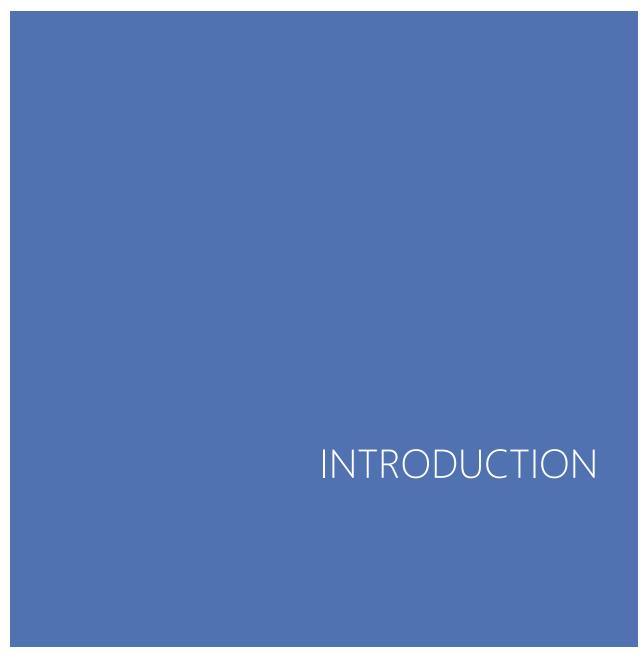
# North Carolina Naloxone Distribution Toolkit

North Carolina Division of Public Health Injury and Violence Prevention Branch

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The North Carolina Naloxone Distribution Toolkit was created by the North Carolina Division of Public Health's, Injury and Violence Prevention Branch to guide local health departments, coalitions, and community organizations through the process of implementing a distribution standing order.

For more information on content in this toolkit and access to materials from the Injury and Violence Prevention Branch, please email:

BeInjuryFreeNC@dhhs.nc.gov or NaloxoneSaves@gmail.com

# Background & Rationale

Opioid overdose deaths have been increasing in the United States and in North Carolina since 1999. Since 2013. deaths due to unintentional opioidinvolved poisonings have increased sharply in North Carolina Deaths associated with heroin and fentanyl have been increasing even more rapidly. Since 2013, the opioid epidemic in North Carolina has consisted

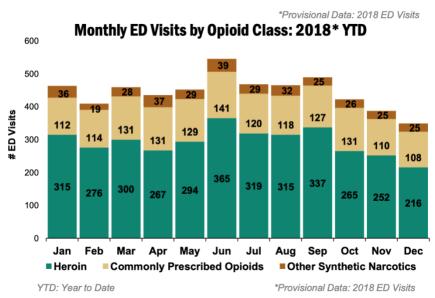


Figure 1: Monthly ED Visits by Opioid Class: 2018\* YTD

largely of deaths due to illicitly-manufactured opioids including heroin and synthetic narcotics (like fentanyl and fentanyl analogues). In 2017, these types of opioids were associated with 80% of unintentional opioid-involved poisoning deaths.

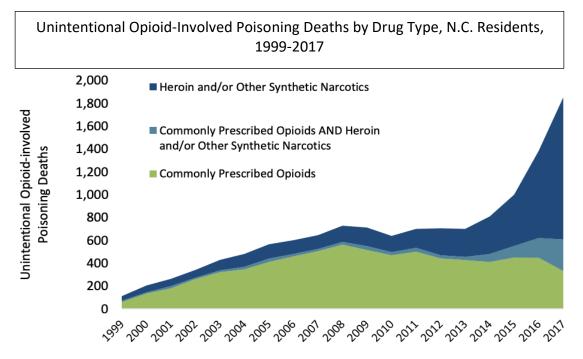


Figure 2: Unintentional Opioid-Involved Poisoning Deaths by drug Type, N.C. Residents, 1999-2017

Deaths due to opioid overdoses can be reduced through the use of naloxone (known by brand names including Narcan® and Evzio®). Naloxone 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 that occurs as a result of overdose. It is an effective, quick acting, non-addictive prescription medication that can be administered through intramuscular, intravenous, subcutaneous, or intranasal pathways. Naloxone only works when an opioid is present in the body. It can only be used to reverse the effects of an opioid; it cannot reverse the effects of other drugs such as benzodiazepines, alcohol, cocaine, or amphetamines. Naloxone is safe to use, has no potential for abuse, has minimal adverse effects, and has no contraindications besides an allergy or sensitivity to naloxone hydrochloride.

Laypersons can easily be trained to use naloxone to reverse overdose. Distribution of naloxone to friends and family of drug users is key to reversing overdoses, as the person experiencing the overdose will unlikely be able to administer the naloxone to himself or herself. Distribution of naloxone to lay persons, particularly those at high-risk for overdose and their family members, has shown to be a safe and cost-efficient way to reduce overdose deaths (Tobin, Sherman, Beilenson, Welsh, & Latkin, 2009) (Wagner et al., 2010) (Wheeler, Jones, Gilbert, & Davidson, 2014).

North Carolina has been a national leader in community distribution of naloxone--most notably through the work of the North Carolina Harm Reduction Coalition (NCHRC). As of January 2019, the NCHRC had distributed over 101,000 free naloxone kits and received 13,394 reports of successful administration of naloxone by lay persons. North Carolina has also been the first state to have an EMS naloxone leave-behind program, whereby EMS personnel give persons 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 in an effort to further promote community distribution of naloxone in North Carolina.



## Naloxone Access Law

To address increasing rates of deaths involving heroin, fentanyl, and other synthetic narcotics, the North Carolina legislature has 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.

Here is a history of naloxone legislation in North Carolina:

**2013:** Naloxone Access Law Passed Under G.S. 90-12.7 (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 persons at risk for an overdose and to those in a position to help others at risk of an overdose (3<sup>rd</sup>-party prescribing). The statute provides criminal and civil liability protection to health care providers who prescribe naloxone and to those who administer naloxone to persons experiencing an overdose. See Appendix 1 for a summary of G.S. 90-12.7.

#### 2016: State Health Director's Standing Order 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 naloxone.

On June 20<sup>th</sup>, 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

**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 standing orders to allow organizations, including local health departments, to distribute naloxone in the community.

# 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 devices to be dispensed by local health department registered nurses that have training specific for medication dispensing to include naloxone. Since naloxone is now 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.</u>

# Standing Orders and Naloxone

A **standing order** is a medical order that authorizes the dispensing <u>or</u> 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 patient-provider 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.

# Dispensing Standing Orders vs. Distribution Standing Orders

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 <u>dispensing healthcare professional</u> to <u>dispense</u> naloxone <u>to</u> 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.

#### State Health Director's Standing Order

The State Health Director's Standing Order allows pharmacists to dispense to organizations in which the agents of that organization will be administering the naloxone 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.

#### Education to be 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 required of pharmacists dispensing under the statewide standing order.)

#### Distribution Standing Order

A distribution standing order allows an <u>organization</u> to <u>distribute</u> 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
- Law enforcement agencies
- Community coalitions
- Harm reduction groups
- Drug user health groups
- Syringe exchange programs

#### Education to be provided along with distribution?

An agent distributing naloxone is required under G.S. 90-12.7 to provide "basic instruction and information" on 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
<ul> <li>Requires an individual patient prescription or meeting the criteria of the statewide standing order or a local standing order</li> </ul>	✓ No specific patient order is required, although the organization needs a distribution standing order
✓ Is performed by a licensed healthcare professional (as listed in table #2)	✓ Is performed by an agent of the organization covered under the distribution order, who need not be a licensed healthcare professional
<ul> <li>✓ Generally, involves payment via insurance, insurance co-pay, or cash, but not required</li> </ul>	✓ Generally, involves <b>no payment</b>

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

Table 2. Disp	able 2: Dispensing vs Distribution in Context								
	DISPENSING		DISPENSING	DISTRIBUTION					
	to		to		by				
	INDIVIDUALS		ORGANIZATIONS		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*</li> <li>Dispensing physician assistants*</li> </ul>	•	Pharmacists	•	An agent of a governmental or nongovernmental 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 highrisk behaviors				
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 dispensing standing order</li> </ul>	•	State Health Director's standing order or local dispensing standing order if organization's agents will administer  OR  Local dispensing standing order authorizing	•	Local standing order signed by a physician, nurse practitioner* or physician assistant* for distribution				
			distribution <u>if organization's</u> <u>agents will distribute</u>						
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>	•	As with any prescription, counseling pursuant to 21 NCAC 46 .2504 is required. Basic instruction and information on how to administer naloxone is recommended generally and is required by the State Health Director's standing order.	•	Basic instruction and information on how to administer naloxone as required by NCGS 90-12.7(c1)				

<sup>\*</sup>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. (per communication with Jill Moore, UNC School of Government, and Phyllis Rocco, NC Division of Public Health, 2018)

# 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 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.

#### Case Examples

#### Case Example 1:

- → Frances Community Outreach Group (FCOG) wants to send volunteers to places where injection drug users are known to spend time to distribute naloxone to those drug users.
- → Frances County Health and Human Services (FCHHS) wants its health educator to distribute naloxone at a county health fair.

#### **BOTH** of the following standing orders are needed:

- A <u>dispensing standing order</u> to enable a pharmacy to dispense naloxone to FCOG or FCHHS, and
- A <u>distribution order</u> to enable FCOG or FCHHS to distribute naloxone to community members.

NOTE: The State Health Director's standing order allows dispensing to people who plan to keep the naloxone for their own use. It does not allow dispensing to an "intermediary" that will go out and distribute the naloxone to others. For this reason, a local dispensing standing order authorizing distribution as well as a distribution standing order, both specific to the organization receiving the naloxone are needed when the organization intends to distribute the naloxone.

#### Case Example 2:

- → Frances County Police Department (FCPD) wants to equip officers with naloxone in case they need to administer it to a community member or to a fellow officer.
- → Frances Samaritan's Kitchen (FSK) wants to keep naloxone on site to enable its employees and volunteers to administer naloxone to clients who overdose while they are at the organization.

**One of the following standing orders** is needed to enable a pharmacy to dispense naloxone to FCPD or FSK:

- The State Health Director's standing order, or
- A <u>local dispensing standing order</u> to enable a pharmacy to dispense naloxone to FCPD or FSK.

NOTE: No distribution standing order is needed since neither FCPD nor FSK plans to distribute naloxone in the community.

# Naloxone Frequently Asked Questions

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

Naloxone (naloxone HCL, Narcan®, Evzio®) 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 to 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 for 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 for 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. In some cases, fentanyl may be so potent that multiple doses of naloxone are required. 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).

Sources: North Carolina Harm Reduction Coalition, Harm Reduction Coalition

#### 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?

A dispensing standing order that allows distribution AND a distribution standing order signed by a physician, nurse practitioner, or physician assistant are 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 different forms of naloxone – which should I order?

Studies have shown there is no difference in efficacy between Narcan® 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 from 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 to 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 Coalition</u>, <u>NaloxoneSaves</u>, <u>NC DHHS: Opioid Epidemic</u>.

Sources: North Carolina Harm Reduction Coalition, Harm Reduction Coalition



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 Standing Order

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

- 1. Acquire and Analyze Local Data
- 2. Engage Stakeholders
- 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

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.

Prescribe to Prevent

NC Harm Reduction Coalition

NaloxoneInfo.org

NaloxoneSaves

NC Division of Public Health, Injury and Violence Prevention Branch

NC DHHS: Opioid Epidemic

The Opioid and Prescription Drug Abuse Advisory Committee

North Carolina Essential Actions to Address the Opioid Epidemic: A Local Health Department's Guide

#### 1. Acquire and Analyze Local Data

Understanding local and regional data related to opioid overdose (overdose deaths, non-fatal overdoses, overdose mapping, etc.) is vital to identifying and expressing 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 stakeholders and/or the community.

See Appendix 2 for a list of data sources that provide statewide and/or county-level data.

#### 2. Engage Stakeholders

Engaging the right stakeholders can help ensure the success of a naloxone standing order 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 families of people who use drugs) and members of organizations and coalitions that engage with the priority population are included and valued as stakeholders in this process.

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

**Table 3: Stakeholders and Assets** 

Stakeholders	Assets
Local health department	Data knowledge, health education and promotion, facility
Medical providers	Medical knowledge, authorizer of standing order
Local pharmacy(ies)	Knowledge of naloxone, access to purchase naloxone
Community coalitions/organizations (e.g. Harm Reduction Coalition, substance use coalitions)	Resources, connection with priority population, lived-experience, facilities
People who use drugs	Lived-experience, knowledge
Local Management Entities (LME) and Managed Care Organizations (MCO)	Resources, funding
First responders	Contact with priority population, opportunity to build rapport and trust with priority population

#### **Trainings**

Stakeholders can host the following trainings for their employees, volunteers, or the community they serve.

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

NCHRC 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 has hosted trainings in-person, via video conference, and over the telephone. Click <a href="https://linearchyclic.com/here">here</a> to learn more about NCHRC's overdose prevention trainings.

To set up a training or to get more information, contact Jesse Bennett:

Jesse Bennett Statewide Overdose Prevention Coordinator North Carolina Harm Reduction Coalition jbennett@nchrc.org (919) 523-4303

NCHRC also works with law enforcement agencies to inform officers about laws related to overdose prevention and needlestick prevention in North Carolina. Click <a href="here">here</a> to learn more about NCHRC's law enforcement trainings.

To set up a training or to get more information contact Melissia Larson:

Melissia Larson
Law Enforcement Assisted Diversion Coordinator (LEAD-C)
North Carolina Harm Reduction Coalition

Mnlarson6@gmail.com
(252) 341-5102

#### NC Office of Emergency Medical Services (NCOEMS)

NCOEMS has sponsored an opioid overdose prevention training for law enforcement and first responders, ideally to be delivered by local EMS. The training is available here: http://www.ncems.org/pdf/OpioidOverdosePrevention.pdf.

#### 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 persons at risk for overdose and candidates for naloxone, and naloxone best practices in the pharmacy. The training is available here:

https://www.ncpharmacists.org/content.asp?contentid=255

#### Project Lazarus

Project Lazarus offers technical assistance to groups and organizations engaged in overdose prevention activities like naloxone distribution and others that align with the Project Lazarus model. Click <a href="here">here</a> to learn more about the Project Lazarus model, what Project Lazarus is doing in North Carolina and across the country, and to view helpful resources like naloxone training videos.

For more information, contact Project Lazarus:

Project Lazarus (336) 667-8100 www.projectlazarus.org

#### 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**

- Injection drug user hangouts
- Syringe exchange programs
- Prisons and jails
- Opioid Treatment Programs
- Hospital-based and private detoxification programs
- Local drug treatment centers
- Pawn Shops

- Mental and behavioral health centers
- Pharmacies and local health-care clinics
- HIV/AIDS service organizations and other community-based organizations
- Laundromats and parking lots
- Locations used by persons engaged in sex work
- Churches, faith-based organizations
- Blood Plasma centers

#### Syringe Exchange Programs

Syringe Exchange programs (SEPs) 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 SEP is an effective way of reaching those who are currently at risk for overdose and those who may be in recovery. Visit the <a href="North Carolina Safer Syringe Initiative">North Carolina Safer Syringe Initiative</a> website for more information about syringe exchange programs in North Carolina.

#### Jails and Prisons

Upon re-entry back into the community, some formerly incarcerated individuals are at a heightened risk of overdose mortality within the first weeks of release. Overdose prevention programs should focus on treatment and services within jails and prisons, training those at-risk to administer naloxone, and providing naloxone upon release. In February 2015, the Durham jail became the first in North Carolina to dispense naloxone kits to inmates as they are leaving the facility.

#### 4. Determine How You Will Acquire Naloxone

#### **Types of Naloxone**

Table 5 describes the types of naloxone available for use by community members. See <u>Appendix</u> <u>3</u> for administration instructions for each type.

**Table 5: Types of Naloxone** 

Table 5: Types of Nalo	oxone		
Method of Administration	Medication	Directions for Use	Additional Materials Needed
Intramuscular  o Vial/Syringe o Auto- Injector	Vial/Syringe Naloxone HCI solution 0.4mg/mL 2 x 1mL single dose vials (SDV)	Inject 1 mL IM into shoulder or thigh. Repeat after 3 minutes if no or minimal response.	2 (two) 3mLintramuscular (IM) syringes, 2 (two) 21G-25G, 1 inch needles
	Auto-Injector (EVZIO®) 2mg/0.4 mL	Follow audio instructions from device. Place on thigh and inject 0.4 mL. Repeat after 3 minutes if no or minimal response.	n/a
Intranasal  O Nasal spray O Pre-filled Syringe	Nasal Spray 4mg (NARCAN®)	Administer a single spray of NARCAN® in one nostril. Repeat after 3 minutes if no or minimal response.	n/a
	Pre-filled Syringe Naloxone HCl solution 2mg/2mL Inj. 2 x 2 mL pre-filled Luer- Lock syringes	Spray 1 mL (1/2 of syringe) in each nostril. Repeat after 3 minutes if no or minimal response.	2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300)

Source: North Carolina Harm Reduction Coalition

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

The <u>Naloxone Product Comparison</u> chart, developed by Prescribe-to-Prevent, provides a visual comparison of each product.

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 organizations in North Carolina.

The average price for generic intramuscular naloxone can be as low as \$15.60 - \$23.72 per single-dose vial, compared to \$75 for Narcan® Nasal Spray and \$2,460 for the Evzio® auto-injector. Please note, this is just a reference and prices may vary.

#### **Usability**

Determining the usability of each type of naloxone depends largely on the population who will be using it. See <u>Appendix 3</u> 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 "<u>Acquiring Naloxone</u>" 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.

#### **Acquiring Naloxone**

Naloxone can be obtained via the following methods:

- 1. Organizations may purchase naloxone through a pharmacy.
- 2. Organizations may purchase naloxone directly from the naloxone manufacturer.
- 3. Organizations may obtain naloxone from another distributing organization by donation.

#### → Purchase via pharmacy

Organizations can work with a pharmacist to establish pricing of naloxone.

Note: The pharmacy will need a dispensing standing order to be able to dispense naloxone to a distributing organization. See <u>Standing Order for Dispensing Naloxone to Organizations for Subsequent Distribution.</u>

If pharmacists have questions regarding naloxone dispensing, refer them to the NC Board of Pharmacy website and the following:

Frequently Asked Questions for Pharmacists on Naloxone Dispensing

#### The Strengthen Opioid Misuse Prevention Act (STOP) of 2017

or ask them to contact:

Amanda Fuller Moore, PharmD
Pharmacist, Division of Public Health
NC Department of Health and Human Services
(Office) 919-707-5299
(Cell) 919-270-0820
Amanda.fullermoore@dhhs.nc.gov

#### → Purchase directly from the manufacturer

Distributing organizations may purchase naloxone directly from a manufacturer. In some cases, organizations may be able to receive discounts for naloxone purchased in bulk. Contact the manufacturer for more information.

Note: Purchasing from a manufacturer must be done in conjunction with either a pharmacy or a prescriber. Some manufactures (i.e. Adapt Pharma) may provide orders requiring signature by a physician that constitute a standing order.

#### FDA-Approved Naloxone Products

To browse a current list of all FDA-approved naloxone products, visit the U.S. Food and Drug Administration <u>website</u> and search for Naloxone.

#### → Donation by other distributing organization 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.

#### **NC Harm Reduction Coalition**

To get advice on ordering and administering intramuscular naloxone kits, contact NCHRC. Availability of kits depends on supply at time of request and population served. NCHRC prioritizes organizations that serve active injection-drug users, people on medication-assisted treatment, people who are formerly incarcerated with a history of opiate use, people engaged in sex work, and people who identify as transgender.

For more information about receiving naloxone kits through NCHRC, contact Jesse Bennett:

Jesse Bennett
Statewide Overdose Prevention Coordinator
North Carolina Harm Reduction Coalition
jbennett@nchrc.org
(919) 523-4303

#### **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:

#### **High Priority**

- 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 (see <u>Appendix 4</u>)

#### **Additional Options**

- Alcohol pads, rescue breathing masks, gloves, etc.
- Toothbrush holder or glasses case (for holding supplies/needles)
- Condoms

Please note that providing materials along with naloxone is not required during distribution.

#### **Example: NCHRC Overdose Rescue Kit**

- **Naloxone** (2 syringes and 2 vials of 0.4 mg of injectable naloxone).
- **Brochure** containing information about overdose recognition and response, reversing the effects of an opioid overdose, resources for treatment, and instructions for reporting naloxone administration. Click <u>here</u> to view brochure.
- UV ray-resistant bag

#### 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 <u>Action 7</u>: "Write the <u>Standing Order</u>."

#### Guidelines for Storing and Labeling Naloxone

- Maintain kits in a secured location that limits access to authorized staff.
- 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.

#### 6. Determine Tracking Procedures

#### **Tracking**

The Naloxone Access Law *does not require* that programs track where and to whom naloxone is distributed. However, the law does require that basic education is provided to each person to whom 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 distributer 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., locations 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. This <u>article</u> provides a list of tips for tracking reversals.

#### **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. See Appendix 5 to view the full form.

	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 whom? How? T=text, C=Call IP=in person

#### 7. Write the Standing Order

Standing orders can be composed by the signing medical provider or by any combination of partners involved.

# <u>Standing Order for Dispensing Naloxone to Organizations for Subsequent Distribution</u>

If the distributing organization will acquire naloxone via a pharmacist, a dispensing standing order 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)

# <u>Template: Standing Order for Dispensing Naloxone to Organizations for Subsequent Distribution</u>

The above link provides a template of a dispensing standing order. The template includes instructions to adapt the standing order as needed. *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 NC Board of Pharmacy website and the following:

<u>Frequently Asked Questions for Pharmacists on Naloxone Dispensing</u> The Strengthen Opioid Misuse Prevention Act (STOP) of 2017

#### or ask them to contact:

Amanda Fuller Moore, PharmD
Pharmacist, Division of Public Health
NC Department of Health and Human Services
(Office) 919-707-5299
(Cell) 919-270-0820
Amanda.fullermoore@dhhs.nc.gov

#### **Standing Order for Distribution of Naloxone by Organizations**

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)

#### Template: Standing Order for Distribution of Naloxone by Organizations

The above link provides a template of a distribution standing order. The template includes instructions to adapt the standing order as needed. *The distribution standing order authorizes the distribution of naloxone by the organization after it has been dispensed to the organization.* 

# Sustainability Planning

Planning for sustainability is critical to the success of a naloxone distribution program.

#### Partnerships and Sponsorships

Partners and sponsors can be a great resource for financial and operational support. Consider partnerships between organizations and agencies that that will be directly impacted by the

distribution of naloxone, such as local health departments, EMS (Emergency Medical Services), Local Management Entity/Managed Care Organization (LME/MCO) agencies on mental health, law enforcement, and substance use/misuse treatment services.

#### **Regional Partnerships**

Several local health departments with adopted standing orders suggest partnering with surrounding counties to purchase naloxone at a bulk rate. This allows for widespread regional distribution and highly discounted prices.

#### **Funding Opportunities**

#### Sources for Funding and Resource Support

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

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

#### National Organizations

- Aetna Foundation
- Open Society Foundations

- MAC AIDS Fund
- Broadway Cares/Equity Fights AIDS Fund

#### State and Local

Local health departments can seek funding through the local government's general fund, the Board of Health, or the Board of County Commissioners to fund the purchase of naloxone.

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 NC DHHS Division of Public Health Injury and Violence
  Prevention Branch distributes Centers for Disease Prevention funds to local health
  departments and districts through the Agreement Addendum process. For information,
  click here.
  - Also visit <u>NCDHHS: Funding Syringe Exchange Programs</u> for additional information about organizations funding harm reduction and opioid-related activities.
- NC DHHS 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 here.
- **Project Lazarus** 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 <u>Projectlazarus.org</u>.
- Blue Cross Blue Shield of NC Foundation is dedicated to improving the health and well-being of all North Carolinians. It offers grants with focuses on increasing access to health services and expanding access to healthy foods, local foods, and places to be active. For more information, click here.

#### 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.

Below are examples of communication campaigns used to promote naloxone:

"I Saved a Life" Awareness Campaign (New York)

"Naloxone Saves" (Ventura County, CA)

"The New Day Campaign" (Maryland)

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# **Appendix**

# List of Appendices

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- 2. Data Sources
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#### Appendix 1: Naloxone Access Law Summary

#### Naloxone Access (G.S. 90-12.7)

A standing order is a medical order that authorizes the dispensing of a medication, like naloxone or the flu vaccine, to any person who meets criteria designated by the prescriber. Under G.S. 90-12.7, a health care provider may write a standing order to allow the dispensing of naloxone to persons at risk for an overdose and to those in a position to help others at risk of an overdose (3<sup>rd</sup>-party prescribing). The statute provides criminal and civil liability protection to health care providers who prescribe naloxone and to those who administer naloxone to persons experiencing an overdose.

G.S. 90—12.7 also establishes the authority of the State Health Director to issue a statewide standing order for naloxone to allow pharmacists to dispense naloxone to persons without a separate prescription from a health care provider. North Carolina's statewide standing order has been in effect in since June 2016. Naloxone is available, without a prescription, at the majority of retail pharmacies in North Carolina. Naloxone dispensed under the statewide standing order is covered by Medicaid and by some commercial insurers.

In 2017, the legislature added a provision allowing health care providers to write standing orders to allow organizations, including local health departments, to distribute naloxone in the community. Thus, typically two different standing orders are required to allow a local health department or a community organization to distribute naloxone—one to provide for the dispensing of the naloxone to the organization itself and one to allow for the distribution of the naloxone by the organization to the community. The chart below summarizes North Carolina law controlling the dispensing and distribution of naloxone.

	DISPENSING to INDIVIDUALS	DISPENSING to ORGANIZATIONS	DISTRIBUTION
Who can perform:	-Pharmacists -Local Health Department nurses trained to dispense -Dispensing physicians, PAs or NPs	-Pharmacists	-Any agent of the organization
Where it takes place:	-Pharmacies -Local health department clinics -Dispensing physician offices	-Pharmacies	-Anywhere

What order	-State Health Director's standing	-State Health Director's	-Distribution standing
is needed:	order	standing order or local	order
	OR	dispensing standing order	
	-Individual prescription	if organization's agents	
	OR	will administer	
	-Local standing order	OR	
		-Local dispensing	
		standing order	
		authorizing distribution if	
		organization's agents will	
		distribute	

#### Appendix 2: Data Sources

- The NC Opioid Data Dashboard, created by the Injury and Violence Prevention Branch (IVPB) of the NC Division of Public Health, provides integration and visualization of state- and county-level metrics from multiple sources to track progress towards North Carolina's Opioid Action Plan (NC OAP) goals. The data dashboard also provides links to additional data sources and partner websites such as the North Carolina Opioid and Prescription Drug Abuse Advisory Committee (NC OPDAAC) and North Carolina Harm Reduction Coalition (NCHRC).
  - <u>IVPB Poisoning Data</u> provides county-, regional-, and state-level data comparisons on opioid-related metrics such as poisonings, emergency department visits, and prescribing.
    - <u>The Core Overdose Data Slides</u> provide basic data trends and public health surveillance around the drug overdose epidemic. Click <u>here</u> for a recorded presentation of these slides.
    - County Level Overdose Slide Decks available via <u>IVPB Poisoning Data</u> provide county-level opioid-related statistics in an easily digestible format for the general public and can be customized for various audiences and presentations.
    - NC Harm Reduction Slides provide details about the implementation of opioid-related policies across the state, including community naloxone reversals, law enforcement naloxone reversals, counties served by syringe exchange programs, etc. These slides are updated monthly by IVPB.
- The North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT) 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.
  - Users affiliated with health departments can be authorized by the NC Division of Public Health to have access to NC DETECT data.
  - o To request access to NC DETECT, please read the Terms of Use and complete the online Account Request form.
  - Health departments can request training for NC DETECT by emailing <u>ncdetect@listserv.med.unc.edu</u>. NC DETECT data <u>can be shared with</u> partners outside the health department by following specific protocols. Contact ncdetect@listserv.med.unc.edu 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.
- → NC Social Determinants of Health 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.

- → North Carolina Health Data Query System 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 State Center for Health Statistics.
- → Centers for Disease Control and Prevention (CDC) Web-based Injury Statistics Query and Reporting System (WISQARS<sup>TM</sup>) 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>TM</sup> data to learn more about the public health and economic burden associated with unintentional and violence-related injury in the United States.

#### Appendix 3: Naloxone Administration Instructions

#### Appendix 3-A

#### Intramuscular (syringe/vial)

Source: Harm Reduction Coalition

(Retrieved from: https://harmreduction.org/wp-content/uploads/2012/11/HRC\_ODprevention\_worksheet13.pdf)

#### WORKSHEET

### Administering Injectable Naloxone

This worksheet is a component of *Guide* to *Developing and Managing Overdose*Prevention and Take-Home Naloxone Projects, produced by Harm Reduction Coalition.

More information at harmreduction.org

#### VERY IMPORTANT:

Remember, naloxone only works if there are opioids involved with the overdose; it will not reverse an overdose resulting solely from cocaine, speed, benzos, alcohol or other nonopioid based drugs.

#### To administer injectable naloxone:

Injectable naloxone comes packaged in several different forms — a multi dose 10 mL vial and single dose 1mL flip-top vials with a pop off top. With all formulations of naloxone, it is important to check the expiration date and make sure to keep it from light if it is not stored in a box. If someone has an injectable formulation of naloxone, all of the steps in recognizing and responding to an overdose are the same except how to give the naloxone.

These are the steps to use injectable naloxone:

- 1. If the person isn't breathing, do rescue breathing for a few quick breaths first.
- 2. Pop off the orange top from the vial.
- 3. Draw up 1cc of naloxone into the syringe:

  1cc=1mL=100u. Use a long needle: 1 to 1 ½ inch
  (called an IM or intramuscular needle) needle
  exchange programs and pharmacies have
  these needles.
- 4. Inject into a muscle thighs, upper, outer quadrant of the butt, or shoulder are best. If possible, clean the skin where you are going to inject with an alcohol swab first. It is okay to inject directly through clothing if necessary. Inject straight in to make sure to hit the muscle.
- If there isn't a big needle, a smaller needle is OK to inject under the skin; however, it is better to inject into a muscle whenever possible.
- to be sure to hit the muscle
- 6. After injection, continue rescue breathing 3 minutes.
- 7. If there is no change in about 3 minutes, administer another dose of naloxone and continue to breathe for the person. If the second dose of naloxone does not revive them, something else may be wrong—either it has been too long and the heart has already stopped, there are no opioids in their system, non-opioid drugs are the primary cause of overdose (even if they have also taken opioids), or the opioids are unusually strong and require more naloxone (can happen with Fentanyl, for example).

Inject straight in

#### **Appendix 3-B**

#### **Intramuscular** (auto-injector)

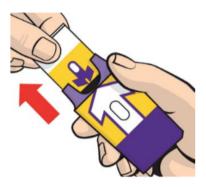
Source: Evzio®

(retrieved from: <a href="https://evzio.com/patient/how-to-use-evzio/">https://evzio.com/patient/how-to-use-evzio/</a>)

#### How to use EVZIO

Step 1. Pull EVZIO from the outer case. See Figure B.

Figure B



**Do not** go to Step 2 (Do not remove the **Red** safety guard.) until you are ready to use EVZIO. **If you are not ready to use EVZIO, put it back in the outer case for later use.** 

Step 2. Pull off the Red safety guard. See Figure C.

To reduce the chance of an accidental injection, do not touch the **Black** base of the auto-injector, which is where the needle comes out.

Figure C



If an accidental injection happens, get medical help right away.

Note: The Red safety guard is made to fit tightly. Pull firmly to remove.

#### Do not replace the Red safety guard after it is removed.

**Step 3.** Place the **Black** end of EVZIO against the outer thigh, through clothing, if needed. **Press firmly** and hold in place for 5 seconds. See Figure D.

If you give EVZIO to an infant less than 1 year old, pinch the middle of the outer thigh before you give EVZIO and continue to pinch while you give EVZIO.

Figure D



**Note:** EVZIO makes a distinct sound (click and hiss) when it is pressed against the thigh. This is normal and means that EVZIO is working correctly. Keep EVZIO firmly pressed on the thigh for 5 seconds after you hear the click and hiss sound. The needle will inject and then retract back up into the EVZIO auto-injector and is not visible after use.

### Step 4. After using EVZIO, get emergency medical help right away.

If symptoms return after an injection with EVZIO, an additional injection using another EVZIO may be needed. Give additional injections using a new EVZIO auto-injector every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

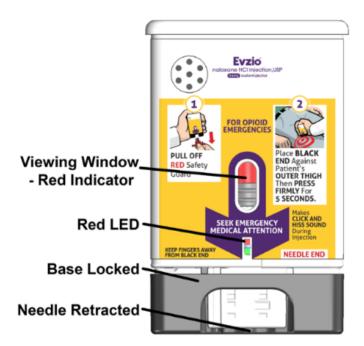
EVZIO cannot be reused. After use, place the auto-injector back into its outer case. Do not replace the **Red** safety guard.

# How to know that EVZIO has been used. See Figure E.

- The Black base will lock into place.
- The voice instruction system will state that EVZIO has been used and the LED will blink red.
- The Red safety guard cannot be replaced.
- The viewing window will no longer be clear. You will see a red indicator.

Figure E

# **Used EVZIO**



#### What to do after EVZIO has been used:

- Get emergency medical help right away.
- Put the used EVZIO back into its outer case.
- Do not throw away the EVZIO in household trash. Do not recycle EVZIO.
- Used EVZIO should be taken to a healthcare setting for proper disposal in a sharps container.

There may be local or state laws about how to throw away used auto-injectors.\*

\*For California Only: This product uses batteries containing Perchlorate Material – special handling may apply. See <a href="https://www.dtsc.ca.gov/hazardouswaste/perchlorate">www.dtsc.ca.gov/hazardouswaste/perchlorate</a>

#### How should I store EVZIO?

- Store EVZIO at room temperature between 59°F to 77°F (15°C to 25°C).
- Keep EVZIO in its outer case until ready to use.
- Occasionally check EVZIO through the viewing window of the auto-injector.
   The solution should be clear. If the EVZIO solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Your EVZIO has an expiration date. Replace it before the expiration date.

### Keep EVZIO and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for: kaleo, Inc., Richmond, VA 23219

Issued: 4/2014

# Appendix 3-C

# **Intranasal (nasal spray)**

Source: Narcan® Nasal Spray

(Retrieved from: https://www.narcan.com/static/NARCAN-Quick-Start-Guide.pdf)



# **QUICK START GUIDE**

# **Opioid Overdose Response Instructions**

Use NARCAN Nasal Spray (naloxone hydrochloride) for known or suspected opioid overdose in adults and children.

Important: For use in the nose only.

Do not remove or test the NARCAN Nasal Spray until ready to use.

Identify Opioid Overdose and Check for Response

Ask person if he or she is okay and shout name.

Shake shoulders and firmly rub the middle of their chest.

#### Check for signs of opioid overdose:

- Will not wake up or respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- · Center part of their eye is very small, sometimes called "pinpoint pupils"

Lay the person on their back to receive a dose of NARCAN Nasal Spray.



Give **NARCAN** Nasal Spray

Remove NARCAN Nasal Spray from the box.

Peel back the tab with the circle to open the NARCAN Nasal Spray.





Hold the NARCAN nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



# Gently insert the tip of the nozzle into either nostril.

· Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.





Press the plunger firmly to give the dose of NARCAN Nasal Spray. • Remove the NARCAN Nasal Spray from the nostril after giving the dose.



Get emergency medical help right away.

Call for emergency medical help, Evaluate. and Support

Move the person on their side (recovery position) after giving NARCAN Nasal Spray.

#### Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.



Repeat Step 2 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.



For more information about NARCAN Nasal Spray, go to www.narcannasalspray.com, or call 1-844-4NARCAN (1-844-462-7226).

# **Appendix 3-D**

# **Intranasal (pre-filled syringe)**

Source: Harm Reduction Coalition

(Retrieved from: https://harmreduction.org/wp-content/uploads/2014/10/IN-instructions-and-kit-assembly.pdf)

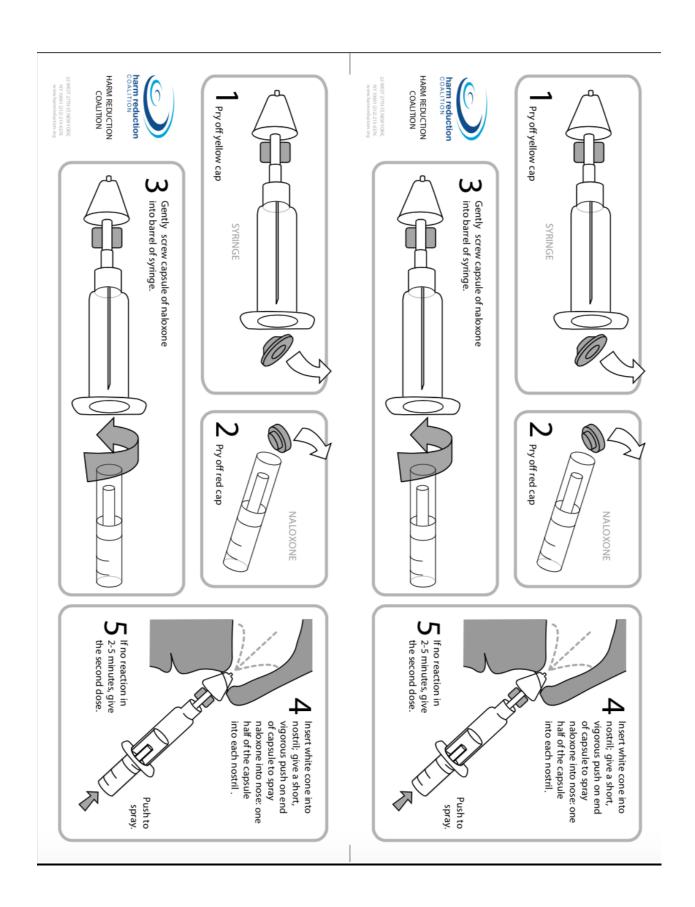
#### Assembling the nasal spray device (partly)

Each dose of naloxone comes in a tan/orange box that contains a syringe with yellow caps on each end, and a capsule of naloxone with a red cap. Each syringe should be screwed onto a white cone, called a Mucosal Atomization Device (MAD), which turns the liquid naloxone into a spray. With these two pieces screwed together, anyone using the kit does not have to lose time putting them together during an emergency.

#### Here's how to do it:

- Open the tan/orange box at the end that does not have the expiration date. This way the date can easily
  be seen. The expiration date is also printed on the naloxone capsule, but it's hard to read. An easy way
  to open the undated end of the box is to squeeze the wide sides together so that the sealed end distorts
  it shape and the flaps are easily grasped to pull apart.
- 2. Remove the syringe from the box, leaving the naloxone capsule with the red/purple cap inside.
- 3. Remove the large yellow cap from the tip of the syringe
- 4. Tear open the plastic wrapping of the MAD without removing it from the bag or touching it. (Look closely at the bag to find where to tear it along the dotted line on one of its long sides.)
- 5. Hold the MAD through its bag to keep it untouched while screwing the syringe onto it. Grip the clear plastic 'wings' on the MAD through the bag; that will make it easier to hold while screwing. (We are trying not to touch the MAD, because when the kit is used, it will be put into the nose of the person being rescued. Another way of keeping the MAD clean is to wear latex gloves while handling it.)
- 6. After screwing the MAD onto the syringe, put them into the tan/orange box. The end with the MAD should be put into the box first. This way, the wide part of the syringe keeps the naloxone capsule from falling out, and the MAD squeezed into the box keeps the syringe from sliding out.
- 7. Put 2 doses into each blue bag, along with one set of instructions.





# Appendix 4: NC's Good Samaritan Law

# <u>Appendix 4-A</u> General Statute Summary

Good Samaritan Laws-Drug Offenses (G.S. 90-96.2) and Alcohol Offenses (G.S. 18B-302.2)

G.S. 90-96.2 states that a person who witnesses an overdose and seeks help for the victim cannot be prosecuted for possession of drug paraphernalia or small amounts of drugs or be considered in violation of a condition of parole, probation, or post-release for those crimes if the evidence for those crimes was obtained because the person called for help. The caller must provide his or her name to 911 or to law enforcement to qualify for the immunity. The individual who experiences the overdose for whom help was sought is also given the same protection. The purpose of the law is to remove the fear of criminal repercussions for calling 911 to report an overdose and to instead focus efforts on getting help to the victim.

G.S. 18B-302.2 gives protection against prosecution for possession and consumption of alcohol (and associated violations of parole, probation, or pre-trial release) for persons under 21 who seek help for someone who is experiencing an alcohol-related overdose. The person calling for help must give his or her name to 911 or law enforcement. The protection also applies to the overdose victim.

# Appendix 4-B

# **Example of Good Samaritan Communication**

Source: North Carolina Harm Reduction Coalition (Retrieved from: http://www.nchrc.org/assets/Syringe-Exchange-resources/Good-Sam2016.pdf)



FACT Under North Carolina law, you can call 911 for help during a drug overdose

FACT The victim and the caller are protected from process that for the caller are protected from prosecution for the following;

FAC

- •Possession of small amounts of most drugs
- Possession of drug paraphernalia
- Underage possession or consumption of alcohol
- •Violating conditions of parole, post-release or probation

FAC

The caller must provide their name to law enforcement or EMS to qualify for the legal protections

As of January 2016, 52 law enforcement departments in North Carolina carry naloxone to save the lives of overdose victims

# WHAT IS NALOXONE?

Naloxone is an effective, non-abuseable medication that reverses opioid drug overdose. Opioids include heroin, methadone and prescription painkillers such as Percocet, Vicodin, Oxy, etc. Naloxone restores breathing in the overdose victim

# LIABILITY UNDER THE LAW

Anyone who uses naloxone to reverse an overdose is immune from civil and criminal liability as long as they do so in good faith. Medical providers who prescribe naloxone and pharmacists who dispense naloxone are also immune from civil/criminal liability.



NORTH CAROLINA HARM REDUCTION COALITION 2416 HILLSBOROUGH STREET.RALEIGH.NC 27607 WWW.NCHRC.ORG

For information on how to get a FREE naloxone kit or about how the law applies to you, contact NCHRC at hnamkoong88@gmail.com or call/text us at 919-218-4505

# Appendix 5: Sample Naloxone Distribution Log

# North Carolina Harm Reduction Coalition Distribution Log

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

# **Appendix 6: Standing Order Templates**

## Appendix 6-A

**Template Standing Order for Dispensing naloxone to Organizations for Subsequent Distribution** 

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

\*This page is information for the signing physician only and should be removed from the order before use. \*

- This document is a template to be customized by each practitioner wishing to authorize the dispensing of naloxone to organizations for subsequent distribution as allowed by NCGS 90-12.7.
  - This template covers only the dispensing of the naloxone from the pharmacy to the organization.
- A separate standing order must be executed authorizing the distribution of naloxone by the organization to eligible candidates.
   The attached template <u>requires</u> edits before signing and use.
- Review all areas highlighted in yellow.
  - Fill in the requested information
  - o Remove the yellow highlighting
- Review the area highlighted in green.
  - Ensure you want all formulations included and that you agree with the provided instructions.
  - Make any edits you feel necessary
  - o Remove the green highlighting
- Remove the "Template" watermark once you have completed the previous steps.
- If you have questions, please contact Amanda Moore Amanda.fullermoore@dhhs.nc.gov

# 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 ( Preferred me	Intramuscular (IM) Inject into shoulder or thigh						
Medication and Required Device for Administration	Naloxone HCl 1 mg/mL Inj.  2 x 2 mL as pre-filled Luer-Lock syringes  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)	Narcan ® 4 mg/0.1 mL Nasal Spray Dispense 1 x two- pack	Naloxone HCI 0.4mg/mL Inj.  2 x 1mL single dose vials (SDV)  2 (two) 3 mL syringe  2 (two) 25 G, 1-inch needle  Naloxone HCI 2 mg/2mL Inj.  Dispense 2 (two) pre-filled syringes  2 (two) 25 G, 1-inch needle					
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 NARCAN® in one 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, 15 kits, to be provided at each dis		imum number, such as no more than					
Refills	PRN							
Individual kit labeling (OPTIONAL, but recommended)	Place individual label on each naloxone kit containing the following:     Tracking number if being used for data keeping     Website for additional information and or phone number for assistance     Instructions for use							
Special Instructions (OPTIONAL, but recommended)								

INSERT SIGNING PHYSICIAN NAME AND CREDENTIALS

INSERT PHYSICIAN TITLE
INSERT PHYSICIAN EMPLOYER

National Provider ID: INSERT NUMBER

**Date Signed** 

(Insert date 1 year from date of signing)

Date Expires

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

\*This page is information for the signing physician only and should be removed from the order before use. \*

- This document is a template to be customized by each practitioner wishing to authorize the distribution of naloxone by an organization as allowed by NCGS 90-12.7.
  - This template does not authorize the dispensing of naloxone to an organization. A separate standing order must be executed to authorize the dispensing of naloxone to the organization..
  - This template is intended to authorize the distribution of the naloxone by the organization after it has been properly dispensed to the organization.
- The attached template <u>requires</u> edits before signing and use.
- Review all areas highlighted in yellow.
  - Fill in the requested information
  - Remove the yellow highlighting
- Review the area highlighted in green.
  - Ensure you want all formulations included and that you agree with the provided instructions.
  - Make any edits you feel necessary
  - Remove the green highlighting
- 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:
  - Date, number of kits distributed, name of distributor, zip code where distribution occurred, confirmation that education was provided.
  - Also include frequency with which logs should be returned and to whom they should be returned.
- Remove the "Template" watermark once you have completed the previous steps.
- If you have questions, please contact Amanda Moore Amanda.fullermoore@dhhs.nc.gov

# **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 Protos	col 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 poisoning</li> <li>Persons with a high dose opioid prescription (&gt;50 morphine mg equivalents per day)</li> <li>Persons with an opioid prescription 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> </ul> </li> <li>Persons with opioid prescription and smoking/COPD or other respiratory illness or obstruction</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> <li>Persons who voluntarily request Naloxone and are in the position to assist a person at risk of experiencing an opiate-related overdose.</li> </ul>					
Route(s) of Administration	Intranasal Preferred m		Intramuscular (IM) Inject into shoulder or thigh			
Medication and Required Device for Administration	Naloxone HCl 1 mg/mL Inj. 2 x 2 mL as pre-filled Luer- Lock syringes  Distribute 2 (two) doses 2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300) Available from: Teleflex (866-	Narcan ® 4 mg/0.1 mL Nasal Spray  Distribute 1 x two-pack	Naloxone HCI 0.4mg/mL Inj.  2 x 1mL single dose vials (SDV)  2 (two) 3 mL syringe 2 (two) 25 G, 1-inch needle  Naloxone HCI 2 mg/2mL Inj.			
Directions for Use	246-6990) or Safety Works, Inc. (800-723-3892)  Call 911. Spray 1 mL in each nostril. Repeat every 3	Call 911. Administer a single spray of	<ul> <li>Distribute 2 (two) pre-filled syringes</li> <li>2 (two) 25 G, 1-inch needle</li> <li>Call 911. Inject the entire solution of the vial or pre-</li> </ul>			
	minutes as needed if no or minimal response.	NARCAN® in one nostril. Repeat every 3 minutes as needed if no or minimal response.	filled syringe IM in shoulder or thigh. Repeat every 3 minutes as needed if no or minimal response.			
Contraindications	A history of known hypersensiti	<u> </u>	•			
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 ste and the use of Naloxone. Examples of educational materials that incorporate the abinformation may be found at <a href="http://www.naloxonesaves.org">http://www.naloxonesaves.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

**Date Signed** 

# INSERT PHYSICIAN TITLE

INSERT PHYSICIAN EMPLOYER
National Provider ID: INSERT NUMBER

(Insert date 1 year from date of signing)

Date Expires

This order is effective immediately upon signing and may be revised or revoked by (INSERT PHYSICIAN TITLE) according to his/her discretion. A copy should be maintained by the authorizing physician and the authorized agency(s).