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)

Tentative Agenda of Public Hearings and Full Board Meeting
March 21, 2017
9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Scheduling Certain Substances: Ryan Logan, Vice-Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
Call for Public Comment:	
• Possible Scheduling of the Certain Chemicals in Schedule I of the Drug Control Act	1-2
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Ryan Logan, Vice-Chairman	
• Approval of Agenda	
• Approval of Previous Board Meeting Minutes:	
○ December 12, 2016, Full Board Meeting	3-11
○ December 12, 2016, Public Hearing for Scheduling Certain Chemicals, Emergency Regulations for Permitting Facilities for Physicians Selling Drugs, Emergency Regulations for Permitting Outsourcing Facilities, and Prohibiting Incentives for Transfer of Prescriptions	12-14
○ December 12, 2016, Formal Hearings	15-17
○ January 17, 2017, Special Conference Committee	18-19
○ February 1, 2017, Formal Hearings	20-22
○ February 21, 2017, Special Conference Committee	23-25
○ February 28, 2017, Regulation Committee	26-60
○ March 8, 2017, Special Conference Committee	61-62
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: David Brown, DC	
Regulatory Actions: Elaine Yeatts	
• Regulatory Update	63
• Legislative Update and Overview of Board of Medicine Emergency Regulations *Governing Prescribing of Opioids and Buprenorphine*	64-79
• Adoption of Regulation to Schedule Certain Chemicals in Schedule I	80-86
• Adoption of Final Regulations for Outsourcing Facilities	87-95
• Adoption of Final Regulations for Permitting Facilities in which Physicians Dispense	96-105

- Adoption of Final Regulations for Prohibition on Incentives to Transfer Prescriptions — 106-109
- Adoption of Emergency Regulations for Controlled Substances Registrations for Naloxone Dispensing and Guidance Document 110-44, *Protocol for Prescribing and Dispensing Naloxone,* and Adopt Guidance Document 110-45, *Protocol for the Prescribing of Naloxone and Dispensing by Trainers* — 110-127
- Adoption of Emergency Regulations for Controlled Substances Registrations for Entities for Purpose of Telemedicine Prescribing — 128-133
- Adoption of Amendments to Parts IV, XIII - XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers) — 134-147
- Adoption of Guidance for Pharmacists Taking Breaks and Amend Guidance for Practice by a Pharmacy Technician Trainee — 148-151
- Amend Regulation 18VAC110-20-310 to Authorize Partial Filling of Schedule II Prescription — 151-158
- Amend Regulation 18VAC110-20-590, Drugs in Correctional Facilities — 159-162
- Amend Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide* — 163-176
- Adopt Proposed Amendments for NOIRAs resulting from Petitions, Refilling Prescription in Quantity up to Total Amount Authorized and Use of Automated Dispensing Systems as Emergency Drug Kits and Stat-Drug Boxes — 177-194

New Business:

- Presentation of 2016 Pharmacist and Pharmacy Technician Workforce Reports — Attachment
- Consider Discontinuing Administration of Virginia Pharmacy Technician Examination — 34-35

Reports:

- Chairman's Report – Ryan Logan, Vice-Chairman
- Report on Board of Health Professions – Ryan Logan
- Report on PMP – Ralph Orr
- Report on Licensure Program – J. Samuel Johnson, Jr. — Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day — Handout
- Executive Director's Report – Caroline D. Juran — Handout

Consideration of consent orders & summary suspension, if any

Adjourn

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

****A panel of the board will convene at 3pm or immediately following adjournment of the meeting, whichever is later.****

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on March 21, 2017** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to March 7, 2017 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified eight (8) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description and chemical name for each compound.

The following compounds are classified as research chemicals. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. 6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The following compounds are powerful synthetic opioids. DFS recommends placing these compounds into Schedule I (§ 54.1-3446(1)).

3. N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

4. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

5. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(7)) in previous legislative sessions.

6. 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

7. quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The following compound is classified as a benzodiazepine, which is a central nervous system depressant. Flubromazepam has no accepted medical use in the United States. Other compounds of this type have been placed in Schedule I (§ 54.1-3446(4)).

8. Flubromazepam, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of Board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 12, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:19am

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody H. Allen (arrived at 9:35am)
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott (arrived at 9:25am)
Sheila K. W. Elliott
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT:
Rebecca Thornbury
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Heather Hurley, Licensing Specialist

QUORUM: With six members present, a quorum was established.

APPROVAL OF AGENDA: The agenda was amended to table the presentation on the NABP E-profile participation to the March full board meeting and to include under regulatory actions, adoption of amended Guidance Document 110-1 to incorporate new licensing categories.

MOTION: **The Board voted unanimously to approve the agenda as amended (motion by Warriner, second by Saenz)**

APPROVAL OF MINUTES: A handout was provided for the November 16, 2016 Special Conference Committee minutes as the copy in the agenda packet contained a typographical error. The following minutes were considered for approval:

DRAFT

- September 7, 2016, Public Hearing of Scheduling Certain Chemicals
- September 7, 2016, Full Board Meeting
- September 7, 2016, Formal Hearing
- September 8, 2016, Special Conference Committee
- September 20, 2016, Special Conference Committee
- September 27, 2016, Special Conference Committee – Pilot Hearings
- October 3, 2016, Panel Formal Hearing
- November 14, 2016, Telephone Conference Call
- November 16, 2016, Special Conference Committee (handout)
- November 29, 2016, Regulation Committee (handout)
- December 6, 2016, Special Conference Committee (handout)

It was noted that the date on page 23 of the agenda packet for the September 7, 2016 Minutes of the Panel of the Board should read 2016, not 2014.

MOTION:

The Board voted unanimously to adopt the minutes from September 7, 2016 through December 6, 2016 as presented and amended. (motion by Warriner, second by Boone)

PUBLIC COMMENTS:

John Beckner, Senior Director of Strategic Initiatives at NCPA, spoke to the Board on behalf of the Virginia Pharmacists Association (VPhA). Mr. Beckner provided a letter written to the Board of Pharmacy from VPhA with comments on the enforcement of USP Chapter 800. The letter states that while VPhA appreciates the intent of the proposed Chapter 800, the proposed July 1, 2018 enforcement date would impact members and their patients greatly and they request a five-year delay or phased-in approach for enforcement by the Board of Pharmacy similar to that when USP Chapter 797 was introduced. He estimated renovation costs could range from $10,000 to $250,000 depending on the pharmacy's volume with the hazardous drugs (HD).

Jamin Engel, Pharmacy Manager at Sentara RMH Medical Center in Harrisonburg, provided comments regarding the implementation of USP Chapter 800. Mr. Engel provided comment regarding contradictory language found between Chapter 800 and Chapter 797. Examples include:

- Exemptions allowed within <797> for isolators (CACI/CAI) that are removed from engineering control configurations within <800>
- Low volume hazardous compounding exemptions currently within <797> and removed from <800>
- Closed-System Transfer Device (CSTD) requirements differ between documents
- Facility control considerations differ between documents

Mr. Engel stated he believes the contradictions could likely be addressed through the formation of a workgroup to develop board guidance on the issues. He also requested the Board to provide guidance to the

4

pharmacies for where there is no previous standard such as what standard to use for CSTD evaluation, as the NIOSH performance standard protocol is still in development. Also, what are the acceptable limits for HD surface contamination, as there are multiple wipe pad tests with varying levels of specificity that could alter results from facility to facility. Mr. Engel also stated that there may be opportunity for capital savings for facilities implementing new <797> and <800> standards.

DHP DIRECTOR'S REPORT:

Dr. Brown provided positive comments regarding the board member orientation day held in October. He reiterated information presented by Maria Everett from the FOIA Council that three or more members together discussing board business constitutes a meeting and a public notice must be given for such meeting. Dr. Brown spoke about the opioid public health emergency issued by the Department of Health and the statewide standing order for naloxone issued by Dr. Levine, State Health Commissioner. In 2015 there were 809 Virginians who died of opioid overdose and in 2016 that number is expected to be over 1000. The Board of Medicine has a buprenorphine workgroup and at the last meeting Delegate Pillion spoke to the workgroup about concerns with the diversion of buprenorphine. Dr. Brown stated DHP now has statutory authority to utilize PMP information to identify suspicious behavior in prescribing and dispensing opioids. Dr. Brown spoke about the website called VaAware in which DHP manages a section for prescribers and dispensers which contains information on continuing education and proper prescribing and dispensing.

REGULATORY ACTIONS:

- Regulatory Update: Ms. Yeatts provided a handout of a chart of pending regulatory actions for review by the board.
- Legislative Update: Ms. Yeatts stated there was no legislative update at this time.
- Adoption of Regulation to Schedule certain chemicals in Schedule I: There was a public hearing conducted at 9:10am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:
Classified as research chemicals:

- 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone),
- 4-chloro-alpha-Pyrrolidinavalerophenone (other name: 4-chloro-alpha-PVP),
- 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP)
- 4-fluoro-alpha-Pyrrolidinoheptiophenone (other anme: 4-

5

fluoro-PV8),

- 1-(4-methyoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9), 4-allyloxy-3,
- 5-dimethoxyphenethylamine (other name: Allylescaline),
- 4-methyl-alpha-ethylaminopentiophenone

Classified as powerful synthetic opioids:

- N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl) piperidinyl]-propanamide (other name: para-fluoroisoputyryl fentanyl)

(motion by Warriner, second by Boone)

- Adoption of Chapter 21 recommendations from the Regulation Committee

The Board adopted a Notice of Intended Regulatory Action (NOIRA) related to the periodic regulatory review of Chapters 20 and 50 which was published on July 11, 2016 with a comment period until August 10, 2016. There were 5 comments; none relating to sections being amended at this meeting. Included in the NOIRA was a recommendation to divide Chapter 20 into two chapters: 1) Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians; and 2) Governing the Practice of Pharmacy. The Regulation Committee met on November 29, 2016 to consider the comments received and develop recommended amendments. It is the recommendation of the Regulation Committee to move the Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians into a new Chapter 21 and adopt the amendments to the regulations for pharmacists and pharmacy technicians as presented in the agenda packet. The Board then reviewed the recommended amendments provided in the agenda packet.

MOTION:

The Board voted unanimously to:

- **adopt the Regulation Committee's recommendation to divide Chapter 20 by moving Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians into a new Chapter 21;**
- **change references to Chapter "20" on page 55 and pages 63-68 of the agenda packet to "21";**
- **strike the pharmacy permit fee as listed in 18VAC110-21-20 C;**
- **not consider the language as presented in Regulations 18VAC110-21-50 and 18VAC110-21-70 at this time as staff needs to continue clarifying the language to ensure it satisfies the intent of the amendment;**
- **amend the proposed language in Regulation 18VAC110-21-90 C to read, "C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited: 1. Maximum of one hour for attendance at a board meeting or formal**

hearing; or 2. Maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or foreign pharmacist applicant obtaining required hours of practical experience."; and,

- **adopt the other recommended amendments to the proposed Chapter 21 as presented.**
- **(motion by Warriner, second by Saenz)**

- Adoption of Regulatory Amendment to Allow CE Credit for Volunteer Hours

House Bill 319 passed by the General Assembly in 2016 amended 54.1-2400 (6) to require boards to promulgate regulations to allow for continuing education credit for individuals registered, certified, or licensed who delivery health care services, without compensation, to low-income individuals receiving health services through a health department or free clinic. The proposed amendments to Regulations 18VAC110-20-90 and 18VAC110-20-106 as recommended and presented by the Regulation Committee were discussed by the Board.

MOTION:

The Board voted unanimously to adopt as a fast-track action the following proposed amendments to 18VAC110-20-90 and 18VAC110-20-106 as recommended by the Regulation Committee:

- **Insert a new subsection D in 18VAC110-20-90 to read "Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.**
- **Insert a new subsection D in 18VAC110-20-106 to read "Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic."**

(motion by Allen, second by Boone)

- Consideration of request to delay enforcement of USP Chapter <800>

Ms. Juran shared that the Regulation Committee discussed this issue in November, but had asked staff to further research this issue and provide additional information at the December full board meeting. She reported that during an informal poll of board members from 38 states attending the recent National Association of Boards of Pharmacy Interactive Member Forum meeting, only Idaho and another unknown state indicated

7

that it may delay enforcement of Chapter <800>, She is aware that North Carolina has decided they will not delay enforcement. Ms. Juran stated that a representative from USP indicated to her that FDA will not delay enforcement and that any state considering a delay would potentially put their licensees in violation of federal requirements.

MOTION: **The Board voted unanimously to develop a workgroup to draft guidance with regard to how to comply with USP Chapter <800>, similar to Guidance Document 110-36 which was developed to educate licensees on how to comply with Chapter <797>, and to not delay the enforcement of USP Chapter <800> past the effective date of July 1, 2018. (motion by Cathcart, second by Allen)**

MOTION: **The Board voted unanimously to begin educating the DHP inspectors and begin inspecting for compliance with USP Chapter <800> in 2017 in an attempt to educate pharmacists, but to not cite deficiencies or issue monetary penalties prior to the effective date of July 1, 2018. (motion by S. Elliott, second by M. Elliott)**

- Amend Guidance Document 110-38, requirement for non-resident pharmacies to submit current inspection report

Ms. Juran provided background on staff's request to amend Guidance Document 110-38 to only allow an opening inspection report for a newly opened pharmacy or a new location of an existing pharmacy if said pharmacy is not performing sterile compounding. If the facility is performing sterile compounding, staff recommends that the facility must provide an operational inspection to satisfy the requirement for obtaining initial registration or renewal as a nonresident pharmacy. She indicated this is consistent with North Carolina's position on the matter.

MOTION: **The Board voted unanimously to adopt the amendment of Guidance Document 110-38 as presented. (motion by M. Elliott, second by Allen)**

- Adopt amendments to naloxone protocol

Ms. Juran provided background on staff's recommended amendments to the naloxone protocol based on the statewide standing order recently issued by Dr. Levine, State Health Commissioner. The recommended amendment also allows a pharmacy to deliver the naloxone to an alternate delivery site such as a local health department if the counseling is provided by a physician, nurse practitioner, physician assistant, nurse, pharmacist, or an approved trainer of the REVIVE! training program at the alternate delivery site.

MOTION: **The Board voted unanimously to adopt the amendments to the naloxone protocol as presented and designate the protocol as a guidance document (motion by M. Elliott, second by S. Elliott)**

- Amend guidance document 110-1, categories of facility licensure

Ms. Juran presented the amended Guidance Document 110-1 that includes new facility categories for licensure, nonresident medical equipment supplier, outsourcing facility and nonresident outsourcing facility. During board discussions, it was noted that the language for in-state medical equipment suppliers should also be reworded to match what

is currently in statute.

MOTION: **The Board voted unanimously to adopt the amendments to Guidance Document 110-1as presented and directed staff to ensure the language for medical equipment suppliers is written consistently with the statute. (motion by Saenz, second by Boone)**

NEW BUSINESS:

- Consideration for requiring CE in a specific subject area in 2017

The Board discussed if a specific topic for continuing education should be mandated for pharmacists in 2017 as authorized in 54.1-3314.1 J. Some of the subject areas discussed were: opioid use, naloxone administration or opioid overdose prevention. The Board also discussed the number of CE units that should be required in this subject if they should decide to require as such. Staff reminded the Board that this requirement will not apply to pharmacy technicians as the law only addresses an ability to mandate up to 2 hours of CE in a specific subject for pharmacists.

MOTION: **The Board voted unanimously to require pharmacists to obtain 1 hour of continuing education credit in the calendar year 2017 in the subject of proper opioid use, opioid overdose prevention, or naloxone administration. (motion by Warriner, second by S. Elliott)**

REPORTS:

Chairman's Report

Ms. Thornbury was absent from this meeting and therefore, no Chairman's report was provided to the Board.

Report on the Board of Health Professions

Mr. Logan stated the Board of Health Professions has not met since the last Board of Pharmacy meeting and therefore, there is nothing to report.

Report on the PMP Advisory Panel

Jody Allen provided a report on the PMP advisory panel on which she and Ryan Logan participate. The PMP advisory panel recently developed criteria to recommend to Dr. Brown for identifying unusual prescribing and dispensing patterns and to provide this information to the Enforcement Division for investigation. The recommended criteria is prescribers and pharmacies with 10 or more patients with a morphine milligram equivalency (MME) greater than 1000 per day or a patient with greater than 2000 MME/day. The advisory panel will meet again in January 2017.

NABP Telepharmacy Task Force Meeting

Freeda Cathcart participated on the NABP Task Force for Telepharmacy in Chicago and this was to create a model act for telepharmacy that all states may utilize to develop law and regulation. The NABP Executive

9

Committee will consider the recommendations and NABP will report out on the issue at its annual meeting in May 2017.

NABP International Membership Task Force Meeting

Cynthia Warriner participated on the NABP International Membership Task Force in Chicago to consider the appropriateness of NABP expanding its international membership. The NABP Executive Committee will consider the recommendations and NABP will report out on the issue at its annual meeting in May 2017.

NABP Interactive Member Forum

Jody Allen participated on the NABP Interactive Member Forum in Chicago, a meeting that is held every other year. A representative from every state is there to collaborate on issues and share best practices. Many other countries were represented such as Canada and the Bahamas. Ms. Allen was a panelist on USP compounding issues. Other topics included: new board member orientation processes; pharmacist prescribing practices in Canada; allowance in Oregon for pharmacists to prescribe oral contraceptives; concerns with opioid overdoses; and expanded access to naloxone.

Report on Licensure Program:

Mr. Johnson reported the Board currently licenses 37,581 individuals and facilities. This is an increase of 743 over the 36,838 for same period in 2015. The Board issued 876 licenses and registrations for the period of September 1, 2016 through November 30, 2016. Inspectors conducted 451 facility inspections including 219 routine inspections of pharmacies: 57 (26%) resulted in no deficiency, 87 (40%) with deficiencies and 75 (34%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Inspection Deficiencies. It was noted that deficiency 142, regarding compliance with CQI requirements, is the most frequently cited deficiency. Other frequently cited deficiencies include deficiencies 13, 14, and 113 regarding drug inventories, deficiency 15 regarding the perpetual inventory, deficiency 109 regarding expired drugs, and 130a regarding the labeling of compounded drug products. There was an increase in Deficiency 7 regarding the submission of an application and undergoing an inspection prior to remodeling or changing the location of a pharmacy.

Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of November 30, 2015; March 24, 2016; June 13, 2016; and December 8, 2016. For the final date, she reported that there were no cases at the entry stage; 75 at the investigation stage; 173 at the probable cause stage; 37 at the administrative proceedings division stage; seven at the informal stage; two at the formal stage; and 132 at the pending closure stage. She explained that these numbers involved all cases, including inspection and continuing education matters. Further, as noted on the handout, the numbers remain fairly consistent and she gave the received and closed case numbers for October 2016 (55/56) and November 2016 (37/40). Future reports will provide more

specific case-type information for the board members.

Executive Director's Report:

Regarding recent or ongoing projects, Ms. Juran reported that staff intends to begin using the NABP universal inspection form for all routine pharmacy inspections in February 2017. She indicated staff received positive feedback during the piloting of the form in August 2016. She reported on recent and upcoming meetings. She sought and received approval from the board to submit an application to NABP for the 2017 Fred T Mahaffey award for convening the pharmacy benefit manager oversight workgroup in 2016. She then provided on update on staffing issues.

SUMMARY SUSPENSION:

CYNTHIA LEE DORTON
Registration No: 0230-003720

Wayne T. Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Ms. Allen, and duly seconded by Mr. Boone, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Cynthia L. Dorton, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Cynthia L. Dorton to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Dorton for the indefinite suspension of her pharmacy technician registration for two years.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 1:55pm.

Ryan Logan, Vice-Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARINGS FOR: SCHEDULING CERTAIN SUBSTANCES; EMERGENCY REGULATIONS FOR PERMITTING FACILITIES FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES; EMERGENCY REGULATIONS FOR PERMITTING OUTSOURCING FACILITIES; AND, REGULATIONS FOR PROHIBITION AGAINST INCENTIVE TO TRANSFER PRESCRIPTIONS

December 12, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearings were called to order at 9:11a.m.

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart (arrived at 9:18 am)
Rafael Saenz
Cynthia Warriner
Sheila K. W. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Heather Hurley, Licensing Specialist

PUBLIC HEARING FOR THE SCHEDULING OF CERTAIN CHEMICALS

CALL FOR PUBLIC COMMENT: Mr. Logan called for comment to consider placement of the following chemical substances into Schedule I:

- 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone),
- 4-chloro-alpha-Pyrrolidinavalerophenone (other name: 4-chloro-alpha-PVP),
- 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP)
- 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8),
- 1-(4-methyoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one

(other name: 4-methoxy-PV9), 4-allyloxy-3,
- 5-dimethoxyphenethylamine (other name: Allylescaline),
- 4-methyl-alpha-ethylaminopentiophenone,
- N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl) piperidinyl]-propanamide (other name: para-fluoroisoputyryl fentanyl).

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

PULIC COMMENT:

Scott May, Chemical Program Manager at the Department of Forensic Science provided information regarding the 8 chemicals it has identified for the Board's consideration to place into Schedule I. Seven of the chemicals are research chemicals and one is a powerful synthetic opioid.

EMERGENCY REGULATIONS FOR PERMITTING FACILITIES FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

CALL FOR PUBLIC COMMENT:

Mr. Logan called for comment to consider the proposed regulations for permitting facilities for practitioners of the healing arts to sell controlled substances. No public comment was offered.

The comment period ends on December 12, 2016 and final adoption will be on the agenda for the Board to consider at the March full Board meeting.

EMERGENCY REGULATIONS FOR PERMITTING OUTSOURCING FACILITIES

CALL FOR PUBLIC COMMENT:

Mr. Logan called for comment to consider the proposed regulations for the permitting of outsourcing facilities. No public comment was offered.

The comment period ends on December 30, 2016 and final adoption will be on the agenda for the board to consider at the

March full board meeting.

REGULATIONS FOR POHIBITION AGAINST INCENTIVES TO TRANSFER PRESCRIPTIONS

CALL FOR PUBLIC COMMENT:

Mr. Logan called for comment to consider proposed regulations to prohibit incentives to transfer prescriptions. No public comment was offered.

The comment period ends on February 10, 2016 and the final regulations will be on the agenda for the board to consider for adoption at the March full board meeting.

ADJOURN:

The public hearings adjourned at 9:19am.

Ryan Logan, Vice-Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

December 12, 2016
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:55 p.m.

PRESIDING: Ryan Logan, Vice Chairperson

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Michael I. Elliott
Sheila K. W. Elliott
Rafael Saenz (left 4:45pm, following conclusion of Bowden case)

STAFF PRESENT:
Caroline D. Juran, Executive Director
Beth O'Halloran, Individual Licensing Manager (left 4:45pm, following conclusion of Bowden case)
James Rutkowski, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With six members of the Board present, a quorum was established.

MacDONALD SNOW BOWDEN
License No. 0202-007456

A formal hearing was scheduled in the matter of MacDonald Snow Bowden to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Mr. Bowden was represented by Lindsey Walton, Esquire.

Following introductions, Mr. Halbleib and Ms. Walton presented the case for reinstatement of Mr. Bowden's pharmacist license to the Board for consideration.

CLOSED MEETING:

Upon a motion by Mr. Boone, and duly seconded by Ms. Allen, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the case of MacDonald S. Bowden. Additionally, he moved that Caroline Juran, Beth O'Halloran, and Jim Rutkowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened in open meeting and announced the decision.

DECISION:

Upon a motion by Mr. Boone, and duly seconded by Mr. Elliott, the panel voted 6-0 to reprimand and reinstate Mr. Bowden's pharmacist license under probation and terms: Mr. Bowden must maintain full time active employment as a pharmacist for a minimum of two years, have an affidavit signed by Mr. Bowden that he has read all pertinent laws and regulations regarding Pharmacy and PMP, Mr. Bowden's employer must submit quarterly reports to the board regarding Mr. Bowden's progress as an employee, and Mr. Bowden must complete two continuing education credits on the subject of HIPPA in addition to the required 15 continuing education credits. These terms were read by Mr. Rutkowski. This case concluded at 4:45pm.

PANEL:

With five members of the Board present, a panel was established.

KELLY LANTZ PIERRE
Registration No.: 0230-026886

A formal hearing was scheduled in the matter of Kelly Lantz Pierre to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Ms. Pierre's registration was recently summarily suspended. She was not present at the Formal Hearing.

CLOSED MEETING:

Upon a motion by Mr. Boone, and duly seconded by Ms. Elliott, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the case of Kelly Lantz Pierre. Additionally, he moved that Caroline Juran and Jim Rutkowski attend the

closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

DECISION: Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the panel voted 5-0 to indefinitely suspend Ms. Pierre's pharmacy technician registration for no less than two years.

ADJOURN: With all business concluded, the meeting adjourned at 5:40p.m.

Ryan Logan, Presiding Chair

Caroline D. Juran, Executive Director

DATE:

DRAFT

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, January 17, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A meeting of the Special Conference Committee of the Board of Pharmacy was called to order at 10:30 a.m.

PRESIDING: Michael Elliott, Committee Chair

MEMBERS PRESENT: Jodi Allen, Committee Member

STAFF PRESENT: J. Samuel Johnson, Deputy Executive Director
Anne G. Joseph, Acting Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist
Beth O'Halloran, Individual Licensing Manager

Dale Alan Moore
License Number 0202-210861

Dale Alan Moore appeared to discuss his application for reinstatement of his license to practice pharmacy, as stated in the December 22, 2016, Notice.

Closed Meeting: Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Dale Alan Moore. Additionally, she moved that J. Samuel Johnson, Anne G. Joseph, Mykl D. Egan, and Beth O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision: Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted deny Mr. Moore's application for reinstatement of his

license to practice pharmacy.

David Winters Hall
License Number 0202-010394

David Winters Hall did not appear to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the December 20, 2016, Notice.

Decision:

Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing, and to offer Mr. Winters a Consent Order for the revocation of his pharmacy license in lieu of a formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 12:20 p.m.

Michael Elliott, Chair

Anne G. Joseph
Acting Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

February 1, 2017
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:35 a.m.

PRESIDING: Jody Allen, Board Member

MEMBERS PRESENT:
Melvin L. Boone, Sr. (arrived 1:55 p.m.)
Michael I. Elliott
Sheila K. W. Elliott (departed 2:15 p.m.)
Freeda Cathcart
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With five members of the Board present, a quorum was established.

ACARIAHEALTH PHARMACY, INC.
Permit No. 0201-004179

A formal hearing was held in the matter of AcariaHealth Pharmacy, Inc. to discuss allegations that they may have violated certain laws and regulations governing the conduct of a pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

AcariaHealth Pharmacy, Inc. was represented by Elizabeth A. Scully, Lee Rosebush. James Whitford, Pharmacist-in-Charge, testified on behalf of the respondent.

Susan Beckmann, DHP Inspector, testified on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Mr. Elliott, and duly seconded by Ms. Elliott, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision

regarding the matter of AcariaHealth Pharmacy, Inc.

Additionally, he moved that Caroline Juran, Kennia Butler and James Rutowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened in open meeting and announced the decision.

DECISION:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Shinaberry, the panel voted 5-0 to impose a monetary penalty of $5,000 to be paid within 30 days from the date of the Order.
Mr. Boone arrived at 1:55 p.m.

SUMMARY SUSPENSION:

DANIEL PATRICK WILSON
Registration No.: 0230-020006

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice by Daniel Patrick Wilson, as a pharmacy technician poses a substantial danger to the public; and therefore, Daniel Patrick Wilson's right to renew his registration to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Mr. Wilson for the indefinite suspension of his right to renew his pharmacy technician registration for not less than two years.
Ms. Elliott departed at 2:15 p.m.

SHERRI KNOX
Registration No.: 0230-008921

A formal hearing was held in the matter of Sherri Knox to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Patricia Harte-Byers, DHP Senior Investigator; Richard Waddell, Walgreens Asset Protection Manager; Schrie Askew, Walgreens Pharmacist-in-Charge; and Maura Keene, Walgreens Store Manager, testified on behalf of the Commonwealth.

Ms. Knox testified on her own behalf.

CLOSED MEETING: Upon a motion by Mr. Elliott, and duly seconded by Mr. Cathcart, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the case of Sherri Knox. Additionally, he moved that Caroline Juran, Kennia Butler and James Rutowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

DECISION: Upon a motion by Ms. Cathcart, and duly seconded by Mr. Boone, the panel voted 6-0 to dismiss case.

ADJOURN: With all business concluded, the meeting adjourned at 5:10p.m.

Jody Allen, Presiding Chair

Caroline D. Juran, Executive Director

Date

DRAFT

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, February 21, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of the Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Cynthia Warriner, Committee Chair
MEMBERS PRESENT:	Melvin L. Boone, Sr., Committee Member
STAFF PRESENT:	Anne G. Joseph, Acting Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist Beth O'Halloran, Individual Licensing Manager Kennia Butler, Discipline Staff
Janet Lawson Registration Number 0230-016750	Janet Lawson did not appear to discuss her application for reinstatement of her registration to practice as a pharmacy technician and allegations that she may have violated certain laws governing pharmacy technician practice.
Decision	Upon a motion by Mr. Boone and duly seconded by Ms. Warriner, the Committee unanimously voted to deny Ms. Lawson's application for reinstatement of her registration to practice as a pharmacy technician. As provided by law, this decision shall become a final Order 30 days after service of such Order on Ms. Lawson, unless a written request is made to the Board within such time from Ms. Lawson requesting a formal hearing on her reinstatement application and the allegations made against her. If service of the Order is made by mail, three days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

Shawanda Gilliam Registration Number 0230-009351	Shawanda Gilliam did not appear to discuss allegations that she may have violated certain laws governing pharmacy technician practice as stated in the January 17, 2017, Notice.
Decision	Upon a motion by Mr. Boone and duly seconded by Ms. Warriner, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing, and to offer Ms. Gilliam a Consent Order for the suspension of her right to renew her pharmacy technician registration in lieu of a formal hearing.
Mark Lee Blanton License No. 0202-010024	Mark Lee Blanton appeared to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the January 17, 2017 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Mark Lee Blanton. Additionally, she moved that Anne G. Joseph, Mykl D. Egan, Beth O'Halloran, and Kennia Butler attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to issue an Order reprimanding Mr. Blanton and requiring him to take 8 hours of additional continuing education. As provided by law, this decision shall become a final Order 30 days after service of such Order on Mr.

Blanton, unless a written request is made to the Board within such time from Mr. Blanton requesting a formal hearing on the allegations made against him. If service of the Order is made by mail, three days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 11:35 a.m.

Cynthia Warriner, Chair	Anne G. Joseph Acting Deputy Executive Director
Date	Date

DRAFT/UNAPPROVED

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, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

Attachment 1

COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Attachment 3

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 § 54.1-3435.3:1 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

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.

DRAFT

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, March 8, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of the Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Michael Elliott, Committee Chair
MEMBERS PRESENT:	Jodi Allen, Committee Member
STAFF PRESENT:	Anne G. Joseph, Acting Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist Beth O'Halloran, Individual Licensing Manager Kennia Butler, Discipline Staff
Ryan Hypes Registration Number 0230-027774	Ryan Hypes did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the Notice of February 7, 2017.
Decision:	Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing, and to offer Mr. Hypes a Consent Order for the suspension of his pharmacy technician registration in lieu of a formal hearing.
Gihan William Seraka License Number 0202-204419	Gihan William Seraka appeared to discuss allegations that she may have violated certain laws governing the practice of pharmacy as stated in the February 7, 2017 Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Gihan William

Seraka. Additionally, she moved that Anne G. Joseph, Mykl D. Egan, Beth O'Halloran, and Kennia Butler attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision: Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to issue an Order reprimanding Ms. Seraka and placing her on indefinite probation for not less than 24 months under certain terms and conditions.

As provided by law, this decision shall become a final Order 30 days after service of such Order on Ms. Seraka, unless Ms. Seraka makes a written request to the Board within such time for a formal hearing on the allegations made against her. If service of the Order is made by mail, three days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 12:45 p.m.

Michael Elliott, Chair	Anne G. Joseph Acting Deputy Executive Director
Date	Date

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] NOIRA - *Register Date: 7/11/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] NOIRA - *Register Date: 11/28/16* *Board to adopt proposed regulations 3/21*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Outsourcing facilities [Action 4452] Proposed - *Register Date: 10/31/16* *Board to adopt final regulations 3/21*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Proposed - *Register Date: 12/12/16* *Board to adopt final regulations 3/21*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	CE credit for volunteer practice [Action 4747] Fast-Track - *Register Date: 3/20/17* *Effective date: 5/5/17*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Addressing hours of continuous work by pharmacists [Action 3755] Final - *Register Date: 1/9/17* *Effective date: 2/8/17*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Scheduling of chemicals in Schedule I [Action 4746] Final - *Register Date: 1/23/17* *Effective date: 2/22/17*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Permits for facilities [Action 4451] Proposed - *Register Date: 10/17/16* *Board to adopt final regulations 3/21*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Permitting of third party logistics providers and registration of nonresident manufacturers [Action 4678] Fast-Track - *At Governor's Office*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - Board to reconsider regulations at June board meeting

Board of Pharmacy

Report of the 2017 General Assembly

HB 1497 Ophthalmic prescriptions; definitions, who may provide prescriptions, requirements.

Chief patron: Farrell

Requirements for ophthalmic prescriptions. Requires, for ophthalmic prescriptions written on or after July 1, 2017, that an ophthalmologist or optometrist establish a bona fide provider-patient relationship with a patient prior to prescribing spectacles, eyeglasses, lenses, or contact lenses, and sets out requirements for establishing such relationship, which includes options for examination of the patient either in person or through face-to-face interactive, two-way, real-time communication or store-and-forward technologies. This bill is identical to SB 1321.

HB 1610 Drug Control Act; Schedule I.

Chief patron: Garrett

Drug Control Act; Schedule I. Adds certain chemical substances to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. The bill also removes two substances, benzylfentanyl and thienylfentanyl, from Schedule I. The bill contains technical amendments. This bill is identical to SB 1546.

HB 1642 Naloxone or other opioid antagonist; possession and administration.

Chief patron: Hope

Possession and administration of naloxone. Adds 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 to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided that they have completed a training program. The bill contains an emergency clause. This bill is identical to SB 1031.

EMERGENCY

HB 1661 Administration of medications to treat adrenal crisis.

Chief patron: Greason

Administration of medications to treat adrenal crisis. Provides that a prescriber may authorize an employee of (i) a school board, (ii) a school for students with disabilities, or (iii) an accredited private school who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medications to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis pursuant to a written order or standing protocol issued within the course of the prescriber's professional practice and with the consent of the student's parents. The bill

provides that any such authorized employee who administers or assists in the administration of such medications to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis in accordance with the prescriber's instructions shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

HB 1750 Dispensing of naloxone; patient-specific order not required.

Chief patron: O'Bannon

Dispensing of naloxone; patient-specific order not required. Provides that a pharmacist may dispense naloxone in the absence of a patient-specific prescription pursuant to a standing order issued by the Commissioner of Health authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

HB 2046 Unused dispensed drugs; guidelines for provision of counseling and information on proper disposal.

Chief patron: Murphy

Prescription drug orders; information on proper disposal. Requires the Board of Pharmacy to develop guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs, including information about pharmacy drug disposal programs in which the pharmacy may participate, by pharmacists to patients for whom a prescription is dispensed.

HB 2161 Opioids; workgroup to establish guidelines for prescribing.

Chief patron: Pillion

Secretary of Health and Human Resources; workgroup to establish educational guidelines for training health care providers in the safe prescribing and appropriate use of opioids. Requires the Secretary of Health and Human Resources to convene a workgroup that shall include representatives of the Departments of Behavioral Health and Developmental Services, Health, and Health Professions as well as representatives of the State Council of Higher Education for Virginia and each of the Commonwealth's medical schools, dental schools, schools of pharmacy, physician assistant education programs, and nursing education programs to develop educational standards and curricula for training health care providers, including physicians, dentists, optometrists, pharmacists, physician assistants, and nurses, in the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. The workgroup shall report its progress and the outcomes of its activities to the Governor and the General Assembly by December 1, 2017. The bill contains an emergency clause. This bill is identical to SB 1179.

EMERGENCY

HB 2163 Buprenorphine without naloxone; prescription limitation.

Chief patron: Pillion

Prescription of buprenorphine without naloxone; limitation. Provides that prescriptions for products containing buprenorphine without naloxone shall be issued only (i) for patients who are pregnant, (ii) when converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed seven days, or (iii) as permitted by regulations of the Board of Medicine or the Board of Nursing. The bill contains an emergency clause and has an expiration date of July 1, 2022. This bill is identical to SB 1178.

EMERGENCY

HB 2164 Drugs of concern; drug of concern.

Chief patron: Pillion

Drugs of concern; gabapentin. Adds any material, compound, mixture, or preparation containing any quantity of gabapentin, including any of its salts, to the list of drugs of concern. This bill contains an emergency clause.

EMERGENCY

HB 2167 Opioids and buprenorphine; Boards of Dentistry and Medicine to adopt regulations for prescribing.

Chief patron: Pillion

Boards of Dentistry and Medicine; regulations for the prescribing of opioids and buprenorphine. Directs the Boards of Dentistry and Medicine to adopt regulations for the prescribing of opioids and products containing buprenorphine. The bill requires the Prescription Monitoring Program at the Department of Health Professions to provide an annual report to the Joint Commission on Health Care on the prescribing of opioids and benzodiazepines in the Commonwealth. The bill contains an emergency clause.

EMERGENCY

HB 2470 Drug Control Act; Schedule II and Schedule V.

Chief patron: Jones

Drug Control Act; Schedule II and Schedule V. Adds thiafentanil to Schedule II of the Drug Control Act and Brivaracetam to Schedule V of the Drug Control Act.

SB 848 Naloxone; dispensing for use in opioid overdose reversal, etc.

Chief patron: Wexton

Dispensing of naloxone. Allows a person who is 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 who is acting on behalf of an organization that provides services to individuals at risk of experiencing 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 pursuant to § 54.1-3423 to

dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the controlled substance registration, provided that the entity possessing the controlled substance registration maintains records in accordance with regulations of the Board of Pharmacy. The bill further provides that a person who dispenses naloxone shall not be liable for civil damages of ordinary negligence for acts or omissions resulting from the rendering of such treatment if he acts in good faith and that a person to whom naloxone has been dispensed pursuant to the provisions of the bill may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. The bill contains an emergency clause. This bill is identical to HB 1453.

EMERGENCY

SB 981 Charity health care services; liability protection for administrators.

Chief patron: Stanley

Charity health care services; liability protection for administrators. Provides that persons who administer, organize, arrange, or promote the rendering of services to patients of certain clinics shall not be liable to patients of such clinics for any civil damages for any act or omission resulting from the rendering of such services unless the act or omission was the result of such persons' or the clinic's gross negligence or willful misconduct. This bill is identical to HB 1748.

SB 1009 Telemedicine, practice of; prescribing controlled substances.

Chief patron: Dunnavant

Practice of telemedicine; prescribing. Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment, for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. The bill contains an emergency clause. This bill is identical to HB 1767.

EMERGENCY

SB 1027 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Chief patron: Marsden

Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide. Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy (the Board) and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. The bill sets limits on the number of permits that the Board may issue and requires that the Board adopt regulations establishing health, safety, and security requirements for permitted processors. The bill provides that only a licensed practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil. The bill also requires that a practitioner who issues a written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board. The bill requires further that a pharmaceutical processor shall not provide cannabidiol oil or THC-A oil to a patient or a patient's parent or legal guardian without first verifying that the patient, the patient's parent or legal guardian if the patient is a minor or incapacitated, and the practitioner who issued the written certification have registered with the Board. Finally, the bill provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana. The bill contains an emergency clause.

EMERGENCY

SB 1230 Opiate prescriptions; electronic prescriptions.

Chief patron: Dunnavant

Opiate prescriptions; electronic prescriptions. Requires a prescription for any controlled substance containing an opiate to be issued as an electronic prescription and prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, beginning July 1, 2020. The bill defines electronic prescription as a written prescription that is generated on an electronic application in accordance with federal regulations and is transmitted to a pharmacy as an electronic data file. The bill requires the Secretary of Health and Human Resources to convene a work group of interested stakeholders to review actions necessary for the implementation of the bill's provisions, to evaluate hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing, and to make recommendations for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures, or interruptions of services. The work group shall report on the work group's progress to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017, and a final report to such Chairmen by November 1, 2018.

SB 1232 Opioids; limit on amount prescribed, extends sunset provision.

Chief patron: Dunnavant

Limits on prescription of controlled substances containing opioids. Requires a prescriber registered with the Prescription Monitoring Program (the Program) to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than seven consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days. Current law requires a registered prescriber to request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than 14 consecutive days and exempts the prescriber from this requirement if the opioid is prescribed as part of a course of

treatment for a surgical or invasive procedure and such prescription is not refillable. The bill extends the sunset for this requirement from July 1, 2019, to July 1, 2022.

SB 1403 Cannabidiol; Board of Pharmacy to deschedule or reschedule upon certain publication.

Chief patron: Dunnavant

Board of Pharmacy to deschedule or reschedule controlled substances. Authorizes the Board of Pharmacy (Board) to designate, deschedule, or reschedule as a controlled substance any substance 30 days after publication in the Federal Register of a final or interim final order or rule designating such substance as a controlled substance or descheduling or rescheduling such substance. Under current law, the Board may act 120 days from such publication date. The bill also provides that a person is immune from prosecution for prescribing, administering, dispensing, or possessing pursuant to a valid prescription a substance approved as a prescription drug by the U.S. Food and Drug Administration on or after July 1, 2017, in accordance with a final or interim final order or rule despite the fact that such substance has not been scheduled by the Board. The immunity provided by the bill remains in effect until the earlier of (i) nine months from the date of the publication of the interim final order or rule or, if published within nine months of the interim final order or rule, the final order or rule or (ii) the substance is scheduled by the Board or by law. This bill is identical to HB 1799.

SB 1484 Prescription Monitoring Program; disclosure of information to certain physicians or pharmacists.

Chief patron: Hanger

Prescription Monitoring Program. Provides that the information in the possession of the Prescription Monitoring Program disclosed by the Director of Health Professions about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist employed by the Virginia Medicaid managed care program may be disclosed to such physician's or pharmacist's clinical designee who holds a multistate licensure privilege to practice nursing or a license issued by a health regulatory board within the Department of Health Professions and is employed by the Virginia Medicaid managed care program.

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING OPIOIDS AND BUPRENORPHINE

VIRGINIA BOARD OF MEDICINE

Title of Regulations: 18 VAC 85-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 29 of Title 54.1 of the *Code of Virginia*

Effective Date:

9960 Mayland Drive, Suite 300
Henrico, VA 23233-2463

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TABLE OF CONTENTS

Part I. General Provisions....3
18VAC85-21-10. Applicability....3
18VAC85-21-20. Definitions....3
Part II. Management of Acute Pain....3
18VAC85-21-30. Evaluation of the acute pain patient....3
18VAC85-21-40. Treatment of acute pain with opioids....4
18VAC85-21-50. Medical records for acute pain....4
Part III. Management of Chronic Pain....5
18VAC85-21-60. Evaluation of the chronic pain patient....5
18VAC85-21-70. Treatment of chronic pain with opioids....5
18VAC85-21-80. Treatment plan for chronic pain....6
18VAC85-21-90. Informed consent and agreement for treatment for chronic pain....6
18VAC85-21-100. Opioid therapy for chronic pain....7
18VAC85-21-110. Additional consultations....7
18VAC85-21-120. Medical records for chronic pain....7
Part IV. Prescribing of Buprenorphine for Addiction Treatment....8
18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment....8
18VAC85-21-140. Patient assessment and treatment planning for addiction treatment....8
18VAC85-21-150. Treatment with buprenorphine for addiction treatment....8
18VAC85-21-160. Special populations in addiction treatment....10
18VAC85-21-170. Medical records for opioid addiction treatment....10

74

Part I. General Provisions.

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to cancer, a patient in hospice care or a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" shall mean the Virginia Board of Medicine.

"Chronic pain" shall mean non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV.

"FDA" shall mean the U. S. Food and Drug Administration.

"MME" shall mean morphine milligram equivalent.

"Prescription Monitoring Program" shall mean the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

Part II. Management of Acute Pain

18VAC85-21-30. Evaluation of the acute pain patient.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1of the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a waivered buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication

prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III. Management of Chronic Pain.

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life and activities of daily living;

5. Psychiatric, addiction and substance abuse history of the patient and any family history of addiction or substance abuse;

6. A urine drug screen or serum medication level;

7. A query the Prescription Monitoring Program as set forth in § 54.1-2522 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance abuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses and refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical records the presence or absence of any indicators for medication misuse, abuse or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The prescriber shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include, but not be limited to permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels, when requested;

2. Query and receive reports from the Prescription Monitoring Program; and

3. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The prescriber shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the prescriber shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. Practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

A. The prescriber shall keep current, accurate and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;

4. Diagnostic, therapeutic and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage and quantity prescribed and refills).

11. Patient instructions; and

12. Periodic reviews.

Part IV. Prescribing of Buprenorphine for Addiction Treatment.

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Prescribers engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from the Substance Abuse Mental Health Services Administration and the appropriate Drug Enforcement Administration registration.

B. Prescribers shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners, who have obtained a waiver from the Substance Abuse Mental Health Services Administration, shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall refer the patient to a mental health service provider as defined in § 54.1-2400.1 of the Code of Virginia for counseling or provide counseling in their practice and document such in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance abuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB.

B. The treatment plan shall include the practitioner's rationale for selecting medication assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction treatment.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or

3. In formulations other than tablet form for indications approved by the FDA.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs). With the exception of those conditions listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than 8 mg. of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider as defined in § 54.1-2400.1 of the Code of Virginia.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women shall be treated with the buprenorphine mono-product, usually 16 mg. per day or less.

B. Patients under the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives which can be identified, quantified and independently verified.

D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and that is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 which prohibits release of medical records, re-disclosure or other information without the patient's consent or a court order, or in cases of a bona fide medical emergency, or in the mandatory reporting of child abuse, shall be followed.

D. Compliance with Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Agenda Item: **Regulatory Action – Adoption of Final Regulations**

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing listing chemicals to be scheduled

Amendment to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

Board action:

Adoption of final regulation

Project 5057 - none

BOARD OF PHARMACY

Scheduling of chemicals

18VAC110-20-322. Placement of chemicals in Schedule I.

A. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl).

2. Flubromazolam.

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT).

4. Cannabimimetic agents:

   a. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA);

   b. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA); and

   c. Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA).

The placement of drugs listed in this subsection shall remain in effect until December 14, 2017, unless enacted into law in the Drug Control Act.

B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);

2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);

3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);

4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);

5. 4-Chloroethcathinone (other name: 4-CEC);

6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);

7. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700);

8. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

9. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);

10. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);

11. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);

12. Clonazolam; and

13. Cannabimimetic agents:

a. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB);

b. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48);

c. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);

d. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005); and

e. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA).

The placement of drugs listed in this subsection shall remain in effect until March 7, 2018, unless enacted into law in the Drug Control Act.

C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD);

2. (2-Methylaminopropyl)benzofuran (other name: MAPB);

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine); and

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until May 10, 2018, unless enacted into law in the Drug Control Act.

D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);

2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);

3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);

4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);

5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);

6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);

7. 4-methyl-alpha-ethylaminopentiophenone; and

8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl).

The placement of drugs listed in this subsection shall remain in effect until August 22, 2018, unless enacted into law in the Drug Control Act.

E. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. 6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Synthetic opioids.

a. N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl), its isomers, esters, ethers, salts, and salts of

isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

b. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

c. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

4. Cannabimimetic agents:

a. 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

5. Benzodiazepine:

Flubromazepam, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until (18 months after the effective date of the regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of Final Regulations for Outsourcing Facilities – replacement of Emergency Regulations

Included in your agenda package are:

A copy of the proposed regulations which are identical to emergency regulations in effect from December 7, 2015 through June 6, 2017

There were no comments on the proposed regulation.
(There was no comment at the Public Hearing conducted on Dec. 12, 2016)

Board action:

Adoption of final regulations identical to the emergency regulations currently in effect

BOARD OF PHARMACY

Outsourcing facilities

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Outsourcing facility permit	$270
~~8.~~ 9. Nonresident pharmacy registration	$270
10. Nonresident outsourcing facility registration	$270
~~9.~~ 11. Controlled substances registrations	$90
~~10.~~ 12. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
~~11.~~ 13. Approval of a pharmacy technician training program	$150
~~12.~~ 14. Approval of a continuing education program	$100
~~13.~~ 15. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy permit – due no later than April 30	$270
5. Physician permit to practice pharmacy – due no later than February 28	$270
6. Medical equipment supplier permit – due no later than February 28	$180
7. Humane society permit – due no later than February 28	$20
8. Outsourcing facility permit – due no later than April 30	$270
~~8.~~ 9. Nonresident pharmacy registration – due no later than the date of initial registration	$270
10. Nonresident outsourcing facility registration – due no later than the date of initial registration	$270
~~9.~~ 11. Controlled substances registrations – due no later than February 28	$90
~~10.~~ 12. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~11.~~ 13. Approval of a pharmacy technician training program	$75 every two years
~~12.~~ 14. Approval of a repackaging training program	$30 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30

2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Outsourcing facility permit	$90
~~8.~~ 9. Nonresident pharmacy registration	$90
10. Nonresident outsourcing facility registration	$90
~~9.~~ 11. Controlled substances registrations	$30
~~10.~~ 12. Approval of a pharmacy technician training program	$15
~~11.~~ 13. Approval of a repackaging training program	$10

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were	

operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Outsourcing facility permit	$240
~~e.~~ f. Nonresident pharmacy registration	$115
g. Nonresident outsourcing facility registration	$240
~~f.~~ h. Controlled substances registration	$180
~~g.~~ i. Approval of a pharmacy technician training program	$75
~~h.~~ j. Approval of a repackaging training program	$50

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	$150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-20-215. Outsourcing facilities.

A. Any facility in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient shall obtain a permit as an

outsourcing facility from the board in accordance with § 54.1-3434.05 of the Code of Virginia. Any outsourcing facility located outside of the Commonwealth that delivers in any manner Schedule II through VI drugs or devices into the Commonwealth without a prescription for a specific patient shall be registered with the board in accordance with § 54.1-3434.5 of the Code of Virginia.

B. In order to obtain or renew a permit or registration, outsourcing facilities shall submit to the board (i) documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act and (ii) a copy of a current inspection report consistent with § 54.1-3434.05 or 54.1-3434.5 of the Code of Virginia. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or 54.1-3434.5 shall not meet the requirements for an initial permit or registration or for renewal of a permit or registration.

C. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV (18VAC110-20-110 et seq.) and VI (18VAC110-20-240 et seq.), with the following exceptions:

1. Subsections E and F of 18VAC110-20-190, relating to dispensed prescriptions.

2. Subsection A of 18VAC110-20-200, relating to prescriptions awaiting delivery.

3. Subsections B and C of 18VAC110-20-240, relating to prescriptions and chart orders.

4. 18VAC110-20-250, relating to automated data processing prescription records.

5. Subsections C, D, E, and F of 18VAC110-20-270, relating to preparation and dispensing of prescriptions.

D. In addition to applicable requirements for pharmacies, outsourcing facilities shall comply with the following:

1. Pharmacist supervision. At all times, such facilities shall be under the supervision of a PIC who routinely practices at the location designated on the permit application. A pharmacist shall be present at all times when the facility is open for business.

2. Records.

a. All records, including the receipt and disposition of drugs or devices, shall be maintained by the facility for a period of five years and shall be available to the board upon request.

b. Compounding records shall include identification and strength of the drugs and shall provide the ingredients, expiration dates, and the source of such ingredients. Records shall also include the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units produced; the national drug code number of the final product, if assigned, or lot number; and an appropriately assigned expiration date or beyond-use date.

c. Outsourcing facilities shall maintain quality control records to include stability and sterility testing for determining beyond-use dating.

E. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations, and requirements, except it shall compound in compliance with current good manufacturing practices under § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)).

Part VIII

Labeling and Packaging Standards for Prescriptions

18VAC110-20-321. Compounding.

A. The compounding of both sterile and nonsterile drug products by a pharmacy that does not share the same physical space with an outsourcing facility shall be performed in accordance with USP-NF compounding standards and § 54.1-3410.2 of the Code of Virginia.

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current good manufacturing practices under § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)).

FORMS (18VAC110-20)

Application for Registration as a Pharmacy Intern (rev. 8/07)

Affidavit of Practical Experience, Pharmacy Intern (rev. 8/07)

Application for Licensure as a Pharmacist by Examination (rev. 11/09)

Instructions for Reinstating or Reactivating a Pharmacist License (rev. 3/11)

Application for Approval of a Continuing Education Program (rev. 8/07)

Application for Approval of ACPE Pharmacy School Course(s) for Continuing Education Credit (rev. 6/09)

Application for License to Dispense Drugs (rev. 8/07)

~~Application for a Pharmacy Permit (rev. 6/10)~~

~~Application for a Nonresident Pharmacy Registration (rev. 7/08)~~

Application for a Pharmacy Permit (rev. 12/2015)

Application for a Non-Resident Pharmacy Registration (rev. 12/2015)

Application for a Non-Resident Outsourcing Facility Registration (12/2015)

Application for an Outsourcing Facility Permit (12/2015)

Application for a Permit as a Medical Equipment Supplier (rev. 3/09)

Application for a Controlled Substances Registration Certificate (rev. 4/09)

Application for Registration as a Pharmacy Intern for Graduates of a Foreign College of Pharmacy (rev. 8/07).

Closing of a Pharmacy (rev. 8/07)

Application for Approval of an Innovative (Pilot) Program (rev. 8/07)

Pharmacy Technician Registration Instructions and Application (rev. 3/09)

Instructions for Reinstating a Pharmacy Technician Registration (rev. 3/11)

Application for Approval of a Pharmacy Technician Training Program (rev. 8/07)

Application for Registration for Volunteer Practice (rev. 8/07)

Sponsor Certification for Volunteer Registration (rev. 8/08)

Application for Reinstatement of Registration as a Pharmacy Intern (eff. 9/07)

Affidavit for Limited-Use Pharmacy Technician (rev. 8/07)

Limited-Use Pharmacy Technician Registration Instructions and Application (rev. 7/08)

Registration for a Pharmacy to be a Collection Site for Donated Drugs (eff. 4/09)

Application for Approval of Repackaging Training Program (eff. 12/10)

Agenda Item: Adoption of Final Regulations for Permitting Facilities in which Practitioners of the Healing Arts dispense controlled substances – replacement of Emergency Regulations

Included in your agenda package are:

A copy of the proposed regulations which are identical to emergency regulations in effect from December 7, 2015 through June 6, 2017

There were no comments on the Notice of Intended Regulatory Action.

Board action:

Adoption of final regulations identical to the emergency regulations currently in effect

Project 4532 - FINAL

BOARD OF PHARMACY

Permits for facilities

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. ~~Fee for initial license for a practitioner of the healing arts to sell controlled substances~~ Initial application fees.

1. ~~The application fee for initial licensure shall be $240~~ License for practitioner of the healing arts to sell controlled substances: $180.

2. ~~The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500~~ Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

C. ~~Renewal of license for a practitioner of the healing arts to sell controlled substances~~ Annual renewal fees.

1. ~~The annual fee for renewal of an active license shall be $90. For the annual renewal due on December 31, 2009, the fee shall be $50~~ License for practitioner of the healing arts to sell controlled substances: $90.

2. ~~The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee~~ Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

~~3. The fee for reinstatement of a license expired for more than one year shall be $210.~~

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substances: $30.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $40.

E. Reinstatement fees. Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances: $150.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: $500.

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit. [Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.]

~~D.~~ G. The fee for reinspection of any facility shall be $150.

~~E.~~ H. The fee for a returned check shall be $35.

Part II

Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 7, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine, or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

~~C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:~~

~~1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and~~

~~2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.~~

18VAC110-30-21. Application for facility permit.

A. After June 7, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner of the healing arts shall apply for the facility permit on a form provided by the board.

B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-30. Renewal of license or permit.

A. A license or facility permit so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or permit, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a ~~license~~ facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted ~~unless another practitioner at the same location has held an active license to sell controlled substances during that period~~. A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on expired status. If no other practitioner of the healing arts licensed to sell controlled substances intends

to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license or facility permit pursuant to this section may request that it be made current again at any time within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

Part III

Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

18VAC110-30-70. ~~Maintenance of a common stock of controlled substances~~ Practitioner in charge in a permitted facility.

~~Any two or more licensees who elect to maintain a common stock of~~ A facility with a permit for practitioners of the healing arts to sell controlled substances ~~for dispensing~~ shall:

1. Designate a ~~licensee~~ practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for ~~licenses which~~ facility permits that indicate a requested inspection date, or requests ~~which~~ that are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates ~~which~~ 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.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120, and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility 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 18VAC110-30-15 prior to a reinspection being conducted.

F. No ~~license~~ facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the ~~the~~ inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be

stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within ~~the immediate vicinity~~ 20 feet of the selling and storage area and not located within an examination room or restroom; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

FORMS (18VAC110-30)

~~Application for a License to Sell Controlled Substances by a Practitioner of the Healing Arts (rev. 8/07).~~

Application for a License to Sell Controlled Substances by a Practitioner of the Healing Arts (rev. 12/2015)

Application for a Facility Permit for Practitioner(s) of the Healing Arts to Sell Controlled Substances (rev. 12/2015)

Agenda Item: Adoption of Final Regulations for a Prohibition on Incentives to Transfer Prescriptions

Included in your agenda package are:

Copy of comment on the proposed regulation
(There was no comment at the Public Hearing conducted on Dec. 12, 2016)

Copy of proposed regulation

Board action:

Adoption of final regulations as proposed; or

Adoption of regulation with changes.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action	**Prohibition against incentives to transfer prescriptions**
Stage	**Proposed**
Comment Period	Ends 2/10/2017

Back to List of Comments

Commenter: Robert Sedaker * 1/18/17 5:28 pm

no prohibition

There should be no prohibition of Pharmacy incentives to switch pharmacies. There is no causal effect of such practice leading to mistakes by pharmacies. Don't make regulations for the sake of regulations! The consumer is the ONLY one hurt by this measure

* Nonregistered public user

107

Project 4549 - FINAL

BOARD OF PHARMACY

Prohibition against incentives to transfer prescriptions

18VAC110-20-25. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing; or

11. Advertising or soliciting in a manner that may jeopardize the health, safety, and welfare of a patient, including incentivizing or inducing the transfer of a prescription absent professional rationale by use of coupons, rebates, or similar offerings.

Agenda Item: Adoption of Regulations for Controlled Substance Registration and Protocols for Naloxone Dispensing

Included in package:

- Copies of SB848 (identical to HB1453) and HB1642 (identical to SB1031)
- Draft amendments to regulations for controlled substances registration as recommended by Regulation Committee
- Draft amendments to Board-approved naloxone protocols as recommended by Regulation Committee

Board action:

- Motion to recommend to full board to amend 18VAC110-20-690, 18VAC110-20-710, and 18VAC110-20-735 as presented or as amended
- Motion to amend Guidance Document 110-44 as presented or as amended
- Motion to adopt Guidance Document 110-45 as presented or as amended

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 8.01-225 and 54.1-3408 of the Code of Virginia, relating to dispensing of naloxone.

[S 848]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-225 and 54.1-3408 of the Code of Virginia are amended and reenacted as follows:

§ 8.01-225. Persons rendering emergency care, obstetrical services exempt from liability.

A. Any person who:

1. In good faith, renders emergency care or assistance, without compensation, to any ill or injured person (i) at the scene of an accident, fire, or any life-threatening emergency; (ii) at a location for screening or stabilization of an emergency medical condition arising from an accident, fire, or any life-threatening emergency; or (iii) en route to any hospital, medical clinic, or doctor's office, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such care or assistance. For purposes of this subdivision, emergency care or assistance includes the forcible entry of a motor vehicle in order to remove an unattended minor at risk of serious bodily injury or death, provided the person has attempted to contact a law-enforcement officer, as defined in § 9.1-101, a firefighter, as defined in § 65.2-102, emergency medical services personnel, as defined in § 32.1-111.1, or an emergency 911 system, if feasible under the circumstances.

2. In the absence of gross negligence, renders emergency obstetrical care or assistance to a female in active labor who has not previously been cared for in connection with the pregnancy by such person or by another professionally associated with such person and whose medical records are not reasonably available to such person shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care or assistance. The immunity herein granted shall apply only to the emergency medical care provided.

3. In good faith and without compensation, including any emergency medical services provider who holds a valid certificate issued by the Commissioner of Health, administers epinephrine in an emergency to an individual shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction.

4. Provides assistance upon request of any police agency, fire department, emergency medical services agency, or governmental agency in the event of an accident or other emergency involving the use, handling, transportation, transmission, or storage of liquefied petroleum gas, liquefied natural gas, hazardous material, or hazardous waste as defined in § 10.1-1400 or regulations of the Virginia Waste Management Board shall not be liable for any civil damages resulting from any act of commission or omission on his part in the course of his rendering such assistance in good faith.

5. Is an emergency medical services provider possessing a valid certificate issued by authority of the State Board of Health who in good faith renders emergency care or assistance, whether in person or by telephone or other means of communication, without compensation, to any injured or ill person, whether at the scene of an accident, fire, or any other place, or while transporting such injured or ill person to, from, or between any hospital, medical facility, medical clinic, doctor's office, or other similar or related medical facility, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care, treatment, or assistance, including but in no way limited to acts or omissions which involve violations of State Department of Health regulations or any other state regulations in the rendering of such emergency care or assistance.

6. In good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation (CPR); cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator (AED); or other emergency life-sustaining or resuscitative treatments or procedures which have been approved by the State Board of Health to any sick or injured person, whether at the scene of a fire, an accident, or any other place, or while transporting such person to or from any hospital, clinic, doctor's office, or other medical facility, shall be deemed qualified to administer such emergency treatments and procedures and shall not be liable for acts or omissions resulting from the rendering of such emergency resuscitative treatments or procedures.

7. Operates an AED at the scene of an emergency, trains individuals to be operators of AEDs, or orders AEDs, shall be immune from civil liability for any personal injury that results from any act or omission in the use of an AED in an emergency where the person performing the defibrillation acts as

423 administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation
424 with the Board of Medicine and the Department of Health.
425 *Y. Notwithstanding any other law or regulation to the contrary, a person who is authorized by the*
426 *Department of Behavioral Health and Developmental Services to train individuals on the administration*
427 *of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that*
428 *provides services to individuals at risk of experiencing an opioid overdose or training in the*
429 *administration of naloxone for overdose reversal and that has obtained a controlled substances*
430 *registration from the Board of Pharmacy pursuant to § 54.1-3423 may dispense naloxone to a person*
431 *who has completed a training program on the administration of naloxone for opioid overdose reversal*
432 *approved by the Department of Behavioral Health and Developmental Services, provided that such*
433 *dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols*
434 *developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of*
435 *Health, and (iii) without charge or compensation. The dispensing may occur at a site other than that of*
436 *the controlled substance registration provided the entity possessing the controlled substances registration*
437 *maintains records in accordance with regulations of the Board of Pharmacy. A person to whom*
438 *naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer*
439 *naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid*
440 *overdose.*
441 **2. That an emergency exists and this act is in force from its passage.**
442 **3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this**
443 **act to be effective within 280 days of its enactment.**

112

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

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113

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.**

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.

Virginia Board of Pharmacy

Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities

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 opioid overdose as authorized in subsection X of §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. ~~Kit must contain~~ Must dispense with 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.

Pharmacies may prepare their own kits ~~obtain kits~~ to have on-hand for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration. A limited supply of kits may also be obtained from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov **Note: Kits from DBHDS do not contain prefilled syringes and may not contain atomizers.**

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 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

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.

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

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~~ Must dispense with 2 prefilled syringes and 2 atomizers, if not included in person's kit, 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 (DBHDS). To request kits, contact REVIVE@dbhds.virginia.gov **Note: Kits from DBHDS do not contain prefilled syringes and may not contain atomizers.**

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

Agenda Item: Adoption of Emergency Regulations for Controlled Substance Registration for CSBs for purpose of Telemedicine prescribing

Included in package:

- Copy of SB1009 (identical to HB1767)
- Draft amendments to regulations for controlled substances registration as

Board action:

- Motion to recommend to full board to amend 18VAC110-20-690, as presented or as amended

VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

CHAPTER 58

An Act to amend and reenact §§ 54.1-3303 and 54.1-3423 of the Code of Virginia, relating to practice of telemedicine; prescribing.

[S 1009]

Approved February 20, 2017

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303 and 54.1-3423 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by 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. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. *A practitioner who performs or has performed an appropriate examination of the patient required pursuant to clause (iii), either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, for the purpose of establishing a bona fide practitioner-patient relationship, may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.*

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability.

D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, *optometry*, or veterinary medicine, *a nurse practitioner, or a physician assistant* authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or

dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research with controlled substances in Schedules II through VI. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase, possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter.

F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.

G. *The Board may register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.*

H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

~~H.~~ *I.* Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

2. That an emergency exists and this act is in force from its passage.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

DRAFT

Emergency Regulations for Issuance of CSR to a Community Services Board entity for purposes of telemedicine prescribing (SB1009 & HB1767)

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, 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 or other person approved by the board who is authorized to administer the controlled substances.

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

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

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

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

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

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

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

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

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

Agenda Item: Periodic Review of Regulations

Included in your agenda package are:

A copy of the Appendix, showing amendments considered during periodic review at meeting of Regulation Committee on November 3, 2015

A copy of the amendments recommended by the Regulation Committee at meeting on February 28, 2017

Staff Note: The Board adopted a NOIRA which was published on July 11, 2016 with a comment period until August 10, 2016. There were 5 comments; none relating to sections being amended at this meeting.
Included in the NOIRA was a recommendation to divide Chapter 20 into two chapters: 1) Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians; and 2) Governing the Practice of Pharmacy

Board action:

Recommendation of the Regulation Committee to adopt amendments to regulations for pharmacies and medical equipment providers

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.

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

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 § 54.1-3435.3:1 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.

Agenda Item: Adoption of Guidance Documents

1) New guidance on continuous hours of work and breaks (offers board interpretation for compliance with new provisions of 18VAC110-20-110.)

2) Revised guidance on practice by a pharmacy technician trainee (Discussed at a previous meeting to address issue of training programs that may exceed 9 months in length)

Board Action:

Adoption of guidance documents as recommended by Regulation Committee on February 28, 2017

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

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.

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot 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 must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must 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 or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

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, the Board interpreted the restriction of nine months of practice for a pharmacy technician trainee to mean **nine consecutive months** from the ~~initial enrollment date in~~ the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of 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 ~~who enrolls in a pharmacy technician training program~~ completes the didactic or classroom portion of a training program and begins performing tasks restricted to a pharmacy technician on January 1st. The technician 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

150

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.

Agenda Item: **Regulatory Action – Adoption of Fast-track regulations**

Partial Fill of Schedule II Drugs

Included in agenda package:

- Copy of amendment to regulation: 18VAC110-20-310, along with relevant section of US Code and amendments to Code section approved in the federal CARA Act.

Staff note: The Regulation Committee asked staff to review the CARA Act to determine the possible impact on this regulation. Ms. Juran will report on that review.

Board action:

Amend as recommended or with additional changes from board members

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.

Agenda Item: Regulatory Action – Adoption of Fast-track regulations

Destruction of drugs in Correctional Facilities

Included in agenda package:

Copy of amendment to regulation: 18VAC110-20-590 as recommended by Regulation Committee

Staff Note:

This issue was brought to the Board's attention by the Department of Corrections in consultation with the DEA. Current regulation requires all unused or discontinued drugs to be returned to the provider pharmacy or secondary pharmacy. However, federal rules do not allow those drugs in Schedules II-V that were dispensed to specific inmates to be returned to provider pharmacies.

Amendments are recommended to conform to federal rules.

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.

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

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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. Do not cite if stored in a combination method as allowed in Guidance Document 110-40.	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

Deficiency	Law/Reg Cite	Conditions	$ Penalty
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
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
21b. Weighing or prepping of drugs for compounding in an area not classified as ISO 8 or better	54.1-3410.2		500

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

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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

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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

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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

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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	

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

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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. Do not cite if stored in a combination method as allowed in Guidance Document 110-40.

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Deficiency	Law/Regulation Cite	Conditions
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	

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Agenda Item: Petitions for rulemaking:

1) Dispensing of Schedule VI substance in amount greater that initially prescribed
2) Use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes

Included in your package are:

2 petitions for rulemaking

Copy of Notice of Intended Regulatory Action

Copies of comment on use of automated dispensing devices

Copies of proposed regulations as recommended by Regulation Committee

Board action:

1) Adopt proposed amendments as recommended by Committee; or

2) Adopt proposed amendments with changes; or

3) Refer to Committee for additional information or action.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

MAY 05 20

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,) PHILLIPS, DEREK, M		
Street Address 936 UPPER HASTINGS WAY	Area Code and Telephone Number 757-652-7385	
City VIRGINIA BEACH	State VA	Zip Code 23452
Email Address (optional) [illegible]@[illegible].COM	Fax (optional)	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-320. REFILLING OF SCHEDULE III THROUGH VI PRESCRIPTIONS

178

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

As a pharmacist, it is necessary to stay current with new processes, ideas, and methods. The intent of this request is to amend 18VAC110-20-320: REFILLING OF SCHEDULE III THROUGH VI PRESCRIPTIONS. Authorization for prescription refills is presumed to be within the prescribed dosage or normal therapeutic use. The pharmacist should have the right to refill a prescription if they believe that filling the prescription is in the best interest of the patient. Any refills may only be dispensed in reasonable conformity with recommended dosage and the exercise of sound professional judgment.

Therefore, I propose that if deemed appropriate in the pharmacist's professional judgment, a patient may receive upon request drug quantities in excess of the face amount of a prescription for a Schedule VI substance, up to the total amount authorized. The pharmacist should not dispense in excess of the face amount of a prescription for a Schedule III, IV, V substance or psychotherapeutic drug without authorization from the prescriber.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.

VIRGINIA BOARD OF PHARMACY HAS LEGAL AUTHORITY FOR REGULATIONS GOVERNING THE PRACTICE OF PHARMACY
§ 54.1-2400 OF THE CODE OF VIRGINIA

Signature:
Date: 4/27/16

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,) StClair, Roger Dale, JR (General Manager on behalf of Remedi SeniorCare)		
Street Address 10448 Lakeridge Parkway	Area Code and Telephone Number 804-955-9310	
City Ashland	State Virginia	Zip Code 23005
Email Address (optional) Dale.StClair@RemediRx.com	Fax (optional)	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-540. Emergency drug kit, 18VAC110-20-550. Stat-drug box, 18VAC110-20-555. Use of automated dispensing devices.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

Remedi SeniorCare seeks the Board of Pharmacy to amend subsections 540 and 550, permitting registered pharmacies providing services to Long Term Care facilities to utilize electronic devices in lieu of manual emergency drug kits and stat-drug boxes to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Current regulation does not designate electronic devices being utilized as unit dose systems purely for FIRST DOSE NON-ROUTINE vs automated dispensing devices utilized for FULL OR ROUTINE DISPENSING in Long Term Care facilities. The Drug Enforcement Administration makes distinction with regard to the different utilization of such devices and is delineated in 45 FR 24128 and 21 CFR §1301.27. This petition is made with the intention of recognizing technological advances in the care of residents in Long Term Care facilities. The utilization of electronic devices to store medications in compliance with 18VAC110-20-540 and 18VAC110-20-550 provides superior control of medications stored in Long Term Care facilities and offers electronic automated tracking of medications stored within such cabinets. The utilization of electronic devices should be delineated based upon the intended utilization of such cabinets though routine or non-routine dispensing. Multiple states have recognized the advances of utilizing electronic cabinets as Emergency Drug Kits and Stat-Drug Boxes to include Pennsylvania, Tennessee, Maryland, North Carolina, Illinois, and Kansas. Electronic cabinets for Emergency/STAT drug kits increase accuracy in the nursing staff administering the correct dose by limiting access for nursing staff to the correct location within the cabinet for first dose administrations. In addition electronic cabinets maintain superior capabilities to track expiration dates of products and accessibility by nursing staff. This petition seeks to allow electronic devices under 18VAC110-20-540 and 18VAC110-20-550 and to exempt them from the requirements contained under 18VAC110-20-555 when utilized under the aforementioned subsections 540 and 550.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

45 FR 24128, April 9, 1980 permits the placement of emergency kits containing controlled substances in non-federal registered Long Term Care facilities and makes no requirement for such kits to be non-electronic.

Signature: Dale Klein **Date:** 07/14/2016

	VA.R. Document Number: R____-_____
	Virginia Register Publication Information Date: 11/28/2016 Issue: 7 Volume: 33
11/4/2016 2:48 pm Date / Time filed with the Register of Regulations	

Transmittal Sheet: Notice of Intended Regulatory Action

Regulatory Coordinator: Elaine J. Yeatts
(804)367-4688
elaine.yeatts@dhp.virginia.gov

Promulgating Board: Board of Pharmacy

NOIRA Notice: Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending the following regulations

Chapters Affected:

18 vac 110 - 20:	Regulations Governing the Practice of Pharmacy

Action Title: Response to petitions for rulemaking

Agency Summary: The purpose of the proposed action is summarized as follows:

The Board acted on a petition for rulemaking to permit a pharmacist to dispense a quantity of a Schedule VI drug greater than the face amount prescribed, up to the total amount authorized in refills. During the comment period which ended June 29, 2016, the board received one comment which supported the request. Currently a pharmacist may not dispense more than the specific quantity prescribed at each dispensing and may not exceed that quantity by taking authorized refills into consideration. The Board voted unanimously to accept the petition for rulemaking authorizing a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills. The Board acted on another petition for rulemaking to amend 18VAC110-20-540, 18VAC110-20-550 and 18VAC110-20-555 to authorize the use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes. The petition states that current regulation does not distinguish between automated dispensing devices being utilized for first dose non-routine administration vs routine drug administration. During the comment period which ended August 31, 2016, the Board received one comment in support of the petition. The Board voted unanimously to accept the petition for rulemaking by amending Regulation 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility. It was determined it was unnecessary to amend other sections of regulations to achieve the petitioner's request.

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Federal:

Is a public hearing planned for the proposed stage? Yes

Public comments may be submitted until 5:00 p.m. on 12/28/2016.

Does the Agency Background Document include an announcement of a periodic/small business impact review?	No
If this stage is the result of a small business impact review does the Agency Background Document include a report of findings?	No
Agency Contact:	Caroline Juran, RPh Executive Director

182

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Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action	**Response to petitions for rulemaking**
Stage	**NOIRA**
Comment Period	Ends 12/28/2016

Back to List of Comments

Commenter: Dale StClair, PharmD - Remedi SeniorCare * 12/28/16 9:37 am

Comment on Notice of Intended Regulatory Action (NOIRA) 18VAC110-20

RE: Comment on Notice of Intended Regulatory Action (NOIRA) 18VAC110-20

Remedi SeniorCare appreciates the Board of Pharmacy's action on the petition for rulemaking to amend 18VAC110-20-540, 18VAC110-20-550 and 18VAC110-20-555. This amendment to regulation will continue to expand the availability of technological advances in the Long Term Care industry allowing pharmacies to better serve the residents of Long Term Care Facilities within the Commonwealth.

Further, we request the board take the following into consideration when revising the regulations to serve this unique population:

- Currently 18VAC110-20-555 permits the use of Automated Dispensing Devices in Long Term Care Facilities (LTCF), but doe not provide any distinction of the device based on the intended use of Routine or Non-Routine Dispensing.

- 18VAC110-20-540 and 18VAC110-20-550 do not specifically permit the utilization of electronic emergency or STAT drug boxes (collectively referred to as Emergency Boxes by the DEA) in Long Term Care Facilities.

- The DEA's policy statement 70 FR 24128 on April 9, 1980, which addresses the use of emergency kits in LTCFs, is still effective and permits DEA registered pharmacies providing services to LTCFs to place controlled substances kits in non-federal registered Long Term Care Facilities pursuant to the specified conditions.

- In response to an inquiry from Arnold Clayman, American Society of Consultant Pharmacists, the DEA issued a letter on November 30, 2016 addressing "whether electronic emergency kits at LTCFs require a separate registration." The DEA response noted the difference between 21 CFR § 1301.27 relating to an "Automated Dispensing System" utilized for routine dispensing in LTCFs. Further the DEA stated "All emergency kits – weather or not they are electronic – remain subject to the 1980 policy statement (and thus need not be separately registered), provided they satisfy the criteria of the 1980 policy statement at all times."

183

- 18VAC110-20-555 outlines the requirements for pharmacies providing services to LTCFs differing from the STAT and Emergency Box Regulations as follows:
  - 18VAC110-20-555 (1) requires the drugs placed in an automated drug dispensing system to be under the control of the pharmacy; however, the controlled substance permit requires a nurse at the facility to be the Responsibility Party with a pharmacist at the pharmacy being the Supervising Practitioner.
  - 18VAC110-20-555 (2) requires that nursing homes without an in-house pharmacy be required to obtain a controlled substance permit which is not required under 18VAC110-20-540 and 18VAC110-20-550.
  - 18VAC110-20-555 (3)(a) requires all orders to be reviewed by the pharmacist and the pharmacist to electronically authorize the access of the drug which is not required under 18VAC110-20-540 and 18VAC110-20-550.
  - 18VAC110-20-555 (3)(d) requires an audit of medical records for a sample of doses recorded as administered which is not required under 18VAC110-20-540 and 18VAC110-20-550.
  - 18VAC110-20-555 (9) requires monthly audits to review a sample of facility administration records from each device for possible charting diversion which is not required under 18VAC110-20-540 and 18VAC110-20-550.

Specifically amending and designating the regulations based upon the intended utilization of the device provides the following benefits:

- The Virginia Regulations will align with DEA policy statements and guidance related to the differences of Automated Dispensing Systems and Emergency Boxes.
- The alignment will provide better guidance and understanding to state and federal investigators understanding the intended utilization of the devices and the quantities being removed from such devices.
- Residents of Long Term Care Facilities will be afforded increased access to medications as well as the ability to receive them in a timelier manner.
- Providing electronically tracked access to devices allows the pharmacy to provide greater safeguards from potential diversion or theft.

In closing, Remedi SeniorCare appreciates the Board of Pharmacy for their review of these important differences regarding the proposed revision to regulation. We look forward to improved care for the residents of Long Term Care Facilities within the Commonwealth.

Best Regards,

Dale StClair, PharmD. RPh

General Manager

Remedi SeniorCare

* Nonregistered public user

Project 4952 - Proposed

BOARD OF PHARMACY

Response to petitions for rulemaking

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with § 54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

a. Each partial dispensing is recorded in the same manner as a refilling;

b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

c. No dispensing occurs after six months after the date on which the prescription order was issued.

B. A prescription for a drug listed in Schedule VI ~~shall~~ <u>may</u> be refilled ~~only~~ as ~~expressly~~ authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in § 54.1-3410 C or subdivision 4 of § 54.1-3411 of the Code of Virginia. <u>Except for drugs used to treat depression, anxiety, or psychoses or drugs of concern as</u>

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.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than one year after the date on which it was issued unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

C. As an alternative to all manual recordkeeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18VAC110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription drugs dispensed.

D. The timing of dispensing an authorized refill of a prescription shall be within reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment. An authorized refill may be dispensed early provided the pharmacist documents a valid reason for the necessity of the early refill.

18VAC110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit or an automated drug dispensing system, as provided in subsection B of this section, shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication, resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

B. Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.

18VAC110-20-550. Stat-drug box.

A. An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

   a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

   b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

   c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time, and the name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-drug box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

B. 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.

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall

have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, 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.

3. 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.

~~3.~~4. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug, including a drug that is stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

5. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

6. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

7. At the time of loading, the delivery record for all Schedule II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

8. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

9. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If

nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

12. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

13. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.