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.

### Naloxone HCl Dispensing Protocol

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

<table>
<thead>
<tr>
<th>Route(s) of administration</th>
<th>Intranasal (IN)</th>
<th>Intramuscular (IM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred method</td>
<td>Naloxone HCl 1 mg/mL Inj.</td>
<td>Naloxone HCl 4 mg/0.1 mL Nasal Spray</td>
</tr>
<tr>
<td></td>
<td>2 x 2 mL as pre-filled Luer-Lock syringes</td>
<td>Dispense 1 x two-pack</td>
</tr>
<tr>
<td></td>
<td>• Dispense 2 (two) doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 (two) x Intranasal Mucosal Atomizing Devices (MAD 300)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Naloxone HCl 0.4mg/mL Inj.</td>
<td></td>
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<tr>
<td></td>
<td>2 x 1mL single dose vials (SDV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dispense 2 (two) SDV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 (two) x intramuscular (IM) syringe, 3mL, 25 G, 1 inch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Naloxone HCl auto-injector</td>
<td></td>
</tr>
</tbody>
</table>

| Directions for use | Spray 1 mL in each nostril. Repeat after 3 minutes if minimal or no response. | Administer a single spray of Naloxone HCl in one nostril. Repeat after 3 minutes if minimal or no response. | Inject 1 mL IM in shoulder or thigh. Repeat after 3 minutes if minimal or no response. | 

<table>
<thead>
<tr>
<th>Refills</th>
<th>PRN</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Contraindications</th>
<th>A history of known hypersensitivity to Naloxone or any of its components</th>
</tr>
</thead>
</table>

| Patient education | Every person dispensed 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](http://www.naloxonesavesSC.org) and attached hereto in Appendix A. | 

| Pharmacist education | 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](http://www.naloxonesavesSC.org). | 

| Notification of participation | 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](http://www.naloxonesavesSC.org). | 

<table>
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<tr>
<th>Required documentation</th>
<th>• A current copy of the Joint Protocol to Initiate Dispensing of Naloxone HCl Without a Prescription, if participating;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Notice of Informed Consent and Affirmation of Naloxone Purchaser with Notice to Primary Care Provider, if identified, for each transaction; and</td>
</tr>
<tr>
<td></td>
<td>• 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>
</tbody>
</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 FORNALOXONE 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
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)
**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: GIVENALOXONE**

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.

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**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

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

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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Recovery Position
NARCAN NASAL SPRAY

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Naloxone Saves
South Carolina

NaloxoneSavesSC.org
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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-on-demand-scpha%20code%202.pdf

Regarding Intranasal Mucosal Atomizing Devices (MAD 300) availability:
   Teleflex (866-246-6990) or
   Safety Works, Inc. (800-723-3892)
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