Virginia Board of Pharmacy

Naloxone or Other Opioid Antagonist Protocols

Virginia Code § 54.1-3408(Y) and (Z) authorize certain persons to dispense prescription-only naloxone or other opioid antagonists used for overdose reversal 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 or other opioid antagonists 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. **Note: this protocol does not apply to over-the-counter formulations of naloxone or other opioid antagonists that are available for anyone to obtain without a prescription.**

I. Protocol for the Prescribing and Dispensing of Naloxone or Other Opioid Antagonist by Persons Listed in Virginia Code § 54.1-3408(Y)

a. Authorized Dispensers

The following individuals may dispense naloxone or other opioid antagonist 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 Y of § 54.1-3408 of the Code of Virginia:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in Virginia Code § 32.1-111.1
- Law-enforcement officers as defined in Virginia Code § 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 by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in Virginia Code § 53.1-1,
- Employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers,
- 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,
- Emergency medical services personnel, as that term is defined in Virginia Code § 32.1-111.1,
- Employees of the Department of Juvenile Justice designated as probation and patrol officers or as juvenile correctional officers,
- resident assistants in a student housing facility at a public institution of higher education who have completed training in the administration of an opioid antagonist for overdose reversal pursuant to Virginia Code § 23.1-802.2, and
- Firefighters.

b. <u>Required Order</u>

i. Prior to dispensing naloxone or other opioid antagonist, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive the drug or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense the drug. 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 Virginia Code § 54.1-3408(Y) shall only dispense formulations for intranasal administration or an autoinjector formulation.

ii. If the naloxone or other opioid antagonist 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 the drug 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	Intranasal
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	Naloxone 2 mg or 5mg #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 or 8mg, #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	Nalmefene nasal spray, #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

medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.		responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives	patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 5 minutes until emergency medical assistance arrives.

c. Required Labeling and Recordkeeping

i. The dispenser shall affix a label to the naloxone or nalmefene container that bears the name and strength of the dispensed drug, 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 drug 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.

d. Instruction

While not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone or nalmefene, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. Such instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! information available on the Department of Behavioral Health and Developmental Services website or by clicking on the link. 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 Virginia Code § 54.1-3408(Z)

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 or other opioid antagonist, 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 or other opioid antagonist as authorized in subsection Z 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 or other opioid antagonist 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 or other opioid antagonist, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone or other opioid antagonist. The standing order must contain the following information at a minimum:

1. Name of organization authorized to dispense naloxone or other opioid antagonist 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***	**Intranasal**
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: 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 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg, #1 twin pack SIG: 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 or 8mg, #1 twin pack 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 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 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #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.	Nalmefene nasal spray, #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 5 minutes until emergency medical assistance arrives.

**** Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of, hypodermic needles and syringes, who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organization has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes.***

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 or other opioid antagonist container that bears the name and strength of the dispensed naloxone or other opioid antagonist, 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 or other opioid antagonist 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. Instruction

While it is not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone or other opioid antagonist, effectiveness and response following administration, adverse effects,

safety, storage conditions, and expiration date. Such instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! information available on the Department of Behavioral Health and Developmental Services website or the link above. 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. 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 or Other Opioid Antagonists to Entities Authorized to Possess, Administer, and Dispense Such Drugs

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone or nalmefene 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 Virginia Code § 32.1-111.1; or

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 Virginia Code § 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, other school board employees or individuals contracted by a school board to provide school health services, and resident assistants in a student housing facility at a public institution of higher education who have successfully completed a training program.

b. In addition to wholesale distributors, third-party logistics providers, or manufacturers, a pharmacy may distribute naloxone or other opioid antagonist via invoice to 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 or other opioid antagonist pursuant to Virginia Code § 54.1-3408(Z). 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 or nalmefene 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! Training information
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit"
c. Prescribe to Prevent Clinician Resource
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