Protocol for the Prescribing of Naloxone and Dispensing by Trainers

Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for opioid overdose reversal shall follow this protocol when dispensing naloxone, and the hypodermic needles and syringes required for injecting such naloxone, to a person, without charge or compensation, for administration to another person believed to be experiencing or about to experience a life-threatening opioid overdose as authorized in § 54.1-3408 (Y), §54.1-3466(F), and §54.1-3467(C). ***Note: Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol may dispense injectable naloxone with hypodermic needles and syringes.***

1) **Controlled Substances Registration:** An organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal on whose behalf an authorized trainer may dispense naloxone pursuant to a standing order shall apply for a controlled substances registration certificate from the Board of Pharmacy. 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 certificate.

2) **Standing Order:** An authorized trainer may dispense naloxone, and the hypodermic needles and syringes required for injecting such naloxone, pursuant to a standing order. The standing order must be issued by an individual prescriber to the organization on whose behalf the authorized trainer is acting. The standing order authorizes a trainer to dispense one or more of the specified naloxone formulations, and may authorize the dispensing of hypodermic needles and syringes for injecting such naloxone, to any person seeking to obtain naloxone following completion of a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services. A standing order is valid for no more than two years from the date of issuance and must contain the following information at a minimum:
   - **a.** Name of organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy on whose behalf the authorized trainer may dispense naloxone pursuant to the standing order;
   - **b.** Drug name, strength, quantity of naloxone to be dispensed, and directions for administration. If hypodermic needles and syringes are to be dispensed 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 part 3 of this protocol;
   - **c.** Prescriber's signature; and

d. Date of issuance.

3) Dispensing Requirements for Intranasal, Auto-Injector, or Injectable Administration:

Intranasal	Auto-Injector	Intranasal	Injection*
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 #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.	Narcan Nasal Spray 4mg, #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.

**** Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol may dispense injectable naloxone with hypodermic needles and syringes.***

Optional items include rescue breathing masks, and latex-free gloves.

Trainers 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

4) Storage, Labeling, Dispensing, and Recordkeeping:

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone, and hypodermic needles and syringes for injecting such naloxone, for opioid overdose reversal pursuant to §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) shall maintain the following records:

1. The prescriber's standing order issued in accordance with §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) authorizing the trained individual to dispense naloxone, and hypodermic needles and syringes for injecting such naloxone.
2. Invoices or other records showing receipts of naloxone, hypodermic needles, and syringes must be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone, description and quantity of hypodermic needles, and syringes transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer, name of trained individual approved by the Department of Behavioral Health and Developmental Services.
4. Record of dispensing indicating name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, description and quantity of hypodermic needles and syringes, if dispensed, and name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

B. The naloxone, hypodermic needles, and syringes shall be labeled with directions for use in accordance with prescriber's standing order, date of dispensing, name of person receiving drug, drug name, strength, name and telephone number for the entity associated with the controlled substances registration.

C. The trainer shall provide 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 Additionally, when dispensing injectable naloxone with hypodermic needles and syringes, the trainer shall provide the current REVIVE! brochure on proper disposal of hypodermic needles and syringes.

D. 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.

E. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate must ensure compliance with any recall

procedures as issued by the manufacturer, United States Food and Drug Administration, or Board to ensure affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

F. Except for a prescriber's standing order which must be maintained on-site for a period of not less than two years from the date of the last dispensing, records must be filed chronologically and maintained for a period of not less than two years from the date of transaction.

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