

Virginia Board of Pharmacy

Naloxone Protocols

54.1-3408 (X) and (Y) authorize certain persons to dispense naloxone pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements.

§54.1-3408

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal other than naloxone in an injectable formulation with a hypodermic needle or syringe in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and

administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 54.1-3408 (X)

a. Authorized Dispensers

The following individuals may dispense naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of §54.1-3408:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- School nurses,

- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services,
- Firefighters, and
- Employees or other persons acting on behalf of a “public place” which means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

b. Required Training

- i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. Required Order

- i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.
- ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
 1. Name of entity or group of entities authorized to dispense naloxone pursuant to standing order;
 2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 3. Prescriber’s signature;
 4. Date of issuance; and
 5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	<u>Intranasal</u>
Naloxone 2mg/2ml prefilled syringe, # 2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2	Naloxone 2 mg #1 twin pack Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone nasal spray 8mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

<p>SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.</p>			
---	--	--	--

d. Required Labeling and Recordkeeping

- i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.
- iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

e. Required Instruction

- i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at <http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf> If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

II. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in 54.1-3408 (Y)

a. Authorized Dispensers

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;
- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.

b. Training

- While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.
- Those persons acting on behalf of such organization and who intend to dispense injectable naloxone formulation with a hypodermic needle or syringe, must first complete training developed by and be authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe

c. Required Order

- i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:
 1. Name of organization authorized to dispense naloxone pursuant to standing order;
 2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
 4. Prescriber's signature;
 5. Date of issuance; and
 6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	Injection*	<u>Intranasal</u>
<p>Naloxone 2mg/2ml prefilled syringe, # 2 syringes</p> <p>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. <u>Call 911.</u> Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.</p>	<p>Naloxone 2 mg #1 twin pack</p> <p>SIG: Use one auto-injector upon signs of opioid overdose. <u>Call 911.</u> Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p>	<p>Naloxone Nasal Spray 4mg, #1 twin pack</p> <p>SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p>	<p>Naloxone 0.4mg/ml #2 single-use 1ml vials</p> <p>SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response.</p> <p>#2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.</p>	<p>Naloxone nasal spray 8mg, #1 twin pack</p> <p>SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p>

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. Required Labeling, Recordkeeping, and Storage

- i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The standing order must be maintained for two years from the last date of dispensing.

- iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).
- v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. Required Instruction

- i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at <http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf> If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.
- ii. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone to Entities Authorized to Possess, Administer, and Dispense Naloxone

- a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:
 - i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1;
 - ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or
 - iii. Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person

dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

- a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum “Understanding and Responding to Opioid Overdose Emergencies Using Naloxone”, available at <http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf>
- b. Substance Abuse Mental Health Services Administration’s “Opioid Prevention Toolkit” (2014), available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>
- c. Prescribe to Prevent, <http://prescribetoprevent.org/pharmacists>
- d. Harm Reduction Coalition, <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials>
- e. Dispensers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov