FINAL

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

February 28, 2017
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 10:07am

PRESIDING: Ryan Logan, Committee Chairman

MEMBERS PRESENT:
Sheila K. W. Elliott – arrived 10:20 am
Ellen B. Shinaberry
Cynthia Warriner
Freeda Cathcart – arrived 10:10 am

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
David Brown, Director Department of Health Professions
Elaine J. Yeatts, Senior Policy Analyst
Beth O'Halloran, Individual Licensing Manager

APPROVAL OF AGENDA: Amended Agenda (Attachment 1) presented for review to include continued periodic regulatory review by developing draft amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy*, chapter 20, adopting guidance for pharmacists taking breaks, amending CSR Regulations for naloxone dispensing and Guidance Document 110-44 – protocol for prescribing and dispensing naloxone, amend regulation to authorize partial filling of Schedule II prescriptions, amend regulation 18VAC110-20-590 regarding drugs in correctional facilities, amend Guidance Document 110-9 – pharmacy inspection deficiency monetary penalty guide, amend Guidance Document 110-20 – practice by a pharmacy technician trainee, drafting amendments for NOIRA for the use of automated dispensing systems as emergency drug kits and stat-drug boxes and for the refilling of a prescription in quantity up to total amount authorized, and consideration for discontinuing the administration of the Virginia Pharmacy Technician Exam.

MOTION: **The Committee voted unanimously to approve the amended agenda as presented for the Regulation Committee meeting (motion by Warriner, second by Cathcart)**

PUBLIC COMMENT: Jenny Lovett, Director of the Chris Atwood Foundation, provided comment to the committee. Ms. Lovett stated she is generally pleased

with the suggested draft amendments for controlled substances registration regulations included in the agenda handout as related to allowing trainers to dispense naloxone in the community. She offered a few suggested areas in regulation for the committee to address. Ms. Lovett supports laypersons dispensing naloxone in the community as this is a relatively safe solution to an opioid overdose. She reminded the committee that the spirit of the law is to save lives from opioid overdose. Ms. Lovett stated that the dispensing will likely be performed by volunteers in their spare time and she hoped the regulations would not be overly restrictive.

AGENDA ITEMS:

Consideration to amend CSR regulations for naloxone dispensing and Guidance Document 110-44, *Protocol for prescribing and dispensing naloxone*

Ms. Juran provided information regarding HB1453 and SB848 that allows persons who have been authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and are acting on behalf of an organization that provides services to individuals at risk of experiencing an overdose, to dispense naloxone free of charge for treatment of opioid overdose. The bills require the organization to obtain a controlled substances registration and therefore, the committee considered possible amendments to these regulations which may be warranted for this allowance. During the discussion there was a suggestion by Ms. Shinaberry to clean up the language in 18VAC110-20-710 (E) to use one term for "alarm system" instead of the current "security device" and "alarm system" language that is included in the regulation. This will be held for the periodic regulatory review of the CSR regulations.

MOTION:

The Committee voted unanimously to recommend to the full board to amend 18VAC110-20-690, 18VAC110-20-700, and 18VAC110-20-710 as indicated in Attachment 2, and to adopt a new section 18VAC110-20-735 as indicated in Attachment 2. (motion by Warriner, second by Cathcart)

The committee also reviewed suggested language for a naloxone protocol as required by HB1453 and SB848. The committee recommended not including language for trainers dispensing naloxone in the existing naloxone protocol for pharmacists, but to adopt a separate protocol for this purpose.

MOTION:

The Committee voted unanimously to recommend to the full board to amend Guidance Document 110-44 as presented and with the following amendments:

- **Change the name of the Guidance Document to "Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities";**

- **In the first sentence, change "opiate" to "opioid" and insert "subsection X" after "authorized in";**
- **In section 4 regarding kit contents, insert "#1 twin pack" after "Narcan Nasal Spray 4mg" and within the sig of this drug, insert "Call 911.";**
- **Amend the title of the section pertaining to law enforcement, etc. to read "Protocol for Distributing to Law Enforcement Officers, Firefighters, and Employees of the Department of Forensic Science, Office of the Chief Medical Examiner, and Department of General Services Division of Consolidated Laboratory Services";**
- **The section pertaining to law enforcement, etc., shall now read:**
- **"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, or the Department of General Services Division of Consolidated Laboratory Services."

- **And the suggested language for trainers to dispense naloxone shall be incorporated in its own separate guidance document. (motion by Cathcart, second by Elliott)**

MOTION:

The Committee voted unanimously to recommend to the full board to adopt a new Guidance Document 110-45 for the

dispensing of naloxone by trainers as indicated in Attachment 3. (motion by Shinaberry, second by Warriner).

Continue periodic regulatory review by developing draft amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy*, Chapter 20

The committee discussed the subjects identified during the November 3, 2015 Regulation Committee Meeting for possible amendment and the draft amendments for the periodic regulatory review, as prepared by staff and presented in the agenda packet, of Parts IV, XIII – XVII of *Regulations Governing the Practice of Pharmacy*, Chapter 20,

- 18VAC110-20-110

Amendments considered by the committee included a requirement that the PIC work not less than an average of 20 hours per week, averaged over a month in each pharmacy that they are designated PIC and that a pharmacist would 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 committee discussed these possible changes and decided against recommending a requirement for a minimum number of hours since there may be pharmacies such as free clinics that are not open a minimum of 20 hours a week. A possible requirement for two years of experience practicing as a pharmacist prior to being eligible to serve as PIC was supported by the committee.

- 18VAC110-20-140

Amendments considered by the committee included a clarification that a complete and accurate inventory of all Schedule II through V controlled substances shall be taken on the date the pharmacist first engages in business under new ownership, and an addition to allow the Board to rescind a pharmacy permit if a pharmacy is not operational within 60 days from the date the permit is issued. Staff is aware of circumstances wherein pharmacy permits have been issued, but the businesses never became operational and nefarious activity appeared to occur. The committee discussed the length of time it may take to obtain a DEA registration and the extenuating circumstances that may occur from the time a permit is issued to when a pharmacy may begin operating. There may also be issues with insurance contracts that can cause a delay or possibly a natural disaster. The agreement was to change the requirement from 60 days to 90 days and allow for the possibility for an extension to be granted for good cause shown.

- 18VAC110-20-150

Amendments considered by the committee included: the allowance for a limited-use pharmacy permit that does not stock prescription drugs to be exempt from having a sink with hot and cold running water; a pharmacy stocking drugs requiring cold temperature storage to record the temperature daily and maintain the record for two years; and, the prohibition of dormitory-style refrigerators for storage of vaccines consistent with CDC guidance. Both the limited-use sink exemption and the temperature log language were accepted by the committee, however, there was much discussion about not allowing a dormitory-style

refrigerator for the storage of vaccines. There was concern that there is no clear definition of a dormitory-style refrigerator. The committee agreed against recommending a specific prohibition for using dormitory-style refrigerators to store vaccines, but to rely on the existing language that all drugs requiring cold temperature storage must be stored within the appropriate temperature ranges.

- 18VAC110-20-180 — Amendments considered by the committee included an alarm system having at least one hard-wired communication method and that the alarm system shall include a feature by which any breach in the alarm is communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy. There was a suggestion from a committee member to clean up language found in this section to be consistent as the word "device" and "alarm system" are both used but refer to the same item.

- 18VAC110-20-200 — An amendment considered by the committee included adding the language in Guidance Document 110-40 regarding storage of Schedule II drugs and allowing for the combination of dispersion and locking. The committee agreed to accept this amendment.

- 18VAC110-20-580 — An amendment considered in this section was to remove the wording that refers to a "humane society" and add the words "public or private" animal shelter. This is to mirror current law. The committee agreed to accept this amendment.

- 18VAC110-20-630 — Several amendments to this section for Medical Equipment Supplier permits were to require the reporting to the Board the hours of operation, the requirement to notify if there is a change in the hours of operation and the circumstances around this, and the requirement to notify the Board of a change in the responsible party for the permit. The committee agreed to recommend these proposed changes.

- 18VAC110-20-680 — Amendments considered in this section included allowing for the transfer of prescriptions/orders from one medical equipment supplier to another and the manner in which these transfers shall be communicated and recorded. The committee agreed to recommend these proposed changes.

- 18VAC110-20-710 — There was one amendment to subsection "C" considered to change Schedule II to Schedule I for those persons who obtain a CSR for the purpose of investigation using Schedule I substances.

MOTION:

The committee voted unanimously to recommend to the full board to amend regulations as presented and summarized in Attachment 4 for the periodic regulatory review of Parts IV, XIII – XVII of *Regulations Governing the Practice of Pharmacy*, Chapter 20 and recommended the board take no action on the following subjects:

- **18VAC110-20-110, specifying a minimum number of**

hours a PIC must practice at the location listed on the pharmacy permit application

- **18VAC110-20-130 and 18VAC110-20-140, requiring inspections for acquisitions and change of ownership. (motion by Cathcart, second by Shinaberry)**

Adopt guidance for pharmacists taking breaks

The committee reviewed the regulations set forth in Minnesota and the suggested guidance prepared by staff to be given to licensees regarding breaks for pharmacists. Ms. Yeatts suggested that the Guidance Document begin with the section of regulation that states "except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any 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".

There was some discussion regarding requiring a pharmacist to take his/her break within the prescription department if not closing the pharmacy. The committee agreed that this may not constitute the intent of the regulation to provide a pharmacist a "mental rest" from the shift they are working and agreed to add the wording "or on premises" to the guidance suggested.

MOTION:

The committee voted unanimously to recommend to the full board to adopt the guidance document for continuous hours worked by pharmacists and breaks as presented and amended as follows:

- **Place subsection B of 18VAC110-20-110 at the beginning of the document;**
- **Insert "or on the premises" at the end of the sentence "If a pharmacy does not close, the pharmacist shall ensure adequate security of the drugs by taking his break within the prescription department."**
- **Strike "If two or more pharmacists are practicing simultaneously and the pharmacy does not close during a break, the pharmacists should stagger their breaks."; and**
- **In the last bullet, change "he" to "he or she". (motion by Elliott, second by Cathcart)**

Amend regulation to authorize partial filling of Schedule II prescriptions

The committee discussed the new allowance for the partial filling of Schedule II prescriptions under the Comprehensive Addiction and Recovery Act (CARA) of 2016 and determined 18VAC110-20-310 should be amended to authorize the partial filling under board regulation. There was discussion regarding whether current regulatory language authorizing partial fills of Schedule II drugs for terminally ill was necessary since the allowance in the CARA Act was written broadly. It was noted that 18VAC110-20-310 states prescriptions for terminally ill may be refilled for a period not to exceed 60 days and the allowance under the CARA Act is for a period not to exceed 30 days. Based on the

suggested draft language presented in the agenda packet, there was a general consensus that perhaps #2 of subsection D should become a new #4 under the suggested subsection E, that #4 of subsection D should be incorporated into the suggested #3 under suggested subsection E, and that #5 of subsection D should become a new #5 under suggested subsection E. The issue was tabled and staff was asked to obtain additional information.

ACTION ITEM:

Board staff will review the federal law and regulations to determine if the CARA Act impacted the federal language for partial filling Schedule II prescriptions for terminally ill. The information will be considered at the March full board meeting to assist the board in determining amendments necessary for 18VAC110-20-310.

Amend regulation 18VAC110-20-590, *Drugs in correctional facilities*

The chief pharmacist at the Virginia Department of Corrections requests the board allow for the destruction of patient-specific dispensed drugs at the site of the correctional facility using a method of destruction which renders the drug unrecoverable since federal law prohibits the dispensed drugs from being returned to the provider pharmacy.

MOTION:

The Committee voted unanimously to recommend to the full board in March to amend Regulation 18VAC110-20-590 as presented and summarized in Attachment 5. (motion by Shinaberry, second by Cathcart).

Amend Guidance Document 110-9, *Pharmacy inspection deficiency monetary penalty guide*

The committee discussed several possible changes to the Guidance Document 110-9 based on concerns identified by board members during recent disciplinary hearings and other concerns expressed by licensees to staff involving CQI deficiencies.

ACTION ITEM:

Regarding a possible amendment to Deficiency 24 within Guidance Document 110-9, Mr. Johnson will research and report at the March full board meeting if all drugs for sterile compounding should be weighed and prepped in an area classified as ISO 8 or better or if this USP requirement applies only to hazardous drugs.

MOTION:

The committee voted unanimously to recommend to the full board to amend Deficiency 142 to read "No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization" and to delete under "Conditions" the 20% threshold and the statement "Do not cite deficiency until July 1, 2015". (motion by Cathcart, second by S. Elliott)

MOTION:

The committee voted unanimously to recommend to the full board to further amend Guidance Document 110-9 as follows:

- **Deficiency 12a and 146 – Insert under "Conditions", "Do not**

cite if stored in a combination method as allowed in Guidance Document 110-40.";

- **Deficiency 20a – Change to read "Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products"; and,**
- **Deficiency 20b – Change to read "Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products". (motion by Warriner, second by S. Elliott)**

Amend Guidance Document 110-20, *Practice by a pharmacy technician trainee*

Based on recent board discussions, staff recommends considering amendments 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. The Guidance Document is proposed to be updated with this information.

MOTION:

The committee voted unanimously to recommend to the full board in March to amend Guidance Document 110-20 as presented (motion by Warriner, second by Shinaberry).

Draft amendments for NOIRA, Use of automated dispensing systems as emergency drug kits and stat-drug boxes

The committee reviewed a petition from Dale St.Clair, a pharmacist who is requesting consideration to amend 18VAC110-20-550 and 18VAC1102-20-555. This was discussed at the September 7, 2016 Full Board Meeting and the petition was accepted with one comment from the public. The draft amendments for NOIRA were reviewed by the committee. Ms. Shinaberry noted that the regulations should indicate who may access the device for those facilities not required to obtain a CSR.

MOTION:

The committee voted unanimously to recommend to the full board in March to adopt the following draft amendments for the NOIRA regarding the use of automated dispensing systems as emergency drug kits and stat-drug boxes:

- **Amend 18VAC110-20-550 to include a new section reading "Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home".**
- **Amend 18VAC110-20-555 (2) by inserting "unless the system is exclusively stocked with drugs that would be kept in a stat-**

box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration" following the word "system"

- **Amend 18VAC110-20-555 by inserting a new #3 that states "For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading"**
- **Amend 18VAC110-20-555 (3) by changing it to #4 and inserting in subsection 4a the phrase "including a drug that is stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550" following the phrase "A drug". (motion by Shinaberry, second by Warriner):**

Draft amendments for NOIRA, refilling prescription in quantity up to total amount authorized

The committee reviewed a petition for rulemaking from Derek Phillips, a pharmacist requesting consideration to amend 18VAC110-20-320 allowing a pharmacist to refill a prescription with a quantity greater than the face amount prescribed, under certain circumstances, not to exceed the total amount authorized. The draft amendments for the NOIRA were reviewed. It was discussed that such an allowance should be allowed for new prescriptions, not just refilled prescriptions. The term "psychotherapeutic" was discussed and the committee determined it would prefer to use "antidepressants, antipsychotics, and drugs of concern".

MOTION:

The committee voted unanimously to recommend to the full board in March the following draft amendments to 18VAC110-20-320 for the NOIRA requesting an allowance for a pharmacist to refill a prescription with a quantity greater than the face amount prescribed, under certain circumstances, not to exceed the total amount authorized and to consider inserting a similar allowance in 18VAC110-20-270 for the dispensing of new prescriptions:

- **Subsection B – following "Schedule VI", change "shall" to "may" and strike "only" and "expressly";**
- **Subsection B – add "Except for drugs used to treat depression, anxiety, or psychoses or drugs of concern as defined in § 54.1-2519, a pharmacist, using professional judgement and upon request by the patient, may refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration." (motion by Warriner, second by Cathcart)**

Consider discontinuing administration of Virginia Pharmacy Technician Exam

Based on the board's contract ending with the current exam administrator on August 31, 2017, staff requested the board consider discontinuing administration of the Virginia Pharmacy Technician Examination. Staff indicated that it is burdensome to routinely prepare items and test forms given the increased workload placed on the board in recent years.

Additionally, there is a national trend for boards discontinuing the administration of their own examinations when alternative national examinations exist. Staff indicated this decision would not require a legislative or regulatory amendment. The board would continue to recognize Pharmacy Technician Certification Board (PTCB) for qualification of initial registration of a pharmacy technician as well as completion of a board-approved pharmacy technician training program and the successful passing of the ExCPT examination.

MOTION:

The committee voted unanimously to recommend to the full board in March that the board no longer administer the Virginia Pharmacy Technician Examination once the current contract with the exam administrator expires on August 31, 2017. (motion by Warriner, second by Shinaberry).

Next meeting TBD.

ADJOURN:

With all business concluded, the meeting concluded at 3:55pm.

Ryan Logan

Ryan Logan, Chairman

3/21/17

DATE

Caroline D. Juran, Executive Director

3/21/17

DATE

Attachment 1

COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233
(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Amended 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	
• Amend CSR Regulations for Naloxone Dispensing and Guidance Document 110-44, Protocol for Prescribing and Dispensing Naloxone	handout
• Continue Periodic Regulatory Review by Developing Draft Amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20	57-64 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
• Draft Amendments for NOIRA, Use of Automated Dispensing Systems as Emergency Drug Kits and Stat-Drug Boxes	handout
• Draft Amendments for NOIRA, Refilling Prescription in Quantity up to Total Amount Authorized	handout
• Consider Discontinuing Administration of Virginia Pharmacy Technician Examination	handout
Adjourn	

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

Attachment 2

Project 5048 - none

BOARD OF PHARMACY

CSR for trainers

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of §54.1-3408 shall maintain the following records:

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

2. Invoices or other records showing receipts of naloxone shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer, name of trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number,

expiration date, and name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

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

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

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

Guidance Document: 110-45

Attachment 3

Adopted: March 21, 2017

Protocol for the Prescribing of Naloxone and Dispensing by Trainers

Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for opioid overdose reversal shall follow this protocol when dispensing naloxone to a person, without charge or compensation, for administration to another person believed to be experiencing or about to experience a life-threatening opioid overdose as authorized in subsection Y of § 54.1-3408.

1) **Controlled Substances Registration:** An organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal on whose behalf an authorized trainer may dispense naloxone pursuant to a standing order shall apply for a controlled substances registration certificate from the Board of Pharmacy. The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration certificate.

2) **Standing Order:** An authorized trainer may dispense naloxone pursuant to a standing order. The standing order must be issued by an individual prescriber to the organization on whose behalf the authorized trainer is acting. The standing order authorizes a trainer to dispense one or more of the specified naloxone formulations to any person seeking to obtain naloxone following completion of a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services. A standing order is valid for no more than two years from the date of issuance and must contain the following information at a minimum:

   a. Name of organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy on whose behalf the authorized trainer may dispense naloxone pursuant to the standing order;

   b. 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.

3) 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. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. No kit is required. Product is commercially available.	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. No kit is required. Product is commercially available.

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

Trainers 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

4) Storage, Labeling, Dispensing, and Recordkeeping:

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of §54.1-3408 shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of §54.1-3408 authorizing the trained individual to dispense naloxone.
2. Invoices or other records showing receipts of naloxone must be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer, name of trained individual approved by the Department of Behavioral Health and Developmental Services.
4. Record of dispensing indicating name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

C. The trainer shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf

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

E. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate must ensure compliance with any recall procedures as issued by the manufacturer, United States Food and Drug Administration, or Board to ensure affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

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

Resources:

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

Attachment 4

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

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. 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.~~C. The ~~pharmacist-in-charge (PIC)~~ 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.~~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.

~~D.~~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.

~~E.~~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.

~~F.~~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.

~~G.~~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.

~~H.~~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.

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.

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. Although 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 90 days from the date the permit is issued, the board shall rescind a pharmacy permit unless an extension is granted for good cause shown.

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.

H. 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.

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, or maintained in a manner that combines the two methods for storage. 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~~ 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 § 54.1-3435.8:1 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.

Attachment 5

Project 5047 - none

BOARD OF PHARMACY

Drug destruction in correctional facilities

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~~ Schedule VI drugs shall be returned to the provider pharmacy or to a secondary pharmacy 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 forwarded by a pharmacist directly from the correctional facility to a returns company after~~ After performing the audit required by subdivision 4 a of this subsection and ensuring the proper maintenance of the administration records, drugs in Schedules II through V shall be destroyed at the site of the correctional facility using a method of destruction which renders the drug unrecoverable.

a. The destruction shall be performed by a nurse, pharmacist, or physicians and witnessed by the nurse supervisor, a pharmacist, or physician.

b. Destruction of drugs shall occur within 30 days of discontinuance.

c. A complete and accurate record of the drugs destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the correctional facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

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.