THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND THE SOUTH CAROLINA BOARD OF PHARMACY'S JOINT PROTOCOL FOR CERTAIN COMMUNITY ORGANIZATIONS TO DISTRIBUTE NALOXONE HCL PURSUANT TO A PRESCRIPTION OR A STANDING ORDER

This joint protocol authorizes a prescriber practicing in the State of South Carolina and licensed by the South Carolina Board of Medical Examiners or the South Carolina Board of Nursing, to directly, or by standing order, prescribe the following Naloxone Hydrochloride products to a community distributor as described herein, a pharmacist licensed by the South Carolina Board of Pharmacy to dispense the following Naloxone Hydrochloride products to a community distributor pursuant to a prescription or standing order as described herein and a community distributor to distribute the following Naloxone Hydrochloride products as set forth herein.

<table>
<tr><th colspan="4">Naloxone HCl Dispensing</th></tr>
<tr><td>Eligible candidates</td><td colspan="3">• A community distributor, which is an organization, either public or private, which provides substance use disorder assistance and services, such as counseling, homeless services, advocacy, harm reduction, alcohol and drug screening, and treatment to individuals at risk of experiencing an opioid-related overdose as approved by DAODAS.

o For purposes of this Joint Protocol, 'caregiver' means a person who is not at risk of an opioid overdose but who, in the judgment of the community distributor, may be in a position to assist another individual during an overdose as cited under § 44-130-70(C)(4) and who has received patient overdose information as required by § 44-130-30.</td></tr>
<tr><td>Route(s) of administration</td><td colspan="2">Intranasal (IN)
Preferred method</td><td>Intramuscular (IM)
Inject into shoulder or thigh</td></tr>
<tr><td>Medication and required device for administration</td><td>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)</td><td>Naloxone HCl 4 mg/0.1 mL Nasal Spray
• Dispense 1 x two-pack</td><td>Naloxone HCl 0.4mg/mL Inj.
2 x 1mL single dose vials (SDV)
• Dispense 2 (two) SDV
2 (two) x intramuscular (IM) syringe, 3mL, 25 G, 1 inch

Naloxone HCl auto-injector</td></tr>
<tr><td>Directions for use</td><td>Spray 1 mL in each nostril. Repeat after 2 minutes if minimal or no response.</td><td>Administer a single spray of Naloxone HCl in one nostril. Repeat after 2 minutes if minimal or no response.</td><td>Inject 1 mL IM in shoulder or thigh. Repeat after 2 minutes if minimal or no response.</td></tr>
<tr><td>Refills</td><td colspan="3">PRN</td></tr>
<tr><td>Contraindications</td><td colspan="3">A history of known hypersensitivity to Naloxone or any of its components</td></tr>
<tr><td>Patient education</td><td colspan="3">Every person dispensed or distributed Naloxone shall receive education regarding the risk factors of overdose, signs of an overdose, overdose response steps, and the use of Naloxone. Examples of education materials that incorporate the above information may be found at http://www.naloxonesavesSC.org and attached hereto in Appendix A. Every person dispensed or distributed Naloxone shall call 911 prior to administration and remain on the line until first responders arrive.</td></tr>
<tr><td>Pharmacist education</td><td colspan="3">Pharmacists should be sufficiently educated regarding the Naloxone HCl product(s) being dispensed to provide appropriate counseling to the persons receiving the medication, as required by S.C. Code Ann. § 40-43-30(14). Suggested training resources are identified in Appendix B attached hereto and may be found on http://www.naloxonesavesSC.org.</td></tr>
<tr><td>Notification of participation</td><td colspan="3">Organizations designated by DAODAS as "community distributors" choosing to participate in the Naloxone community distribution will be identified on the www.justplainkillers.com website maintained by DAODAS and will notify the State Board of Pharmacy when initiating their participation for inclusion on www.naloxonesavesSC.org website maintained by LLR.</td></tr>
<tr><td>Required documentation to obtain DAODAS Community Distributor designation</td><td colspan="3">• A letter of intent outlining the applicant's purpose and involvement in the delivery of substance use disorder assistance and services to individuals at risk of experiencing an opioid-related overdose;
• Proof of IRS identification or tax designation;
• Evidence of an organizational mission statement or charter that identifies the applicant as meeting the definition of "Community Distributor" under S.C. Code § 44-130-20(2); and
• Two references from a credible state or local entity, such as, but not limited to a substance use disorder treatment provider, a community mental health center, city or county governmental officials, faith organization, or local law enforcement officials.</td></tr>
</table>

Required documentation	• Prescription/standing order from active, unencumbered South Carolina licensed prescriber; • All pertinent records relative to dispensing of Naloxone HCl, which must be maintained by the dispensing pharmacy for a period of 2 years; • A current copy of the Joint Protocol For Certain Community Organizations To Distribute Naloxone HCl Pursuant To A Prescription Or A Standing Order; and • If a Community Distributor, written confirmation of community distributor designation from DAODAS.

Jeff A. Welsh, M.D.
President, SC Board of Medical Examiners
November 14, 2018

Spencer A. Morris, Pharm.D., BCPS
Chairman, SC Board of Pharmacy
October 30, 2018

APPENDIX A

THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND THE SOUTH CAROLINA BOARD OF PHARMACY'S JOINT PROTOCOL TO INITIATE DISPENSING OF NALOXONE HCl WITHOUT A PRESCRIPTION

This joint protocol authorizes any pharmacist practicing in the State of South Carolina and licensed by the South Carolina Board of Pharmacy to dispense the following Naloxone Hydrochloride products to persons without a prescription as directed below pursuant to § 44-130-40 of the South Carolina Code of Laws.

<table>
<tr><th colspan="4">Naloxone HCl Dispensing Protocol</th></tr>
<tr><td>Eligible candidates</td><td colspan="3">• Persons who voluntarily request Naloxone and are at risk of experiencing opioid-related overdose, including but not limited to:
- Current illicit or non-medical opioid users or persons with a history of such use;
- Persons with a history of opioid intoxication or overdose and/or emergency medical care for acute opioid poisoning;
- Persons with an opioid prescription, especially those who have:
• known or suspected concurrent alcohol abuse;
• COPD or other respiratory illness or obstruction or currently smoke;
• renal dysfunction, Hepatic disease, cardiac disease, or HIV/AIDS; or
• concurrent Benzodiazepine prescription;
- Persons from an opioid detoxification and mandatory abstinence program;
- Persons entering methadone maintenance treatment programs (for addiction or pain);
- Persons who may have difficulty accessing emergency medical services;

and/or

• Persons who voluntarily request Naloxone and are the caregiver of a person at risk of experiencing an opioid overdose.</td></tr>
<tr><td>Route(s) of administration</td><td colspan="2">Intranasal (IN)
Preferred method</td><td>Intramuscular (IM)
Inject into shoulder or thigh</td></tr>
<tr><td>Medication and required device for administration</td><td>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)</td><td>Naloxone HCl 4 mg/0.1 mL Nasal Spray
• Dispense 1 x two-pack</td><td>Naloxone HCl 0.4mg/mL Inj.
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2 (two) x intramuscular (IM) syringe, 3mL, 25 G, 1 inch

Naloxone HCl auto-injector</td></tr>
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<tr><td>Pharmacist education</td><td colspan="3">Pharmacists should be sufficiently educated regarding the Naloxone HCl product(s) being dispensed to provide appropriate counseling to the persons receiving the medication, as required by S.C. Code Ann. § 40-43-30(14). Suggested training resources are identified in Appendix B attached hereto and may be found on http://www.naloxonesavesSC.org.</td></tr>
<tr><td>Notification of participation</td><td colspan="3">Pharmacies choosing to participate in the Naloxone distribution may notify the State Board of Pharmacy when initiating their participation. See directions for notification at http://www.naloxonesavesSC.org.</td></tr>
<tr><td>Required documentation</td><td colspan="3">• A current copy of the Joint Protocol to Initiate Dispensing of Naloxone HCl Without a Prescription, if participating;
• Notice of Informed Consent and Affirmation of Naloxone Purchaser with Notice to Primary Care Provider, if identified, for each transaction; and
• All pertinent patient records relative to dispensing of Naloxone HCl without a prescription, which must be maintained for a period of 2 years.</td></tr>
</table>

Stephen R. Gardner, MD
President, SC Board of Medical Examiners
November 17, 2016

Carole S. Russell, R.Ph.
Chairman, SC Board of Pharmacy
November 17, 2016

APPENDIX A

EDUCATIONAL MATERIALS FOR NALOXONE PURCHASERS

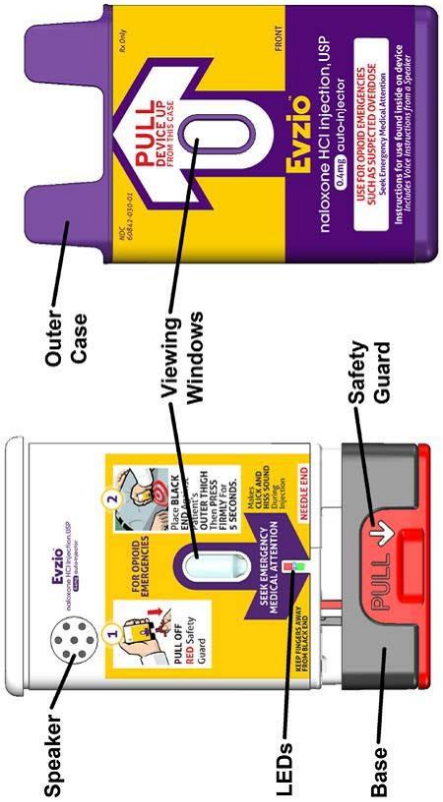
1. Educational Tri-fold for Autoinjector

2. Educational Tri-fold for Injectable Naloxone

3. Educational Tri-fold for Mucosal Atomizing Devices (MAD 300)

4. Educational Tri-fold for Nasal Narcan

EVZIO AUTO INJECTOR



SUMMARY:

1. Identify overdose
2. Call 9-1-1
3. Give naloxone
4. CPR
5. Stay until help arrives

For assistance with finding substance abuse treatment, support groups, or recovery support services in your community please call:
1-800-662-HELP (4357)

NaloxoneSavesSC.org

Naloxone Saves

South Carolina

Naloxone

What is naloxone?

Naloxone is a remedy for opioid overdose. In an overdose, opioids slow and stop breathing and cause sedation that can lead to death. Naloxone is a medication that reverses the effects that lead to death.

Opioids may include prescription medications (eg, oxycodone, fentanyl, hydrocodone, etc.) or heroin.

Who should take naloxone?

Naloxone only works if opioids are in the body; it has no effect if they are not. It does not work on effects of other drugs or alcohol. Naloxone may take effect in 3 to 5 minutes and can last up to 60 to 90 minutes.

Step 1: IDENTIFY OVERDOSE

Opioids can be dangerous because they can suppress breathing, which may lead to death. If someone is not breathing or is struggling to breathe after taking opioids, try calling the victim's name and rubbing your knuckles on their chest.

If the victim does not respond he or she may be experiencing an overdose. **Other signs** that may help you identify an overdose are: **blue or pale skin color, small pupils, low blood pressure, slow heartbeat, slow or shallow breathing, snoring sound, gasping for breath.**

Step 2: CALL 9-1-1

When you think an overdose is happening, get help as quickly as possible. **Call 9-1-1.** Be sure to say the victim is unresponsive and not breathing or is struggling to breathe. Give a clear address and location. Also send for Automated External Defibrillator (AED) and naloxone.

Step 3: GIVE NALOXONE

Naloxone is available as a nasal spray or injection. See specific products for administration instructions. If the first dose is unsuccessful in three minutes or begins to wear off, administer a second dose.

Store naloxone in an easy to reach place, in case of emergency. Make sure your friends and family know where it is stored.

Step 4: BEGIN CPR

If the victim is still unresponsive with no breathing or only gasping, begin CPR with rescue breathing.

Make sure nothing is in the victim's mouth blocking their breathing. • Place one hand on the chin and tilt the head back. With the other hand pinch the nose closed. • Administer two slow breaths and look for the chest to rise. • Continue administering 1 breath every 5 seconds until the victim starts breathing on his or her own. • If victim no longer has a pulse, administer chest compressions in addition to rescue breathing.

If the victim is breathing, move them to the **recovery position.**

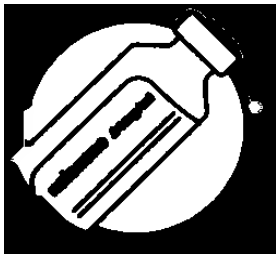
Step 5: STAY UNTIL HELP ARRIVES

It is important to stay with someone after giving naloxone.

Naloxone can reverse an overdose, but can also cause withdrawal symptoms including but not limited to: restlessness, nervousness, nausea and vomiting.

Recovery Position

INJECTABLE NALOXONE



1. Remove cap from naloxone vial and uncover the needle.

2. Insert needle through rubber plug with vial upside down.

Pull back on plunger and take up 1 mL.

3. Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks).

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Naloxone Saves

South Carolina

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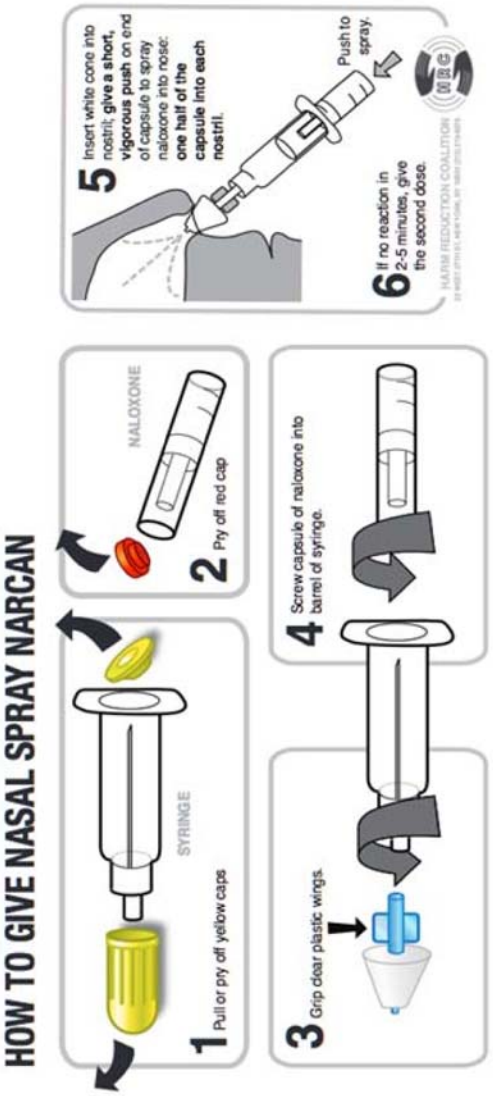
Recovery Position

NARCAN NASAL SPRAY



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Recovery Position

APPENDIX B

SUGGESTED EDUCATIONAL RESOURCES FOR PHARMACISTS

http://www.opioidprescribing.com/naloxone_module_1-landing

https://cpnp.org/guideline/naloxone

https://www.prescribetoprevent.org

http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742

https://www.evzio.com/

http://www.narcan.com/

https://scpa.memberclicks.net/assets/Events/naloxone-ondemand-scpha%20code%202.pdf

Regarding Intranasal Mucosal Atomizing Devices (MAD 300) availability:

Teleflex (866-246-6990) or
Safety Works, Inc. (800-723-3892)

Affirmation of Eligibility and Informed Consent for Naloxone Dispensed Without a Prescription
Purchaser's Name:
Purchaser's Address:
Purchaser's Date of Birth:

APPENDIX C
AFFIRMATION OF ELIGIBILITY AND INFORMED CONSENT FOR NALOXONE DISPENSED WITHOUT A PRESCRIPTION

AFFIRMATION OF ELIGIBILITY TO PURCHASE NALOXONE

By signing below, I hereby affirm that either:

I *am* at risk of experiencing an opioid-related overdose. I have received patient overdose information, including risk factors of overdose, signs of an overdose, overdose response steps, and information about the use of Naloxone from the pharmacist dispensing Naloxone to me.

OR

I *am not* personally at risk of an opioid-related overdose, but I am the caregiver of a person who is at risk of experiencing an opioid-related overdose and am in a position to assist this person in the event of an opioid-related overdose. I have received patient overdose information, including risk factors of overdose, signs of an overdose, overdose response steps, and information about the use of Naloxone from the pharmacist dispensing Naloxone to me.

INFORMED CONSENT OF NALOXONE PURCHASER

By signing below, I acknowledge that this pharmacy is providing Naloxone to me without a prescription based upon my affirmation of eligibility to purchase Naloxone. I understand the eligibility to purchase Naloxone without a prescription is not a substitute for an ongoing relationship with a primary care provider to address ongoing medical issues and opioid overdose prevention. I understand the pharmacy will provide the primary care provider I identify with records of the Naloxone purchase so that my medical records may be complete and that it is recommended that I take my personal records with me to my next appointment as well.

I have received written materials or verbal instructions about the medication Naloxone. I understand the risks and benefits of using Naloxone, how to prevent and recognize an opioid overdose, and the importance of calling 911 emergency telephone services for medical assistance with an opioid overdose. I have been provided an opportunity to learn how to administer the correct dosage of Naloxone and ask questions, which have been answered to my satisfaction, and have been advised on how to care for an overdose victim after the administration of Naloxone. I wish to receive the Naloxone and hereby give consent for the dispensing pharmacist identified below to provide this document to the primary care practitioner, who is listed below.

Affirmation of Eligibility and Informed Consent for Naloxone Dispensed Without a Prescription
Purchaser's Name:
Purchaser's Address:
Purchaser's Date of Birth:

_____ _____

Naloxone Purchaser's Signature Date

_____

Naloxone Purchaser's Name

_____

Naloxone Purchaser's Date of Birth

_____

Naloxone Purchaser's Designated Primary Care Physician

_____

Name of Dispensing Pharmacist

_____

Contact Information for Dispensing Pharmacist