COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting

February 28, 2017

10AM

TOPIC	PAGES
Call to Order: Ryan Logan, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Continue Periodic Regulatory Review by Developing Draft Amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20	1-21
• Adopt Guidance for Pharmacists Taking Breaks	22-28
• Amend Regulation to Authorize Partial Filling of Schedule II Prescription	29-35
• Amend Regulation 18VAC110-20-590, Drugs in Correctional Facilities	36-38
• Amend Guidance Document 110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide	39-53
• Amend Guidance Document 110-20, Practice by a Pharmacy Technician Trainee	54-56
• Amend Guidance Document 110-44, Protocol for Prescribing and Dispensing Naloxone	57-64
Adjourn	

****The Committee will have a working lunch at approximately 12pm.****

Continue Periodic Regulatory Review by Developing Draft Amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy*, chapter 20

Included in Agenda Packet:

- Minutes from Regulation Committee Meeting, 11/3/15 - Excerpt
- Draft Regulatory Amendments Prepared by Staff
- "Refrigerator and Freezers for Vaccine storage" from Oklahoma State Dept. of Health

Board Action:

- Motion to recommend to full board to adopt amendments as presented or as amended.

FINAL/APPROVED
Attachment 1

- Suggested wording in (B) (2) be changed from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of CE
- Consider striking ability for board to approve and accept board-approved CE programs
- Committee discussed recommendations for requiring live CE and having ability to carry over hours into subsequent year, but concluded a statutory amendment would be necessary. Staff will research what other state boards of pharmacy may require live CE.
- Committee discussed recommendation for requiring CE annually in the subject of opioids. Statutory ability to specify topic for CE annually also discussed. No final recommendation was made.

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove ability for board to approve CE programs.

PART III Requirements For Pharmacy Technician Registration

18VAC110-20-102 Criteria for approval of training programs

- Consider including training program approval number to be printed on certificate awarded by training program.
- Consider requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Consider changing "certificates" to "documentation" in both sentences of subsection D.

PART IV Pharmacies

18VAC110-20-110 Pharmacy permits generally

- Consider specifying minimum number of hours PIC must practice at the location listed on the pharmacy permit application
- Consider requiring minimum number of years of experience for PIC eligibility. There was discussion for a possible ability for exceptions, but no final recommendation made.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider requirement for inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider amending to allow Board to rescind pharmacy permit if not opened within 60 days of issuing permit. Concern raised that board counsel may recommend criteria if the term "may" is used as proposed in the agenda packet.

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FINAL/APPROVED
Attachment 1

18VAC110-20-150 Physical standards for all pharmacies

- Consider specifying acceptable refrigeration facilities based on CDC guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Consider requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Consider clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient. Committee discussed whether pharmacist must practice at the pharmacy or if acceptable to notify district supervisor pharmacist who does not necessarily practice at location. No final recommendation made.
- Discussed whether regulation should clarify how long security system auxiliary source of power must last, but concluded that it may be problematic to address this issue.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Add language from Guidance Document 110-40 regarding dispersion of Schedule II drugs
- Discussed clarifying subsection D to include old chemicals used for compounding, but concluded that the board should consider adopting guidance indicating subsection D includes old chemicals and that it will be a violation of this regulation to use old chemicals that exceed the expiration date that is assigned based on USP standards.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amend regulation based on recent amendments to §54.1-3423 changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Add language to regulation that applications must include name of responsible party
- Requirement to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Consider adding language from Guidance Document 110-19 for MES to transfer prescriptions based on amended handout.
- Consider adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

FINAL/APPROVED
Attachment 1

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

- Amend schedules to include Schedule I

Additional subjects recommended for inclusion in board regulations:

18VAC110-20-22 (as proposed by staff in 11/3/15 agenda packet) – Submission of corrective action related to inspections

- Consider adding requirement in the General Provisions for PIC, responsible party, or owner to respond to inspection deficiencies within 14 days. This would be added to all relevant facility chapters.

18VAC110-20-10

- Review definition for "robotic pharmacy system"; appears to encompass more than traditional robot addressed in 18VAC110-20-425.

General ability for pharmacist to delegate to someone else to enter pharmacist's initials when required for recordkeeping purposes

Regulations discussed but <u>not</u> recommended for inclusion in the NOIRA:

18VAC110-20-40 Procedure for gaining practical experience

- Discussed adding requirement for licensees to submit certain documents when individual's name changes. However, decided not to require licensee change name in regulation, but to continue addressing in policy the documents needed to change a licensee's name.

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date: November 16, 2016

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Periodic Regulatory Review, Draft Amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20

18VAC110-20-10

"Dormitory-style refrigerator" is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Part IV. Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. The PIC shall be fully engaged and in full and actual charge not less than an average of 20 hours per week averaged over a month in each pharmacy wherein designated the PIC.

C. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another state. The board may grant an exception to the minimum number of years of experience for good cause shown.

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

C. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

D. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

F. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the

board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-111. Pharmacy technicians.

18VAC110-20-120. Special or limited-use pharmacy permits.

18VAC110-20-121. Innovative program approval.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.

A. At least 14 days prior to the date a pharmacy closes in accordance with §54.1-3434.01 of the Code of Virginia or goes out of business, the owner shall notify the board. The proposed disposition of all Schedule II through VI drugs, prescription dispensing records, patient information records, and other required records shall be reported to the board. If the pharmacy drug stock and records are to be transferred to another licensee, the owner shall inform the board of the name and address of the licensee to whom the drugs and records are being transferred and the date of transfer. Prescription records for prescriptions with active refills shall be transferred to another pharmacy where a patient may obtain access for the purpose of obtaining refills either at that location or in accordance with the transfer provisions of 18VAC110-20-360.

B. Exceptions to the public notice as required in §54.1-3434.01 of the Code of Virginia and the notice required in subsection A of this section shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmacy is not able to meet the notification requirements of § 54.1-3434.01, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

C. In the event of an exception to the notice as required in §54.1-3434.01 of the Code of Virginia and in subsection A of this section, the PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmacy, the prescription dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of pharmacy services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

3. The format of the prescription dispensing records which are transferred to a new owner shall comply with the requirements of Chapter 34 (§54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, and this chapter. Failure to comply with this chapter during a change in ownership shall be deemed to be a closing of the existing pharmacy for which the existing pharmacy owner shall be required to provide notice to the board and public in accordance with §54.1-3434.01 of the Code of Virginia and subsection A of this section.

18VAC110-20-135. Change of hours in an existing pharmacy.

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by §32.1-127.1:03 of the Code of Virginia.

C. While a closing inventory is not required, a complete and accurate inventory shall be taken of all Schedule II through V controlled substances on hand, in accordance with §54.1-3404, on the date the pharmacist first engages in business under the new ownership. Inventories associated with any change in PIC shall also be performed in accordance with 18VAC110-20-110.

~~C.~~D. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

1. Pharmacy permit applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which 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.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18 VAC 110-20-20 prior to a reinspection being conducted.

~~D.~~E. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

~~E.~~F. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

G. If the pharmacy is not operational within 60 days from the date the permit is issued or a change of ownership is approved, the board shall rescind a pharmacy permit.

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet U.S.P.-N.F. specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary record keeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs.

1. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

2. A dormitory-style refrigerator shall not be used for storage of vaccines.

18VAC110-20-160. Sanitary conditions.

18VAC110-20-170. Required minimum equipment or resources.

18VAC110-20-180. Security system.

A. A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:

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

2. The device shall have at least one hard-wired communication method, be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

5. The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy.

B. Exceptions to provisions in this section:

1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, 2, and 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

3. This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, a security system that meets the requirements of subdivisions A 1 through 4 of this section.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy which detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe, <u>or maintained in a manner which combines the two methods for storage.</u> The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-210. Disposal of drugs by pharmacies.

18VAC110-20-211. Disposal of drugs by authorized collectors.

Part XIII. Other Institutions and Facilities

18VAC110-20-570. Drugs in infirmaries/first aid rooms.

18VAC110-20-580. Humane societies and animal shelters.

A humane society or animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of §54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a ~~humane society or~~ public or private animal shelter as defined in § 3.2-6500 shall only be stored and administered at the address of the ~~humane society or~~ shelter.

2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the person(s) responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

3. The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

4. Drugs shall be stored in a secure, locked place and only the person(s) responsible for administering may have access to the drugs.

5. All invoices and order forms shall be maintained for a period of two years.

6. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

18VAC110-20-590. Drugs in correctional facilities.

Part XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600. Excluded substances.

18VAC110-20-610. Exempted chemical preparations.

18VAC110-20-620. Exempted prescription products.

18VAC110-20-621. Exempted anabolic steroid products.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

Part XV. Medical Equipment Suppliers.

18VAC110-20-630. Issuance of a permit as a medical equipment supplier.

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit, or for acquisition of an existing medical equipment supplier. The application shall designate the hours of operation the location will be open to service the public and shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.

B. Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.

1. Such notification of a change in hours of operation is not required when the change is necessitated by emergency circumstances beyond the control of the owner or when the change will result in an expansion of the current hours of operation.

2. If the medical equipment supplier is unable to post the change in hours 14 days in advance, the responsible party or owner shall ensure the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

C. Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.

~~B~~D. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

~~C~~E. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

18VAC110-20-640 through 18VAC110-20-670. (Repealed.)

18VAC110-20-680. Medical equipment suppliers.

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

E. A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, or by facsimile machine or by electronic transmission.

1. The transferring medical equipment supplier shall:

a. Record the word "VOID" on the face of the invalidated order;

b. Record on the reverse of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information; and,

2. The receiving medical equipment supplier shall:

a. Write the word "TRANSFER" on the face of the transferred prescription.

b. Provide all information required to be on a valid order to include:

(1) Date of issuance of original order;

(2) Original number of refills authorized on the original order;

(3) Date of original dispensing, if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Medical equipment supplier name and address from which the order information was transferred; and

(6) Name of transferring individual, if transferred orally.

3. Both the original and transferred order shall be maintained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for storage and retrieval of dispensing information.

~~E~~F. A nonresident medical equipment supplier shall register and practice in accordance with § 54.1-3435.3:1 of the Code of Virginia.

Part XVI. Controlled Substances Registration for Other Persons or Entities.

18VAC110-20-685. Definitions for controlled substances registration.

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

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

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~~ I 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, and teaching institutions possessing only Schedule VI drug.

18VAC110-20-720. Requirements for recordkeeping.

18VAC110-20-725. Repackaging by a CSB, BHA, or PACE site.

18VAC110-20-726. Criteria for approval of repackaging training programs.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB, BHA or PACE.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

18VAC110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

DRAFT

Refrigerators and Freezers for Vaccine Storage

Immunization Service
Oklahoma State Department of Health

Freezers and refrigerators are available in many different sizes, types (e.g., stand-alone versus combination), and grades (e.g., household, commercial, and pharmaceutical).

The Centers for Disease Control and Prevention (CDC) strongly recommends stand-alone freezers and refrigerators without freezers. Studies have demonstrated they maintain the required temperatures better than combination units.

An alternative to stand-alone units would be to use the refrigerator compartment of a combination refrigerator/freezer unit to store refrigerated vaccines. A separate stand-alone freezer would be used to store frozen vaccines. CDC has received multiple reports of incidences when refrigerated vaccines have been compromised by exposure to freezing temperatures in a combination unit.

At a minimum, a combination refrigerator/freezer unit sold for home use with separate exterior doors and thermostat controls for each compartment is acceptable (but not recommended). CDC recommends the use of units designed for storing biologics.

Any freezer or refrigerator used for vaccine storage should have its own exterior door that seals tightly and properly, as well as thermostat controls.

It must be able to maintain the required temperature range throughout the year.

The unit should be dedicated to the storage of biologics and it must be large enough to hold the year's largest vaccine inventory without crowding (including flu vaccine).

A storage unit that is frost-free or has an automatic defrost cycle is preferred. If using a combination freezer-refrigerator unit to store vaccines, care must be taken to ensure that the freezer is not so cold that the refrigerator temperature drops below the recommended temperature range.

Use of a dormitory-style refrigerator for storage of vaccine provided by the Vaccines for Children Program (VFC) is not allowed at anytime.
A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Based on research published in December 2009, the National Institute of Standards and Technology (NIST) concluded that "the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance."

Providers have many options for finding affordable, office-appropriate stand-alone units. **Stand-alone units can be under-the-counter size as discussed here or full-size. Clinics** can shop local home improvement stores or appliance dealers or purchase laboratory or pharmaceutical grade units.

Manufacturers to Consider*
Marvel Scientific - www.marvelscientific.com/
Lab Research Products - www.labresprod.com/
Panasonic – http://www.panasonic.com/business/healthcare/biomedical/vaccine/
American Biotech Supply - http://www.americanbiotechsupply.com/Products/Refrigerators/Pharmacy-Refrigerators.aspx
Migali Scientific - http://www.migaliscientific.com/
Sun Frost - http://www.sunfrost.com/vaccine_refrigerators.html
Dulas Solar for Life - http://www.dulas.org.uk/products/solar-powered-refrigerators.cfm

*The Oklahoma State Immunization Service does not endorse any specific product or manufacturer. This list is provided for informational purposes only. Providers and their staff should do their own research and choose a product that best fits the needs of the practice.

Adopt Guidance for Pharmacists Taking Breaks

Included in Agenda Packet:

- Draft Guidance Document Prepared by Staff
- Draft rules from Minnesota

Possible Board Action:

- Motion to recommend to full board to adopt guidance document as presented or as amended.

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and breaks:

- While a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to close when a pharmacist is on break;
- If a pharmacy does not close, the pharmacist shall ensure adequate security of the drugs by taking his break within the prescription department.
- If two or more pharmacists are practicing simultaneously and the pharmacy does not close during a break, the pharmacists should stagger their breaks;
- The pharmacist on-duty shall determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

from *Regulations Governing the Practice of Pharmacy*

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

C. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

E. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

H. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

I. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Pharmacy Working Conditions

AGENCY: Board of Pharmacy

MINNESOTA RULES: Chapter 6800

The attached rules are approved for
publication in the State Register

Lauren C. Bethke

Lauren C. Bethke
Assistant Revisor

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Board of Pharmacy

Proposed Permanent Rules Relating to Pharmacy Working Conditions

6800.2150 PHARMACIST ON DUTY.

Subpart 1. **Requirement to have a pharmacist on duty.** ~~A.~~ A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except ~~that~~ for brief absences of the pharmacist arising out of and in the course of pharmacy practice ~~are allowable~~.

Subp. 2. **Limiting access to pharmacies.** ~~B.~~ When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800.7530. ~~In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.~~

6800.2160 PHARMACY WORK CONDITIONS.

Subpart 1. **Limitation on continuous hours worked.** A pharmacy licensed under Minnesota Statutes, section 151.19, subdivision 1, which is located within Minnesota, shall not require a pharmacist, pharmacist-intern, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.

Subp. 2. **Requirements for breaks.**

A. A pharmacist, pharmacist-intern, or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30-minute, uninterrupted break.

B. A pharmacist, pharmacist-intern, or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.

2.1 C. A pharmacy may, but is not required to, close when a pharmacist is on
2.2 a break. If the pharmacy does not close, the pharmacist shall either remain within the
2.3 licensed pharmacy or within the establishment in which the licensed pharmacy is located
2.4 in order to be available for emergencies. In addition, the following apply:

2.5 (1) pharmacy technicians, pharmacist-interns, and other supportive staff,
2.6 authorized by the pharmacist on duty, may continue to perform duties as allowed under
2.7 this chapter;

2.8 (2) no duties reserved to pharmacists and pharmacist-interns under any
2.9 part of this chapter, or that require the professional judgment of a pharmacist, may be
2.10 performed by pharmacy technicians or other supportive staff; and

2.11 (3) only prescriptions that have been certified by a pharmacist, as required
2.12 by part 6800.3100, may be dispensed while the pharmacist is on break; except that
2.13 prescriptions that require counseling by a pharmacist, including all new prescriptions
2.14 and those refill prescriptions for which a pharmacist has determined that counseling is
2.15 necessary, may be dispensed only if the following conditions are met:

2.16 (a) the pharmacy develops a list of drugs that may not be dispensed
2.17 while a pharmacist is taking an allowed break, without the patient receiving counseling
2.18 from a pharmacist, when counseling would normally be required;

2.19 (b) the patient, or other individual who is picking up the prescription
2.20 on behalf of the patient, is told that the pharmacist is on a break and is offered the chance
2.21 to wait until the pharmacist returns from break in order to receive counseling;

2.22 (c) if the patient or caregiver declines to wait, a telephone number at
2.23 which the patient or a caregiver can be reached is obtained;

2.24 (d) after returning from the break, the pharmacist makes a reasonable
2.25 effort to contact the patient or a caregiver by telephone and provides counseling; and

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3.1 (c) the pharmacist documents the counseling that was provided or
3.2 documents why counseling was not provided, including a description of the efforts made
3.3 to contact the patient or caregiver. The documentation shall be retained by the pharmacy,
3.4 and be made available for inspection by the board or its authorized representatives, for a
3.5 period of at least two years.

3.6 D. In pharmacies staffed by two or more pharmacists, the pharmacists shall
3.7 stagger breaks so that at least one pharmacist remains on duty at all times that the
3.8 pharmacy remains open for the transaction of business.

3.9 Subp. 3. **Exceptions for emergencies.** Subpart 1 and subpart 2, item A, shall not
3.10 apply in the event that an emergency necessitates that a pharmacist, pharmacist-intern, or
3.11 pharmacy technician work longer than 12 continuous hours, work without taking required
3.12 meal breaks, or have a break interrupted in order to minimize immediate health risks for
3.13 patients.

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Amend Regulation to Authorize Partial Filling of Schedule II Prescription

Included in Agenda Packet:

- Relevant excerpt from CARA Act, Board Regulation, suggested amendment prepared by staff

Possible Board Action:

- Motion to recommend to full board that it amend Regulation 18VAC110-20-310 as presented or amended

Title 21 United States Code (USC) Controlled Substances Act

SUBCHAPTER I — CONTROL AND ENFORCEMENT

Part C — Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential

Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) Controlled substances dispensed by means of the Internet

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

from *S. 524 (114th): Comprehensive Addiction and Recovery Act (CARA) of 2016*

702.
Partial fills of schedule II controlled substances

(a)
In general

Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

(f)
Partial fills of schedule II controlled substances

(1)
Partial fills

A prescription for a controlled substance in schedule II may be partially filled if—

(A)
it is not prohibited by State law;

(B)
the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

(C)
the partial fill is requested by the patient or the practitioner that wrote the prescription; and

(D)
the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2)
Remaining portions

(A)
In general

Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i)
may be filled; and

(ii)
shall be filled not later than 30 days after the date on which the prescription is written.

(B)
Emergency situations

In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i)
may be filled; and

(ii)
shall be filled not later than 72 hours after the prescription is issued.

(3)
Currently lawful partial fills

Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.

(b)
Rule of construction

Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

from *Regulations Governing the Practice of Pharmacy*, November 16, 2016

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, he shall make a reasonable effort to determine that the oral authorization came from a practitioner using his phone number as listed in the telephone directory or other good-faith efforts to ensure his identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person, by mail postmarked within the seven-day period, or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to him. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

Draft Amendment Prepared by Staff:

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

A. The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and he makes a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

B. Prescriptions for Schedule II drugs written for patients in long-term care facilities may be dispensed in partial quantities, to include individual dosage units. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II drugs in all partial dispensing shall not exceed the total quantity prescribed. Schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

C. Information pertaining to current Schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, identification of the long-term care facility, identification of drug authorized (to include dosage form, strength, and quantity), listing of partial dispensing under each prescription and the information required in subsection B of this section.

2. Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.

D. A prescription for a Schedule II drug may be filled in partial quantities to include individual dosage units for a patient with a medical diagnosis documenting a terminal illness under the following conditions:

1. The practitioner shall classify the patient as terminally ill, and the pharmacist shall verify and record such notation on the prescription.

2. On each partial filling, the pharmacist shall record the date, quantity dispensed, remaining quantity authorized to be dispensed, and the identity of the dispensing pharmacist.

3. Prior to the subsequent partial filling, the pharmacist shall determine that it is necessary. The total quantity of Schedule II drugs dispensed in all partial fillings shall not exceed the total quantity prescribed.

4. Schedule II prescriptions for terminally ill patients may be partially filled for a period not to exceed 60 days from the issue date unless terminated sooner.

5. Information pertaining to partial filling may be maintained in a computerized system under the conditions set forth in subsection C of this section.

E. A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:

1. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

2. The prescription is written and filled in accordance with state and federal law.

3. The remaining portions shall be filled not later than 30 days after the date on which the prescription is written.

Amend Regulation 18VAC110-20-590, Drugs in Correctional Facilities

Background:

Issue brought to Board's attention by the Department of Corrections, in consultation with DEA. Regulation currently requires all unused or discontinued drugs to be returned to provider pharmacy or secondary pharmacy. However, federal rules do not allow unused or discontinued drugs in Schedules II-V that were dispensed to specific inmates to be returned to provider pharmacies. It is recommended that the Board amend the regulation to conform with federal requirements.

In agenda packet:

Suggested amendment to 18VAC110-20-590 prepared by staff.

Possible Board Action:

Motion to recommend to full board in March to amend Regulation 18VAC110-20-590 as presented or as amended.

18VAC110-20-590. Drugs in correctional facilities.

A. All prescription drugs at any correctional facility shall be subject to the following conditions:

1. Notwithstanding the allowances in subsections B, C, and D of this section, prescription drugs shall be obtained only on an individual prescription basis.

2. All prepared drugs shall be maintained in a suitable locked storage area with only the person responsible for administering the drugs having access.

3. Complete and accurate records shall be maintained of all drugs received, administered and discontinued. The administration record shall show the:

a. Patient name;

b. Drug name and strength;

c. Number of dosage units received;

d. Prescriber's name; and

e. Date, time and signature of the person administering the individual dose of drug.

4. All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Such drugs shall be returned to the provider pharmacy or to a secondary pharmacy, unless prohibited by federal law, along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within 30 days of discontinuance.

a. The provider or secondary pharmacy shall conduct random audits of returned drug administration records for accountability.

b. The drug administration records shall be filed in chronological order by the provider or secondary pharmacy and maintained for a period of one year or, at the option of the facility, the records may be returned by the pharmacy to the facility.

c. Drugs may be returned to pharmacy stock in compliance with the provisions of 18VAC110-20-400.

d. Other drugs shall be disposed of or destroyed by the provider pharmacy in accordance with local, state, and federal regulations.

5. Alternatively, drugs for destruction may be destroyed at the site of the correctional facility using a method of destruction which renders the drug unrecoverable ~~forwarded by a pharmacist directly from the correctional facility to a returns company~~ after performing the audit required by subdivision 4 a of this subsection and ensuring the proper maintenance of the administration

records. The destruction shall be performed by a nurse, pharmacist, or physician and witnessed by the nurse supervisor, a pharmacist, or physician. Disposal records shall be maintained. Such drugs shall be destroyed within 30 days of discontinuance.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants.

C. A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and shall be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

D. Except for drugs in an emergency box, stat-drug box, or a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline, prescription drugs, including but not limited to vaccines, may be floor-stocked only at a medical clinic or surgery center that is part of a correctional facility and that is staffed by one or more prescribers during the hours of operation, provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-720.

Amend Guidance Document 110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide

Background:

Staff recommends considering amendments to Guidance Document 110-9 based on concerns identified by board during recent disciplinary hearing and other concerns expressed by licensees to staff involving CQI deficiencies.

In agenda packet:

Suggested amendments to Guidance Document 110-9 prepared by staff.

Possible Board Action:

Motion to recommend to full board in March to amend Guidance Document 110-9 as presented or as amended.

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		1000
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio First Offense – Deficiency 143 Second Offense – Deficiency 6	100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250

Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Deficiency 9a if a drug loss occurred during the period of non-compliance. Deficiency 144 if no drug loss.	250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190	Deficiency 11 if there is evidence that non-compliance contributed to a drug loss. Deficiency-145 if no drug loss.	500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

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Deficiency	Law/Reg Cite	Conditions	$ Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Deficiency 12a if there is evidence that non-compliance contributed to a drug loss. Deficiency 146 is no drug loss.	250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	500
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250

Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting ~~final~~ verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting ~~final~~ verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000

Deficiency	Law/Reg Cite	Conditions	$ Penalty
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas or the weighing, prepping of hazardous drugs for compounding in an area not classified as ISO 8 or better.	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Penalty
25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. High-risk compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test or gloved fingertip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500

Deficiency	Law/Reg Cite	Conditions	$ Penalty
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

If five (5) or more deficiencies in this category are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional deficiency cited in this category, over the initial five.

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold

Deficiency	Law/Regulation Cite	Conditions
stock container)		
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	

Deficiency	Law/Regulation Cite	Conditions
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	

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Deficiency	Law/Regulation Cite	Conditions
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold

Deficiency	Law/Regulation Cite	Conditions
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization~~, to include any zero reports~~. Record maintained and available for 12 months from date of analysis of dispensing error, ~~to include any zero reports,~~ but is not in compliance	18VAC110-20-418	~~20% Threshold.~~ Do not cite deficiency until July 1, 2015
143. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	Per each technician over the ratio First offence –Deficiency 143 Second Offense –Deficiency 6
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Deficiency 144 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Deficiency 9a if drug loss.
145. Insufficient enclosures or locking devices	18VAC110-20-190	Deficiency 145 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 11 if drug loss.
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Deficiency 146 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 12a if drug loss.
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	

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Amend Guidance Document 110-20, Practice by a Pharmacy Technician Trainee

Background:

Based on recent board discussions, staff recommends considering amendment to Guidance Document 110-20 to re-interpret intent of the nine-month allowance for a pharmacy technician trainee to perform tasks restricted to a pharmacy technician prior to becoming registered as a pharmacy technician. It was previously discussed that some training programs require didactic courses that may take several months to complete prior to allowing trainee to perform duties and therefore, the interpretation that the nine months begins upon enrollment in the program was problematic. It was generally thought that the board could interpret the regulation such that the nine months begins when the trainee actually begins performing the duties restricted to pharmacy technicians.

In agenda packet:

Suggested amendments to Guidance Document 110-20 prepared by staff.

Possible Board Action:

Motion to recommend to full board in March to amend Guidance Document 110-20 as presented or as amended.

Virginia Board of Pharmacy

Practice by a Pharmacy Technician Trainee

Regulations of the Board of Pharmacy allow a person enrolled in a Board-approved pharmacy technician training program to perform duties restricted to pharmacy technicians, for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia, for no more than nine months without that person becoming registered as a pharmacy technician. (*See Regulations 18VAC110-20-101, 18VAC110-20-111, and definition of "pharmacy technician trainee" in 18VAC110-20-10*)

At its meeting on ~~June 12, 2012~~ March 21, 2017, the Board interpreted the restriction of nine months of practice for a pharmacy technician trainee to mean **nine consecutive months** from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of ~~initial enrollment date in~~ a Board-approved pharmacy technician training program. ~~regardless of whether the trainee successfully completes the program or enrolls in a different training program during those nine months~~. For example, a pharmacy technician trainee completes the didactic or classroom portion of a training program and begins performing tasks restricted to a pharmacy technician ~~who enrolls in a pharmacy technician training program~~ on January 1st. He may conduct tasks restricted to a pharmacy technician until October 1st of that year. If he ceases enrollment in the pharmacy technician training program in March and enrolls in a second pharmacy technician training program in July, he may still only perform tasks restricted to a pharmacy technician until October 1st of that year. By that date, the trainee must either be registered with the Board as a pharmacy technician or cease performing any tasks restricted to pharmacy technicians.

18VAC110-20-101. Application for registration as a pharmacy technician.

D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians ***for no more than nine months*** *without becoming registered as a pharmacy technician.*

18VAC110-20-111. Pharmacy technicians.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians ***for no more than nine months*** *without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.*

18VAC110-20-10 Definitions.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:
1. The entry of prescription information and drug history into a data system or other record keeping system;
2. The preparation of prescription labels or patient information;
3. The removal of the drug to be dispensed from inventory;
4. The counting, measuring, or compounding of the drug to be dispensed;
5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;
7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and
8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.
B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.
C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.
D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.
E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.
F. The Board shall waive the initial registration fee and the first examination fee for the Board-approved examination for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

Amend Guidance Document 110-44, Protocol for Prescribing and Dispensing Naloxone

Included in Agenda Packet:

- HB1642
- Guidance Document 110-44 with staff's suggested amendments

Possible Board Action:

- Motion to recommend to full board to amend Guidance Document 110-44 as presented or as amended

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 54.1-3408 of the Code of Virginia, relating to the administering of naloxone.

[H 1642]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and

57 administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.
58 F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course
59 of his professional practice, such prescriber may authorize licensed athletic trainers to possess and
60 administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use
61 in emergency situations; and epinephrine for use in emergency cases of anaphylactic shock.
62 G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the
63 course of his professional practice, and in accordance with policies and guidelines established by the
64 Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or
65 licensed practical nurses under the immediate and direct supervision of a registered nurse to possess and
66 administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of
67 Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers
68 for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall
69 be updated to incorporate any subsequently implemented standards of the Occupational Safety and
70 Health Administration and the Department of Labor and Industry to the extent that they are inconsistent
71 with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe
72 the categories of persons to whom the tuberculin test is to be administered and shall provide for
73 appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the
74 nurse implementing such standing protocols has received adequate training in the practice and principles
75 underlying tuberculin screening.
76 The Health Commissioner or his designee may authorize registered nurses, acting as agents of the
77 Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein
78 derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and
79 policies established by the Department of Health.
80 H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his
81 professional practice, such prescriber may authorize, with the consent of the parents as defined in
82 § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in
83 § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19
84 as administered by the Virginia Council for Private Education who is trained in the administration of
85 insulin and glucagon to assist with the administration of insulin or administer glucagon to a student
86 diagnosed as having diabetes and who requires insulin injections during the school day or for whom
87 glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall
88 only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not
89 present to perform the administration of the medication.
90 Pursuant to a written order issued by the prescriber within the course of his professional practice,
91 such prescriber may authorize an employee of a provider licensed by the Department of Behavioral
92 Health and Developmental Services or a person providing services pursuant to a contract with a provider
93 licensed by the Department of Behavioral Health and Developmental Services to assist with the
94 administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who
95 requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of
96 hypoglycemia, provided such employee or person providing services has been trained in the
97 administration of insulin and glucagon.
98 I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the
99 administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is
100 not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses
101 under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in
102 accordance with established protocols of the Department of Health may authorize the administration of
103 vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who
104 holds an advanced life support certificate issued by the Commissioner of Health under the direction of
105 an operational medical director when the prescriber is not physically present. The emergency medical
106 services provider shall provide documentation of the vaccines to be recorded in the Virginia
107 Immunization Information System.
108 J. A dentist may cause Schedule VI topical drugs to be administered under his direction and
109 supervision by either a dental hygienist or by an authorized agent of the dentist.
110 Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist
111 in the course of his professional practice, a dentist may authorize a dental hygienist under his general
112 supervision, as defined in § 54.1-2722, to possess and administer topical oral fluorides, topical oral
113 anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions,
114 as well as any other Schedule VI topical drug approved by the Board of Dentistry.
115 In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI
116 nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI
117 local anesthesia.

118 K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the
119 course of his professional practice, such prescriber may authorize registered professional nurses certified
120 as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically
121 present to possess and administer preventive medications for victims of sexual assault as recommended
122 by the Centers for Disease Control and Prevention.
123 L. This section shall not prevent the administration of drugs by a person who has satisfactorily
124 completed a training program for this purpose approved by the Board of Nursing and who administers
125 such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of
126 administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to
127 security and record keeping, when the drugs administered would be normally self-administered by (i) an
128 individual receiving services in a program licensed by the Department of Behavioral Health and
129 Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision
130 Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the
131 placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program
132 participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of
133 any facility authorized or operated by a state or local government whose primary purpose is not to
134 provide health care services; (vi) a resident of a private children's residential facility, as defined in
135 § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department
136 of Behavioral Health and Developmental Services; or (vii) a student in a school for students with
137 disabilities, as defined in § 22.1-319 and licensed by the Board of Education.
138 In addition, this section shall not prevent a person who has successfully completed a training
139 program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of
140 Nursing and been evaluated by a registered nurse as having demonstrated competency in administration
141 of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from
142 a program licensed by the Department of Behavioral Health and Developmental Services to such person
143 via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via
144 percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.
145 M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.)
146 of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any
147 assisted living facility licensed by the Department of Social Services. A registered medication aide shall
148 administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to
149 dosage, frequency, and manner of administration; in accordance with regulations promulgated by the
150 Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living
151 facility's Medication Management Plan; and in accordance with such other regulations governing their
152 practice promulgated by the Board of Nursing.
153 N. In addition, this section shall not prevent the administration of drugs by a person who administers
154 such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of
155 administration and with written authorization of a parent, and in accordance with school board
156 regulations relating to training, security and record keeping, when the drugs administered would be
157 normally self-administered by a student of a Virginia public school. Training for such persons shall be
158 accomplished through a program approved by the local school boards, in consultation with the local
159 departments of health.
160 O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in
161 a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a
162 local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant
163 to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has
164 satisfactorily completed a training program for this purpose approved by the Board of Nursing and
165 taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of
166 medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or
167 guardian; (c) administers drugs only to the child identified on the prescription label in accordance with
168 the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d)
169 administers only those drugs that were dispensed from a pharmacy and maintained in the original,
170 labeled container that would normally be self-administered by the child or student, or administered by a
171 parent or guardian to the child or student.
172 P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by
173 persons if they are authorized by the State Health Commissioner in accordance with protocols
174 established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has
175 declared a disaster or a state of emergency or the United States Secretary of Health and Human Services
176 has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public
177 health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such
178 persons have received the training necessary to safely administer or dispense the needed drugs or

179 devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and
180 supervision of the State Health Commissioner.
181 Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by
182 unlicensed individuals to a person in his private residence.
183 R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his
184 authority and scope of practice and the provisions of this section to a Board agent for use pursuant to
185 subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid
186 prescriptions.
187 S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care
188 technicians who are certified by an organization approved by the Board of Health Professions or persons
189 authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary
190 course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical
191 needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the
192 purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the
193 orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and
194 direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a
195 patient care dialysis technician trainee from performing dialysis care as part of and within the scope of
196 the clinical skills instruction segment of a supervised dialysis technician training program, provided such
197 trainee is identified as a "trainee" while working in a renal dialysis facility.
198 The dialysis care technician or dialysis patient care technician administering the medications shall
199 have demonstrated competency as evidenced by holding current valid certification from an organization
200 approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).
201 T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be
202 authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.
203 U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a
204 prescriber may authorize the administration of controlled substances by personnel who have been
205 properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not
206 include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for
207 such administration.
208 V. A physician assistant, nurse or a dental hygienist may possess and administer topical fluoride
209 varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a
210 standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to
211 standards adopted by the Department of Health.
212 W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may
213 authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse,
214 licensed practical nurse under the direction and immediate supervision of a registered nurse, or
215 emergency medical services provider who holds an advanced life support certificate issued by the
216 Commissioner of Health when the prescriber is not physically present.
217 X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order
218 issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in
219 consultation with the Board of Medicine and the Department of Health, a pharmacist may dispense
220 naloxone or other opioid antagonist used for overdose reversal and a person may possess and administer
221 naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be
222 experiencing or about to experience a life-threatening opiate overdose. Law-enforcement officers as
223 defined in § 9.1-101, *employees of the Department of Forensic Science, employees of the Office of the*
224 *Chief Medical Examiner, employees of the Department of General Services Division of Consolidated*
225 *Laboratory Services,* and firefighters who have completed a training program may also possess and
226 administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation
227 with the Board of Medicine and the Department of Health.
228 **2. That an emergency exists and this act is in force from its passage.**

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Virginia Board of Pharmacy

Protocol for the Prescribing and Dispensing of Naloxone

Pharmacists shall follow this protocol when dispensing 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 opiate overdose as authorized in §54.1-3408.

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling unless the pharmacist is able to verify successful completion of the REVIVE! training program. If the naloxone is delivered by a pharmacy to an alternate delivery site, e.g., a local health department, and the recipient has not completed the REVIVE! training program, the aforementioned counseling shall be provided by a physician, nurse practitioner, physician assistant, nurse, or an approved trainer of the REVIVE! training program at the alternate delivery site.
   b) The pharmacist 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 If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

2) **Product Selection:** The pharmacist who dispenses naloxone pursuant to an oral, written or standing order shall dispense the drug and other items for the kit, if applicable, as prescribed and in accordance with this protocol.

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order issued to a specific individual, a pharmacist may dispense naloxone pursuant to a standing order. The standing order may be issued by an individual prescriber to a specific pharmacy or pharmacies, or the standing order may be issued by the Health Commissioner to all pharmacies located and permitted in Virginia. The standing order authorizes a pharmacist to dispense one or more of the specified naloxone formulations to any person seeking to obtain naloxone. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   a) Name of pharmacy authorized to dispense naloxone pursuant to standing order if the standing order is issued by a prescriber for a particular pharmacy or pharmacies;
   b) Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration, to include quantity of drug and directions for administration;
   c) Prescriber's signature; and
   d) Date of issuance.

4) Kit Contents for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	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. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.	Narcan Nasal Spray 4mg, #1 twin pack SIG: 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.
Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	No kit is required. Product is commercially available.	No kit is required. Product is commercially available.

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

Pharmacies may obtain kits to have on-hand for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

5) Labeling and Records:

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation. A standing order issued by an individual prescriber or the Health Commissioner shall be maintained by the pharmacist for two years from the date of the last dispensing prior to expiration or discontinuation of the standing order.

Protocol for Dispensing to Law-Enforcement Officers, ~~and~~ Firefighters, and Other Employees

~~Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department. Training shall be conducted in accordance with policies and procedures of the law enforcement agency or fire department.~~

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to:

1. Designated employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, and employees of the Department of General Services Division of Consolidated Laboratory Services who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services; or
2. Designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department.

Training shall be conducted in accordance with policies and procedures of the law enforcement agency, fire department, Department of Forensic Science, Office of the Chief Medical Examiner, and the Department of General Services Division of Consolidated Laboratory Services.

6) 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