# NORTH CAROLINA NALOXONE DISTRIBUTION TOOLKIT

NCDHHS Division of Public Health



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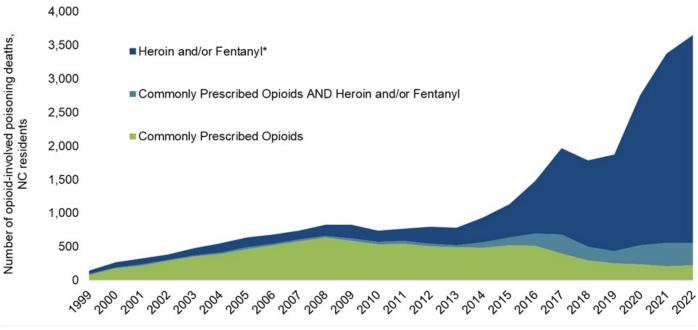
# INTRODUCTION

The North Carolina Naloxone Distribution Toolkit was created by the North Carolina Department of Health and Human Services, Division of Public Health's Injury and Violence Prevention Branch to guide local health departments, harm reduction agencies, and other community-based organizations through the process of implementing a naloxone distribution program.

For more information on content in this toolkit and access to materials from the Injury and Violence Prevention Branch, please email: <u>BeInjuryFreeNC@dhhs.nc.gov</u> or <u>NaloxoneSaves@gmail.com</u>.

### **Background & Rationale**

Opioid overdose deaths have been steadily increasing in the United States and in North Carolina since 1999. Since 2013, North Carolina has seen a steady increase in overdose deaths consisting of illicitly manufactured opioids, predominately fentanyl. In 2022, these types of opioids were involved in 94% of all unintentional opioid-involved poisoning deaths. Additionally, a growing number of overdose deaths involve multiple substances in combination (i.e., polysubstance use).



\*Heroin and/or Fentanyl (mainly illicitly manufactured fentanyl and fentanyl analogues)

Technical Notes: Cases with only an Opium (T40.0) or only Other and Unspecified Narcotics (T40.6) code are excluded;

All intent medication and drug poisoning: X40-X44 and any mention of T40.1 (Heroin), T40.2 (Other Opioids), T40.3 (Methadone), T40.4 (Fentanyl/fentanyl

- analogues) and/or T40.6 (Other/unspecified narcotics); Limited to NC residents
- Source: Deaths-NC State Center for Health Statistics, Vital Statistics, 1999-2022

Analysis by Injury Epidemiology and Surveillance Unit

Deaths due to opioid overdoses can be reduced with a medication called naloxone (known by brand names including Narcan<sup>®</sup>). Naloxone belongs to a group of medications called opioid antagonists. It works by binding to opioid receptors in the brain and blocking the effects of the opioid drug for 30-90 minutes, reversing the respiratory depression (slow/shallow breathing) that occurs as a result of overdose. It is an effective, quick acting medication that can be administered through intramuscular, intravenous, subcutaneous, or intranasal pathways. Naloxone only works when an opioid is present in the body and cannot reverse the effects of other drugs such as benzodiazepines, alcohol, cocaine, or stimulants. However, these drugs are often mixed with opioids, in which cases naloxone may be effective. Naloxone is safe to use, has no potential for misuse, has minimal adverse effects, and has no contraindications with the exception of an allergy or sensitivity to naloxone hydrochloride.

Laypeople can easily be trained to use naloxone to reverse an overdose. Community-based distribution of naloxone to those at highest risk of overdose and their close contacts has shown to be an effective, safe, and cost-efficient strategy to reduce overdose deaths (Wheeler et al., 2014) (Naumann et al., 2019) (Irvine et al., 2022).

North Carolina has been a national leader in community distribution of naloxone – most notably through the work of established syringe services programs (SSPs). From 2022-2023, NC SSPs distributed over 109,000 naloxone kits and received nearly 17,000 overdose reversal reports. (See NC Safer Syringe Initiative Annual Report here). North Carolina was also the first state to have an EMS naloxone leavebehind program, whereby EMS personnel give people who decline transport to the hospital after an overdose a free naloxone kit.

This toolkit intends to help organizations understand the laws and logistics implicated in naloxone distribution to further promote community distribution of naloxone in North Carolina.



# LAWS & POLICIES

### Naloxone Access Law

To address increasing rates of deaths involving opioids, the North Carolina legislature authorized the community distribution of naloxone. By promoting community distribution, state law increases access to naloxone for North Carolinians who are at highest risk for overdose and who may be unable to get a naloxone prescription or unlikely to visit a pharmacy to get naloxone.

## History of Naloxone Legislation in North Carolina

- 2013: Naloxone Access Law Passed Under <u>G.S. 90-12.7</u> (formerly codified as G.S. 90-106.2), first passed in 2013, a health care provider may write a standing order to allow the dispensing of naloxone to people at risk for an overdose and to those in a position to help others at risk of an overdose (third-party prescribing). The statute provides criminal and civil liability protection to health care providers who prescribe naloxone and to those who administer naloxone to people experiencing an overdose.
- 2014: Naloxone Added to Local Health Department Drugs and Devices Dispensed by Trained Local Health Department Registered Nurses.

In January 2014, the NC Board of Pharmacy expanded the <u>local health department list of drugs and</u> <u>devices to be dispensed by local health department registered nurses that have training specifically for</u> <u>medication dispensing</u> to include naloxone. Since naloxone is on that list, a health department's medical director or other health department qualified prescriber can write a standing order or individual patient prescription to allow naloxone to be dispensed by trained registered nurses in a local health department and off site on community outreach.

#### 2016: State Health Director's Standing Order for Pharmacists Signed

In 2016, G.S. 90-12.7 was amended to establish the authority of the State Health Director to issue a statewide standing order for dispensing of naloxone by pharmacists.

On June 20, 2016, the State Health Director of North Carolina signed a standing order to authorize any pharmacist practicing in the state and licensed by the North Carolina Board of Pharmacy to dispense naloxone to any person who voluntarily requests naloxone and is either:

- At risk of experiencing an opiate-related overdose
- A family member or friend of a person at risk of experiencing an opiate-related overdose
- A person in the position to assist another person at risk of experiencing an opiate-related overdose

In 2023, Session 2023-15 expanded the state's definition of opioid antagonist to include all FDA approved opioid antagonists for the treatment of opioid overdose. The State Health Director's Standing Order for Pharmacists was updated accordingly and can be found <u>here</u>, along with the list of approved products for pharmacist dispensing <u>here</u>.

2017: Provision Allowing Distribution Standing Orders to be Written by Medical Providers

In 2017, as part of the STOP Act, the NC Legislature added a provision to G.S. 90-12.7 allowing health care providers to write distribution standing orders to allow organizations, including local health departments and other community-based organizations, to distribute naloxone in the community.

## Standing Orders and Naloxone

A **standing order** is a medical order that authorizes the dispensing **or** distribution of a medication to any person who meets criteria designated by the prescriber.

Traditionally, a prescriber could only prescribe medication to a person with whom he or she has a patientprovider relationship. However, this arrangement is not practical in the context of naloxone because 1) many of the people at high risk for overdose do not regularly see a prescriber, and 2) naloxone cannot be self-administered when someone is experiencing an overdose; thus, bystanders need to be able to obtain naloxone in order to administer the lifesaving drug.

The Naloxone Access Law aims to reduce barriers to getting naloxone into the hands of those who need it by encouraging the adoption and use of standing orders.

The Naloxone Access Law allows medical providers to:

- Issue standing orders that authorize the **dispensing** of naloxone to any person who meets the criteria that the law specifies, even if they are not traditional patients of that provider, and
- Issue standing orders to organizations to distribute naloxone to any person who meets the criteria that the law specifies, even if they are not traditional patients of that provider.

\*Over-the-counter (OTC) naloxone implications: Standing orders are not required when distributing OTC formulations of naloxone. Please note that not all forms of naloxone are designated as OTC. Prescription forms of naloxone are designated by "Rx only" on the product or packaging.

There are two types of naloxone standing orders in North Carolina:

### Dispensing Standing Orders

### Distribution Standing Orders

### What is the difference between dispensing and distribution?

"Dispensing" describes how an individual or a distributing organization comes to possess naloxone. The naloxone is "dispensed" to them by a licensed healthcare professional such as a pharmacist.

"Distribution" comes into play **after** an organization has naloxone in its possession - after naloxone has been "dispensed" to it. The organization can then "distribute" the naloxone out into the community.

### **Dispensing Standing Order**

A dispensing standing order allows a **dispensing healthcare professional** to *dispense* naloxone **to an individual or an organization.** 

### WHO CAN DISPENSE NALOXONE UNDER A DISPENSING STANDING ORDER?

### **Dispensing to Individuals**

Under G.S. 90-12.7, the following list of medical professionals can dispense naloxone to individuals:

- Pharmacists
- Public health nurses trained to dispense
- Dispensing physicians
- Dispensing nurse practitioners
- Dispensing physician assistants

### **Dispensing to Organizations**

Under G.S. 90-12.7, pharmacists are the only healthcare professionals allowed to dispense naloxone to organizations.

Depending on its terms, a dispensing standing order may authorize pharmacists to dispense naloxone to organizations in which the agents of that organization will:

- Keep possession of the naloxone in order to be able to administer it themselves, and/or
- Distribute the naloxone to community members.

A standing order may state specific terms that limit the authorized activities.

# *Can a pharmacist use the State Health Director's Standing Order to dispense naloxone to an organization?*

It depends. The State Health Director's Standing Order allows **pharmacists** to dispense opioid antagonists to organizations in which the agents of that organization will be administering the medication themselves (e.g., law enforcement agencies that plan to administer naloxone in the field, but not give it out). It does not allow pharmacists to dispense naloxone to organizations in which the agents will *distribute* naloxone to others to use.

If the organization plans to obtain naloxone in bulk from a pharmacy and then distribute those kits, they will need both a dispensing standing order for subsequent distribution (described in section 7 of the Implementation section of this toolkit) **and** a distribution standing order.

### EDUCATION PROVIDED ALONG WITH DISPENSING

The dispensing healthcare professional is **required** to provide counseling pursuant to 21 NCAC 46 .2504. It is **highly recommended** that the healthcare professional dispensing naloxone provide basic instruction and information on how to administer the drug (this is also required of pharmacists dispensing under the statewide standing order).

### **Distribution Standing Order**

A distribution standing order allows an **organization** to *distribute* naloxone that has already been dispensed to that organization.

### WHO CAN DISTRIBUTE NALOXONE UNDER A DISTRIBUTION STANDING ORDER?

Under G.S. 90-12.7, an agent of "any governmental or nongovernmental organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors" can be authorized to distribute naloxone under a distribution standing order.

Organizations distributing naloxone can include, but are not limited to:

- Local health departments
- Emergency medical services agencies
- Community coalitions
- Syringe services programs or other harm reduction organizations
- Jails or prisons

#### EDUCATION PROVIDED WHEN DISTRIBUTING

An agent distributing naloxone is required under G.S. 90-12.7 to provide "basic instruction and information" on how to administer naloxone. This includes information on the risk factors of overdose, how to identify signs of an overdose, the steps to responding to an overdose, and how to administer naloxone.

## **Compare and Contrast Standing Orders**

This section provides a series of resources to help you better understand the differences between dispensing and distribution (Table 1) and the settings and requirements for both types of standing orders (Table 2) and provides examples of specific scenarios and the necessary standing order(s).

### Table 1: Dispensing vs. Distribution

	Dispensing		Distribution
	Requires an <b>individual patient prescription</b> or meeting the <b>criteria of the statewide standing</b>	~	No specific patient order is required, although the organization needs a distribution standing order
	order or a local standing order	$\checkmark$	Is performed by an <b>agent of the organization</b>
$\checkmark$	Is performed by a licensed healthcare		covered under the distribution order, who need
	professional (as listed in table #2)		not be a licensed healthcare professional

- ✓ Generally, involves payment via insurance, insurance co-pay, or cash, but not required
- ✓ Generally, involves **no payment**

### **Table 2: Dispensing vs Distribution in Context**

	DISPENSING to INDIVIDUALS	DISPENSING to ORGANIZATIONS	DISTRIBUTION by ORGANIZATIONS
Who can perform:	<ul> <li>Pharmacists</li> <li>Local health department nurses trained to dispense</li> <li>Dispensing physicians</li> <li>Dispensing nurse practitioners &amp; physician assistants*</li> </ul>	Pharmacists	<ul> <li>An agent of a governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors</li> </ul>
Where it takes place:	<ul> <li>Pharmacies</li> <li>Local health department clinics</li> <li>Dispensing physician offices</li> </ul>	Pharmacies	Anywhere
What order is needed:	<ul> <li>State Health Director's standing order OR</li> <li>Individual prescription OR</li> <li>Local standing order</li> </ul>	<ul> <li>State Health Director's standing order if organization's agents will administer OR</li> <li>Local standing order allowing distribution</li> </ul>	<ul> <li>Local standing order signed by a physician, nurse practitioner or physician assistant* for distribution</li> </ul>
Education to be provided:	<ul> <li>As with any prescription, counseling pursuant to 21 NCAC 46 .2504 is required.</li> <li>Basic instruction and information on how to administer naloxone is recommended generally and is required by the State Health Director's standing order.</li> </ul>	<ul> <li>As with any prescription, counseling pursuant to 21 NCAC 46 .2504 is required.</li> <li>Basic instruction and information on how to administer naloxone is recommended generally and is required by the State Health Director's standing order.</li> </ul>	<ul> <li>Basic instruction and information on how to administer the opioid antagonist as required by NCGS 90- 12.7(c1)</li> </ul>

\*A nurse practitioner or physician assistant may dispense naloxone or issue a standing order so long as the issuance of such are included and consistent with the nurse practitioner's collaborative practice agreement or the physician assistant's supervisory arrangements.

# What is the difference between the State Health Director's standing order and a local standing order?

The State Health Director's standing order allows any NC pharmacist to dispense naloxone to any person meeting certain broad criteria. It ostensibly covers every person in the state, so people commonly refer to it as the "statewide standing order."

On the other hand, we use the term "local standing order" in this toolkit to refer to a standing order written by a healthcare practitioner on a more limited scale – for example, a standing order allowing patients at a particular health department to receive naloxone or one allowing a particular organization to distribute naloxone. We are not using the term "local" in a geographic sense *per se;* rather, we use it to distinguish this more limited type of standing order from the statewide standing order.

# IMPLEMENTATION

This section intends to guide local leaders and organizations through the planning, implementation, and sustainability of a naloxone distribution program.

### Plan and Implement a Distribution Program

The following is a checklist of actions suggested to implement a naloxone distribution program. Each action will be further detailed throughout this section.

- 1. ACQUIRE AND ANALYZE LOCAL DATA
- 2. ENGAGE PARTNERS
- 3. DETERMINE WHERE AND BY WHOM NALOXONE SHOULD BE DISTRIBUTED
- 4. DETERMINE HOW YOU WILL ACQUIRE NALOXONE
- 5. DETERMINE INFRASTRUCTURE FOR STORING NALOXONE
- 6. DETERMINE TRACKING PROCEDURES
- 7. WRITE THE STANDING ORDER (IF APPLICABLE)

National and local programs provide resources and education that can be useful throughout this process. The following is a list of organizations and websites that specialize in overdose prevention, harm reduction, naloxone, and other pertinent topics.

- Division of Public Health, Injury and Violence Prevention Branch
- NCDHHS: Overdose Epidemic
- NaloxoneSaves
- <u>Prescribe to Prevent</u>
- NC Harm Reduction Coalition
- Substance Abuse and Mental Health Services Administration

### **1. ACQUIRE AND ANALYZE LOCAL DATA**

Understanding local and regional data related to opioid overdose (overdose deaths, non-fatal overdoses, emergency department visits, etc.) is vital to identifying and expressing the need for distribution of naloxone in a community. Presenting drug overdose statistics is a powerful way to start a dialogue surrounding prevention and need with partners and/or the community.

See Appendix 1 for a list of data sources that provide statewide and/or county-level data.

### 2. ENGAGE PARTNERS

Engaging the right partners can help ensure the success of a naloxone program by gathering a variety of experience and resources to answer important questions.

- What is the context of need for naloxone distribution in the community?
- Where are ideal location(s) for naloxone distribution?
- What **organization(s) are the best fit to distribute** naloxone to the priority population?
- What resources are available to help create and sustain a naloxone distribution program?

# It is vital to ensure the priority population (people who use drugs and close contacts) and members of organizations that engage with the priority population are included and valued as partners in this process.

Table 3 provides a list of possible partners to engage and examples of assets each partner can bring to the planning and implementation of a naloxone distribution program.

### **Table 3: Partners and Assets**

Partners	Assets
<ul> <li>Local health department</li> <li>Medical providers</li> <li>Local pharmacy(ies)</li> <li>Harm reduction organizations and community coalitions (e.g., syringe services programs, substance use coalitions)</li> </ul>	<ul> <li>Data knowledge, health education and promotion, facility</li> <li>Medical knowledge, authorizer of standing order</li> <li>Knowledge of naloxone, access to purchase naloxone</li> <li>Resources, connection with priority population, lived-experience, facilities</li> </ul>
<ul> <li>People who use drugs</li> </ul>	<ul> <li>Lived-experience, knowledge</li> </ul>
Local Management Entities (LME) and	Resources, funding
<ul><li>Managed Care Organizations (MCO)</li><li>First responders</li></ul>	<ul> <li>Contact with priority population, opportunity to build rapport and trust with priority population</li> </ul>
NC Department of Health and Human Services	Resources, grant funding, technical assistance

### **Trainings**

While there is no formalized training or certification required to distribute naloxone, it is important that dispensers/distributors of naloxone familiarize themselves with how to respond to an overdose and administer naloxone, so they can instruct others.

Training resources can be found here:

### The North Carolina Harm Reduction Coalition (NCHRC)

<u>NCHRC</u> offers overdose prevention trainings to organizations or individuals, including education about risk factors for overdose, signs of overdose, and how to respond to save a victim of overdose. NCHRC also works with law enforcement agencies to inform officers about laws related to overdose prevention and needlestick prevention in North Carolina.

### NC Association of Pharmacists (NCAP)

NCAP has developed a naloxone training for pharmacists. The training reviews key elements of NC's statewide standing order for naloxone, naloxone pharmacology and product availability, how to identify people at risk for overdose and candidates for naloxone, and naloxone best practices in the pharmacy. The training is available here: <a href="https://www.ncpharmacists.org/opioid-resources-for-pharmacists">https://www.ncpharmacists.org/opioid-resources-for-pharmacists</a>

Your local health department and/or syringes services program (SSP) may also be willing to host an inservice naloxone training for your agency. You can contact your nearest SSP <u>here</u>. Additionally, a number of training materials/patient education resources can be found on naloxonesaves-nc.org, <u>here</u>.

### 3. DETERMINE WHERE AND BY WHOM NALOXONE SHOULD BE DISTRIBUTED

Creating an effective naloxone distribution program depends on whether you are able to reach the priority population. It is important to consider whom in your community is best poised to provide access to naloxone to the population and where is an effective place to distribute it.

The following chart identifies possible locations for effective outreach. *Consider which partners could be engaged to help address the needs specific to your community.* 

### **Table 4: Locations for Possible Outreach**

Locations for Outreach						
<ul> <li>Syringe services programs</li> <li>Local health departments</li> <li>Prisons and jails</li> <li>Opioid treatment programs</li> <li>Hospital-based and private detoxification programs</li> <li>Local drug treatment centers</li> <li>Mental and behavioral health centers</li> </ul>	<ul> <li>Pharmacies and local health-care clinics</li> <li>HIV/AIDS service organizations and other community-based organizations</li> <li>Locations used by people engaged in sex work</li> <li>Faith-based organizations</li> <li>Blood Plasma centers</li> <li>Libraries</li> <li>Schools and universities</li> <li>Tribal entities</li> </ul>					
<ul> <li>Pawn shops, laundromats, hotels and parking lots, gas stations, public transit stations</li> </ul>	<ul> <li>Other locations with high rates of overdose identified</li> </ul>					

Syringe Services Programs (SSPs) seek to reduce the risks associated with injection drug use and offer various services to people who use drugs and those that are in recovery. Providing naloxone through an SSP is an incredibly effective way of reaching those who are currently at risk for overdose. Visit the <u>North</u> <u>Carolina Safer Syringe Initiative</u> website for more information about SSPs in North Carolina.

### **Jails and Prisons**

Upon re-entry into the community, some formerly incarcerated individuals are at a heightened risk of overdose mortality within the first weeks of release. <u>Data</u> shows that in the 2 weeks following prison release, risk of opioid overdose is 50 times greater than the general population (Hoover et al., 2023). Overdose prevention programs should focus on treatment and services within jails and prisons, training those at-risk on overdose prevention strategies, and providing naloxone upon release. In February 2015, the Durham jail became the first in North Carolina to dispense naloxone kits to individuals as they are leaving the facility. Many jails within NC utilize models such as vending machines to provide naloxone to individuals upon release and/or their family members.

### Resources:

- NC Harm Reduction Coalition Jail-Based Overdose Prevention Education and Naloxone Distribution Toolkit: <u>https://injuryfreenc.dph.ncdhhs.gov/resources/docs/Jail\_OEND\_Curriculum\_NCHRC.pdf</u>
- RTI Primer for Implementation of Overdose Education and Naloxone Distribution in Jails and Prisons: <a href="https://harmreduction.org/wp-content/uploads/2020/09/A-primer-for-implementation-of-OEND-in-jails-and-prisons-Wenger-2019-RTI.pdf">https://harmreduction.org/wp-content/uploads/2020/09/A-primer-for-implementation-of-OEND-in-jails-and-prisons-Wenger-2019-RTI.pdf</a>

### Vending Machines or Naloxone "Boxes"

Implementing harm reduction vending machines or similar tools that include naloxone can be an effective way to distribute naloxone, particularly in settings such as detention centers or local health departments. These may also provide 24/7 access and privacy for individuals who are concerned about stigma.

For specific questions on harm reduction vending machines, please reach out to <u>naloxonesaves@gmail.com</u> or see one of the resources below.

#### Resources:

- Readiness Assessment for Harm Reduction Vending Machines: <u>https://americanhealth.jhu.edu/sites/</u> <u>default/files/Readiness%20Assessment%20for%20HRVMs%20Toolkit\_Final\_10.2022.pdf</u>
- National Council for Mental Wellbeing Enhancing Harm Reduction Services in Health Departments: Harm Reduction Vending Machines: <u>https://www.thenationalcouncil.org/resources/harm-reduction-vending-machines/</u>

### Schools

Given the rise in overdoses among adolescents, access to naloxone in schools is an important strategy. For questions regarding implementing a naloxone program in schools, please see the FAQ in Appendix 4 or contact your regional school health nurse consultant, found <u>here.</u>

### **Emergency Departments (EDs)**

Emergency departments often engage with individuals who have recently experienced an overdose or may be at risk and are an important distribution point for naloxone. For resources on implementing an ED-based naloxone distribution program, CA Bridge has an excellent resource <u>here.</u>

### 4. DETERMINE HOW YOU WILL ACQUIRE NALOXONE

### **Types of Naloxone**

Table 5 below describes the types of naloxone available for use by community members. See Appendix 2 for administration instructions for each product. Note that some instructions put administration of naloxone first, followed by a call to 911. Other protocols instruct to first call 911, then administer naloxone. Either is fine – the two go hand-in-hand.

### Table 5: Types of Naloxone (Last updated April 2024)

Product	Route of Administration	Directions for Use in Event of Suspected Opioid Overdose	Ancillary Products Required
Naloxone 4 mg/0.1 mL Nasal Spray Dispense one carton containing two doses	Intranasal	Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given in the alternate nostril.	N/A
Naloxone 8 mg/0.1 mLIntranasalNasal SprayIntranasalDispense one carton containing two dosesIntranasal		Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given in the alternate nostril.	N/A

Naloxone 1 mg/1 mL Dispense two 2 mL Luer- Jet™ Luer-Lock prefilled syringes (for use with mucosal atomization device)	Intranasal	Call 911. Spray 1 mL (1/2 of prefilled syringe contents) into each nostril via intranasal mucosal atomization device. If no to minimal response after 2-3 minutes, may repeat dose.	Two intranasal mucosal atomization devices (MAD 300)
Naloxone 3 mg/0.1mL	Intranasal	Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given.	N/A
Naloxone 0.4 mg/1 mL Dispense two 1 mL single dose vials	Injection	Call 911. Inject 1 mL into the muscle of the outer thigh or upper arm. If no to minimal response after 2-3 minutes, may repeat dose.	Two 3 mL syringes Two 23-25 gauge, 1- 1.5 inch needles
Naloxone 5 mg/0.5 mL <sup>1</sup> Dispense one carton containing two doses	Injection	Call 911. Inject contents of one prefilled syringe intramuscularly or subcutaneously into the anterolateral aspect of the thigh. If no to minimal response after 2-3 minutes, may repeat dose.	N/A

### **Comparing and Contrasting Naloxone Products**

To browse the most up- to-date list of all FDA-approved naloxone products, visit the U.S. Food and Drug Administration <u>website</u> and search for naloxone.

There are many factors that may influence the type of naloxone an organization chooses to distribute. The main factors distributing organizations may want to consider are cost, usability, and accessibility.

### Cost

Intramuscular (syringe/vial) naloxone is by far the most affordable type of naloxone to purchase. It is the most common form of naloxone distributed by harm reduction organizations in North Carolina.

### Usability

Determining the usability of each type of naloxone depends largely on the population who will be using it. See Appendix 2 to view instructions for each method of administration. Because of its low cost, intramuscular (syringe/vial) naloxone is ideal for distribution to anyone who is comfortable using a syringe.

### Accessibility

Access to naloxone is another factor that may affect the type of naloxone organizations choose to distribute. Read the next section "Acquiring Naloxone" to get an understanding of the different ways in which an organization can obtain a naloxone supply. The type of naloxone the organization will acquire may be limited depending on the route chosen for acquiring it.

### What dose of naloxone should I select?

There are now multiple approved doses of naloxone available on the market. It is important to note that high dose naloxone products have the potential to cause increased rates of withdrawal signs and symptoms and may not be needed. See the <u>CDC Morbidity and Mortality Weekly Report (MMWR)</u> from February 2024 for more information on this topic.

### Acquiring Naloxone

Naloxone can be obtained via the following methods (note: this is not a comprehensive list):

- 1. Organizations may purchase some forms of naloxone over the counter from pharmacies or other retailers (also available online).
- Organizations may purchase naloxone directly from the manufacturer or a pharmaceutical wholesaler.

   a. In some cases, organizations may qualify for public interest pricing for naloxone. Contact the
   manufacturer for more information.
  - b. To purchase NARCAN<sup>®</sup> 4mg nasal spray: <u>https://narcandirect.com/</u>
  - c. To purchase RiVive<sup>™</sup> 3mg nasal spray: <u>https://www.harmreductiontherapeutics.org/</u>
  - d. To purchase Kloxxado<sup>®</sup> 8mg nasal spray: <u>https://kloxxado.com/kloxxadodirect/</u>
- 3. Organizations can apply for grant funded kits from NCDHHS on <u>naloxonesaves-nc.org</u> under the tab "How to get naloxone." Please note, requests are not guaranteed and are subject to grant funding. Organizations serving populations at highest risk of overdose will be prioritized.
- 4. Organizations can apply for other state/federal grant funding for naloxone. Resources are available in this toolkit under the section Sustainability Planning.
- 5. Organizations may obtain naloxone from another distributing organization by either donation or purchase. Examples include:
  - **a. Direct Relief:** Direct Relief is a humanitarian aid organization active in all 50 states and abroad. With the goal of strengthening health systems that care for vulnerable populations, Direct Relief aims to extend medication access, leverage resources, and reduce procurement costs of medications. Direct Relief has provided naloxone to organizations around the country. Visit their <u>website</u> to learn more and apply.
  - **b. Remedy Alliance/For The People:** Remedy Alliance provides access to low-cost naloxone (both intramuscular and some forms of nasal naloxone) to harm reduction organizations and local health departments. Visit their <u>website</u> to learn more.

Additional resources for people who use drugs (PWUD):

 For individuals in need of naloxone who are not able to access it, <u>NEXT Distro</u> is an online and mailbased harm reduction program that provides naloxone to people who use drugs and those closely connected to them.

### **Naloxone Kits**

A "naloxone kit" or "overdose rescue kit" is a kit of information and/or supplies that is provided along with naloxone medication during community distribution.

Possible items to include in a naloxone kit are:

- Naloxone administration and overdose response instructions
- Risk factors and signs of overdose
- Local service info (linkage to local harm reduction center and treatment centers, SAMHSA Treatment Line: 1-800-662-HELP, etc.)
- Reminder of NC's Good Samaritan Law

Additional ideas:

- Alcohol pads, rescue breathing masks, gloves, etc.
- Fentanyl and/or xylazine test strips and instructions
- Toothbrush holder or glasses case (for holding supplies/needles)
- Condoms

### 5. DETERMINE INFRASTRUCTURE FOR STORING NALOXONE

Proper storage and transportation of naloxone is important to preserving the medication's effectiveness. The following guidelines for bulk storage of naloxone are outlined in the sample distribution standing order provided in Action 7: "Write the Standing Order".

### **General Guidelines for Storing Naloxone:**

- Maintain kits in a place that is unlocked and accessible.
- Store at controlled room temperature 59°F to 77°F. Excursions permitted between 39°F to 104°F. Do not freeze. Protect from light.
- Inventory stored kits monthly to ensure expiration dates have not passed. If you have kits that are
  nearing expiration, please connect with a local syringe services program who may be able to help
  distribute them quickly.

### 6. DETERMINE TRACKING PROCEDURES

### Tracking

The Naloxone Access Law *does not* require that programs track where and to whom naloxone is distributed. In fact, it is not best practice to collect any identifying information including the name of recipient of naloxone, phone number, address, etc. to reduce barriers, such as fear or stigma.

That said, the law does require that basic education is provided to each person to whom prescription naloxone is distributed. One mechanism of documenting this could be to keep a log that records the day the naloxone was distributed to the individual and requires a signature/initial by the distributor indicating that education was given.

Tracking systems can be helpful in determining the reach and success of standing orders. Local health departments or other organizations that are distributing naloxone can create tracking systems of their own to understand the reach and utilization of naloxone in their county (e.g., zip codes, types of location, and number of overdose reversals). A simple tracking system could consist of numbering naloxone kits and providing a phone number for people to call and report a reversal, or creating a QR code to be included with kit.

### **Example: NCHRC Distribution Log**

The distribution log used by NCHRC tracks both naloxone distribution and utilization. Often, the person receiving the naloxone is seeking a refill for naloxone he or she has administered and is able to provide tracking information in-person. NCHRC also tracks utilization through text/phone call to a number provided in the naloxone kit.

	North Carolina Harm Reduction Naloxone Log										
Name	Town	Date of Distribution	# of kits	Kit Type E, IM, N	Kit Serial #	1st Kit ever?	Any Reversals? If yes, town	#of doses	E, N, IM?	Time between doses?	OD reported to <b>whom?</b> How? T=text, C=Call IP=in person

### 7. WRITE THE STANDING ORDER (IF APPLICABLE)

Standing orders can be composed by the signing medical provider or by any combination of partners involved. Again, standing orders are not required if an over-the-counter version of naloxone is being distributed.

### Standing Order for Dispensing Naloxone to Organizations for Subsequent Distribution

If the distributing organization will acquire naloxone via a pharmacy, a dispensing standing order for subsequent distribution is needed to authorize the dispensing of naloxone to the organization by the pharmacist.

This type of standing order requires descriptions of the following:

- Eligible organization(s) [list of organizations to which the pharmacist may dispense naloxone]
- Routes of administration
- Medication and required device for administration
- Directions for use
- Number of kits to be dispensed
- Refills
- Individual kit labeling (optional, but recommended)
- Special instructions (optional, but recommended)

This standing order can be signed by any medical provider authorized to prescribe medications. A template of a dispensing standing order for subsequent distribution can be found in Appendix 3. The template includes instructions to adapt the standing order as needed. *As a reminder, this order only covers dispensing from the pharmacy to the organization. The medical provider must execute a separate standing order authorizing distribution to eligible candidates.* 

If pharmacists have questions regarding naloxone dispensing, refer them to the FAQ on the NC Board of Pharmacy website <u>Frequently Asked Questions for Pharmacists on Naloxone Dispensing</u> or ask them to contact <u>naloxonesaves@gmail.com</u>

### Standing Order for Distribution of Naloxone by Organizations

Once the agency has acquired naloxone, either from a pharmacy or other source, they will need a distribution standing order to authorize the distribution of those kits.

A distribution standing order requires descriptions of the following:

- Eligibility for candidates receiving the naloxone via distribution
- Routes of administration that will be distributed
- Medication and required device for administration
- Directions for use
- Contraindications
- Patient education
- Storage
- Record keeping (not required, but highly recommended)

This standing order can be signed by any medical provider authorized to prescribe medications. A template of a distribution standing order can be found in Appendix 3. The template includes instructions to adapt the standing order as needed.

## Sustainability Planning

Planning for sustainability is critical to the success of a naloxone distribution program. Partners and sponsors can be a great resource for financial and operational support. Consider partnerships between organizations and agencies that will be directly impacted by the distribution of naloxone, such as local health departments, Emergency Medical Services (EMS), Local Management Entity/Managed Care Organization (LME/MCO) agencies, law enforcement, and substance use treatment services.

### FUNDING OPPORTUNITIES

The following are lists of possible sources of funding or resources support. These lists are not comprehensive of all possible sources for funding and support.

### **Federal Government Agencies**

- <u>Centers for Disease Control and Prevention</u>
- The National Information Center on Health Services Research and Health Care Technology (NICHSR)
- <u>Substance Abuse and Mental Health Services Administration (SAMHSA)</u>
- US Health Resources and Services Administration (HRSA)
- US Department of Justice

#### **State and Local**

Local health departments can seek funding through the local government's general fund, the Board of Health, or the County Board of Commissioners to fund the purchase of naloxone. Distribution of naloxone is also an approved use of opioid settlement funds under the NC Memorandum of Agreement. You can learn more about NC's opioid settlements here: <u>https://ncopioidsettlement.org/</u>

Join the NC Opioid and Prescription Drug Abuse Advisory Committee (OPDAAC) <u>listserv</u> to receive notifications of funding opportunities in North Carolina.

The following are possible sources for funding and resources:

- When possible, the NCDHHS Division of Public Health Injury and Violence Prevention Branch distributes Centers for Disease Control and Prevention funds to local health departments and districts through the Agreement Addendum process. For information, click <u>here.</u>
- Also visit NCDHHS: Funding Syringe Services Programs for additional information about organizations funding harm reduction and opioid-related activities.
- NCDHHS Office of Rural Health (ORH) focuses on improving access, quality, and efficiency of health care in rural and underserved communities. Applications for ORH grants are typically due in the first part of the year (Jan-March). For information, click <u>here</u>.
- NCDHHS Division of Mental Health/Developmental Disabilities/Substance Use Services (DMH/DD/SUS) often releases grant opportunities that allow for the purchase of naloxone. For information, click <u>here.</u>
- Project Lazarus offers technical assistance and funding (when available) to organizations that are implementing programs that align with the Project Lazarus model. For more information, visit Projectlazarus.org
- Blue Cross Blue Shield of NC Foundation is dedicated to improving the health and well-being of all North Carolinians and offers grants with a focus on increasing access to health services. For more information, click <u>here</u>.
- Other local or regional health foundations

### PUBLIC AWARENESS CAMPAIGN

Planning communication activities, like a public awareness campaign, can help the success of a naloxone distribution program. Communication tools (social media advertisements, posters, etc.) can inform the priority population about the naloxone distribution program, inform the public about relevant laws related to naloxone access, educate about overdose and overdose reversal, and more. Communication plans should identify platforms and locations that best allow the communication to reach the target population. It is also critical to include perspectives from people who use drugs in the development of your materials.

Here are some examples of effective media campaigns:

- Vital Strategies: <u>https://www.supportharmreduction.org/campaign/page/</u>
- New York State Prevent Overdose: <u>https://oasas.ny.gov/prevent-overdose-campaign</u>





- NC Opioid and Substance Use Dashboard; Retrieved from: <u>https://injuryfreenc.shinyapps.io/</u> <u>OpioidActionPlan/</u>
- National Harm Reduction Coalition. Opioid Overdose Basics: Understanding Naloxone (2020). Retrieved from: <u>https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/</u>
- Wheeler E, Jones TS, Gilbert MK, Davidson PJ; CDC. Opioid overdose prevention programs providing naloxone to laypersons—United States, 2014. MMWR Morb Mortal Wkly Rep 2015;64:631–5.
- Naumann RB, Durrance CP, Ranapurwala SI, Austin AE, Proescholdbell S, Childs R, Marshall SW, Kansagra S, Shanahan ME. Impact of a community-based naloxone distribution program on opioid overdose death rates. Drug Alcohol Depend. 2019 Nov 1;204:107536. doi: 10.1016/j. drugalcdep.2019.06.038. Epub 2019 Aug 30. PMID: 31494440; PMCID: PMC8107918.
- Irvine M.A., Oller D., Boggis J., Bishop B., Coombs D., Wheeler E., Doe-Simkins M., Walley A.Y., Marshall B.D.L., Bratberg J., Green T.C. Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study. Lancet Public Health. 2022 doi: 10.1016/S2468-2667(21)00304-2. S2468-2667(21)00304-2.
- FAQ on Naloxone, Standing Orders and How the Good Samaritan Law Affects Pharmacists. (n.d.) Retrieved from: <u>http://www.ncbop.org/faqs/FAQNaloxoneGoodSamaritanNCHRC.pdf</u>
- Hoover DB, Korthuis PT, Waddell EN, et al. Recent Incarceration, Substance Use, Overdose, and Service Use Among People Who Use Drugs in Rural Communities. JAMA Netw Open. 2023;6(11):e2342222. doi:10.1001/jamanetworkopen.2023.42222.

## Appendix 1: Overdose Data Sources

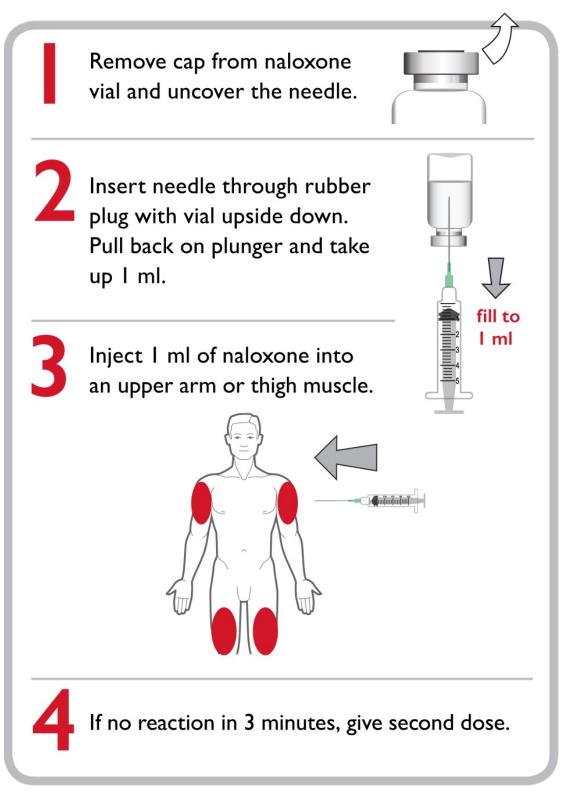
- The <u>NC Opioid and Substance Use Data Dashboard</u>, created by the Injury and Violence Prevention Branch (IVPB) of the NCDHHS Division of Public Health, provides integration and visualization of state- and county-level metrics from multiple sources to track progress toward North Carolina's Opioid and Substance Use Action Plan (NC OSUAP) goals. The data dashboard also provides links to additional data sources and partner websites such as the <u>North Carolina</u> <u>Opioid and Prescription Drug Abuse Advisory Committee (OPDAAC)</u>.
- <u>IVPB Overdose Data</u> provides monthly surveillance reports, county-level overdose slide sets, and data tables on overdose deaths, hospitalizations, and ED visits. On this page, you can also find Overdose Data Slides that provide basic data trends and public health surveillance around the drug overdose epidemic as well as County Level Overdose Slide Decks which present opioidrelated statistics in an easily digestible format for the general public and can be customized for various audiences and presentations.
- The IVPB can complete <u>custom data requests</u> and offers <u>bookings with an epidemiologist</u>.
- <u>The North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT)</u> is NC's statewide syndromic surveillance system. Authorized users are able to view data, including overdose and behavioral health data (e.g., suicidal thoughts) from emergency departments, the Carolinas Poison Center, and Emergency Medical Services (EMS). Data are updated at least once daily.
  - o Users affiliated with health departments can be authorized by the NCDHHS Division of Public Health to have access to NC DETECT data.
  - To request access to NC DETECT, please read the Terms of Use and complete the online <u>Account Request form.</u> Health departments can request training for NC DETECT by emailing <u>ncdetect@listserv.med.</u> <u>unc.edu</u>. NC DETECT data can be shared with partners outside the health department by following specific protocols. Contact <u>ncdetect@listserv.med.unc.edu</u> for more information.
- <u>ODMAP</u> is an application-based mapping system in which first responders (EMS, law enforcement, and fire) can track overdoses along with other relevant descriptors like fatal vs. non-fatal or the number of naloxone administrations per event. ODMAPS is free and displays overdose activity across multiple jurisdictions. Health departments can request access to this database.
- <u>NC Social Determinants of Health</u> maps are interactive, online maps showing social determinants of health indicators in NC, including the economic, social, housing, and transportation status of residents across the state. A cumulative index is calculated from the metrics to provide an overall measure of social determinants of health indicators.
- <u>North Carolina Health Data Query System</u> is an interactive database system that provides customized reports of health data based on user-specified selection of variables (e.g., age, race, county) and is maintained by the <u>State Center for Health Statistics.</u>
- <u>Centers for Disease Control and Prevention (CDC) Web-based Injury Statistics Query and</u> <u>Reporting System (WISQARS™)</u> is an interactive, online database that provides data on fatal and non-fatal injury (including drug poisonings), violent death, and cost of injury from a variety of trusted sources. Researchers, the media, public health professionals, and the public can use WISQARS<sup>™</sup> data to learn more about the public health and economic burden associated with unintentional and violence-related injury in the United States.

# Appendix 2: Naloxone Administration Instructions

### **APPENDIX 2-A**

### Intramuscular (syringe/vial)

Source: Family Health Centers of San Diego; retrieved from <a href="https://www.fhcsd.org/opioid-safety/">https://www.fhcsd.org/opioid-safety/</a>



### **APPENDIX 2-B**

### Naloxone 4 mg nasal spray

Source: Emergent Devices; retrieved from https://narcan.com/resources

# DIRECTIONS



### Step 1: CHECK if you suspect an overdose

- <u>CHECK</u> for a <u>suspected overdose</u>: the person will not wake up or is very sleepy or not breathing well
  - » yell "Wake up!"
  - » shake the person gently
  - » if the person is not awake, go to Step 2



3. CALL

4. WATCH

### Step 2: GIVE 1st dose in the nose

- HOLD the nasal spray device with your thumb on the bottom of the plunger
- INSERT the nozzle into either NOSTRIL
- PRESS the plunger firmly to give the 1<sup>st</sup> dose
- 1 nasal spray device contains 1 dose

### Step 3: CALL

 <u>CALL 911</u> immediately after giving the 1<sup>st</sup> dose

### Step 4: WATCH & GIVE

- WAIT 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work
- if the person wakes up: Go to Step 5
- if the person does <u>not wake up</u>:
  - » <u>CONTINUE TO GIVE</u> doses every 2-3 minutes until the person wakes up
  - » it is safe to keep giving doses



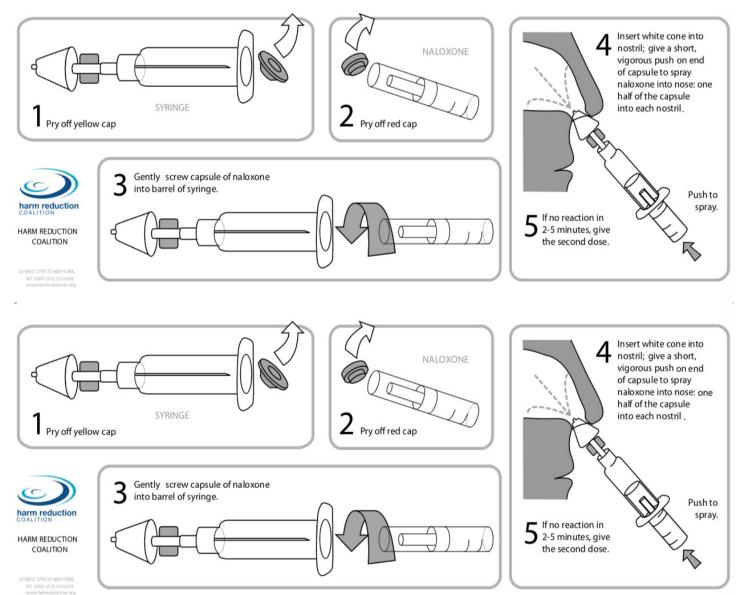
### Step 5: STAY

- <u>STAY</u> until ambulance arrives: even if the person wakes up
- GIVE another dose if the person becomes very sleepy again
- You may need to give all the doses in the pack

### **APPENDIX 2-C**

### Intranasal (pre-filled syringe)

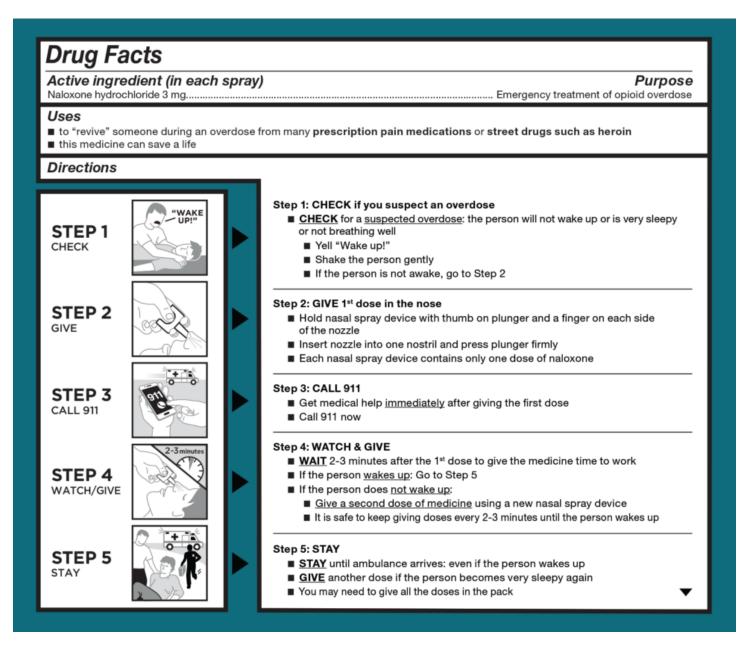
Source: Harm Reduction Coalition; retrieved from: <u>https://harmreduction.org/wp-content/uploads/2014/10/IN-instructions-and-kit-assembly.pdf</u>



### **APPENDIX 2-D**

### **RiVive 3mg naloxone nasal spray**

Source: Harm Reduction Therapeutics



### **APPENDIX 2-E**

### Naloxone 8mg nasal spray

Source: Hikma; retrieved from https://kloxxado.com/how-to-use/

# How to administer Kloxxado™ nasal spray



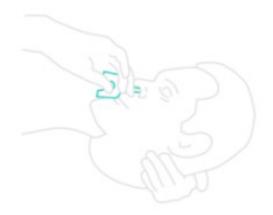


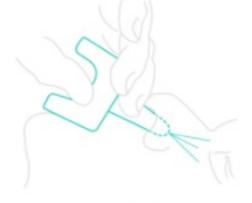
# REMOVE

REMOVE Kloxxado<sup>™</sup> nasal spray from the box. Peel off the back tab with the triangle (p) to open the Kloxxado<sup>™</sup> nasal spray blister.

## HOLD

HOLD it with your thumb on the bottom and your first and middle fingers on either side of the nozzle.





## INSERT

INSERT the tip of the nozzle into one nostril until your fingers are against the bottom of the person's nose.

### PRESS

PRESS the plunger firmly to give the dose of Kloxxado<sup>™</sup> nasal spray.

### **APPENDIX 2-F**

#### Naloxone 5mg autoinjector

Source: Adamis Pharmaceuticals; retrieved from https://zimhi.com/patients-and-caregivers/how-to-use-zimhi/

# 4 SIMPLE STEPS TO USE ZIMHI™ (naloxone HCI Injection): PRESS, PUSH, PULL, PLACE

ZIMHI IS USED FOR OPIOID EMERGENCIES (KNOWN OR SUSPECTED OVERDOSES)<sup>1</sup> Please read full ZIMHI Instructions For Use on ZIMHI.com before use.

As soon as possible, call for emergency medical help. ZIMHI DOES NOT TAKE THE PLACE OF EMERGENCY MEDICAL CARE.





# PRESS

<u>PRESS</u> needle into outer thigh after twisting off needle cap. Do not touch the plunger until this step is completed.



#### PUSH

<u>PUSH</u> plunger until it clicks and hold for 2 seconds before removing the needle. The correct dose has been given if the plunger has been pushed all the way down and blocks part of the solution window. It is normal for most of the medicine to remain in the syringe after the dose has been injected.

If you are giving ZIMHI to a young child, hold the leg firmly in place while giving the injection.



PULL

<u>PULL</u> the safety guard down using one hand with fingers behind the needle. Do this right after you give the injection.



PLACE

<u>PLACE</u> the used syringe into the blue case, close it, and call 911. Give the used ZIMHI syringe to the healthcare provider for inspection and for proper disposal.

If the person is unresponsive after 2 to 3 minutes, give an additional dose of ZIMHI using a new device.

If you are giving ZIMHI to a baby under the age of 1 year, pinch the thigh muscle while giving the injection.

#### INDICATION

ZIMHI is a prescription medicine used in adults and children for the treatment of an opioid emergency, such as an overdose or a possible overdose with signs of breathing problems and severe sleepiness or not being able to respond. ZIMHI is to be given right away by a caregiver and does not take the place of emergency medical care. Get emergency medical help right away after the first dose of ZIMHI, even if the person wakes up.

#### IMPORTANT SAFETY INFORMATION

Do not use ZIMHI if you are allergic to naloxone hydrochloride or any of the ingredients in ZIMHI.

ZIMHI is used to temporarily reverse the effects of opioid medicines. The medicine in ZIMHI has no effect in people who are not taking opioid medicines. Use ZIMHI right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death.

ZIMHI<sup>™</sup> (naloxone HCI Injection) 5mg/0.5mL FAST WHEN IT MATTERS MOST

# Appendix 3: Standing Order Templates

- These documents are a template to be customized by each practitioner wishing to authorize the dispensing or distribution of naloxone as allowed by NCGS 90-12.7.
- Review all areas highlighted in yellow.
  - o Fill in the requested information
  - o Remove the yellow highlighting
- Review the area highlighted in green.
  - o Ensure you want all formulations included and that you agree with the provided instructions.
  - o Make any edits you feel necessary
  - o Remove the green highlighting
- Remove the "Template" watermark once you have completed the previous steps.
- For the distribution standing order template:
- Complete the row for Record Keeping highlighted in orange with any information the distributing
  agency should log and where logs should be submitted. While it is not required to maintain logs of
  individuals receiving naloxone, it is a best practice to log basic information on kit distribution to collect
  data to support and track distribution efforts. Consider recoding the following information:
  - o Date, number of kits distributed, name of distributor, zip code where distribution occurred, confirmation that education was provided.
  - o Also include frequency with which logs should be returned and to whom they should be returned.

# APPENDIX 3-A: TEMPLATE STANDING ORDER FOR DISPENSING NALOXONE TO ORGANIZATIONS FOR SUBSEQUENT DISTRIBUTION

### Naloxone Standing Order for Dispensing to Organizations for Subsequent Distribution

This standing order signed by the (INSERT PHYSICIAN TITLE AND/OR NAME) authorizes any pharmacist practicing within the (INSERT LOCAL HEALTH DEPARTMENT PHARMACY OR OTHER PHARMACY NAME) and licensed by the North Carolina Board of Pharmacy to dispense Naloxone as directed below. Naloxone dispensing to an organization is permitted by NCGS 90-12.7. This order only covers dispensing from the pharmacy to the organization. The organization and provider must execute a separate order authorizing distribution to eligible candidates.

Naloxone HCI Dispensing Protocol						
Eligible Organization(s)	<ul> <li>List each Organization(s) name and Primary Point of contact including phone number, mailing address and email.</li> <li>Use Organization(s) name in the patient name field.</li> </ul>					
Route(s) of Administration	Intranasal (	(IN)	Intramuscular (IM)			
Medication and Required Device for Administration	<ul> <li>Naloxone HCl 1 mg/mL Inj.</li> <li>2 x 2 mL as pre-filled</li> <li>Luer-Lock syringes</li> <li>Dispense 2 (two) doses 2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300) Available from: Teleflex (866-246-6990) or Safety Works, Inc. (800-723-3892)</li> </ul>	Naloxone 4 mg/0.1 mL Nasal Spray • Dispense 1 x two- pack	<ul> <li>Naloxone HCI 0.4mg/mL Inj.</li> <li>2 x 1mL single dose vials (SDV)</li> <li>2 (two) 3 mL syringe</li> <li>2 (two) 25 G, 1-inch needle</li> <li>Naloxone HCI 2 mg/2mL Inj.</li> <li>Dispense 2 (two) pre-filled syringes</li> <li>2 (two) 25 G, 1-inch needle</li> </ul>			
Directions for Use	Call 911. Spray 1 mL in each nostril. Repeat every 3 minutes as needed if no or minimal response.	Call 911. Inject the entire solution of the vial or pre-filled syringe IM in shoulder or thigh. Repeat every 3 minutes as needed if no or minimal response.				
Number of kits to be dispensed	Provide either a specific number, kits, to be provided at each dispe		num number, such as no more than 15			
Refills	PRN					
Individual kit labeling (OPTIONAL, but recommended)	<ul> <li>Place individual label on each naloxone kit containing the following:</li> <li>Tracking number if being used for data keeping</li> <li>Website for additional information and or phone number for assistance</li> <li>Instructions for use</li> </ul>					
Special Instructions (OPTIONAL, but recommended)	<ul> <li>Include information here such as:         <ul> <li>Any logs to be kept by distribution organization and whether pharmacy should collect logs for distributed kits</li> <li>Any information/reminders that should be provided to the organization performing distribution at time of pick up from pharmacy.</li> <li>Information on name to be used on signature log at pick up (i.e. name of person presenting to pick up or distribution organization name)</li> <li>Any reminders such as storage information [Store at controlled room temperature 59°F to 77°F (15°C to 25°C). Excursions permitted between 4°C to 40°C (39°F to 104°F). Do not freeze. Protect from light.]</li> </ul> </li> </ul>					

	Date Signed
INSERT SIGNING PHYSICIAN NAME AND CREDENTIALS	
INSERT PHYSICIAN TITLE	
INSERT PHYSICIAN EMPLOYER	Date Expires
National Provider ID: INSERT NUMBER	

This order is effective immediately upon signing and may be revised or revoked by (INSERT PHYSICIAN TITLE) according to his/her discretion.

# APPENDIX 3-B: TEMPLATE STANDING ORDER FOR DISTRIBUTION OF NALOXONE BY ORGANIZATIONS

### **Distribution Order for Naloxone**

I hereby authorize (INSERT AUTHORIZED AGENCY/GOUP/ORGANIZATION NAME(s) HERE) to distribute naloxone in the state of North Carolina to persons as directed below.

Distribution Protocol for Naloxone HCI						
Eligible Candidates	<ul> <li>Persons who voluntarily request Naloxone and are at risk of experiencing an opiate-related overdose, including, but not limited to:         <ul> <li>Current illicit or non-medical opioid users or persons with a history of such use</li> <li>Persons with a history of opioid intoxication or overdose and/or recipients of emergency medical care for acute opioid prescription (&gt;50 morphine mg equivalents per day)</li> <li>Persons with an opioid detoxification and known or suspected concurrent alcohol use</li> <li>Persons from opioid detoxification and mandatory abstinence programs</li> <li>Persons entering methadone maintenance treatment programs (for addiction or pain)</li> <li>Persons with an opioid prescription who also suffer from renal dysfunction, hepatic disease, cardiac disease, HIV/AIDS</li> <li>Persons who may have difficulty accessing emergency medical services</li> <li>Persons who voluntarily request Naloxone and are the family member or friend of a person at risk of experiencing an opiate-related overdose.</li> </ul> </li> </ul>					
Douto(a) of Administration	experiencing an opiate-related o					
Route(s) of Administration	Intranasal (IN)		Intramuscular (IM)			
Medication and Required Device for Administration	<ul> <li>Naloxone HCl 1 mg/mL Inj.</li> <li>2 x 2 mL as pre-filled Luer-Lock syringes</li> <li>Distribute 2 (two) doses</li> <li>2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300 Available from: Teleflex (866-246-6990) or Safety Works, Inc. (800-723-3892)</li> </ul>	Naloxone 4 mg/0.1 mL Nasal Spray • Distribute 1 x two-pack	<ul> <li>Naloxone HCI 0.4mg/mL Inj.</li> <li>2 x 1mL single dose vials (SDV)</li> <li>2 (two) 3 mL syringe</li> <li>2 (two) 25 G, 1-inch needle</li> <li>Naloxone HCI 2 mg/2mL Inj.</li> <li>Distribute 2 (two) pre-filled syringes</li> <li>2 (two) 25 G, 1-inch needle</li> </ul>			
Directions for Use	Call 911. Spray 1 mL in each nostril. Repeat every 3 minutes as needed if no or minimal response. Call 911. Administer a single spray of naloxone in one nostril. Repeat every 3 minutes as needed if no or minimal response. Call 911. Inject the entire solution of t vial or pre-filled syringe IM in should or thigh. Repeat every 3 minutes as needed if no or minimal response.					
Contraindications	A history of known hypersensitivity	to Naloxone or any o	of its components			
Patient Education	Every person provided naloxone under this distribution order shall receive education regarding the risk factors of overdose, signs of an overdose, overdose response steps, and the use of naloxone. Examples of educational materials that incorporate the above information may be found at <a href="http://www.naloxonesaves-nc.org">http://www.naloxonesaves-nc.org</a>					
Storage	<ul> <li>Maintain kits in a secured location that limits access to authorized staff.</li> <li>Store at controlled room temperature 59°F to 77°F (15°C to 25°C). Excursions permitted between 4°C to 40°C (39°F to 104°F). Do not freeze. Protect from light.</li> <li>Inventory stored kits monthly to ensure expiration dates have not passed.</li> </ul>					
Record Keeping						

INSERT SIGNING PHYSICIAN NAME AND CREDENTIALS INSERT PHYSICIAN TITLE INSERT PHYSICIAN EMPLOYER Date Signed \_

Date Expires \_\_\_

National Provider ID: INSERT NUMBER

This order is effective immediately upon signing and may be revised or revoked by (INSERT PHYSICIAN TITLE) according to his/her discretion.

## Appendix 4: Naloxone in Schools FAQ

# INALOXONE

# WHY is it important for schools to have naloxone available?

According to Centers for Disease Control and Prevention data, overdose deaths among adolescents (aged 10-19 years) have increased significantly since 2019, particularly those involving fentanyl. According to <u>NC School</u> <u>Health Services Report</u>, during the 2022-23 school year, naloxone was administered 21 times by school staff or a School Resource Officer due to a suspected overdose that occurred on a school campus. This is a 50% increase from 2021-22 when 14 doses were administered. Naloxone is a safe, effective, and life-saving antidote to opioid overdose that should be accessible for emergency use in school settings.

# WHERE should naloxone be stored?

Each school should store naloxone in a secure but unlocked location that is easily accessible to individuals trained to administer the medication. The manufacturer's recommendations for storage should be followed.

# WHO can administer naloxone in a school setting?

Best practice is for personnel who have received training and information on how to administer the opioid antagonist to administer naloxone according to local policy and procedures. School systems that obtain naloxone using the State Health Director's standing order or using a written prescription by a private provider may administer naloxone as described in G.S. § 90-12.7 (d).

School systems that choose to make naloxone available via <u>NC BON Standing Orders</u> written by their physician advisor or local health department provider, should keep in mind that such an order could only be implemented by the school nurse and is not delegable to unlicensed assistive personnel (UAP).





# WHAT policies or standing orders are required?

School systems should develop a very clear policy and procedures on naloxone administration. Collaboration between school nurses, administration, school legal authority, and other staff is encouraged.

# WHERE can I find resources or templates?

Resources to assist with writing local policies, procedures and protocols are available in the <u>National Association</u> of School Nurses (NASN) Naloxone in Schools Toolkit, NC Naloxone Distribution Toolkit, SAMHSA Toolkit, Arizona Department of Health Services, and <u>Minnesota Department of Health School Toolkit</u>. Templates for standing orders can be found on the <u>NC Public Health Pharmacy website</u>.

# Am I protected legally if I administer NALOXONE IN SCHOOLS?

G.S. § 90-12.7 (e) provides civil and criminal immunity to individuals administering naloxone if they have good faith belief that the other person is experiencing a drug-related overdose. Licensed individuals are held to standards reflective of their positions.



# WHERE can I obtain naloxone?

Naloxone can be obtained through pharmaceutical wholesalers/retailers, as well as directly from the manufacturer for some products.

You can also work with your local health department or LME/ MCO which may have grant funding available for naloxone.



# Is there a specific naloxone TRAINING CURRICULUM REQUIRED?

There is no specialized training curriculum required by law; however, on a practical basis, training should cover how to recognize signs of an overdose and respond to an overdose, including administration of naloxone and calling 911.

# WHO can I contact if I have additional questions?

Please contact your Regional School Health Consultant here: https://www.ncdhhs.gov/shnc-map-12-2022pdf/open



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# NALOXONE FAQS

### What is naloxone and how does it work?

Naloxone is an FDA-approved medication that reverses the effects of an opioid overdose by blocking receptors in the brain and restoring breathing.

### What are the signs of an opioid overdose?

Signs may include unresponsiveness, slow or shallow breathing, pinpoint (constricted) pupils, blue fingernails or lips, vomiting, or gurgling noises.

### What should I do in the event of witnessing an opioid overdose?

Call 911 first and try to keep the person awake, then administer naloxone. If the individual is not breathing, begin to perform rescue breathing and chest compressions, also called CPR, if trained to do so. An additional dose of naloxone may be given after 2-3 minutes if there is no minimal response. Stay with the individual until help arrives. For specific instructions on naloxone administration, refer to the medication insert or NC Naloxone Distribution Toolkit.

The Good Samaritan Law protects people who call 911 to help someone who has overdosed from prosecution for possession of small amounts of certain drugs and possession of drug paraphernalia. The person calling 911 must give his or her real name to receive these legal protections.

### Will naloxone work in an alcohol or benzodiazepine (Valium®, Klonopin®, Xanax®) overdose?

No. Naloxone only reverses the effects of opioids. Examples of opioids include hydrocodone, oxycodone, fentanyl, morphine, and heroin. However, if an opioid overdose also involved other substances such as alcohol or benzodiazepines, naloxone may help. Naloxone will have no effect on an individual if an opioid is not present in their system.

### What are the side effects of naloxone?

Naloxone is a generally safe medication but may cause some individuals to experience withdrawal. Symptoms of withdrawal include confusion, sweating, vomiting, and irritability. Rarely do individuals become combative.

### Can someone overdose on naloxone if given too much?

No. However, if the individual is dependent on opioids, they may experience increased withdrawal symptoms with repeated doses of naloxone.

### Is there anyone that naloxone should not be given to?

Naloxone should not be given to anyone with an allergy or sensitivity to naloxone hydrochloride. When necessary, naloxone may be used in pregnant women at the lowest possible dose to prevent fetal distress. Contact your healthcare provider with any questions or concerns.

### Is naloxone addictive?

No, naloxone is non-addictive and has no potential for abuse.

# I've heard a lot about fentanyl. Is naloxone effective against it? What happens if I am exposed to it while helping someone?

Yes, naloxone is effective against fentanyl. Incidental skin exposure to fentanyl is very unlikely to harm you.

If you believe you may have come in contact with fentanyl, wash your hands with soap and water as soon as you can-especially before eating or touching your mouth or nose (i.e., mucous membranes).

### Can expired naloxone still be used?

If it is the only thing available, yes. Like most medications, the efficacy of naloxone may begin to decline past the expiration date and should be replaced. It is also important to store naloxone at room temperature (59° to 77° F) and protected from direct light.

# I work at a local health department that would like to begin distributing naloxone. What type of standing order is required?

If you plan to distribute a prescription form of naloxone, a distribution standing order signed by a physician, nurse practitioner, or physician assistant is required. For templates and more information on types of standing orders, please refer to the NC Naloxone Distribution Toolkit.

### Can I be held liable for distributing naloxone?

No. The North Carolina Naloxone Access Law protects any agent of a community-based organization that distributes naloxone under the standing order of a medical provider from civil or criminal liability.

### Do I need to have any training to distribute naloxone?

It is recommended that all individuals distributing naloxone receive training on recognizing the signs and responding to an overdose. Also, the Naloxone Access Law requires that basic instruction and information on how to administer naloxone be included with any distribution. Please refer to NC Naloxone Distribution Toolkit for organizations that offer tailored training.

### How does an organization go about acquiring naloxone?

Naloxone may be purchased from a pharmacy or directly through the manufacturer. Some organizations may donate naloxone based on availability and population of individuals served. Refer to the NC Naloxone Distribution Toolkit for details on acquiring naloxone and materials required.

### Is there any difference between the forms of naloxone - which should I order?

Studies have shown there is no difference in efficacy between nasal and intramuscular forms of naloxone. Choice of product depends on cost, availability, and comfort level of the individual.

### Am I required to track the number of naloxone kits distributed by my organization?

No. However, the law requires that basic education is provided to each person receiving naloxone. One mechanism of documenting this is maintaining a log of the date each kit was distributed and initial/signature of the distributor to indicate education was provided. Tracking systems can also be helpful in determining the success of a standing order in the community.

### Doesn't naloxone enable people to overdose by acting as a safety net?

No, this is a common misconception. Research has shown that communities with naloxone distribution and education programs have decreased rates of overdose deaths. For this reason, several health organizations have endorsed naloxone distribution as a strategy for combating the opioid epidemic.

### Where can I learn more about naloxone?

There are several resources with valuable information including <u>Prescribe to Prevent</u>, <u>NC Harm Reduction</u> <u>Coalition</u>, <u>NaloxoneSaves</u>, <u>NCDHHS: Overdose Epidemic</u>.

<sup>&</sup>lt;sup>1</sup>Sources: North Carolina Harm Reduction Coalition, Harm Reduction Coalition





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