

DISPENSING OF DRUGS BY PUBLIC HEALTH NURSES

Part I Addendum Naloxone Dispensing

***Naloxone dispensing training does not substitute for the RN Dispensing Manual parts I and II training (available at publichealth.nc.gov). For a registered nurse to dispense naloxone in North Carolina health departments, he/she must have completed RN Dispensing training, parts I, II and live pharmacist training in addition to naloxone training (part I addendum).**

March 2014

Acknowledgements

Thank you to the NC DHHS NC Division of Public Health, Injury and Violence Prevention Branch staff for their significant contributions to this manual.

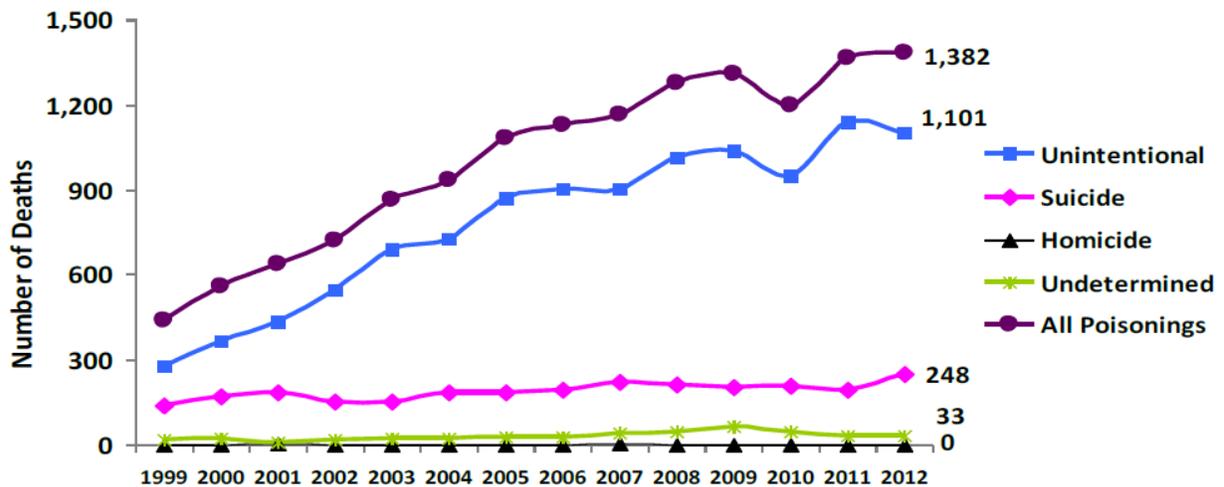
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Introduction: The Need

In North Carolina, in 2012, there were 1,101 people who died from unintentional poisonings, second only to 1,185 deaths due to motor vehicle crashes. Unintentional poisonings do not receive as much attention as other causes of deaths; however, unintentional poisoning deaths exceed the number of deaths from hypertension, atherosclerosis, homicide, HIV, or liver disease. Since 1999, 10,952 North Carolina residents have lost their lives from unintentional poisonings; a nearly 300 percent increase, from 297 to 1,101 in yearly deaths, due to unintentional poisonings (Fig. 1).¹

Figure 1: Poisoning Deaths by Intent: N.C. Residents, 1999-2012

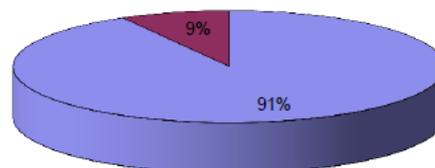


The vast majority of unintentional deaths are drug or medication-related, occurring when people misuse or abuse prescription opioid medications (Fig.2).

Figure 2: Medication/Drug vs Non-Medication Types of Unintentional Poisonings: N.C. Residents, 2012

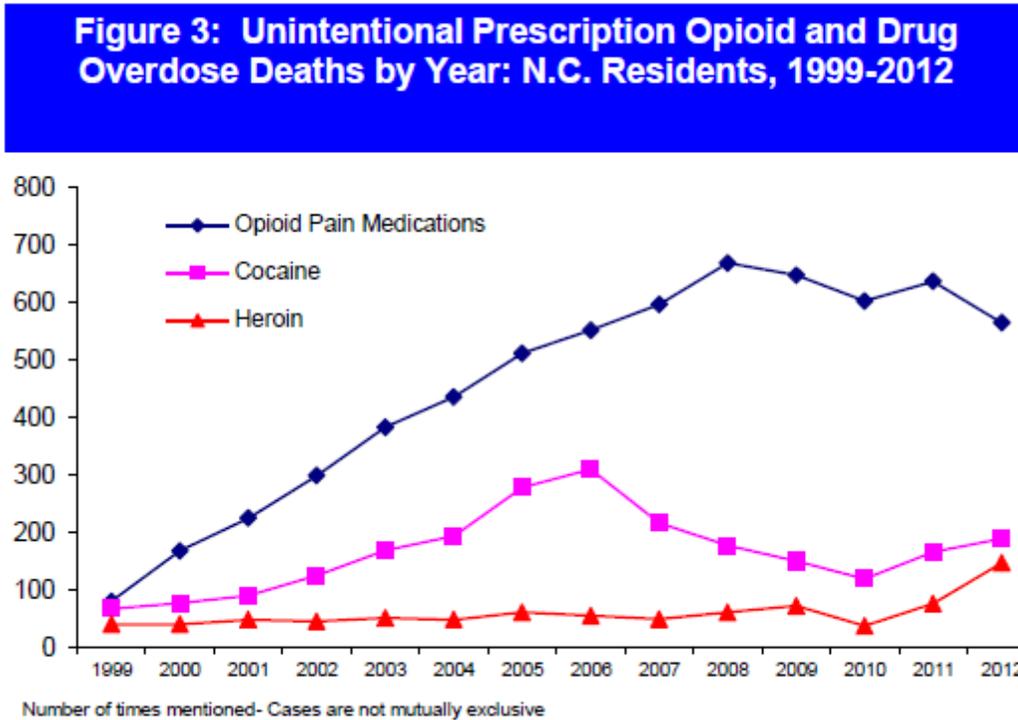
-Of these unintentional poisoning deaths, 91 percent are caused by drugs and medications (Over-the-counter, prescription and illicit) (Fig 2). Nine percent are toxins or chemicals (non-medication/non-drug).

-Prescription opioid analgesics, heroin and cocaine are the cause of death in over half (60%) of these poisoning deaths (Fig 2).



Medication/Drug--91%
 -Opioids/Cocaine--60%
 -Other/Unspecified drugs--28%
 -Anti-epileptic and sedative-hypnotic drugs--3%
 -Non-opioid--<1%

In particular, opioid analgesic deaths involving medications such as methadone, oxycodone, and hydrocodone have increased significantly in North Carolina. Opioid analgesics are now involved in more drug deaths than cocaine and heroin combined (Fig. 3)



For additional information on medication overdose in North Carolina visit: www.injuryfreenc.ncdhhs.gov/About/poisoning.htm. More detailed information is available in “The Burden of Unintentional Poisoning in North Carolina” available on the website.

The Response

The “SB20 911 Good Samaritan/Naloxone Access law became effective April 9, 2013. It states that individuals who experience a drug overdose or persons who witness an overdose and seek help for the victim can no longer be prosecuted for possession of small amounts of drugs, paraphernalia, or underage drinking. 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.”¹

“The Naloxone Access portion of SB20 removes civil liabilities from doctors who prescribe and bystanders who administer naloxone, or Narcan, an opiate antidote which reverses drug overdose from opiates, thereby saving the life of the victim. SB20 also allows community based organizations to dispense Naloxone under the guidance of a medical provider.”¹

Recognizing that fatal and non-fatal overdoses from opioids play an increasing role in the mortality and morbidity of North Carolina residents, the North Carolina Department of Health and Human Services approached the North Carolina Board of Pharmacy to implement new Naloxone Clinics in North Carolina, utilizing local health departments to provide wider access to patients at risk for an overdose.

The North Carolina Board of Pharmacy agreed to partially waive enforcement of 21 N.C.A.C. 46.2401 and .2403 to allow registered nurses to begin dispensing naloxone kits in a manner consistent with G.S. 96-106.2 (the “Good Samaritan/Naloxone” statute)(Appendix I & II) and a standing order submitted to, and reviewed by, the Board at its January 2014 meeting. (Appendix III)

The NC Board of Pharmacy, at its February meeting, published a “Notice of public hearing on proposed amendments to rule 21 N.C.A.C. 46.2401 and .2403- Dispensing in Health Departments” for public comments. The proposed rule/amendment language is attached. (Appendix IV)

What are Opioids?

Opioids are chemicals that are either derived from the opium poppy or are synthetically manufactured by pharmaceutical companies. Whether synthetic or naturally occurring, opioids all act in similar ways at specific sites in the body. They are depressants, and slow down the central nervous system. At high levels, opioids reduce consciousness and decrease breathing (respiratory depression). Opioids attach to specific receptors in the brain, spinal cord, and gastrointestinal tract and block the transmission of pain messages. They induce euphoria and users generally report feeling warm, drowsy, and content. Opioids relieve stress and discomfort by creating a relaxed detachment from pain, desires, and activity. They also cause slow heart rate, constipation, a widening of blood vessels, and decrease the natural drive to breathe.²

Opioids can be prescription medications, such as codeine, morphine, hydromorphone, methadone, oxycodone, hydrocodone, meperidine, propoxyphene and fentanyl; or illicit drugs, such as heroin.

A complete listing of opioid derivatives can be found on the National Institute on Drug Abuse website at www.drugabuse.gov.

The Role of Naloxone

Naloxone is an opioid antagonist which means it displaces the opioid from receptors in the brain. An overdose occurs because the opioid is attached to the same receptor site in the brain that is responsible for breathing. Naloxone usually acts dramatically, allowing slowed or absent breathing to resume. It is both safe and effective and has no potential for abuse, nor any serious adverse effects.²

Naloxone may work immediately, but can take up to 8 minutes to have the desired effect. The effect of the naloxone will only last for about 30 to 90 minutes in the body. Because most opioids last longer than 30 to 90 minutes, the naloxone may wear off before the effects of the opioids wear off and the person could go into an overdose again. Naloxone administration may be repeated without harm if needed.

Naloxone will only be effective when opioids are contributing to an overdose. The more non-opioid substances that contribute to the overdose, the less effective naloxone will be. **Due to the complex nature of these medical emergencies, it further emphasizes the necessity of calling 911 in an overdose situation.**²

How to recognize an opioid overdose and what to do

With opioid overdoses, the difference between surviving and dying depends on **breathing and oxygen**. Fortunately, opioid overdose is rarely instantaneous; people slowly stop breathing after the drug was used. There is usually time to intervene between when an overdose starts and a victim dies. Furthermore, not all overdoses are fatal. Without any intervention, some overdose victims may become unresponsive with slowed breathing, but will still take in enough oxygen to survive and wake up.²

The signs of an opioid overdose (what to look for):

- Blue skin tinge- usually lips and fingertips show first
- Body very limp
- Face very pale, skin clammy
- Pulse (heartbeat) slow, erratic, or not there at all
- Throwing up
- Passing out
- Choking sounds or a gurgling/snoring noise
- Breathing is very slow, irregular, or has stopped
- Unable to respond

How to respond to an opioid overdose

To determine if an individual is experiencing an overdose, the most important things to consider are **presence of breathing and responsiveness to stimulation**. Some relatively harmless ways to stimulate a person are:

- Yelling their name, and if no response,
- Rubbing knuckles over either the upper lip or up and down the front of the rib cage (sternal rub)

If the individual responds to these stimuli, they may not be experiencing an overdose at that time. It is best to stay with them to make sure they wake up.²

If the individual does not respond to stimulation, it is important to:

1. **Call 911** to get help
2. Perform **rescue breathing** to provide oxygen (if the person is not breathing)
3. Administer **naloxone**
4. **Stay** with the person until help arrives
5. Put the person in the **recovery position** (lying on side with body supported by bent knee, hand under head and face turned to the side)



Recovery position

Calling 911- What to say

It is important to say the victim's breathing has slowed or stopped, he or she is unresponsive, and the exact location of the victim.

If naloxone was given and did not work, this should be reported to the emergency responders upon their arrival.



Perform rescue breathing **2. RESCUE BREATHING**

When someone has stopped breathing and is unresponsive, rescue breathing should be done as soon as possible because it is the quickest way to get oxygen into the body. Steps for rescue breathing are:

1. Place the person on his or her back and pinch their nose.
2. Tilt the chin up to open the airway. Check to see if there is anything in the mouth blocking the airway. If so, remove it.
3. Give 2 slow breaths sealing their mouth with yours.
4. Blow enough air into the lungs to make the chest rise.

5. Turn your head after each breath to ensure the chest is rising and falling. If not, tilt the head back more.
6. Breathe again every 5 seconds until the victim resumes breathing or medical help arrives.

Administer naloxone

Naloxone may be administered by intramuscular injection or as a nasal spray, using different formulations. The standing order must state the administration route you will be using in your health department, per the local practitioner's preference.



Intra-nasal naloxone

Intramuscular naloxone

To administer intra-nasal naloxone:

1. Remove the two yellow caps and one red (or purple) cap from the naloxone syringe and the plastic delivery device.
2. Hold the nasal atomizer device and screw it onto the top of the plastic delivery device.
3. Screw the naloxone syringe gently into the delivery device.
4. Spray half of the medicine up one side of the nose and half up the other side of the nose.
5. If there is no breathing, or very shallow breathing, continue to perform rescue breathing while waiting for the naloxone to take effect.
6. If no response in 3-5 minutes, repeat naloxone.

To administer intramuscular naloxone:

1. Remove the cap from the naloxone vial and the shield from the syringe.
2. Insert syringe into vial and draw up 1 ml of naloxone
3. If practical, don gloves and prepare injection site with alcohol pad.

4. Administer 1 ml of naloxone via intramuscular injection into upper arm, buttock, or thigh.
5. If there is no breathing, or very shallow breathing, continue to perform rescue breathing while waiting for the naloxone to take effect.
6. If no response in 3-5 minutes, repeat naloxone.

Continue to monitor the victim and wait for emergency responders to arrive.

How to Dispense Naloxone Kits

Naloxone is a prescription medication and must be dispensed following all prescription medication rules and regulations, including **all prescription labeling requirements**. The NC Board of Pharmacy has specified that the prescription label should be affixed to the kit in a stable manner.

Naloxone inventory must be tracked and signed in and out of the pharmacy on a pharmacy log. Some sample prescription logs are available in the appendix (Appendix V)

All of the regulatory pharmacist oversight, patient counseling guidelines and prescription dispensing regulations must be observed as well, as listed in detail in the RN Dispensing Manual part I.

Naloxone kits may be dispensed to clients at risk of experiencing an opiate-related overdose or who are in a position to assist a family member, friend or other person at risk of experiencing an opiate-related overdose. Client must report no known sensitivity or allergy to naloxone and must be provided sufficient education regarding preventing, recognizing, and responding to a suspected opioid overdose.

The intramuscular kit should be assembled in appropriate packaging and contain at a minimum:

Prescription label

2 vials of 0.4mg/ml naloxone

2 syringes (3ml, 25G x 1")

Alcohol swabs

Gloves

Disposable CPR shield

Instructions for use

Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of summoning emergency responders

The intranasal kit should be assembled in appropriate packaging and contain at a minimum:

Prescription label

2 prefilled syringes of 2mg/2ml naloxone (with plastic delivery device)

Nasal atomizer piece

Disposable CPR shield

Instructions for use

Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of summoning emergency responders

***Naloxone dispensing training does not substitute for the RN Dispensing Manual parts I and II training (available at publichealth.nc.gov). For a registered nurse to dispense naloxone in North Carolina health departments, he/she must have completed RN Dispensing training, parts I, II and live pharmacist training in addition to this naloxone training (part I addendum).**

Appendix I

GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2013 SENATE BILL 20 RATIFIED BILL

S20-v-6

AN ACT TO PROVIDE LIMITED IMMUNITY FROM PROSECUTION FOR (1) CERTAIN DRUG-RELATED OFFENSES COMMITTED BY AN INDIVIDUAL WHO SEEKS MEDICAL ASSISTANCE FOR A PERSON EXPERIENCING A DRUG-RELATED OVERDOSE AND (2) CERTAIN DRUG-RELATED OFFENSES COMMITTED BY AN INDIVIDUAL EXPERIENCING A DRUG-RELATED OVERDOSE AND IN NEED OF MEDICAL ASSISTANCE; TO PROVIDE IMMUNITY FROM CIVIL OR CRIMINAL LIABILITY FOR (1) PRACTITIONERS WHO PRESCRIBE AN OPIOID ANTAGONIST TO CERTAIN THIRD PARTIES AND (2) CERTAIN INDIVIDUALS WHO ADMINISTER AN OPIOID ANTAGONIST TO A PERSON EXPERIENCING A DRUG-RELATED OVERDOSE; AND TO PROVIDE LIMITED IMMUNITY FROM PROSECUTION FOR CERTAIN ALCOHOL-RELATED OFFENSES COMMITTED BY PERSONS UNDER THE AGE OF 21 WHO SEEK MEDICAL ASSISTANCE FOR ANOTHER PERSON.

The General Assembly of North Carolina enacts:

SECTION 1. Article 5 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-96.2. Drug-related overdose treatment; limited immunity.

(a) As used in this section, "drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, coma, or death resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be a drug overdose that requires medical assistance.

(b) A person acting in good faith who seeks medical assistance for an individual experiencing a drug-related overdose shall not be prosecuted for (i) a misdemeanor violation of G.S. 90-95(a)(3), (ii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of cocaine, (iii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of heroin, or (iv) a violation of G.S. 90-113.22 if the evidence for prosecution under those sections was obtained as a result of the person seeking medical assistance for the drug-related overdose.

(c) A person who experiences a drug-related overdose and is in need of medical assistance shall not be prosecuted for (i) a misdemeanor violation of G.S. 90-95(a)(3), (ii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of cocaine, (iii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of heroin, or (iv) a violation of G.S. 90-113.22 if the evidence for prosecution under those sections was obtained as a result of the drug-related overdose and need for medical assistance.

(d) Nothing in this section shall be construed to bar the admissibility of any evidence obtained in connection with the investigation and prosecution of other crimes committed by a person who otherwise qualifies for limited immunity under this section."

SECTION 2. Article 5 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-106.2. Treatment of overdose with opioid antagonist; immunity.

(a) As used in this section, "opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.

(b) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following:

(1) The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose.

(2) The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose:

a. A family member, friend, or other person.

b. In the position to assist a person at risk of experiencing an opiate-related overdose.

(c) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section may administer an opioid antagonist to another person if (i) the person has a good faith belief that the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist.

(d) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section:

(1) Any practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this section.

(2) Any person who administers an opioid antagonist pursuant to subsection (c) of this section."

SECTION 3. Chapter 18B of the General Statutes is amended by adding a new section to read:

"§ 18B-302.2. Medical treatment; limited immunity.

Notwithstanding any other provision of law, a person under the age of 21 shall not be prosecuted for a violation of G.S. 18B-302 for the possession or consumption of alcoholic beverages if law enforcement, including campus safety police, became aware of the possession or consumption of alcohol by the person solely because the person was seeking medical assistance for another individual. This section shall apply if, when seeking medical assistance on behalf of another, the person did all of the following:

- (1) Acted in good faith, upon a reasonable belief that he or she was the first to call for assistance.
- (2) Used his or her own name when contacting authorities.
- (3) Remained with the individual needing medical assistance until help arrived."

SECTION 4. This act is effective when it becomes law.

In the General Assembly read three times and ratified this the 4th day of April, 2013.

s/ Daniel J. Forest

President of the Senate

s/ Thom Tillis

Speaker of the House of Representatives

Pat McCrory

Governor

Approved _____ .m. this _____ day of _____, 2013

Appendix II

North Carolina Board of Pharmacy- “Order of the Board”, January 21, 2014

NORTH CAROLINA BOARD OF PHARMACY

In re:)
)
21 N.C.A.C. 46.2510) **ORDER OF THE BOARD**
Partial Waiver of Enforcement of)
21 N.C.A.C. 46.2401 and)
21 N.C.A.C. 46.2403)
)

Pursuant to authority granted by 21 N.C.A.C. 46.2510, the Board of Pharmacy (“Board”) hereby partially waives enforcement of 21 N.C.A.C. 46.2401 and 21 N.C.A.C. 46.2403 as follows:

1. 21 N.C.A.C. 46.2510, promulgated by the Board pursuant to statutory authority, states that “Board may waive the enforcement of specific rules” under certain circumstances.
2. The North Carolina General Assembly has passed, and the Governor has signed into law, G.S. 96-106.2, which provides statutory authority for authorized practitioners to prescribe naloxone, an opioid antagonist medication, to a person at risk of experiencing an opiate-related overdose or to a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.
3. G.S. § 90-85.34A, authorizes registered nurses in a local health department to dispense prescription drugs and devices with certain conditions. Among them, the registered nurse may dispense “[o]nly prescription drugs and devices contained in a formulary recommended by the Department of Health and Human Services and approved by the Board.”
4. Acting State Health Director Robin Gary Cummings, M.D., has recommended that naloxone be added to the formulary from which health department registered nurses may dispense.
5. 21 N.C.A.C. 46.2401(a)(1) provides that a “registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions: (1) Drugs and devices may be dispensed only to health department patients.”
6. 21 N.C.A.C. 46.2401(a)(4) provides that “[o]nly the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse.” Neither naloxone specifically, nor opioid antagonist medications generally, are among the prescription drugs that may be dispensed pursuant to 21 N.C.A.C. 46.2403.

7. The Board partially waives enforcement of 21 N.C.A.C. 46.2401 to allow registered nurses in local health departments to dispense naloxone to a health department patient or to others as permitted by G.S. 90-106.2.

8. The Board partially waives enforcement of 21 N.C.A.C. 46.2403 to allow registered nurses in local health departments to dispense an opioid antagonist prescribed pursuant to G.S. 90-106.2.

9. The Board has determined that a partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 will: (i) positively impact the delivery of pharmaceutical care; and (ii) will not compromise patient health and safety. 21 N.C.A.C. 46.2510(1), (2).

10. Any registered nurse at a local health department who chooses to dispense an opioid antagonist medication pursuant to this partial waiver of enforcement shall conform to the policies and procedures set forth in a naloxone standing order submitted to, and reviewed by, the Board on January 21, 2014. 21 N.C.A.C. 46.2510(3).

11. The partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 is subject to continuing study by the Board. 21 N.C.A.C. 46.2510(4). The waiver shall continue until such time as the Board either promulgates amendments to 21 N.C.A.C. 46.2401 and .2403, or Board determines, after appropriate notice and hearing, that continuation of the waiver would no longer meet the standards of 21 N.C.A.C. 46.2510.

This is the 21st day of January, 2014.

NORTH CAROLINA BOARD OF PHARMACY

by:



Jack W. Campbell IV
Executive Director

Appendix III

Naloxone (Narcan) Standing Order

_____ County Health Department

Naloxone is indicated for the reversal of opioid overdose induced by natural or synthetic opioids and exhibited by respiratory depression or unresponsiveness. It is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

This standing order covers the possession and distribution of naloxone kits, to include naloxone hydrochloride, intramuscular syringes, alcohol pads and related injection supplies, and overdose prevention materials.

Public Health Nurses at the _____ County Health Department, who have been appropriately trained by the NC Board of Pharmacy approved training, may possess and distribute naloxone kits to a person at risk of experiencing an opiate-related overdose or a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

Assessment:

Subjective Findings:

- Client is at risk of experiencing an opiate-related overdose or is in a position to assist a family member, friend, or other person at risk of experiencing an opiate-related overdose
- Client reports no known sensitivity or allergy to naloxone hydrochloride

Objective findings:

- Client is oriented to person, place, and time and able to understand and learn the essential components of overdose response and naloxone administration.

Plan of Care:

- Provide education regarding preventing, recognizing, and responding to a suspected opioid overdose.
- Dispense one naloxone kit, either IM or intra-nasal, to include at a **minimum**:

For intramuscular injection kits:

- Prescription label
- Two 1mL vials of naloxone hydrochloride
- Two intramuscular syringes (1mL vials)
- Disposable CPR shield
- Alcohol pads and gloves
- Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of summoning emergency responders
-

For intra-nasal kits:

- Prescription label
- 2 prefilled syringes of 2mg/2ml naloxone (with plastic delivery device)
- Nasal atomizer piece
- Disposable CPR shield
- Instructions for use
- Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of summoning emergency responders

Nursing/Provider Actions:

- Screen client for contraindications/precautions to prescription or dispensing
- If a contraindication/precaution exists, refer client to medical provider for evaluation.
- Show Opioid Overdose Prevention video (if available) or provide naloxone administration training to client and answer any client questions.
- Authorized dispenser will dispense naloxone kit and explain contents to client
- Authorized dispenser will log all dispensed kits on a form approved by the ordering physician.
- Provide information and/or referral for substance abuse or behavioral health treatment options.

Follow Up Requirements:

- Instruct client/parent/guardian to call medical provider if questions, concerns or problems arise
- Instruct client/parent/guardian to return for refill as needed, subject to use and expiration of naloxone (18 months)
- Encourage opioid user to communicate with primary care provider regarding overdose, use of naloxone, and availability of behavioral health services
- Refer client as needed for other needed services (i.e. well child care, WIC, Maternity Care Coordination, Child Care Coordination, Health Check, other providers, etc.)

Legal Authority:

- Nurse Practice Act, G.S. 90-171.20 (7) (f) & (8) (c)
- Good Samaritan Law/Naloxone Access, G.S. 90-106.2

Indications and Usage

- Naloxone is indicated for the complete or partial reversal of opioid overdose induced by natural or synthetic opioids and exhibited by respiratory depression or unresponsiveness.

Precautions

- Pre-existing cardiac disease or seizure disorder
- Persons who are known or suspected to be physically dependent on opioids (including newborns of mothers with narcotic dependence. Reversal of narcotic effect will precipitate acute abstinence syndrome.)

- Use in Pregnancy:
 - Teratogenic Effects: pregnancy category C, no adequate or well-controlled studies in pregnant women.
 - Non-teratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms as well.
- Nursing Mothers: caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.
- Geriatric Use: choose lower range doses taking precautions for potential decreased hepatic, renal and cardiac function, as well as, concomitant disease and other drug therapy.
- If a contraindication/precaution exists, refer client to medical provider for evaluation.

Contraindications

- Patients known to be hypersensitive to naloxone hydrochloride.
- If a contraindication/precaution exists, refer client to medical provider for evaluation.

Adverse Reactions

- Adverse reactions are related to reversing dependency and precipitating withdrawal (fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, yawning, sneezing.) These symptoms may appear within minutes of Naloxone administration and subside in approximately 2 hours. The severity and duration of the withdrawal syndrome is related to the dose of Naloxone and the degree of opioid dependence.
- Adverse effects beyond opioid withdrawal are rare.

Dosage and Administration

Dosage

Intramuscular Injection

- 1 mL vial of 0.4 mg/mL naloxone
- Administer with at least a 1 inch needle

Administer naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

1. If practical, activate emergency medical services
2. If indicated, initiate rescue breathing
3. Remove lid from naloxone vial
4. Insert syringe into vial and draw up 1mL of naloxone
5. If practical, don gloves and prepare injection site with alcohol pad
6. Administer 1mL of naloxone via intramuscular injection into upper arm, buttock or thigh
7. Continue rescue breathing and monitor respiration and responsiveness of naloxone recipient
8. If no response in 3-5 minutes, repeat naloxone.

Intra-nasal administration

- Naloxone 1mg/ml vial with plastic delivery device
- Nasal atomizer

Administer naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

1. If practical, activate emergency medical services
2. If indicated, initiate rescue breathing
3. Remove the two yellow caps and one red (or purple) cap from the naloxone syringe and the plastic delivery device.
4. Hold the nasal atomizer device and screw it onto the top of the plastic delivery device.
5. Screw the naloxone syringe gently into the delivery device.
6. Spray half of the medicine up one side of the nose and half up the other side of the nose.
7. If there is no breathing, or very shallow breathing, continue to perform rescue breathing while waiting for the naloxone to take effect.
8. If no response in 3-5 minutes, repeat naloxone.

This standing order shall remain in effect for one (1) year, until _____.

Approved by: _____

Medical Director

Date: _____

Appendix IV

PROPOSED AMENDMENTS TO RULE 21 NCAC 46 .2401 AND .2403 - DISPENSING IN HEALTH DEPARTMENTS.

21 NCAC 46 .2401 MEDICATION IN HEALTH DEPARTMENTS

A registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions:

- (1) Drugs or devices may be dispensed only to health department patients, with the exception of opioid antagonists, which may be dispensed either to health department patients or to others as permitted by G.S. 90-106.2;
- (2) No drugs or devices may be dispensed except at health department clinics;
- (3) The health department shall secure the services of a pharmacist-manager who shall be responsible for developing and supervising a system of control and accountability of all drugs dispensed from the health department;
- (4) Only the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse;
- (5) All drugs or devices dispensed pursuant to G.S. 90-85.34A and these rules shall be packaged in suitable safety-closure containers, where appropriate, and shall be properly labelled (including necessary auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;
- (6) A suitable and perpetual record of drugs or devices dispensed shall be maintained in the health department. The pharmacist-manager shall verify the accuracy of the records at least weekly, and where health department personnel dispense to 30 or more patients in a 24-hour period per dispensing site, the pharmacist-manager shall verify the accuracy of the records within 24 hours after dispensing occurs;
- (7) The duties of the pharmacist-manager set out in Paragraphs (1) through (6) in this Rule may be delegated to a pharmacist licensed by the Board. The pharmacist-manager shall remain personally responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs.

History Note: Authority G.S. 90-85.6; 90-85.34A; 90-106.2;

Eff. March 1, 1987;

Amended Eff. August 1, 2014; May 1, 1989.

21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED

(a) Pursuant to the provisions of G.S. 90-85.34A(a)(3), prescription drugs and devices included in the following general categories may be dispensed by registered nurses in local health department clinics when prescribed for the indicated conditions:

- (1) Anti-tuberculosis drugs, as defined by the latest edition of Drug Facts and Comparisons, as published by Facts and Comparison Div., J.B. Lippincott Co., or as recommended by the Tuberculosis Control Branch of the North Carolina Division of Health Services, when used for the treatment and control of tuberculosis;

- (2) Anti-infective agents used in the control of sexually-transmitted diseases as recommended by the United States Centers for Disease Control;
 - (3) Natural or synthetic hormones and contraceptive devices when used for the prevention of pregnancy;
 - (4) Topical preparations for the treatment of lice, scabies, impetigo, diaper rash, vaginitis, and related skin conditions; and
 - (5) Vitamin and mineral supplements; and supplements.
 - (6) Opioid antagonists prescribed pursuant to G.S. 90-106.2.
- (b) Regardless of the provisions set out in this Rule, no drug defined as a controlled substance by the United States Controlled Substances Act, 21 U.S. Code 801 through 904, or regulations enacted pursuant to that Act, 21 CFR 1300 through 1308, or by the North Carolina Controlled Substances Act, G.S. 90-86 through 90-113.8, may be dispensed by registered nurses pursuant to G.S. 90-85.34A.

History Note: Authority G.S. 90-85.6; 90-85.34A; 90-106.2;

Eff. March 1, 1987;

Amended Eff. August 1, 2014; May 1, 1989.

MEDICATION DISTRIBUTION RECORD

Floor Stock
 Delivery

Number	Name of Patient		Name of Drug Name of Prescriber	Directions for Use		Name of Dispenser/Deliverer	Quantity
	Date						
1							
2							
3							
4							
5							
6							
7							
8							
9							
0							

Key Organizations Working to Reduce Prescription and Drug Overdose in North Carolina

Community Cares of North Carolina (CCNC), Chronic Pain Initiative (CPI). Contact: Theo Pikoulas (tpikoulas@n3cn.org)

Controlled Substance Reporting System (CSRS). Contact: Bill Bronson (william.bronson@dhhs.nc.gov)

Project Lazarus. Contact: Fred Brason (fbrason@projectlazarus.org)

Operation Medicine Drop. Contact: Kelly Randsell (kelly.randsell@ncdoi.gov)

Carolinas Poison Center. Contact: Dr. Marsha Ford (Marsha.Ford@carolinashealthcare.org)

Injury Prevention Research Center (IPRC), UNC-CH. Contact: Mariana Garrettson (marianag@email.unc.edu)

N.C. Injury & Violence Prevention Branch. Contact: Scott Proescholdbell (scott.proescholdbell@dhhs.nc.gov)

Governor's Institute. Contact: Dr. Sara McEwen (sara.mcewen@governorsinstitute.org)

North Carolina Harm Reduction Coalition. Contact: Robert Childs (robert.bb.childs@gmail.com)

For additional information on prescription and drug overdose: www.injuryfreenc.ncdhhs.gov/About/poisoning.htm

¹1-The Burden of Unintentional Poisoning in North Carolina, North Carolina Injury & Violence Prevention Branch:2013 Anna Austin, Stephanie Finkbeiner

2-Massachusetts Department of Public Health: Opioid Overdose Education and Naloxone Distribution Guide