Jessica Krizo, PhD,† Spencer Prete, MD,* Thomas Langlois, MD,* Ashley Pajela, MD,*
Caroline Mangira, BSN, MPH,† Erin Simon, DO,* and Amy Raubenolt, MD*

Drug Alcohol Depend. 2021 September 01; 226: 108838. doi:10.1016/j.drugalcdep.2021.108838.

Neurocognitive impairments and brain abnormalities resulting from opioid-related overdoses: A systematic review

Erin L. Winstanley^{a,b,*}, James J. Mahoney III^{a,b}, Felipe Castillo^c, Sandra D. Comer^c

Addiction Biology
Open Access

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ADDICTION

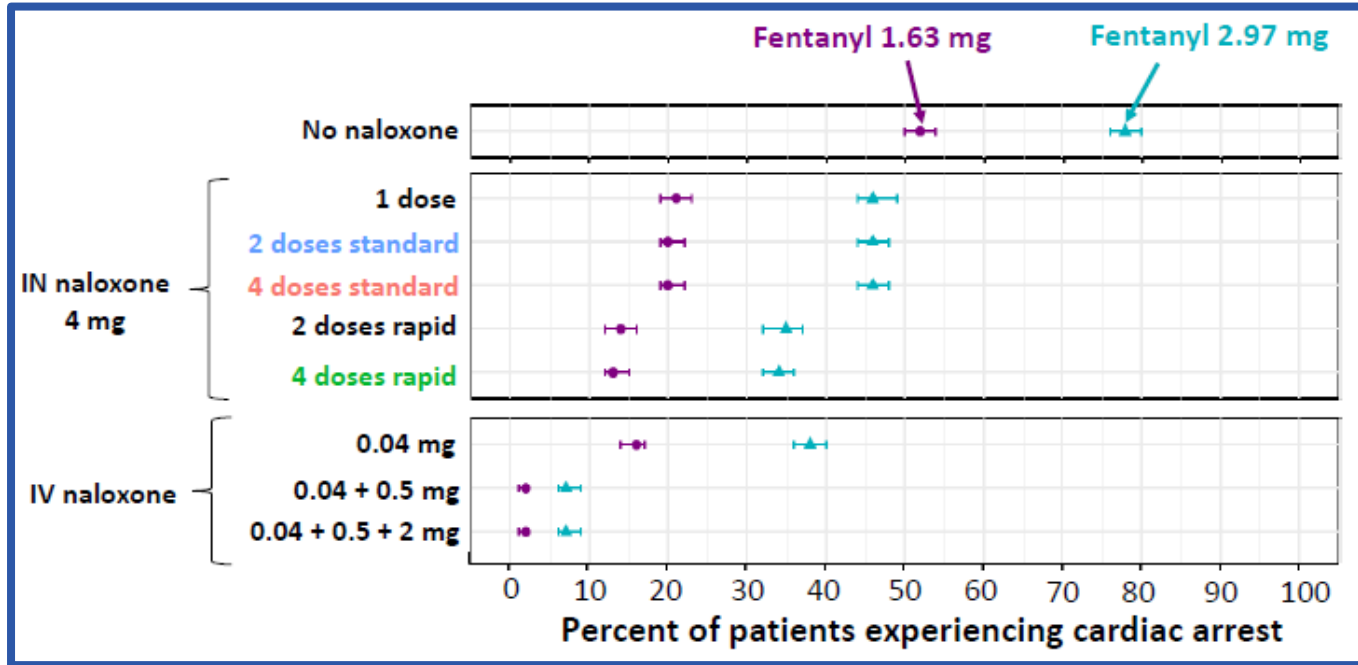
ORIGINAL ARTICLE |  Open Access |  

Hippocampal volume loss in individuals with a history of non-fatal opioid overdose

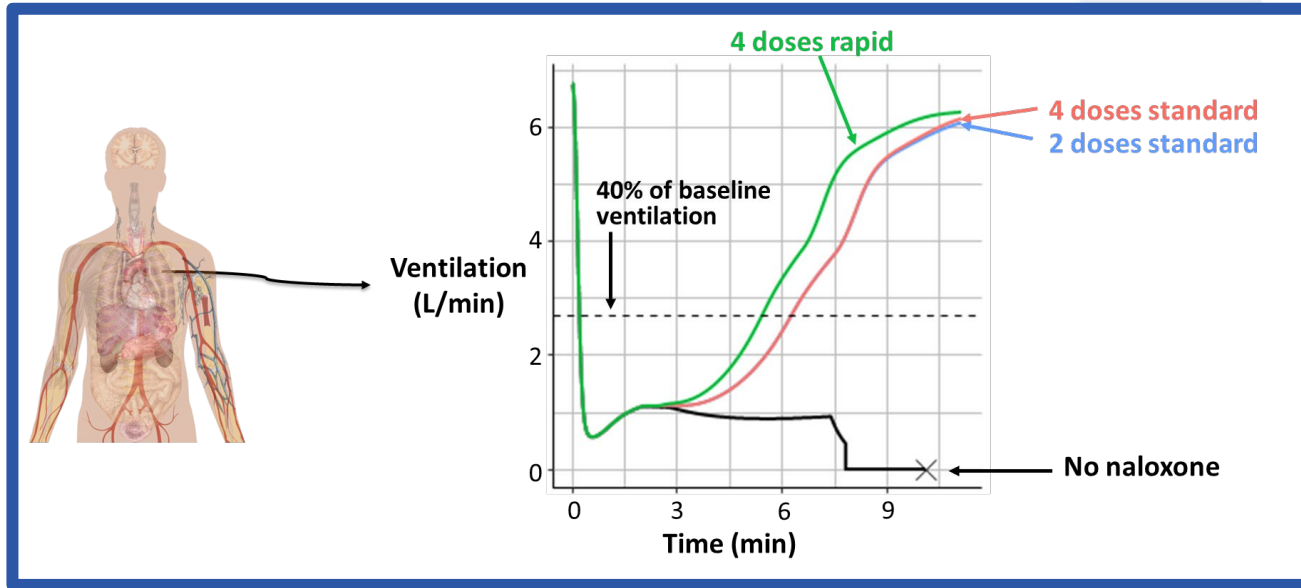
Dustin R. Todaro, Xinyi Li, Laila S. Pereira-Rufino, Peter Manza, Ilya M. Nasrallah, Sandhitsu Das, Anna Rose Childress, Henry R. Kranzler, Nora D. Volkow, Daniel D. Langleben ... [See all authors](#) ▾

First published: 20 September 2023 | <https://doi.org/10.1111/adb.13336>

Modeling Reversal of Opioid-Induced Effects



Translational Research to Optimize Naloxone Dosing in the Community



Overdose Reversal: Recent Real-World Data

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search

Morbidity and Mortality Weekly Report (*MMWR*)

Comparison of Administration of 8-Milligram and 4-Milligram Intranasal Naloxone by Law Enforcement During Response to Suspected Opioid Overdose — New York, March 2022–August 2023

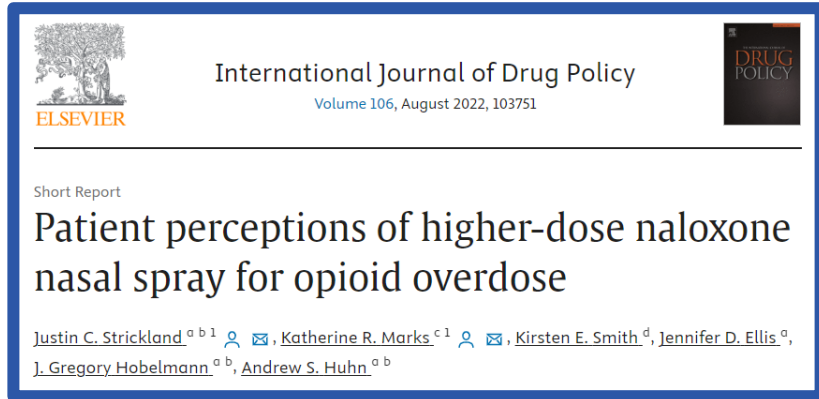
Weekly / February 8, 2024 / 73(5);110–113

[Print](#)

Please note: This report has been corrected.

Emily R. Payne, MSPH¹; Sharon Stancliff, MD¹; Kirsten Rowe, MS¹; Jason A. Christie²; Michael W. Dailey, MD³ ([VIEW AUTHOR AFFILIATIONS](#))

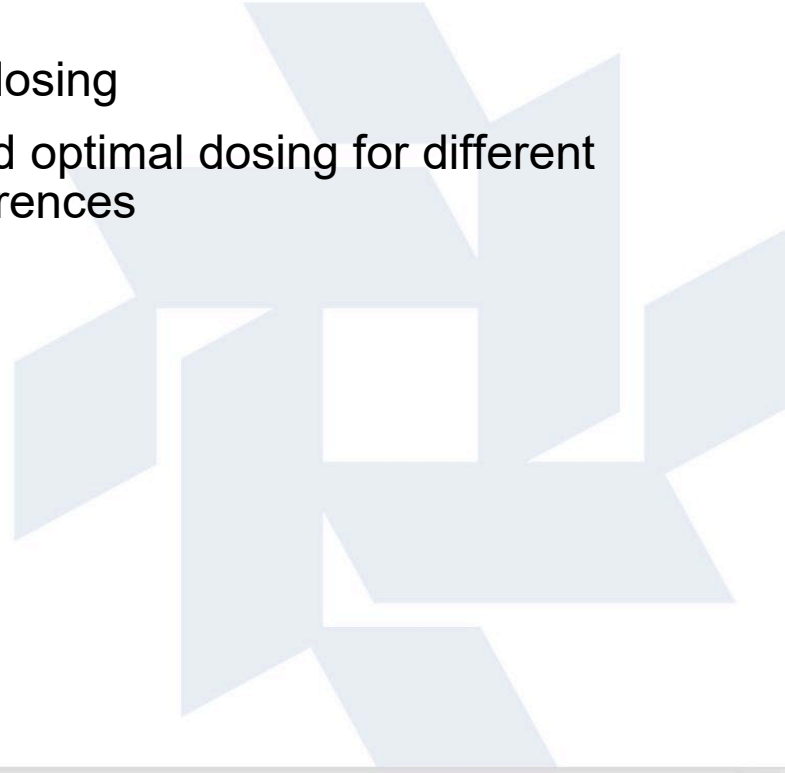
What Do Patients with OUD Think?



- Distribution efforts of higher-dose naloxone may be impacted by concerns of precipitated withdrawal
- In study of OUD patients (n=1152), little evidence for widespread avoidance of higher-dose formulations was found
 - Most patients had no preference (48.4%) or preferred a higher-dose formulation (35.9%) if experiencing an overdose
- High-dose preference was related to recent suspected fentanyl exposure

Conclusion

- FDA continues working to broaden access to overdose reversal agents, including Rx and non-Rx naloxone
- There is no one answer to optimal naloxone dosing
 - More work needs to be done to understand optimal dosing for different populations with different needs and preferences



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- David Strauss, MD, PhD



Thank you!





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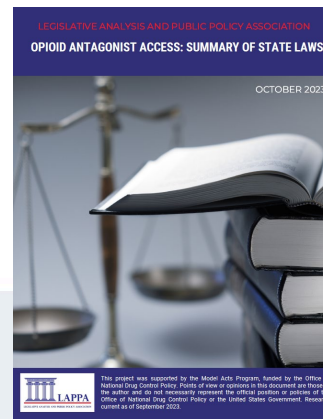
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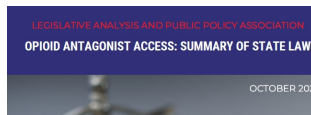
Legislative Analysis and Public Policy Association



- <https://legislativeanalysis.org/>
- 501(c)(3) nonprofit organization
- Recipient of ONDCP's Model Acts Program Grant (2019-21, 2021-23, 2023-25)
- Primary activities
 - Draft model state legislation
 - Conduct legal and legislative research and policy analysis



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Opioid Antagonist Access: Summary of State Laws

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NEW HAMPSHIRE	
Statute(s), regulation(s), and effective date(s)	<ul style="list-style-type: none">• N.H. REV. STAT. ANN. § 318-B:15 (West 2023) (eff. June 2, 2015) (immunity provisions).• N.H. REV. STAT. ANN. § 417:4 (West 2023) (eff. July 1, 2019) (insurance practices).
Term(s) used	Opioid antagonist.
Substantive amendment(s) to law(s)	None.
Standing order	New Hampshire does not have a statewide naloxone standing order, but N.H. REV. STAT. ANN. § 318-B:15 (West 2023) allows naloxone to be dispensed through a standing order. A licensed medical provider can have a prescription on file at any pharmacy that allows pharmacists to dispense naloxone to anyone requesting it.
Persons who can prescribe	Health care professional authorized to prescribe an opioid antagonist.
Prescriber immunity	No health care professional who, acting in good faith and with reasonable care, prescribes an opioid antagonist directly or by standing order is subject to any criminal or civil liability, or any professional disciplinary action for any action related to the prescribing of naloxone or any outcome resulting from said action.
Persons who can dispense or distribute	<ul style="list-style-type: none">• Health care professional authorized to prescribe an opioid antagonist.• Pharmacist.
Dispenser immunity	No health care professional or pharmacist who, acting in good faith and with reasonable care, dispenses an opioid antagonist directly or by standing order is subject to any criminal or civil liability or any professional disciplinary action for any action related to the prescribing of naloxone or any outcome resulting from said action.
Persons who can receive or administer ("laypersons")	<ul style="list-style-type: none">• Person at risk of experiencing an opioid-related overdose.• Family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.
Layperson possession without prescription	Not directly addressed by statute.
Layperson administration	A person may administer an opioid antagonist to another person who he or she believes is suffering an opioid-related overdose.
Layperson immunity	No person who, acting in good faith and with reasonable care, administers an opioid antagonist to another person who the person believes is suffering an opioid-related drug overdose is subject to any criminal or civil liability, or any professional disciplinary action related to the act of administering the opioid antagonist.

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Opioid Antagonist Access: Summary of State Laws

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NEW HAMPSHIRE	
Training and education requirements	Not addressed by statute.
Co-prescription requirements	Not addressed by statute.
Requirements placed on insurers	It is unfair discrimination in the business of life, life annuity, or disability coverage, to refuse to insure or to continue to insure, or limit the amount, extent, or kind of coverage based on the applicant who is also the proposed insured having filled a prescription for an opioid antagonist, when that prescription is not relevant to the applicant's health, but rather is designed to promote the health of someone else. For any such prescription, the carrier must inquire with the applicant as to the reason for the prescription and may request documentation that verifies the applicant's response prior to issuing an underwriting decision.
Opioid antagonists in schools	Not addressed by statute.
Dispensing or administration reported to PDMP	According to information PDMP/TIAC, New Hampshire tracks naloxone administration in the PDMP. ⁴⁶ LAPPA did not locate a statute or regulation directing this reporting.
Other provisions of note	None.
Recently proposed legislation	None.

⁴⁶ "PDMP Policies and Capabilities," Prescription Drug Monitoring Program Training and Technical Assistance Center, last accessed August 2023, https://www.odmcp.org/sites/default/files/summaries/New_Hampshire_Summary_Profile.pdf

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Legislative Analysis and Public Policy Association

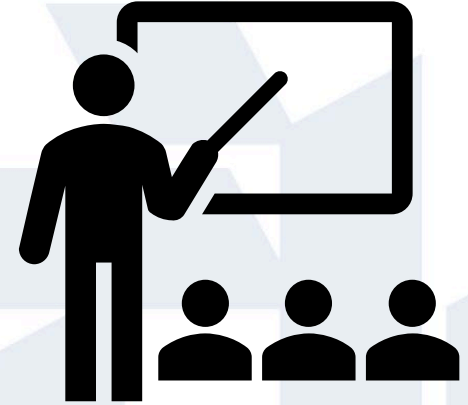


- Model Acts grant
 - ❖ Model laws (17 published)
<https://legislativeanalysis.org/model-laws/>
 - ❖ 50-state Summary of Laws (18 published)
<https://legislativeanalysis.org/research/>
 - ❖ Fact sheets (41 published)
<https://legislativeanalysis.org/fact-sheet/>
 - ❖ Case Law Monitor (six per year)
<https://legislativeanalysis.org/case-law-monitor/>
 - ❖ News Bites (six per year)
<https://legislativeanalysis.org/news-bites/>
 - ❖ Knowledge Lab webinars (six in fall 2023)
<https://legislativeanalysis.org/model-law-virtual-knowledge-labs/>
 - ❖ Technical assistance (TA)
- TA on other subawards



Presentation content

- Return to ideas offered during 2023 Rx Summit session
- Rx and OTC overdose reversal agent (ORA) options
- Recent surveys about OTC availability in pharmacies
- How does OTC fit into an in-force ORA access law?
- State legislation expressly addressing OTC products



Where are we right now?

“In theory, it’s good. In retrospect, we’ll be happy that this happened as an event in history. Right now, it’s distracting.”

Maya Doe-Simkins, Co-director, Remedy Alliance

Source: Sara G. Miller and Berkeley Lovelace Jr., *Where’s the Narcan? At pharmacies across the US, the OTC antidote can be hard to find*, NBC News (March 11, 2024), <https://www.nbcwashington.com/news/national-international/wheres-the-narcan-at-pharmacies-across-the-us-the-otc-antidote-can-be-hard-to-find/3564493/>

2023 Rx Summit questions/thoughts

- What happens to OTC overdose reversal agent (ORA) market?
- How will individuals pay for OTCs?
- Will Congress/states enact laws re OTC cost/coverage?
- Do states change standing orders, co-prescribing requirements, layperson administration, and other ORA provisions in statutes?
- Will Rx(s) for ORAs still be needed?
- What will the in-store buying process look like?



Rx and OTC overdose reversal agent options

OORMS AVAILABLE TO THE PUBLIC

OORM	Brand	Formulation	Dosage	Availability
Naloxone	N/A	Adaptable Nasal Spray	2 mg/ml	Rx, community naloxone distribution, harm reduction organizations
Naloxone	RiVive™	Single-use Nasal Spray	3 mg	Rx, OTC, community naloxone distribution, harm reduction organizations
Naloxone	Narcan, generic	Single-use Nasal Spray	4 mg/0.1 ml	Rx, OTC, community naloxone distribution, harm reduction organizations

Naloxone	N/A	Single-dose Vial Intramuscular Injection; can also be given intravenously or subcutaneously	0.4 mg/ml	Rx, community naloxone distribution, harm reduction organizations
Naloxone	Zimhi®	Intramuscular or subcutaneous Auto-Injection	5 mg/ml	Rx, community naloxone distribution, harm reduction organizations
Naloxone	Kloxxado®	Single-use Nasal Spray	8mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations
Nalmefene	Opvee	Single-use Nasal Spray	2.7 mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations

Source: *Overdose Prevention and Response Toolkit*, Substance Abuse and Mental Health Services Administration (January 2024), <https://store.samhsa.gov/product/overdose-prevention-response-toolkit/pep23-03-00-001>

OTC availability in pharmacies

Narcan, Now Available Without a Prescription, Can Still Be Hard to Get
KFF Health News – October 11, 2023

Narcan saves lives but can be hard to find in Kansas City
Missouri Independent - January 2, 2024

Narcan saves lives — but finding it can be onerous in Massachusetts
Boston Globe - January 18, 2024

Access to Narcan varies across local pharmacies
Worcester Telegram & Gazette – February 4, 2024

The drug that stops opiate overdoses is now over-the-counter. Why it can be hard to find
The MetroWest Daily News – February 14, 2024

Lifesaving Narcan tough to find in Texas pharmacies
Texas Tribune – March 7, 2024

Where's the Narcan? At pharmacies across the US, the OTC antidote can be hard to find
NBC News— March 11, 2024

OTC availability in pharmacies



MAURA T. HEALEY
Governor

KIMBERLEY DRISCOLL
Lieutenant Governor

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

KATHLEEN E. WALSH
Secretary

ROBERT GOLDSTEIN, MD, PhD
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

December 20, 2023

TO: Massachusetts Retailers

FROM: Massachusetts Department of Public Health

RE: Over the Counter (OTC) Naloxone

This memo outlines information on the availability of the new over the counter (OTC) naloxone in Massachusetts. It also directs you to resources available for you and your customers to facilitate availability and access to naloxone.

What to know: The approval of OTC intranasal naloxone products is intended to increase the accessibility of naloxone as a key strategy to reducing fatal overdoses in communities. The addition of OTC naloxone access also aims to mitigate the stigma associated with seeking out this product.

On March 29th, 2023, the Food and Drug Administration (FDA) approved a 4-mg intranasal naloxone formulation (Narcan, Emergent Biosolutions) for over the counter (OTC) sale. A generic version of the 4-mg product (Padagis, Padagis) and a 3-mg intranasal branded formulation of naloxone (RiVive, Harm Reduction Therapeutics) were both approved in July 2023. The first formulation of OTC naloxone—the 4-mg intranasal by Emergent Biosolutions more commonly known as “Narcan”—officially became available for retailers to sell in September, 2023.

OTC availability in pharmacies

Cost and coverage: OTC naloxone access aims to reduce the stigma of acquiring and carrying naloxone. However, OTC access does not mean that the cost of naloxone will make it affordable for all people at risk of overdose and their networks. To reduce the financial burden of purchasing OTC naloxone, retailers should advertise and foster the use of healthcare savings or flexible spending accounts that can be used to cover the entire cost of OTC naloxone. Some insurance companies may cover the OTC naloxone products. **MassHealth will cover most prescription and OTC naloxone with no prior authorization and at \$0 copay.**

for Massachusetts retailers

Placement of OTC naloxone: Retailers should enable anonymous access to naloxone directly on a shelf, without locking it behind a cabinet nor in a container that necessitates contacting an employee to access it. Stocking OTC naloxone exclusively behind the counter limits access to the product to those willing to ask to purchase it from a clerk or pharmacy staff member. Businesses that can select where products will be shelved should consider placing OTC naloxone toward the front of stores or cash registers to maximize visibility.

formulation (Narcan, Emergent Biosolutions) for over the counter (OTC) sale. A generic version of the 4-mg product (Padagis, Padagis) and a 3-mg intranasal branded formulation of naloxone (RiVive, Harm Reduction Therapeutics) were both approved in July 2023. The first formulation of OTC naloxone—the 4-mg intranasal by Emergent Biosolutions more commonly known as “Narcan”—officially became available for retailers to sell in September, 2023.

OTC availability in pharmacies



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

The Board of Registration in Pharmacy

Policy 2024-01: Naloxone Dispensing

Although several naloxone products are now available over-the-counter, [M.G.L. c. 94C, § 19B](#) provides for a statewide standing order that continues to allow any person to purchase it using their prescription insurance. Massachusetts state law specifically allows for an individual to obtain naloxone with the intention to administer it to another person.

Pharmacists and other pharmacy licensees may administer naloxone to someone appearing to be experiencing an opioid-related overdose and will not be subject to criminal or civil liability or any professional disciplinary action in accordance with [state law](#).

Since all areas of Massachusetts experience high incidences of opioid-related overdoses or deaths, Massachusetts pharmacies are required to stock naloxone in accordance with [M.G.L. c. 94C, § 19C](#). Pharmacies must maintain a continuous, sufficient supply of naloxone to meet the needs of the community.

Additionally, as required by [M.G.L. c. 94C, § 19B](#), each Massachusetts pharmacy must report the number of naloxone doses dispensed. See section II for details.

I. General Naloxone Dispensing

1. Naloxone rescue kits must be labeled with the expiration date of the included naloxone unit(s).
2. A pharmacy may dispense naloxone either pursuant to a patient-specific prescription or via the [statewide standing order](#).

Adopted: 1/11/24

Page 1 of 3

3. The pharmacist should consider recommending naloxone when >50 MME per day of opioids is prescribed.
4. The pharmacy must make a reasonable effort to determine if the purchaser's prescription insurance covers naloxone.
5. For insurance billing and cost-sharing purposes, the pharmacy must treat the transaction as the dispensing of a prescription to the person purchasing naloxone. However, "Naloxone Rescue Kit" should be used in place of the name and address in order to create a patient profile and prescription label.
6. Although there may be limits to the amount of naloxone covered by insurance, there is no regulatory limit to the amount of naloxone that may be dispensed to an individual.
7. The pharmacy must counsel the individual and distribute an Opioid Antagonist Information Pamphlet. Any of the following may be used for the Opioid Antagonist Information Pamphlet:
 - a) [Stop an Overdose Wallet Card](#) in English, Portuguese, and Spanish
 - b) [Steps of Naloxone Administration](#)
 - c) [Opioid Overdose Basics](#)
 - d) [Massachusetts overdose education and naloxone rescue information](#)

How does OTC fit into ORA access laws?

Standing order	Persons who can receive or administer (“laypersons”)	Co-prescription requirements
Persons who can prescribe		Requirements placed on insurers
Prescriber immunity		Opioid antagonists in schools
Persons who can dispense or distribute		Dispensing or administration reported to PDMP
Dispenser immunity		
	Layperson possession without prescription	Other provisions of note
	Layperson administration	
	Layperson immunity	
	Training and education requirements	

Source: *Opioid Antagonist Access: Summary of State Laws*, Leg. Analysis & Pub. Policy Assoc. (October 2023), <https://legislativeanalysis.org/opioid-antagonist-access-summary-of-state-laws/>

Federal and state legislation

- January 1, 2023 to March 14, 2024
- Congress
 - Bills introduced referencing ORAs→ 42
 - Bills enacted referencing ORAs→ 1
 - Bills introduced referencing OTC→ 9
- State legislatures
 - Bills introduced bills referencing ORAs→ 800+
 - Bills enacted referencing ORAs→ 175+
 - Bills enacted referencing OTC→ 14



Federal and state legislation (enacted)

- California
 - CAL. HEALTH & SAFETY CODE § 127697 (West 2024)
 - California Health and Human Services Agency (CHHSA) “may enter into partnerships regarding OTC naloxone products”
- Connecticut
 - CONN. GEN. STAT. ANN. § 12-412(120) (West 2024)
 - “Opioid antagonists” added to list of “nonprescription drugs or medicines” not subject to state sales tax
- North Carolina
 - N.C. GEN. STAT. ANN. § 90-12.7 (West 2024)
 - Reference to OTC products added to statute covering distribution of ORAs and immunity for administration



Federal and state legislation (proposed)

- Congress - S.1373 / H.R.4005

<https://www.congress.gov/bill/118th-congress/senate-bill/1373?q=%7B%22search%22%3A%22s1373%22%7D&s=4&r=1>

<https://www.congress.gov/bill/118th-congress/house-bill/4005?q=%7B%22search%22%3A%22hr4005%22%7D&s=1&r=1>

- “Naloxone Affordability Act of 2023”
- Requires GAO to study health insurance coverage and out-of-pocket costs for “naloxone” as an OTC medication

- Congress - H.R.6161

<https://www.congress.gov/bill/118th-congress/house-bill/6161?q=%7B%22search%22%3A%22h>

- “SAVE Act of 2023”
- Amends tax code to allow amounts paid for OTC “naloxone” to be used in medical expense deduction

- Congress – H.R.5506

<https://www.congress.gov/bill/118th-congress/house-bill/5506/text?s=3&r=1&q=%7B%22search%22%3A%22hr5506%22%7D>

- “Hospitals As Naloxone Distribution Sites Act”
- Requires no-cost coverage under Medicaid for ORAs furnished by hospitals to patients



Federal and state legislation (proposed)

- 2023 California Assembly Bill No. 1060 (vetoed)
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240AB1060
 - ORAs (including OTC) must be covered by health insurers with a \$10 co-pay cap
- 2023 California Assembly Bill No. 2271
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240AB2271
 - like AB 1060, but contingent on funding from Naloxone Distribution Project
- 2023 California Senate Bill No. 997
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240SB997
 - authorizes schools to adopt policies allowing 6-12th graders to carry OTC “naloxone” at school
- 2024 Maryland House Bill No. 736 / Senate Bill No. 497 (both withdrawn by sponsors) –
<https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB0736?ys=2024RS>
<https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/SB0497?ys=2024RS>
 - ORAs (including OTC) must be covered by health insurers with a \$10 co-pay cap

Federal and state legislation (proposed)

- 2023 Massachusetts House Bill No. 1142 / Senate Bill No. 667
<https://malegislature.gov/Bills/193/H1142>
<https://malegislature.gov/Bills/193/S667>
 - prohibits insurer cost sharing for ORAs (could be read to include OTCs)
- 2024 Missouri House Bill No. 1852
<https://house.mo.gov/Bill.aspx?bill=HB1852&year=2024&code=R>
 - relates to keeping “naloxone” on hand in schools and training of high school students and teachers; “naloxone” defined as OTC naloxone
- 2023 New York Assembly Bill No. 8075 –
https://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=ab8075&term=&Summary=Y&Text=Y
 - changes “opioid antagonist” to ORA in law and requires department of health to make available any formulation or dosage approved by FDA (presumably includes OTC)



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Federal Efforts to Expand Access to Naloxone and Other Opioid Overdose Reversal Medications

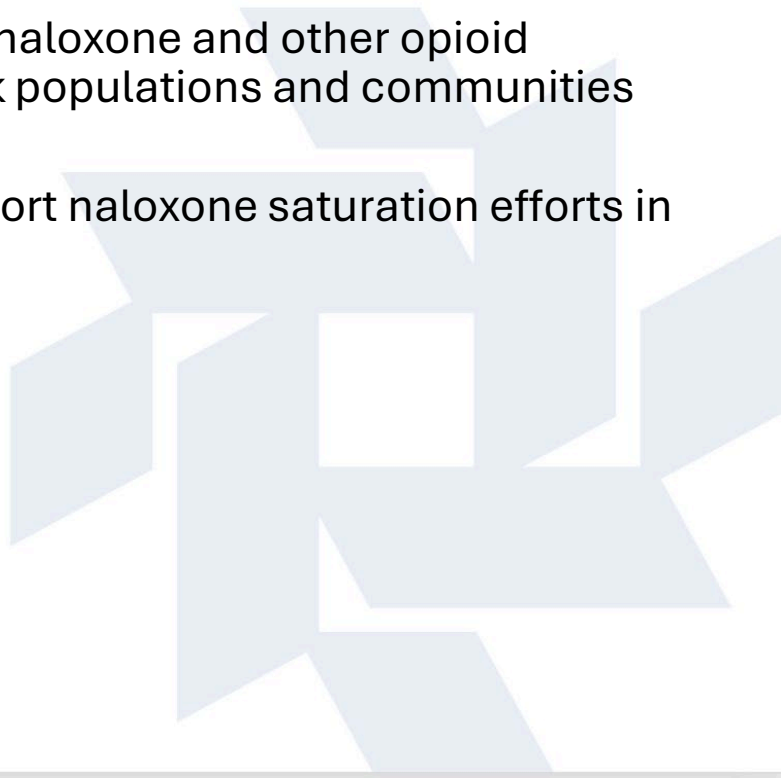
Yngvild K. Olsen, MD, MPH

*Director, Center for Substance Abuse Treatment (CSAT)
Substance Abuse and Mental Health Services Administration
U.S. Department of Health & Human Services*

Learning Objectives

At the end of this session, attendees will be able to

1. Discuss 2 federal efforts to increase access to naloxone and other opioid overdose reversal medications among high-risk populations and communities
2. Explain how federal grants can be used to support naloxone saturation efforts in states and communities



SAMHSA Overdose Prevention and Response Toolkit



- Updated to reflect latest overdose trends
- Practical tips for preventing, recognizing, and responding to an overdose
- Information on available opioid overdose reversal medications (OORM)
- Information for specific audiences
 - People who use drugs
 - People who take prescription opioids
 - Practitioners and health systems
 - First Responders
 - Policy and systems considerations

Specifics on OORM and Harm Reduction Strategies

OORM	Brand	Formulation	Dosage	Availability	Considerations
Naloxone	N/A	Adaptable Nasal Spray	2 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Assembly required to attach nasal spray adapter to needle-less syringe. Not approved by FDA. Possible to titrate to meet the needs of the patient and facilitate a gentler overdose reversal with potential for less severe withdrawal in people with opioids in their body.
Naloxone	RiVive™	Single-use Nasal Spray	3 mg	Rx, OTC, community naloxone distribution, harm reduction organizations	Lower dose can facilitate a gentler overdose reversal with less severe withdrawal in people with opioids in their body.
Naloxone	Narcan, generic	Single-use Nasal Spray	4 mg/0.1 ml	Rx, OTC, community naloxone distribution, harm reduction organizations	May cause withdrawal symptoms in people who have opioids in their body.
Naloxone	N/A	Single-dose Vial Intramuscular Injection; can also be given intravenously or subcutaneously	0.4 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Has been studied and used in the real world to reverse overdoses for decades; cheapest naloxone available; easy to use.
Naloxone	Zimhi®	Intramuscular or subcutaneous Auto-Injection	5 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Accessible product format that auto-injects the medication; high dose compared to other products; may cause severe withdrawal symptoms in people with opioids in their body.
Naloxone	Kloxxado®	Single-use Nasal Spray	8mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations	High dose compared to other products; may cause severe withdrawal symptoms in people with opioids in their body.
Nalmefene	Opvee	Single-use Nasal Spray	2.7 mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations	Longer lasting than naloxone, but may cause severe extended withdrawal in people with opioids in their body.

RISK FACTOR AND ASSOCIATED HARM REDUCTION STRATEGY

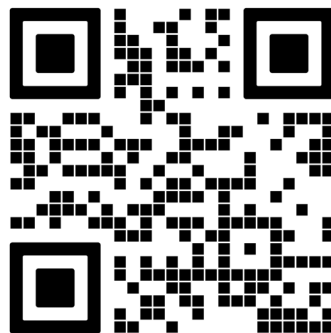
Overdose Risk Factor	Harm Reduction Strategy to Reduce Risk of Overdose
You experience a recent period of not taking any opioids, such as an emergency department stay, jail, or detox, or you are starting to use opioids again after a period of non-use or administration of an opioid antagonist such as naloxone.	<ul style="list-style-type: none"> Never use drugs alone, tell a friend or call 988 to talk about overdose risk with a professional or peer counselor. Start with the lowest possible amount of drug. Use or consume drugs slowly and observe their effects. Test unregulated drugs purchased on the street for fentanyl. If you took medications such as methadone or buprenorphine while incarcerated but then stopped, starting to use street drugs upon release increases risk of overdose.
You are using any kind of drug.	<ul style="list-style-type: none"> Start low and go slow. Start with a low dose and only increase gradually. Do not use alone. Use with a trusted person who is alert and can respond in the event of overdose or let a trusted person know to check on you. Look up a local "never use alone" hotline. Stagger your use. If you are using with a group, be sure that someone is alert and can respond in the event of overdose. Avoid using drugs, including opioids, with alcohol. Taking opioids in combination with alcohol and/or other depressant medications like benzodiazepines or tranquilizers can greatly increase the risk of overdose. Always carry an OORM. Be familiar with signs of an overdose and be prepared to respond with an OORM. See earlier section on OORM and responding to an overdose. Test it. Using test strips or other drug checking equipment to determine the presence of fentanyl and other drugs can help you decide how to use a drug to reduce risk for overdose. Listen to your body. Overall health can impact overdose risk. Rest, eat, and hydrate^{15,16}
You are changing your method of administration of an opioid, altering the opioid by crushing it, or taking opioids differently from how they were prescribed.	<ul style="list-style-type: none"> If you obtain unregulated opioids on the street, consider the increased risk of switching between different types and strengths of opioids, and test drugs to know the contents. Your risk of overdose increases when injecting or smoking opioids as compared to snorting or swallowing them. You can reduce risk by using alternatives to injecting or smoking. Crushing or otherwise manipulating prescription opioids can make the dose unpredictable, and risk of overdose increases if you snort instead of swallowing a drug.

Overdose Response Dos and Don'ts

OVERDOSE RESPONSE STEPS

Check for a response.

- 1) Give naloxone or other OORM.
- 2) Call 911 and support the person's breathing. Administer rescue breaths or place the person in the recovery position.
- 3) Wait for EMS to arrive.



DO attend to the person's breathing and cardiovascular needs by performing rescue breathing and/or chest compressions. Rescue breathing can be lifesaving itself. If you have access to it, administering supplemental oxygen can also be helpful.

DO administer an opioid overdose reversal medication if the person is not breathing. Give an additional dose if there is no response within 2-3 minutes of each dose.

DO put the person in the "recovery position" on their side, if you must leave them unattended for any reason, or if their breathing has returned but they are still not fully awake. In this case, monitor breathing closely.

DO stay with the person and keep the person warm.

DON'T slap or forcefully try to stimulate the person; it will only cause further injury. If you cannot wake the person by shouting or rubbing your knuckles on the sternum (center of the chest or rib cage), the person may be unconscious.

DON'T put the person into a cold bath or shower. This increases the risk of falling, drowning, or going into shock.

DON'T inject the person with any substance (e.g., saltwater, milk, stimulants). The only safe and appropriate treatment is an opioid overdose reversal medication.

DON'T try to make the person vomit drugs that may have been swallowed. Choking or inhaling vomit into the lungs can cause a fatal injury.

Naloxone and Other Opioid Overdose Reversal Medications in SAMHSA Grant Programs

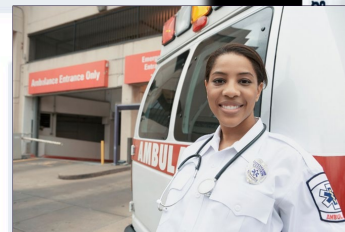
- Harm Reduction Grant Program
- Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths
- First Responders-Comprehensive Addiction and Recovery Grants
- Improving Access to Overdose Treatment
- Tribal Opioid Response Grant Program
- State Opioid Response Grant Program
- Substance Use Prevention, Treatment, and Recovery Services Block Grant



<https://www.samhsa.gov/grants/grants-dashboard/forecasts>

Naloxone Saturation Efforts

- FY22: SAMHSA Required all states to submit Naloxone saturation plans
 - Learning Community Jan 2023
 - Policy Academy July 2023
 - Learning collaborative 2024
 - 2nd Policy Academy April 9-10, 2024
 - Individual state technical assistance



Q&A