TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710; adding 18VAC110-20-735).**

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Effective Dates: May 8, 2017, through November 7, 2018.

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Preamble

Section 2.2-4011 of the Code of Virginia authorizes agencies to adopt emergency regulations in situations in which Virginia statutory law or the appropriation act requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia. Chapters 55 and 58 of the 2017 Acts of Assembly, which became effective on February 20, 2017, establish additional circumstances under which the Board of Pharmacy is authorized to issue a controlled substance registration and require the board to promulgate regulations within 280 days of the enactment.

The emergency regulation authorizes issuance of a controlled substances registration (i) to persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training and (ii) to an entity for the purpose of establishing a bona fide practitioner-patient relationship for prescribing when treatment is provided by telemedicine in accordance with federal rules. The amendments include applicable recordkeeping, security, and storage requirements.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, ~~or~~ pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration, provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; ~~or~~ (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation, or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking which meets the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, <u>persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal,</u> and teaching institutions possessing only Schedule VI drugs.

<u>18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.</u>

<u>A. Persons 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 pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:</u>

<u>1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.</u>

<u>2. Invoices or other records showing receipts of naloxone shall 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 site or off site. All</u>

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 transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect them from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

E. 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 shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

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