**Protocol for Naloxone Distribution**

**Narcan® Nasal Spray**

**I. PURPOSE**

The purpose of this document is to ensure that those providing naloxone to the community are providing consistent training and following the regulations set forth by the West Virginia Board of Pharmacy in regard to counseling, distribution, and storage. Providing naloxone training and distribution in the community setting provides access to this life saving medication for those who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons in a position to assist a person at risk of experiencing an opioid-related overdose.

**II. CRITERIA**

Persons eligible to dispense naloxone under WV Code include:

* Registered pharmacists (per WV Code § 16-46-3a and the West Virginia Department of Health and Human Resources (DHHR) Naloxone Standing Order - *Appendix A*).
	+ Pharmacy interns, under the supervision of a registered pharmacist.
* Prescribers within the scope of practice.
	+ Must be present at the time of dispensing unless designating personnel via local standing orders.
		- See “Persons eligible to distribute naloxone under WV State Code § 16-46-3.”

Persons eligible to distribute naloxone under WV Code § 16-46-3 include:

* An agent of a governmental or non-governmental organization including:
	+ Local health department
	+ Law enforcement agency
	+ An organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors
* Must have a local standing order signed by a local healthcare provider for distribution

Refer to specific reporting requirements for pharmacist or prescriber.

***Pharmacist Dispensing***

Dispensing to an individual

* Must be present.
	+ The pharmacist is not required to perform the training and counseling (this may be delegated to a trained staff member) but must be present at the time of dispensing.
* Must be a registered pharmacist in the State of West Virginia.
* Pharmacist must at a minimum provide or oversee the counseling points listed under Section IV of this document (EDUCATION).
	+ May designate another individual to provide training - examples include pharmacy intern, nurse, peer recovery coach, law enforcement, or emergency medical services (EMS)
* Pharmacist may provide DHHR’s Office of Emergency Medical Services (OEMS) Naloxone Training class if the individual has completed the OEMS Train-the-Trainer Program.
	+ Must complete sign-in sheet and submit to OEMS contact.
* Pharmacist must report to the West Virginia Board of Pharmacy Controlled Substance Monitoring Program (CSAPP) if operating in a pharmacy that automatically reports to CSAPP. If a pharmacist does not work in a pharmacy that automatically reports, naloxone dispensing must be reported to the West Virginia Department of Health and Human Resources, Office of Drug Control Policy (ODCP).
* Pharmacist must provide brochures required per legislation (*See Appendix B*).
* Pharmacist must label each kit distributed (*See Appendix C*).
* Pharmacist must request completion of survey after training and distribution (*See* *Appendix I*).
	+ Appendix I must be emailed or mailed to UCSOP at least monthly (or more frequently when appropriate). – ONLY FOR NALOXONE OBTAINED THROUGH UCSOP GRANT.
* Pharmacist must manage inventory.
* Pharmacist or designated individual must collect and report required information for the granting institutions [if product distributed is in connection with a grant funded program, such as the Prescription Drug Overdose (PDO) grant, State Targeted Response to the Opioid Crisis (STR) grant, or other related grants allowing for the purchase of naloxone].

Dispensing to an Organization or Community Group

* Organization or community group MUST provide a copy of the Standing Order under which they will be operating and distributing.
* Pharmacist MUST maintain an inventory and maintain record of all dispensing to organizations.
	+ Record must contain:
		- * Name of organization or community group
			* Contact person for organization or community group
			* NDC/product provided
			* Lot number and expiration date of product provided
			* Copy of Standing Order
	+ Pharmacist is NOT responsible for reporting of kits distributed through the organization or community group.
	+ It is the responsibility of the receiving organization or community group to maintain documentation, train, and complete all necessary forms/reporting.
		- See (*Distribution by an Agent of a Governmental or Non-Governmental Organization*)

***Prescriber Dispensing (MD, DO, PA)***

* **If the prescriber is present**
	+ The prescriber is not required to train and provide counseling but must be present (may designate another individual to provide the training and counseling).
	+ Prescriber must be licensed in West Virginia.
	+ Prescriber must at minimum provide or oversee the counseling points listed under Section IV (EDUCATION).
		- May designate another individual to provide training or counseling - examples include pharmacy intern, medical student, nurse, peer recovery coach, law enforcement, or EMS
	+ Prescriber may provide the OEMS Naloxone Training class if the individual has completed the OEMS Train-the-Trainer Program.
		- Must complete sign-in sheet and submit to WVOEMS contact.
	+ Prescriber or designated individual must report to ODCP. – See Section VIII REPORTING
		- Alternate reporting method is through West Virginia Board of Pharmacy through CSAPP if program software has the ability to automatically report.
	+ Prescriber must report to the West Virginia Board of Medicine or appropriate board for prescribing provider.
		- West Virginia Board of Medicine reporting annually (February 1) - report quantity distributed
	+ Prescriber must provide brochures required per legislation (*See Appendix B*).
	+ Prescriber must label each kit distributed (*See Appendix C*).
	+ Prescriber must request completion of survey after training and distribution (*See* *Appendix I*).
		- Appendix I must be emailed or mailed to UCSOP at least monthly (or more frequently when appropriate). - ONLY FOR NALOXONE OBTAINED THROUGH UCSOP GRANT
	+ Prescriber must manage inventory or designate individual to perform this task.
	+ Prescriber must collect and report required information for the granting institutions (if product distributed is in connection with a grant such as the PDO grant, STR grant, or other related grant) or designate individual to perform this task.

* **If the prescriber is NOT present**
	+ See *Distribution by an Agent of a Governmental or Non-Governmental Organization*

***Distribution by an Agent of a Governmental or Non-Governmental Organization (§ 16-46-3)***

* Individuals **must be designated under a local standing order** signed by local healthcare provider.
* Examples of individuals that would be able to provide naloxone distribution under § 16-46-3 include but not limited to:
	+ An employee, intern, or other agent within a health department providing training and distribution of naloxone (may include nursing staff, peer recovery coach, etc.)
	+ A law enforcement officer providing training and distribution of naloxone to other officers or through a Quick Response Team
	+ An employee, intern, or other agent of a prevention organization, Medication Assisted Treatment (MAT) Program, Recovery Program, or other organization promoting scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors that is providing training and distribution of naloxone
	+ All agents must be designated under a local standing order to distribute naloxone (example provided in *Appendix D*).
		- Standing Order MUST include:
			* Purpose of the order
			* Who is eligible to distribute (by title)
				+ Eligible person MUST have completed naloxone training by a pharmacist, physician, or the OEMS training (Naloxone Training or Train-the-Trainer Program).
			* Who is eligible to receive naloxone (under what circumstances)
			* Formulation and directions
			* Counseling requirements/training requirements
				+ Education materials (See EDUCATION)
		- Designated individual must report to the ODCP by the 10th of each month.
		- Prescriber is responsible for ensuring this task is completed.
		- Agent must provide brochures required per legislation (*See Appendix B*).
		- Agent must label each kit distributed (*See Appendix C*).
		- Agent must request completion of survey after training and distribution (*See* *Appendix I*). – ONLY FOR NALOXONE OBTAINED THROUGH UCSOP GRANT
			* Appendix I must be emailed or mailed to UCSOP at least monthly (or more frequently when appropriate).
		- Agent must manage inventory and maintain patient information.
		- Organization obtaining naloxone from a pharmacist MUST maintain patient/records securely and must be able to contact individuals in the event of a drug recall.
		- Agent must collect and report required information for the granting institutions (if product distributed is in connection with a grant such as the PDO grant, STR grant, or HRP related grant) - or designate individual to perform this task.

Persons eligible to receive naloxone under this protocol include (but not limited to):

1. Persons with a history of receiving emergency medical care for acute opioid poisoning or overdose
2. Persons with a suspected history of substance abuse or nonmedical opioid use
3. Persons receiving high-dose opioid prescriptions (e.g. >50 mg morphine equivalent)
4. Persons who are opioid naïve and receiving a first prescription for methadone for pain
5. Persons starting buprenorphine or methadone for addiction treatment
6. Persons taking opioid prescriptions for pain in combination with:
	1. Smoking, COPD, emphysema, sleep apnea, or other respiratory illness
	2. Renal dysfunction, hepatic disease, or cardiac disease
	3. Known or suspected alcohol use
	4. Concurrent benzodiazepine or other sedative prescription
	5. Concurrent antidepressant prescription
7. Persons who may have difficulty accessing emergency medical services
8. Voluntary request by person or agency
9. Any person at risk of an opioid overdose
10. Family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose

**III. MEDICATION FORMULATION AND DIRECTIONS**

*Intranasal administration:*

**Narcan® Naloxone HCl 4 mg/0.1 ml Nasal Spray**

Distribute #1 Box (2 units each)

SIG: Call 911. Do not prime device. Spray contents of one device into nostril upon signs of opioid overdose. Ensure head is tilted back and nostril is not blocked prior to administration. May repeat in 3 minutes in opposite nostril if breathing has not returned. Dosing may be repeated as needed until breathing returns or until EMS arrives.

**IV. EDUCATION**

Prior to distributing naloxone, education must be provided to individual receiving naloxone. All distributing personnel must provide counseling points on naloxone (see below). Counseling MAY NOT be waived. All individuals receiving naloxone MUST be counseled.

* Pharmacist or prescriber dispensing
	+ Refer to counseling points listed on *Appendix E*.
	+ Counseling must be provided each time the individual receives naloxone.
* Agent of a governmental or non-governmental organization
	+ MUST PROVIDE COUNSELING POINTS LISTED BELOW (Opioid Overdose, Instructions for Use of the Product, and Importance of Calling 911)
	+ Counseling must be provided each time the individual receives naloxone.
* **ALL PERSONS DISTRIBUTING MUST** supply a copy of both brochures provided through and maintained by OEMS and ODCP. These appendices are subject to changes and updates. Copies of the brochures may be found on the OEMS website and the West Virginia Board of Pharmacy Naloxone Protocol webpage (*Appendix B*).

**Counseling points:**

*Opioid overdose*

* Signs/symptoms of an opioid overdose
	+ Difficulty or stopped breathing, turning blue (lips and finger tips) – lack of oxygen is what causes brain damage and death
	+ Not responsive to verbal or physical cues (shouting or sternal rub)
	+ Suspicion of possible overdose
* Importance of ensuring open airway and breathing, if possible
	+ Maintain an OPEN airway – straighten throat/neck and airway
	+ Encourage to take a CPR class to ensure training on rescue breathing
	+ Assist with breathing – use one-way valve mask or another form of CPR mask
* Provide the recipient with the number to talk with someone regarding available substance use disorder treatment and recovery services (1-844-HELP4WV). Provide copy of both brochures which include opioid-related prevention and resources for treatment programs

*Instructions for Use of the Product*

* Dosing and proper administration of product distributed
	+ Call 911. Do not prime device. Spray contents of one device into nostril upon signs of opioid overdose. Ensure head is tilted back and nostril is not blocked prior to administration. May repeat in 3 minutes in opposite nostril if breathing has not returned. Dosing may be repeated as needed until breathing returns or until EMS arrives. When person begins to breathe, wake up, or vomit, place person on his/her side in the recovery position. Make sure to put space between you and the individual to protect yourself.
* Side effects
	+ Nausea and vomiting, blood pressure and heart rate will increase, sweating, shaking, return of pain, and possible aggressive behavior
* Storage conditions (Room temperature – avoid hot and cold). Excursions permitted between 41°F and 104°F. Do not freeze or expose to temperatures above 104°F. Protect from light. (Prescribing Information – Narcan**®** Package Insert)

*Legal aspects*

* Importance of calling 911 as soon as possible either before or after administration of naloxone and the risks associated with failure to contact emergency services following administration of opioid antagonist
* If 911 is NOT contacted:
	+ Individual is not protected from liability if they do not call 911 or get the person to the hospital.
	+ Naloxone may wear off, and the patient can stop breathing again even if the individual does not take more opioids.
		- Remain with the person.
	+ Do not put the person in ice water.

**V. STORAGE**

*Medication storage*

All areas where drugs and devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures, which will ensure the integrity of the drugs. Store at 20°C to 25°C (68°F to 77°F) (room temperature). Excursions are permitted between 41°F to 104°F (5°C to 40°C). Do not freeze or expose to temperatures above 104°F (40°C). Protect from light. (Prescribing Information – Narcan**®** Package Insert)

*Security*

The storage area shall be separated from other areas in the facility by a floor to ceiling, physical barrier or partition, with entry doors that can be securely locked. There should be limited key access to the storage area where drug (naloxone) is held.

**VI. DISPOSAL**

* Expired product may not be distributed and should be discarded in accordance with facility policies and procedures for expired medications.
* Used product returned should be discarded according to the product manufacturer.

**VII. DOCUMENTATION**

* Distribution form must be completed by each individual receiving naloxone (*Appendix F*).
* Survey must be completed by each individual receiving naloxone that is grant funded (STR, PDO, CARA, etc.) (*Appendix I*).
* Data must be collected and maintained on a locked, password-protected document.
* Documentation should be stored on a secure computer with each facility and should have limited access.
	+ Paper documentation may be kept if unable to secure data on a facility computer. Paper documentation should be stored in a locked cabinet with limited access (may consider storing in same area as naloxone to ensure security).
	+ Lot number, expiration date, and patient contact information should be readily available in the event of a drug recall.
* Retain documentation of records for 5 years.
	+ Must be easily retrievable and secure

**VIII. REPORTING**

***Pharmacists, pharmacies, or providers that currently automatically report to the West Virginia Board of Pharmacy through CSAPP***

* Continue to report to West Virginia Board of Pharmacy CSAPP. If pharmacist does not work for a pharmacy that automatically reports, naloxone dispensing must be reported to the ODCP.
* Automatic reporting to West Virginia Board of Pharmacy CSAPP is required within 24 hours of dispensing.

***Distribution by an Agent of a Governmental or Non-governmental Organization (§ 16-46-6) OR Granting Institutions, Pharmacists, Pharmacies, or medical providers that do not currently automatically report to the West Virginia Board of Pharmacy***

* After distributing naloxone to an eligible individual, the distributing personnel must report information to the ODCP by the 10th of each month (UNLESS PROGRAM SOFTWARE AUTOMATICALLY REPORTS TO THE WEST VIRGINIA BOARD OF PHARMACY).
* Required information to be reported:
	+ - The name and address of the entity dispensing or distributing naloxone
		- Type of entity
		- The name and NDC (national drug code) for each formulation dispensed or distributed
			* Narcan (naloxone) 4mg nasal spray NDC 69547-353-02
		- The total quantity of each formulation of naloxone dispensed or distributed
* Additional Reporting for physicians
	+ Annual reporting (February of each year) - report total number distributed

***Instructions for Reporting to the ODCP***

The form may be accessed [**here**](http://www.wvdhhr.org/EpiInfoWebSurvey/Home/c652ac27-f205-4932-b03f-0c485aebbfff)**. The link is listed below.** (<http://www.wvdhhr.org/EpiInfoWebSurvey/Home/c652ac27-f205-4932-b03f-0c485aebbfff>)

After reaching the survey page, select the **Begin Survey** button as seen below, to start. *Remember to record the passcode if you intend to save and complete the survey later*.

Once all information has been entered, select the **Submit Survey** button located in the lower right of the form.

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***Additional reporting for ALL entities***

* Monthly reporting (IF RECEIVING GRANT FUNDED NALOXONE THROUGH UCSOP)
	+ Must report required information monthly to the institution supplying naloxone
	+ Each grant providing product may require specific information - refer to grant agreement with institution
		- Each individual receiving naloxone MUST complete the post-training survey (*Appendix I*). Scan and email (or mail) forms after completion of training (at least monthly or more often if applicable). All required documentation needed for grant purposes is contained in the post-training survey. Each location should also maintain records (*Appendix G*) and may be asked at least quarterly to verify # of kits remaining:
			* lindsayacree@ucwv.edu
			* University of Charleston School of Pharmacy

c/o Lindsay Acree

2300 MacCorkle Avenue SE

Charleston WV, 25304

* + Example spreadsheet to document trainings and distribution provided in *Appendix G*
* Weekly reporting for refilled naloxone (ALL ENTITIES)
	+ Must report reason for refill on *Appendix I* – If receiving grant funded naloxone (See above)
	+ Report ALL opioid overdose reversals to the West Virginia Poison Control Center
		- Patient must complete the form (*Appendix H*)
		- Form to be faxed or emailed.
			* Email to Elizabeth Scharman at escharman@hsc.wvu.edu
			* Fax to 304-347-3908

**IX. TERMS**

This protocol is in effect until [3/1/2021]

It will be reviewed, and may be updated, if there is relevant new information about naloxone administration, or at least annually. Updates to legislation may occur, therefore, document may be updated prior to expiration of agreement.

**X. SIGNATURES (will differ per location)**

|  |  |
| --- | --- |
| **Physician Signature** | **Date** |
| **Physician Name (print)** |

|  |  |
| --- | --- |
| **Pharmacist Signature** | **Date** |
| **Pharmacist Name (print)** |

**FAQs about West Virginia Board of Pharmacy Naloxone Distribution and Dispensing**

In 2016, the WV Legislature began passing laws to improve access to naloxone as a tool in the fight against the opioid epidemic. There are now even more options for the public to access naloxone. This document will explain the pathways for numerous entities to access, dispense, or distribute naloxone.

**What is dispensing?**

* Naloxone dispensing is preparation, verification and delivery of a drug and device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

**What is distribution?**

* Naloxone distribution occurs when any governmental or non-governmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high risk behaviors provides naloxone and basic education and information on how to administer it to a person at risk of experiencing an opiate-related overdose or a family member, friend, or other person in a position at risk of experiencing an opiate-related overdose.
* **This is authorized by** [**WV State Code § 16-46-1 *et seq***](http://www.wvlegislature.gov/wvcode/code.cfm?chap=16&art=46)***.***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **DISPENSING TO INDIVIDUALS** | **DISPENSING TO ORGANIZATIONS** | **DISTRIBUTION BY ORGANIZATIONS TO INDIVIDUALS** |
| **Who can perform:** | * Pharmacists
* Dispensing physicians
* Physician assistants
 | * Pharmacists
 | * An agent of a governmental or nongovernmental organization including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors
 |
| **Where can it happen:** | * Pharmacies
* Local health department clinics
* Dispensing physician offices
 | * Pharmacies
 | * Anywhere
 |
| **What order is needed:** | * State Health Officer’s standing order OR
* Individual prescription OR
* Local standing order
 | * Local standing order allowing distribution
 | * Local standing order signed by local healthcare provider for distribution
 |
| **Education that is required to person receiving the naloxone:** | * Counseling as required by protocol - pharmacist or interns furnishingopioid antagonist, Naloxone Hydrochloride.
* (1) The proper administration of the opioid antagonist; (2) the importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist; and (3) the risks associated with failure to contact emergency services following administration of an opioid antagonist.
* Opioid-related prevention and treatment programs and Instruction on how to administer the opioid antagonist.
* Refer to Appendix E.
 | * The organization must have all designees trained to provide education on opioid-related prevention and treatment programs and Instruction on how to administer the opioid antagonist.
* The importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist.
* The risks associated with failure to contact emergency services following administration of an opioid antagonist.
 | * Opioid-related prevention and treatment programs and Instruction on how to administer the opioid antagonist.
* The importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist.
* The risks associated with failure to contact emergency services following administration of an opioid antagonist.
 |

**Chart Adapted From North Carolina Division of Public Health.** <https://publichealth.nc.gov/lhd/dispensingTraining/DispensingVersusDistributionOfNaloxoneChart.pdf>

**What are the key differences between dispensing and distributing naloxone?**

|  |  |
| --- | --- |
| **Dispensing** | **Distribution** |
| * Requires the State Health Officer’s standing order, a local standing order, or a prescription.
* Is provided by a licensed healthcare provider.
 | * Requires the organization to have a local dispensing and distribution standing order.
* This permits the pharmacist to dispense the naloxone to the organization and the organization to distribute the naloxone to the individuals covered under the standing order of distribution.
* Is performed by a trained agent of the organization covered under the distribution order, who does not need to be a licensed healthcare professional.
 |

**Chart Adapted From North Carolina Division of Public Health.** <https://publichealth.nc.gov/lhd/dispensingTraining/DispensingVersusDistributionOfNaloxoneChart.pdf>

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