# 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)

## Tentative Agenda of Public Hearings and Full Board Meeting
*June 27, 2017*
**9:00AM**

| TOPIC | PAGES |
|---|---|
| **Call to Order of Public Hearing for Scheduling Certain Substances:** Rebecca Thornbury, 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 |
| **Adjournment of Public Hearings** | |
| **Call to Order of Full Board Meeting:** Rebecca Thornbury, Chairman | |
| • Approval of Agenda | |
| • Approval of Previous Board Meeting Minutes: | |
| ○ March 21, 2017, Full Board Meeting | 2-12 |
| ○ March 21, 2917, Public Hearing for Scheduling Certain Chemicals | 13-14 |
| ○ March 22, 2017, Special Conference Committee | 15-19 |
| ○ April 4, 2017, Possible Summary Suspension | 20-21 |
| ○ April 4, 2017, Formal Hearings | 22-24 |
| ○ April 25, 2017, Special Conference Committee | 25-27 |
| ○ May 10, 2017, Regulation Committee | 28-33 |
| ○ May 30, 2017, Special Conference Committee | 34-40 |
| ○ June 8, 2017, Special Conference Committee | handout |
| **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/Guidance:** Elaine Yeatts/Caroline Juran | |
| • Regulatory Update | 41-44 |
| • Adoption of Regulation to Schedule Certain Chemicals in Schedule I | 45-59 |
| • Adoption of Amendments Chapter 20 *Regulations Governing the Practice of Pharmacy* Parts VI - VIII, X - XII and Chapter 50 *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers* Parts I-II | 60-101 |
| • 2018 Legislative Proposals | |
| ○ Require reporting of Schedule V drugs and naloxone to the PMP | 102-104 |
| ○ Nonresident third-party logistics provider and nonresident warehouser | |

- Amend Guidance Document 110-1 *Categories of Facility Licensure* 105-108
- Formation of ad hoc committee to address HB1956, HB2046, and develop guidance on USP Chapter <800> 109-117

**New Business:**

- Presentation regarding NABP e-Profile, Neal Watson 118-119
- Request to Amend Pharmacist Healthcare Workforce Survey regarding Collaborative Practice Agreements Handout
- Select Standard for the Admissibility of Expert Testimony, Jim Rutkowski 120
- Elections for Chairman and Vice-Chairman

**Reports:**

- Chairman's Report – Rebecca Thornbury
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report – Caroline D. Juran Handout 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 1:30pm 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 June 27, 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 June 13, 2017 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

The Virginia Department of Forensic Science (DFS) has identified three (3) compounds for recommended inclusion into the Code of Virginia. A brief description and chemical name for each compound is as follows:

**The following compound is classified as a research chemical. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.**

1. **4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH)**, 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 compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(7)) in previous legislative sessions.**

2. **Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA )**, 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 a powerful synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

3. **N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran 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.

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF BOARD MEETING**

March 21, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:11am

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Sheila K. W. Elliott
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner (departed at 11:10am)

MEMBERS ABSENT:
Rebecca Thornbury
Michael I. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David E. Brown, Director, DHP (arrived approx. 10:30am)
Elaine J. Yeatts, Senior Policy Analyst, DHP (arrived approx. 10:30am)
James Rutkowski, Assistant Attorney General

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

APPROVAL OF AGENDA: The agenda was approved as presented.

APPROVAL OF MINUTES: The following minutes were considered for approval:

- December 12, 2016, Public Hearing of Scheduling Certain Chemicals
- December 12, 2016, Full Board Meeting
- December 12, 2016, Formal Hearing
- January 17, 2017, Special Conference Committee
- February 1, 2017, Formal hearings
- February 21, 2017, Special Conference Committee
- February 28, 2017, Regulation Committee
- March 8, 2017, Special Conference Committee

The February 1st formal hearing minutes were amended to clarify that Mr.

Boone arrived at 1:55pm, because he was recused from the hearing regarding AcariaHealth Pharmacy, Inc. hearing. No other changes were made to the minutes presented.

**MOTION:**

**The Board voted unanimously to adopt the minutes from December 12, 2016 through March 8, 2017 as presented and amended. (motion by Allen, second by Warriner)**

PUBLIC COMMENTS:

Ms. Becky Laniers-Bower offered comment regarding the proposed amendments to 18VAC110-20-690 (F) for a controlled substance registration (CSR) to be issued to a facility participating in telemedicine when there is no DEA registrant on-site and the facility does not maintain a DEA registration. Ms. Laniers-Bower stated that most community service boards have an executive director that is often not a medical professional, but should perhaps qualify as the responsible party if the intent of the responsible party is to assume responsibility for all facility operations. Ms. Juran responded that the responsible party on the CSR is responsible only for ensuring compliance with the subject for which the CSR is issued, i.e, telemedicine in this case.

PRESENTATION OF 2016 PHARMACIST AND PHARMACY TECHNICIAN WORKFORCE REPORT

Elizabeth Carter, PhD with the Department of Health Professions presented the 2017 Healthcare Workforce Survey results to the Board. Dr. Carter indicated that their department is adding more professions to their surveys each year and by the end of the current year should have 30 professions that they survey. Dr. Carter provided the Board with an overview of the growing programs that the Healthcare Workforce Data Center oversees or partners with such as Virginia CareForce Snapshots, Virginia Health Workforce Briefs and the new Healthcare Occupational Roadmap which will be used in high schools to encourage students to join health professions that do not necessarily require a bachelor's degree such as pharmacy technician, respiratory therapist, and dental hygienist.

Mr. Saenz noted that the survey indicates 74% of our registered pharmacy technicians already hold national certification; 66% PTCB and 9% ExCPT.

REGULATORY ACTIONS:

- Adoption of Regulations to Schedule certain chemicals in Schedule I

There was a public hearing conducted at 9:08am 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:**

- **6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD)**



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- **6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD)**

**Classified as powerful synthetic opioids:**

- **N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl)**
- **N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl)**
- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl)**

**Classified as cannabimimetic agents:**

- **1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006)**
- **Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22)**

**Classified as benzodiazepine:**

- **Flubromazepam**

**(motion by Warriner, second by Boone)**

- Adoption of final regulations for Outsourcing Facilities

Ms. Juran provided a brief review of the emergency regulations for outsourcing facilities that are in effect December 7, 2015 through June 6, 2017 and stated there have been no comments on the proposed regulations.

**MOTION:**

**The Board voted unanimously to adopt the final regulations for outsourcing facilities as presented which will replace the emergency regulations currently in effect (motion by Warriner, second by Cathcart)**

- Adoption of final regulations for permitting facilities in which practitioners of the healing arts sell controlled substances

Ms. Juran provided a brief overview of the emergency regulations for permitting facilities in which practitioners of the healing arts sell controlled substances that are in effect December 7, 2015 through June 6, 2017 and noted there were no comments on the notice of intended regulatory action.

**MOTION:**

**The Board voted unanimously to adopt the final regulations identical to the emergency regulations currently in effect for permitting facilities in which practitioners of the healing arts dispense controlled substances as presented (motion by Allen, second by Saenz)**

- Adoption for final regulations for a prohibition on incentives to transfer prescriptions

Ms. Juran provided a brief background of the proposed regulation and the one comment received in opposition. The action results from a petition for rulemaking received in 2014 from a practicing pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews. The proposed language mirrors language adopted by Oregon several

years ago. The Board discussed the need for such prohibition on transfers as a public safety issue so that a more cohesive accurate medication record for a patient may be maintained. Ms. Juran stated there is a similar regulation that recently went into effect in Tennessee.

**MOTION:**

**The Board voted unanimously to adopt the final regulations for prohibition on incentives to transfer prescriptions as proposed and presented. (motion by Warriner, second by Shinaberry)**

- Adoption of regulations for controlled substance registration and protocols for naloxone dispensing

The Board reviewed SB848 and HB1642 which authorizes trainers of the REVIVE! Training program who are authorized by DBHDS to possess and dispense naloxone free of charge at the conclusion of training events if a controlled substance registration is obtained by the entity for whom the trainer is dispensing. The board must amend its regulations for controlled substances registrations to facilitate this practice. Additionally, the second bill allows employees of certain agencies, e.g., Office of the Chief Medical Examiner and the Department of Forensic Science to possess naloxone as well for reversal of accidental overdose when exposed at work to potent chemicals. The recommendations from the Regulation Committee from February 28, 2017 were shared with the board. Ms. Cathcart suggested that all funeral home directors be alerted to this potential hazard as well.

**ACTION ITEM:**

**Ms. Juran to share with the executive director of the Board of Funeral Directors and Embalmers Ms. Cathcart's suggestion that they educate their licensees on the importance of having naloxone on-hand for possible accidental overdose due to exposure of potent chemicals on the deceased bodies.**

**MOTION:**

**The Board voted unanimously to amend 18VAC110-20-690, 18VAC110-20-710, 18VAC110-20-735, and Guidance Document 110-44 as presented and to adopt Guidance Document 110-45 as presented (motion by Warriner, second by Allen)**

- Adoption of emergency regulations for controlled substance registration for CSBs for purpose of telemedicine prescribing

The Board reviewed SB1009 and the proposed amendments to 18VAC110-20-690 (F) for a controlled substance registration (CSR) to be issued to a facility participating in telemedicine when there is no DEA registrant on-site with the patient and the facility where the patient is located does not maintain a DEA registration. It was stated that it may be cleaner to require a CSR specifically for this activity and to not allow an existing CSR to be amended for this activity. The CSR will allow the facility to apply for a corresponding DEA registration as a medical clinic. It was suggested that the CSR could have "telemedicine only" printed on the license to indicate that the CSR does not enable the ordering of drugs in Scheduled II-VI from a wholesale distributor, manufacturer, or pharmacy. A separate CSR could be issued for this purpose, if necessary.

**MOTION:**

**The Board voted unanimously to adopt the emergency regulations for controlled substances registrations for the purpose of telemedicine as presented. (motion by Shinaberry, second by Allen)**

- Adoption of amendments to Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers)

The Board is currently undergoing a periodic review of regulations in chapters 20 and 50. In February 2017, the Regulation Committee reviewed suggested amendments to Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers). One suggested edit was offered to the amendments recommended by the Regulation Committee. It was noted that the phrase "A humane society or animal shelter,..." in 18VAC110-20-580 should be changed to "A public or private animal shelter,...." The Regulation Committee will consider suggested amendments to the third and final section of regulations at the May 2017 Regulation Committee meeting. The Board will adopt the proposed regulatory amendments for all of chapters 20 and 50 at its June 2017 full board meeting.

**MOTION:**

**The Board voted unanimously to adopt the amendments to regulations in Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers) as recommended by the Regulation Committee and presented, to include an amendment to the language presented for 18VAC110-20-580 which strikes the term "humane society" in the first sentence and replaces with "public or private animal shelter". (motion by Warriner, second by S. Elliott)**

DIRECTOR'S REPORT:

Dr. Brown spoke to the Board about the recent General Assembly session with regard to the opioid crisis in Virginia. In 2015, 811 Virginians died from an opioid overdose. Final numbers are not in for 2016, however, this number is expected to be over 1100 which is a rise of over 30% in 1 year. These overdoses are due mostly to heroin and illicit fentanyl. He stated 80% of opioid users began abusing drugs with a prescription opioid drug. Many of the bills in this General Assembly focused on addressing this topic. Prescribers must now check PMP for prescriptions given for opioids expected to last more than 7 days. E-prescribing for all opioid prescriptions expected by 2020. Board of Counseling is now beginning to regulate Peer Recovery Specialists which will allow reimbursement for some services in this area. The Department of Health will now begin a needle exchange program to reduce the incidence of hepatitis and HIV. It is believed that an abuser who interacts with representatives at a needle exchange program is more likely to seek help with addiction. Board of Medicine and Board of Dentistry are working to put emergency prescribing regulations in place for opioids and buprenorphine, the most diverted drug in southwest Virginia. There is also a bill that allows approved trainers of the REVIVE! Training program to dispense naloxone free of charge.

- Regulatory update

Ms. Yeatts briefly reviewed the chart of regulatory actions provided in the agenda and gave updates on the status of the regulatory actions in progress.

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| • Legislative update and overview of board of medicine emergency regulations governing prescribing of opioids and buprenorphine | Ms. Yeatts mirrored the sentiments provided in the director's report regarding the legislative update and gave an overview of the new Board of Medicine prescribing regulations for opioids and buprenorphine. |
| • Adoption of guidance document on hours of continuous work and breaks for pharmacists | Staff reviewed the suggested language for guidance for pharmacists taking breaks and hours of continuous work as recommended by the Regulation Committee. |
| **MOTION:** | **The Board voted unanimously to adopt Guidance Document 110-39 as presented for Continuous Hours Worked By Pharmacists and Breaks (motion by Shinaberry, second by S. Elliott)** |
| • Revision of Guidance Document 110-20, practice by a pharmacy technician trainee | The Regulation Committee recommends revising this guidance document to redefine the start time for the allowable nine months of performing duties restricted to a pharmacy technician without holding registration as a pharmacy technician. The committee recommends the nine months begin when the pharmacy trainee starts actually performing the duties of a pharmacy technician trainee. In the past this was determined to be the date when the trainee first enrolled in a board-approved pharmacy technician training program. However, some programs are longer than nine months and the trainee does not begin performing duties restricted to pharmacy technicians until after nine months from enrollment. |
| **MOTION:** | **The Board voted unanimously to amend Guidance Document 110-20, Practice by a Pharmacy Technician Trainee, as presented and recommended by the Regulation Committee. (motion by Saenz, second by Shinaberry)** |
| • Amend Regulation 18VAC110-20-310 to authorize partial filling of Schedule II prescription | Ms. Juran provided the Board with a brief overview of the CARA Act and the effect it had on the changes to partial filling of Schedule II prescriptions. The Regulation Committee reviewed the CARA Act at its meeting in February and requested that staff confer with Board counsel to determine if the language for the various allowances for partial filling of a Schedule II could be consolidated into one subsection. Ms. Juran stated counsel recommends keeping the various allowances in separate subsections which appears to mirror the federal allowances. |
| **MOTION:** | **The Board voted unanimously to adopt a fast-track regulatory amendment of 18VAC110-20-310 by creating a new subsection E authorizing the partial filling of Schedule II prescriptions as indicated in the federal CARA Act. (motion by Allen, second by Boone)** |
| • Amend regulation 18VAC110-20-590, drugs in correctional | At the request of the pharmacist at the Department of Corrections and in consultation with DEA, the Regulation Committee recommends amendments to 18VAC110-20-590 to conform with federal rules that do |

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| facilities | not allow Schedules II-V drugs that were dispensed to specific inmates to be returned to provider pharmacies for destruction. Currently, the regulations require all unused or discontinued drugs to be returned to a provider or secondary pharmacy. The amendment authorizes the destruction of such drugs at the correctional facility. |
| **MOTION:** | **The Board voted unanimously to adopt a fast-track regulatory amendment of 18VAC110-20-590 as recommended by the Regulation Committee to authorize the destruction of patient-specific drugs in Schedules II-V at the correctional facility in order to conform with federal rules. (motion by S. Elliott, second by Saenz)** |
| • Amend Guidance Document 110-9, pharmacy inspection deficiency monetary penalty guide | Staff provided an overview of the proposed changes to Guidance Document 110-9 as recommended by the Regulation Committee. Following discussion, it was determined that the suggested edit to Deficiency 21b should be changed to "Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better." |
| **MOTION:** | **The Board voted unanimously to amend Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide as presented and recommended by the Regulation Committee, with the exception of Deficiency 21b which was amended to read "Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better". (motion by Allen, second by Boone)** |
| • 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. | The Board reviewed two petitions for rulemaking provided in the agenda packet requesting clarifications regarding the use of automated dispensing devices as emergency kits and stat drug boxes and an allowance for a pharmacist to dispense a quantity of certain Schedule VI drugs up to the maximum allowable quantity prescribed, upon request by the patient. In February 2017, the Regulation Committee reviewed and proposed regulations to address the petitions. Ms. Shinaberry provided an additional amendment to subsection B in 18VAC110-20-320 to read "Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for 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." This language intends to clarify the classes of drugs which a pharmacist is not allowed to refill up to the maximum quantity authorized on the prescription. |
| **MOTION:** | **The Board voted unanimously to adopt the following amendments: 18VAC110-20-320** |



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- **Subsection B - following "Schedule VI", change "shall" to "may" and strike "only" and "expressly";**
- **Subsection B – add "Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for 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."**

**18VAC110-20-540**

- **In subsection 2, following "kit" insert "or an automated drug dispensing system, as provided in subsection B of this section,"**
- **Insert new subsection B to read "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**

- **Insert "A" for subsection A**
- **Insert new subsection B that reads ""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**

- **In (2) after "system", insert "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"**
- **Insert 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 (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 Saenz, second by Shinaberry)**

- Consider discontinuing the administration of the Virginia Pharmacy Technician Examination

The Board discussed the Virginia Pharmacy Technician Examination and the possibility of its discontinuation as the current contract with the examination administrator expires August 31, 2017. Mr. Saenz pointed out that 74% of our registered pharmacy technicians hold some type of national certification according to the health practitioner workforce data



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survey. Staff has also contacted the Department of Education to confirm the ability for high school students to partake in both national exams if the Virginia Pharmacy Technician Exam was to be discontinued and board staff was informed that national certification exams would meet their students' needs. Staff would inform key stakeholders of this decision.

**MOTION:**

**The Board voted unanimously to cease administering the Virginia Pharmacy Technician Examination at the completion of the current contract with the examination administrator, August 31, 2017 (motion by Saenz, second by S. Elliott)**

REPORTS

- Report on Board of Health Professions

Mr. Logan gave a brief overview of the Board of Health Professions meeting held on February 23, 2017 in which they discussed several items such as the new Healthcare Workforce Data Survey and sanctioning reference points and disciplinary case overload.

- Report on PMP

Mr. Orr presented information on the legislation in 2017 regarding the PMP. As of January 1, 2017, reporting to PMP within 24 hours of dispensing or the next business day has gone into effect. This General Assembly session, HB 2164 went into effect immediately upon passage, which placed gabapentin as a drug of concern which is now reportable to the PMP. As of January 25, 2017 and effective July 1, 2017, there are new regulations regarding reporting to PMP. There is a new platform for reporting and new required data elements such as the NPI of the prescriber, whether the prescription is a partial fill, a gender code, a species code and the electronic prescription reference number if the Rx is an electronic prescription. Also of note is that Virginia may now access the PMP for Washington DC as they now participate in the PMP interoperability program. In 2017 there were over 1.7 million requests to the PMP and over 66,000 registered users. There is also some integration of the PMP with electronic health records through "NarxCare" technology which will make the step of checking PMP easier for prescribers and pharmacists by integrating the PMP query into the existing workflow. Under a grant awarded by Purdue Pharma, the goal is to improve the performance, access and usability of the PMP program data for 18,000 prescribers and 400 pharmacists in the Commonwealth by the end of 2017.

- Report on Licensure Program

Mr. Johnson reported the Board currently licenses 35,025 individuals and facilities. The Board issued 876 licenses and registrations for the period of December 1, 2016 through February 28, 2017. Inspectors conducted 420 facility inspections including 197 routine inspections of pharmacies:

50 (25%) resulted in no deficiency, 74 (38%) with deficiencies and 73 (37%) with deficiencies and a consent order. Mr. Johnson discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012 and reviewed the most frequently cited deficiencies for the reporting period.

- Report on Disciplinary Program

Ms. Reiniers-Day reported that Pharmacy has a total of 363 cases as of the March 9, 2017, 135 patient care cases and 228 non-patient care cases. A new report charting the number of cases based on priority level was also provided to the board. The report was developed to assist staff with monitoring case management.

- Executive Director's Report

Ms. Juran indicated she did not have a handout for her report as indicated on the agenda. She reported that the Virginia inspectors began using the NABP universal inspection form as of March 2017. Additionally, she indicated she recently emailed letters to Senators Kaine and Warner, at the request of NABP and upon approval of the board chairman, expressing concern for proposed legislation allowing for the use of "Canadian" drugs. She reported that Beth O'Halloran recently presented information on the Drug Control Act to a Chinese Delegation visiting Virginia. Ms. Juran will present at the upcoming VSHP meeting and to students at Appalachian College of Pharmacy in May. Ms. Reiniers-Day has resumed full time work, Ms. Anne Joseph will cease assisting the board in an acting capacity, Ms. Kennia Butler began working for the board as disciplinary administrative assistant in January, and that the board is currently recruiting for an executive assistant. The board's cash balance remains in good condition.

JESSICA LIN SAFFELL

- Registration No: 0230-021805

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

**MOTION:**

**Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Allen, the Board voted 7-0 in favor of the motion that, according to the evidence presented, the continued practice by Jessica Lin Saffell, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Jessica Lin Saffell to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Saffell for the indefinite suspension of her pharmacy technician registration for not less than two years.**

- **CONSIDERATION OF CONSENT ORDER**

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| Closed Meeting: | Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Boone, the Board voted 7-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. |
| Reconvene | The Board voted unanimously that only public business matters lawfully exempt from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting |
| **MOTION:** | **Upon a motion by Ms. Allen and duly seconded by Mr. Saenz, the Board voted 7-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Carter Allen Moore, a pharmacy technician.** |
| ADJOURN: | With all business concluded, the meeting adjourned at 1:48pm. |

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| Ryan Logan, Vice-Chairman | Caroline D. Juran, Executive Director |
| DATE | DATE |

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY

## PUBLIC HEARINGS FOR SCHEDULING CERTAIN SUBSTANCES

March 21, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearings were called to order at 9:08a.m.

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart
Rafael Saenz
Cynthia Warriner
Sheila K. W. Elliott
Jody Allen
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Beth O'Halloran, Individual Licensing Manager

PUBLIC HEARING FOR SCHEDULING OF CERTAIN CHEMICALS

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

Classified as research chemicals:

- 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD)
- 6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD)

Classified as powerful synthetic opioids:

- N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl)
- N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl)
- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl)

Classified as cannabimimetic agents:

- 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006)
- Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22)

Classified as benzodiazepine:

- Flubromazepam

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the 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 (DFS) provided information regarding the 8 chemicals it has identified for the Board's consideration to place into Schedule I. Two of the chemicals are research chemicals, three are powerful synthetic opioids, two are cannabimimetic agents, and one is a benzodiazepine with no accepted medical use in the United States. The chemicals have been identified in the DFS labs across the Commonwealth.

ADJOURN: The public hearing adjourned at 9:11am.

Ryan Logan, Vice-Chairman

Caroline D. Juran, Executive Director

Date

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, March 22, 2017
Commonwealth Conference Center
Second Floor
Hearing Room #5

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Rafael Saenz, Committee Chair

MEMBERS PRESENT: Melvin L. Boone, Sr., Committee Member

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

RX 3
Permit# 0201003685

Christopher K. Currin, Pharmacist-In-Charge, and Nathan Kottkamp, attorney from McGuire Woods, attended the meeting to discuss allegations that RX 3 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2017 Notice.

Closed Meeting: Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of RX 3. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $250 monetary penalty.

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As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on RX 3, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from RX 3 within such time. If service of the Order is made by mail, three (3) additional 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.

CARILION STONEWALL JACKSON HOSPITAL PHARMACY DEPARTMENT
Permit #0201000993

Regina Donald, Pharmacist-In-Charge, attended the meeting to discuss allegations that Carilion Stonewall Jackson Hospital Pharmacy Department may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2017 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Carilion Stonewall Jackson Hospital Pharmacy Department. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee found no violation of law or regulation and therefore no order was issued to Carilion Stonewall Jackson Hospital Pharmacy Department.

HOME I.V. CARE
Permit #0201002399

Wesley Gibbs Hric, Pharmacist-In-Charge, attended the meeting to discuss allegations that Home I.V. Care may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2017 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Home I.V. Care. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $5000 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Home I.V. Care, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Home I.V. Care within such time. If service of the Order is made by mail, three (3) additional 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.

RUSTBURG FAMILY PHARMACY
Permit #0201004144

Edward B. Breslow, Pharmacist-In-Charge, attended the meeting to discuss allegations that Rustburg Family Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2017 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Rustburg Family Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $3000 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Rustburg Family Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Rustburg Family Pharmacy within such time. If service of the Order is made by mail, three (3) additional 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.

APPOMATTOX DRUG STORE
Permit #0201001785

H. Broderick Pack, III, Pharmacist-In-Charge, attended the meeting to discuss allegations that Appomattox Drug Store may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2017 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Appomattox Drug Store. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $1750 monetary penalty. Appomattox Drug Store shall be subject to one unannounced inspection within six months from the date of entry of this Order, at the expense of the licensee, by an inspector of the Department of Health Professions. The inspection shall be conducted during normal business hours and shall include a review of the perpetual inventory.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Appomattox Drug Store, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Appomattox Drug Store within such time. If service of the Order is made by mail, three (3) additional 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 2:30pm

_____
Rafael Saenz, Chair

_____
J. Samuel Johnson, Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY MINUTES
## POSSIBLE SUMMARY SUSPENSION

April 4, 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 the Board of Pharmacy ("Board") was called to order at 9:50a.m.

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody Allen
Michael Boone (via telephone)
Freeda Cathcart
Michael I. Elliott
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

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

POSSIBLE SUMMARY SUSPENSION:

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

CLOSED MEETING: Upon a motion by Ms. Allen, and duly seconded by Ms. Cathcart, 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 this matter. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler 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.

MOTION: No motion was made.

ADJOURN: With all business concluded, the meeting adjourned at 10:53 a.m.

Ryan Logan, Vice Chairman

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF A PANEL OF THE BOARD

April 4, 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 11:08 a.m.

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody Allen
Freeda Cathcart
Michael Elliott
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

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

CHRISTEN REID
Registration No. 0230-019129

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

Mykl Egan, DHP Adjudication Specialist, presented the case with the assistance of James Schliessmann, Senior Assistant Attorney General.

Ms. Reid was not present.

J.W. Turner, DHP Investigator, testified via telephone and Laura Duke, CVS Regional Loss Prevention Manager, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Allen, and duly seconded by Ms. Shinaberry, 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 Christen Reid. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler 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 an open meeting and announced the decision.

DECISION:

Upon a motion by Ms. Allen, and duly seconded by Ms. Cathcart, the panel voted 5-0 to indefinitely suspend Ms. Reid's pharmacy technician registration for not less than two years.

REBECCA HASTY
Registration No.: 0230-017435

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

James Schliessmann, Senior Assistant Attorney General, presented the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Kim Martin, DHP Senior Investigator, testified in person and Michelle Kershaw, CVS Senior Advisor, testified via telephone on behalf of the Commonwealth.

Ms. Hasty testified on her own behalf.

CLOSED MEETING:

Upon a motion by Ms. Allen, and duly seconded by Mr. 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 Rebecca Hasty. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler and Jim Rutkowski attend the closed meeting.

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| 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 an 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 revoke Rebecca Hasty's registration to practice as a pharmacy technician. |
| ADJOURN: | With all business concluded, the meeting adjourned at 4:40 p.m. |

Ryan Logan, Vice Chairman

Cathy Reiniers-Day
Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, April 25, 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 10:00 a.m.

PRESIDING: Cynthia Warriner, Committee Chair

MEMBERS PRESENT: Melvin L. Boone, Sr., Committee Member

STAFF PRESENT: Cathy Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Deputy Executive Director (arriving at 11:00 a.m.)
Beth O'Halloran, Licensing Manager (arriving at 11:00 a.m.)
Mykl D. Egan, DHP Adjudication Specialist
Alina Kilpatrick, DHP Adjudication Specialist

ADRIAN TAYLOR
Registration No. 0230-014159

Adrian Traylor appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the February 9, 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 Adrian Taylor. Additionally, she moved that Cathy Reiniers-Day, Mykl D. Egan and Alina Kilpatrick 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 offer Ms. Taylor a Consent Order for the indefinite suspension of her pharmacy technician registration

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SENTARA HOME INFUSION PHARMACY
Permit No. 0201-003309

Earl Dontel Morris, Pharmacist-in-Charge; Jim Shwamberger, Director of Pharmacy; Lou Di'Orio, LDT Health Systems; and Nathan Kottkamp, their attorney, appeared on behalf of Sentara Home Infusion Pharmacy to discuss allegations that Sentara Home Infusion Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 23, 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 Sentara Home Infusion Pharmacy. Additionally, she moved that Cathy Reiniers-Day, J. Samuel Johnson, Mykl D. Egan and Alina Kilpatrick 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 enter an Order with terms to include the assessment of a monetary penalty.

As provided by law, this decision shall become a final Order 30 days after service of such Order on Sentara Home Infusion Pharmacy, unless a written request is made to the Board within such time from Sentara Home Infusion Pharmacy requesting a formal hearing on the allegations made against it. 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.

HELAL KAKAR
Pharmacy Technician
Registration No. 0230018509

Helal Kakar appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the April 14, 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 § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Helal Kakar. Additionally, he moved that J. Samuel Johnson, Beth O'Halloran, Mykl D. Egan and Alina Kilpatrick 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Adjourn:

The meeting adjourned at 4:00 p.m.

Cynthia Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Date

DRAFT/UNAPPROVED

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF REGULATION COMMITTEE MEETING

May 10, 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 10:06am.

PRESIDING: Ryan Logan, Committee Chairman

MEMBERS PRESENT: Jody H. Allen
Ellen B. Shinaberry
Cynthia Warriner
Freeda Cathcart

NON-VOTING MEMBER PRESENT: Rafael Saenz

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

APPROVAL OF AGENDA: Ms. Yeatts provided a one-page handout to the committee entitled *Report of Regulatory Actions* and requested the committee to include this additional item on the agenda so she may provide a status update of the Board's current regulatory actions.

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

PUBLIC COMMENT: Lauren Schmitt, representing the Virginia Society of Health-System Pharmacists, provided comment on several items in the agenda regarding the periodic regulatory review. VSHP supports the deletion of the random check by a pharmacist for certain robotically picked orders and questioned if this included carousel technology. If so, then VSHP also supports that concept. VSHP also supports changing the wording on page 19 of the agenda packet to "prescriber". Lastly, VSHP supports streamlining 18VAC110-20-490 regarding automated dispensing devices, but also does not take issue with the current wording.



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Pharmacist Gill Abernathy, speaking on her own behalf, provided comment regarding the suggested amendments in the agenda packet for the periodic regulatory review. Ms. Abernathy stated that there is now widespread use of automated dispensing machines and her suggestion is that the regulations may want to be more general, focusing on the security of drugs rather than a specific type of dispensing machine. Ms. Abernathy also stated that the Board may want to consider regulations that address the time allowed for a person to be terminated from access to the dispensing system once a violation is identified and who in an organization may grant access to the devices. Ms. Abernathy also suggested that the Board include language regarding the inventory of controlled substances in that it may not be clear to everyone that even if a pharmacy maintains no controlled substances, they are still required to have an inventory completed. Ms. Abernathy stated that on page 15 of the agenda, item D, may want to separate the last sentence into two sentences to be more concise in the wording. Ms. Abernathy would also like supervision to be clarified in the regulations, specifically for compounding devices and in ensuring product validation.

AGENDA ITEMS:

Report of Regulatory Actions: Ms. Yeatts provided a brief overview of the regulatory actions that are pending for the Board of Pharmacy as indicated on the one-page handout. Several actions have become effective in the past three months and there are four that will become effective in June 2017.

Continue periodic regulatory review by developing draft amendments to Parts VI-VIII, X-XII of *Regulations Governing the Practice of Pharmacy*, Chapter 20 and Parts I-II of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, Chapter 50

The committee discussed the areas of regulations identified during the November 3, 2015 Regulation Committee Meeting for possible amendment (pages A-E of the agenda packet) and the suggested amendments for the periodic regulatory review, as prepared by staff and presented in the agenda packet (pages 7-37). The meeting was suspended at 1pm for a previously scheduled presentation of a possible summary suspension and resumed at 1:55pm.

- 18VAC110-20-10 — The committee recommended that the definition for "robotic pharmacy system" be clarified to include intravenous (IV) admixture robotics.
- 18VAC110-20-20 — The committee recommended striking the fees for humane society permits as the board no longer issues this type of permit.
- 18VAC110-20-50 — The committee offered no amendments at this time.
- 18VAC110-20-112 — Committee recommends moving the current language in 18VAC110-20-270 A and B into a new section 18VAC110-20-112 so to include this requirement affecting individuals in chapter 20, instead of the proposed new chapter 21 affecting pharmacy facilities. Additionally, the

committee recommends changing the word "acting" in subsection A to "performing duties".

- 18VAC110-20-240 — Committee agreed with the suggested amendments as presented in the agenda packet with the following exceptions: consider inserting a reference to 18VAC110-20-286 in subsection C; and, clarify that the procedures stated in subsection C, 1, b must be followed.

- 18VAC110-20-270 — Amendments considered by the committee include: separating subsections A and B from the rest of this regulation and creating a new section 18VAC110-20-112; in current subsection E change the wording from "shall" to "may" with regard to returning a prescription that is fraudulent; and, adding language from Guidance Document 110-32 regarding the use of drop boxes into a new subsection G, but editing the last sentence to regulate pharmacists and not the consumer with regard to leaving containers which contain drug or drugs in the drop box. It was suggested the language should state "pharmacists shall inform patients not to leave unused drugs" in the drop box. Regarding the second bullet on page B of the agenda packet, "Addressing concerns in subsection B by VPhA with pharmacists not being provided adequate support", the committee agreed that this should not be handled with a regulatory change, but rather handled at the corporate level. It was noted that VPhA did not offer the Board specific language for amending the regulation. The requirement for a pharmacy to pull the originally filled prescription and refile it when on-hold was already addressed in a previous regulatory action.

- 18VAC110-20-275 — The committee recommended no amendments to this section until it received the results of the NABP study on white/brown bagging and consider possible amendments at that time. No recommendations were considered for further clarifying this regulation.

- 18VAC110-20-277 — It was recommended in November 2015 that a new regulation 18VAC110-20-277 be created to clarify that all prescriptions unless electronically transmitted, must include manual signature, and a quantity or duration of treatment. The committee decided that this information was best addressed in 18VAC110-20-270.

- 18VAC110-20-280 — Committee agreed with the amendment as presented to insert "manual" into subsections B and D. No additional amendments were offered for this section as it was discussed that the long term care provider pharmacies originally requested the allowance in 18VAC110-20-280 A, 4, C and that staff was not aware of any request to remove the allowance.

- 18VAC110-20-290 — An amendment considered by the committee was to include language from Guidance Document 110-41 regarding changes a pharmacist may make to a Schedule II prescription. The committee agreed with the suggested amendment in concept, but requested staff to clarify the language in the last sentence.

- 18VAC110-20-355 — The committee discussed the suggested amendment in subsection A and suggested changing it to read "or other unique identifier" to identify the pharmacist who verified the accuracy of the process. Committee also agreed to include a requirement in a new subsection C to require repackaging to be performed in compliance with USP-NF standards.

- 18VAC110-20-425 — The committee discussed streamlining the robotic pharmacy regulations by: striking the requirement in subsection 5 for a 5% random check of all dispensed drugs from a robotic pharmacy system; changing 7 to remove requirement for reporting to board and instituting a manual check of all doses or compliance packages, but recommended requiring a manual check of all affected doses or compliance packages, require performance of a root cause analysis, and compliance with policies and procedures prior to resuming operations of the device for the affected drug; striking 8 b, c, and d; addressing downtime in policies and procedures; focusing oversight on the front end of the process with packaging and assignment of bar codes to ensure accuracy; and, clarify expectation for complying with any policy and procedures.

- 18VAC110-20-470 — The committee supported the amendment in subsection 2 to change the word "practitioner" to "prescriber".

- 18VAC110-20-490 — Amendments supported by the committee included: adding the word "ensuring" to subsection C, 2 wherein the pharmacist is responsible for ensuring reconciliation of the discrepancy or reporting of the loss; subsection D, 1, adding language to allow for the record to maintained electronically; subsection E, included an amendment to clarify that the requirement for discrepancy reports are for Schedule II-V drugs and drugs of concern; subsection F, 3, included an amendment to state that the PIC or designee shall conduct at least a monthly audit to "review dispensing and administration records" of Schedule II-V drugs; and subsection F, 3, a, the word "from" was recommended to be changed to "for".

- 18VAC110-20-530 — The committee supported the amendment to create a new subsection B as presented in the agenda packet to allow a pharmacy providing services to a long term care facility to provide prescription information of Schedule VI drugs to a back-up pharmacy without constituting the need for transferring the prescription, with the following exception: in subsection B, 1, after "to be provided" insert ", recordkeeping associated with the dispensing,". The committee concluded amendments to 18VAC110-20-530 sufficiently addressed the issue and amendments to 18VAC110-20-515 and 18VAC110-20-360 were not necessary.

- 18VAC110-20-550 — The committee supported the following amendments as presented: clarifying in subsection 5, b that the allowance for substituting one unit of liquid for a solid dosage form is allowable for each drug schedule, and that a pharmacy may provide a facility with more than one stat-drug box and that the contents of the multiple boxes do not need to be uniform.

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| • 18VAC110-20-555 | The committee concluded that 18VAC110-20-490 should remain as written, with the following exception: The first sentence should be amended to also include residential facilities licensed by the Department of Behavioral Health and Developmental Services and hospice programs licensed by the Virginia Department of Health wherein only licensed nurses, pharmacists, or prescribers are administering drugs. |
| • 18VAC110-50-40 | The committee supported an amendment to subsection B, 2 as presented, with the following exception: the beginning word in the sentence, "The", should be changed to "One". During discussions, the committee also agreed that a hard-wired communication line would include a Voice over Internet Protocol (VoIP) communication method. The committee supported an additional amendment in subsection B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. |
| • 18VAC110-50-60 | An amendment was supported by the committee as presented to expand the ability to issue a limited-use permit for certain entities. |
| • 18VAC110-50-70 | The committee did not recommend amending this regulation as the information from Guidance Document 110-34 regarding the submission of a social security number or control number has already been addressed in a previous regulatory action. |
| • 18VAC110-50-80 | The committee supported an amendment to require a federal criminal history check, not simply a criminal history record check through the Virginia criminal records as this database generally would not have information on individuals associated with non-resident facilities. |
| • 18VAC110-20-70 through 18VAC110-20-140 | The committee concluded additional amendments to 18VAC110-20-70 through 18VAC110-20-140 to require similar requirements for manufacturers were not needed at this time as the risk for introducing counterfeit drugs into the supply chain does not appear as high with manufacturers as it is with other types of facilities. |

**ACTION ITEM:** **Staff to amend 18VAC110-20-425, as referenced in this document, and the definition of robotic pharmacy system in 18VAC110-20-10 to include carousels and intravenous (IV) admixture robotics and present to the full Board for consideration at the June full board meeting.**

**MOTION:** **As part of the periodic regulatory review, the committee voted unanimously to recommend to the full board to amend regulations in Parts VI-VIII, X-XII of *Regulations Governing the Practice of Pharmacy*, Chapter 20 and Parts I-II of *Regulations Governing Wholesale Distributors, Manufacturers and Warehousers,* Chapter 50**

**as summarized in this document. (motion by Warriner, second by Allen)**

Legislative Proposal for dispensed Schedule V drugs to be reported to the Prescription Monitoring Program

The committee reviewed a legislative proposal for requiring dispensers to report the dispensing of Schedule V drugs to the Prescription Monitoring Program. An identical recommendation was adopted by the Board in June 2016, but legislation was not advanced to the General Assembly.

**MOTION:**

**The committee voted unanimously to recommend to the full board that it request the Prescription Monitoring Program advance a legislative proposal to amend the definition of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances (motion by Allen, second by Warriner).**

ADJOURN:

With all business concluded, the meeting adjourned at approximately 2:53 pm.

**Ryan Logan, Chairman**

**Caroline D. Juran, Executive Director**

**DATE**

**DATE**

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# VIRGINIA BOARD OF PHARMACY
# SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, May 30, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

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

| | |
|---|---|
| PRESIDING: | Michael Elliott, Committee Chair |
| MEMBERS PRESENT: | Jody Allen, Committee Member |
| STAFF PRESENT: | Cathy Reiniers-Day, Deputy Executive Director<br>J. Samuel Johnson, Deputy Executive Director (arrived at 2:00 p.m.)<br>Mykl D. Egan, DHP Adjudication Specialist<br>Alina Kilpatrick, DHP Adjudication Specialist |
| Mary Grimes<br>License Number 0202-205800 | Mary Grimes appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 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 Mary Grimes. Additionally, she moved that Cathy Reiniers-Day, Mykl D. Egan and Alina Kilpatrick 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. |

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| Decision: | Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to issue an Order that Ms. Grimes must obtain one hour of continuing education in the subject of medication errors. |
| Rozano Ronase<br>Registration Number 0230-018705 | Rozano Ronase did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Ronase's legal address of record. |
| 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 Rozano Ronase. Additionally, she moved that Cathy Reiniers-Day, Mykl D. Egan and Alina Kilpatrick 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 to dismiss this matter. |
| Mohand Elsayed Younes<br>License Number 0202-207047 | Mohand Elsayed Younes appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2017 Notice. |

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| 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 Mohand Elsayed Younes. Additionally, she moved that Cathy Reiniers-Day, Mykl D. Egan and Alina Kilpatrick 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 to reprimand Mr. Younes. |
| Hailu Tekleslassie Wakjera<br>License Number 0202-206385 | Hailu Tekleslassie Wakjera did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Wakjera's legal address of record. |

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| 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 Hailu Tekleslassie Wakjera. Additionally, she moved that Cathy Reiniers-Day, Mykl D. Egan and Alina Kilpatrick 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 that Ms. Wakjera must obtain four hours of continuing education in the subject of medication errors. |
| Anthony Oley<br>License Number 0202-006078 | Anthony Oley appeared with Christopher Bain, his attorney to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the March 15, 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 Anthony Oley. Additionally, she moved that Cathy Reiniers-Day, J. Samuel Johnson, Mykl D. Egan and Alina Kilpatrick attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |

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| 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 to dismiss this matter. |
| Cedarfield Pharmacy<br>Permit Number 0201-003348 | Anthony Oley, the PIC and Christopher Bain, it's attorney, appeared on behalf of Cedardfield Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 15, 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 Cedardfield Pharmacy. Additionally, she moved that Cathy Reiniers-Day, J. Samuel Johnson, Mykl D. Egan and Alina Kilpatrick 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. |

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| Decision: | Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to issue an Order imposing a monetary penalty. |
| Timothy Oley<br>License Number 0202-212095 | Timothy Oley appeared with Christopher Bain, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 15, 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 Timothy Oley. Additionally, she moved that Cathy Reiniers-Day, J. Samuel Johnson, Mykl D. Egan and Alina Kilpatrick 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 to dismiss this matter. |
| Family Care Pharmacy<br>Permit Number 0201-003368 | Timothy Oley, the PIC and Christopher Bain, it's attorney, appeared on behalf of Family Care Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 15, 2017 Notice. |

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| 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 Family Care Pharmacy. Additionally, she moved that Cathy Reiniers-Day, J. Samuel Johnson, Mykl D. Egan and Alina Kilpatrick 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 imposing a monetary penalty. |
| ADJOURN: | With all business concluded, the meeting adjourned at 6:32 p.m. |

_____
Michael Elliott, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

_____
Date

# Board of Pharmacy

## Chart of Regulatory Actions as of June 8, 2017

**Board** **Board of Pharmacy**

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Controlled substances registration for nalozone and teleprescribing [Action 4789]<br>Emergency/NOIRA - *Register Date: 5/29/17*<br>*Emergency effective: 5/8/17* |
| [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]<br>NOIRA - *Register Date: 7/11/16*<br>*Adoption of proposed: 6/27/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Response to petitions for rulemaking [Action 4694]<br>Proposed - *At Governor's Office for 2 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Drug destruction in correctional facilities [Action 4788]<br>Fast-Track - *At Governor's Office for 19 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Partial fill of Schedule II drugs [Action 4790]<br>Fast-Track - *At Governor's Office for 19 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Scheduling of chemicals [Action 4787]<br>Final - *Register Date: 5/15/17*<br>*Effective: 6/14/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Outsourcing facilities [Action 4452]<br>Final - *Register Date: 5/29/17*<br>*Effective: 6/28/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>Final - *At Governor's Office for 2 days* |
| [18 VAC 110 - 30] | Regulations for Practitioners of the Healing Arts to Sell Controlled Substances | Permits for facilities [Action 4451]<br>Final - *Register Date: 5/29/17*<br>*Effective: 6/28/17* |
| [18 VAC 110 - 50] | Regulations Governing Wholesale Distributors, Manufacturers and Warehousers | Permitting of third party logistics providers and registration of nonresident manufacturers [Action 4678]<br>Fast-Track - *Register Date: 5/15/17*<br>*Effective: 6/29/17* |

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|---|---|---|
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors [Under development] | New regulations [Action 4695]<br>Emergency/NOIRA - *At Governor's Office for 19 days* |

**Summary of regulations for Opioid Prescribing and Prescribing of Buprenorphine for Addiction**
**(Doctors of Medicine, Osteopathic Medicine, and Podiatry; Physician Assistants; Nurse Practitioners)**

**Acute Pain**

- Treatment with opioids for acute pain must be with short-acting opioids, and for a seven-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- Treatment with opioids as part of treatment for a surgical procedure must be for a fourteen-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- An appropriate history and examination must be performed, including a check of the PMP in accordance with state law.
- Morphine Milligram Equivalent (MME) should be considered, and naloxone must be co-prescribed if the MME exceeds 120 MME/day. There is a link to the CDC calculator for MME on the Board of Medicine webpage.

**Chronic Pain**

- An appropriate history and examination must be performed, as detailed in the regulations.
- The practitioner must discuss risks, benefits, proper storage and disposal with the patient.
- Naloxone must be prescribed for any patient when one or more of the following risk factors is present: prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine.
- Urine drug screen or serum medication levels shall be conducted 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.

In addition, Part IV of these regulations covers the treatment of addiction with buprenorphine. Medication Assisted Treatment (MAT) is an essential part of recovery for many individuals but unfortunately the mono-product form (Subutex) is increasingly being diverted and abused. Key provisions of the buprenorphine regulations include:

- Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate Drug Enforcement Administration registration.
- Buprenorphine without naloxone (ie, the mono-product) shall only be prescribed when a patient is pregnant, when converting a patient from methadone, and in formulations other than tablet form for indications approved by the FDA.

**Additions to emergency regulations to be considered by Board of Medicine on June 22, 2017:**

1) Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

2) Additional exception for prescribing buprenorphine mono-product:

For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

**Summary of regulations for Opioid Prescribing – Dentistry (effective 4/24/17)**

**Acute pain** – same as Medicine

**Chronic pain** – required to either refer the patient to a doctor who is a pain specialist or follow Board of Medicine regulations for prescribing opioids for chronic pain

**Summary of regulations for Opioid Prescribing – Veterinary Medicine (not yet effective)**

- Shall not exceed a seven-day supply, unless extenuating circumstances are clearly documented in the patient's record. May prescribe a controlled substance for an additional seven days if medically necessary and consistent with an appropriate standard of care, and after a re-evaluation of the patient as documented in the patient record.
- May prescribe a controlled substance beyond 14 days for management of certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea or related conditions. For treatment of chronic pain or a chronic condition with an opioid beyond 14 days, the treatment plan shall include measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with physical impairment. For any prescribing of a controlled substance beyond 14 days, the patient shall be seen and re-evaluated at least every six months, and the justification for such prescribing documented in the patient record.
- Prescribing of buprenorphine for out-patient administration is allowed under certain conditions & in accordance with standard of care.

**Agenda Item: Adoption of Regulation to Schedule certain chemicals in Schedule I of the Drug Control Act**

**Staff Note:**

There was a Public Hearing conducted at 9:00 this morning pursuant to requirements of § 54.1-3443 of the Drug Control Act.

**Included in your packet:**

Notice of hearing and request for comment (none received)

Copy of regulation to schedule certain chemicals

Copy of HB1610 – placement of chemicals by legislative action; deletion in regulation

**Board action:**

Adoption of amendments to section 18VAC110-20-322 for placement of chemicals in Schedule I and deletion of subsections listing chemicals scheduled by action of the 2017 General Assembly. Action to be filed after July 1, 2017. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

# 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 June 27, 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 June 13, 2017 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

The Virginia Department of Forensic Science (DFS) has identified three (3) compounds for recommended inclusion into the Code of Virginia. A brief description and chemical name for each compound is as follows:

**The following compound is classified as a research chemical. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.**

1. **4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH)**, 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 compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(7)) in previous legislative sessions.**

2. **Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA )**, 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 a powerful synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

3. **N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran 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.

**Project 5166 - none**

## BOARD OF PHARMACY

## Chemicals in Schedule I

### 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.

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. 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 December 31, 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. 4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH), 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. Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA ), 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.

3. N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran 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 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.

# VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

## CHAPTER 414

*An Act to amend and reenact § 54.1-3446 of the Code of Virginia, relating to Drug Control Act; Schedule I drugs; addition of substances.*

[H 1610]

Approved March 13, 2017

**Be it enacted by the General Assembly of Virginia:**

**1. That § 54.1-3446 of the Code of Virginia is amended and reenacted as follows:**

**§ 54.1-3446. Schedule I.**

The controlled substances listed in this section are included in Schedule I:

1. Any of the following opiates, including their 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:

*1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP);*

*1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP);*

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

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

*Acetyl fentanyl (other name: desmethyl fentanyl);*

Acetylmethadol;

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

Betacetylmethadol;

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetylbutyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Morpheridine;

*N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl);*

*N-[1-(1-methyl-2-phenylethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl);*

*N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl);*

*N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine, alpha-methylfentanyl);*

*N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);*

*N-[3-methyl-1-(2-hydroxy-2-phenylethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl);*

*N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl);*
*N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);*
*N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl);*
*N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl);*
Noracymethadol;
Norlevorphanol;
Normethadone;
Norpipanone;
*N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);*
*N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl);*
*N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);*
*N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl);*
Phenadoxone;
Phenampromide;
Phenomorphan;
Phenoperidine;
Piritramide;
Proheptazine;
Properidine;
Propiram;
Racemoramide;
Tilidine;
Trimeperidine.

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:
Acetorphine;
Acetyldihydrocodeine;
Benzylmorphine;
Codeine methylbromide;
Codeine-N-Oxide;
Cyprenorphine;
Desomorphine;
Dihydromorphine;
Drotebanol;
Etorphine;
Heroin;
Hydromorphinol;
Methyldesorphine;
Methyldihydromorphine;
Morphine methylbromide;
Morphine methylsulfonate;
Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Pholcodine;
Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):
Alpha-ethyltryptamine (some trade or other names: Monase;a-ethyl-1H-indole-3-ethanamine; 3-2-aminobutyl] indole; a-ET; AET);
4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-4-bromo-2,5-dimethoxyphenyl]-1-aminoethane;alpha-desmethyl DOB; 2C-B; Nexus);
3,4-methylenedioxy amphetamine;
5-methoxy-3,4-methylenedioxy amphetamine;
3,4,5-trimethoxy amphetamine;
Alpha-methyltryptamine (other name: AMT);

Bufotenine;
Diethyltryptamine;
Dimethyltryptamine;
4-methyl-2,5-dimethoxyamphetamine;
2,5-dimethoxy-4-ethylamphetamine (DOET);
2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);
Ibogaine;
5-methoxy-N, N-diisopropyltryptamine (other name: 5-MeO-DIPT);
Lysergic acid diethylamide;
Mescaline;
Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo -b, d] pyran; Synhexyl);
Peyote;
N-ethyl-3-piperidyl benzilate;
N-methyl-3-piperidyl benzilate;
Psilocybin;
Psilocyn;
Salvinorin A;
Tetrahydrocannabinols, except as present in marijuana and dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration;
Hashish oil (some trade or other names: hash oil; liquid marijuana; liquid hashish);
2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);
3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;
3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);
N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);
4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);
4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);
Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);
Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl) -pyrrolidine, PCPy, PHP);
Thiophene analog of phencyclidine (some other names: 1-/1-(2-thienyl) -cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);
1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);
3,4-methylenedioxypyrovalerone (other name: MDPV);
4-methylmethcathinone (other names: mephedrone, 4-MMC);
3,4-methylenedioxymethcathinone (other name: methylone);
Naphthylpyrovalerone (other name: naphyrone);
4-fluoromethcathinone (other name: flephedrone, 4-FMC);
4-methoxymethcathinone (other names: methedrone; bk-PMMA);
Ethcathinone (other name: N-ethylcathinone);
3,4-methylenedioxyethcathinone (other name: ethylone);
Beta-keto-N-methyl-3,4-~~benzodioxyolybutanamine~~ *benzodioxolylbutanamine* (other name: butylone);
N, N-dimethylcathinone (other name: metamfepramone);
Alpha-pyrrolidinopropiophenone (other name: alpha-PPP);
4-methoxy-alpha-pyrrolidinopropiophenone (other name: MOPPP);
3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (other name: MDPPP);
Alpha-pyrrolidinovalerophenone (other name: alpha-PVP);
6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (other name: MDAI);
3-fluoromethcathinone (other name: 3-FMC);
4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E);
4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I);
4-Methylethcathinone (other name: 4-MEC);
4-Ethylmethcathinone (other name: 4-EMC);
N, N-diallyl-5-methoxytryptamine (other name: 5-MeO-DALT);
Beta-keto-methylbenzodioxolylpentanamine (other name: Pentylone, bk-MBDP);
Alpha-methylamino-butyrophenone (other name: Buphedrone);
Alpha-methylamino-valerophenone (other name: Pentedrone);

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3,4-Dimethylmethcathinone (other name: 3,4-DMMC);
4-methyl-alpha-pyrrolidinopropiophenone (other name: MPPP);
4-Iodo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 25-I, 25I-NBOMe, *2C-I-NBOMe*);
Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE);
4-Fluoromethamphetamine (other name: 4-FMA);
4-Fluoroamphetamine (other name: 4-FA);
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (other name: 2C-D);
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C);
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-2);
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-4);
2-(2,5-Dimethoxyphenyl)ethanamine (other name: 2C-H);
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 2C-N);
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (other name: 2C-P);
(2-aminopropyl)benzofuran (other name: APB);
(2-aminopropyl)-2,3-dihydrobenzofuran (other name: APDB);
4-chloro-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-C-NBOMe, 25C-NBOMe, *25C*);
4-bromo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-B-NBOMe, 25B-NBOMe, *25B*);
Acetoxydimethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);
Benocyclidine (other names: BCP, BTCP);
Alpha-pyrrolidinobutiophenone (other name: alpha-PBP);
3,4-methylenedioxy-N, N-dimethylcathinone (other names: Dimethylone, bk-MDDMA);
4-bromomethcathinone (other name: 4-BMC);
4-chloromethcathinone (other name: 4-CMC);
4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25I-NBOH);
Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP);
Alpha-Pyrrolidinoheptiophenone (other name: PV8);
*5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT);*
*Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);*
*1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);*
*1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);*
*1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);*
*4-Chloroethcathinone (other name: 4-CEC);*
*3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);*
*1-propionyl lysergic acid diethylamide (other name: 1P-LSD);*
*(2-Methylaminopropyl)benzofuran (other name: MAPB).*

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including 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:
*Clonazolam;*
*Etizolam;*
*Flubromazolam;*
Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);
Mecloqualone;
Methaqualone.
~~Etizolam.~~

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:
*2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine);*
Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine);
~~N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);~~
~~Fenethylline;~~
~~Ethylamphetamine;~~
Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;
*Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);*
*Ethylamphetamine;*
*Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);*

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*Fenethylline;*

Methcathinone (some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)-propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432);

~~Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);~~

*N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);*

N, N-dimethylamphetamine (other names: N, N-alpha-trimethyl-benzeneethanamine, N, N-alpha-trimethylphenethylamine).

6. ~~Any material, compound, mixture or preparation containing any quantity of the following substances:~~

~~N-3-methyl-1-(2-phenethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl), its optical and geometric isomers, salts, and salts of isomers;~~

~~1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP), its optical isomers, salts and salts of isomers;~~

~~1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP), its optical isomers, salts and salts of isomers;~~

~~N-1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl] propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine), alpha-methylfentanyl);~~

~~N-1-(1-methyl-2-phenethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl), its optical isomers, salts and salts of isomers;~~

~~N-1-(1-methyl-2-2-thienyl)ethyl-4 piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl), its optical isomers, salts and salts of isomers;~~

~~N-1-benzyl-4-piperidyl]N-phenylpropanamide (other name: benzylfentanyl), its optical isomers, salts and salts of isomers;~~

~~N-1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl), its optical isomers, salts and salts of isomers;~~

~~N-3-methyl-1-(2-hydroxy-2-phenethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers;~~

~~N-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl), its optical and geometric isomers, salts and salts of isomers;~~

~~N-1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (other name: thienylfentanyl), its optical isomers, salts and salts of isomers;~~

~~N-phenyl-N-1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl), its optical isomers, salts and salts of isomers;~~

~~N-(4-fluorophenyl)-N-1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl), its optical isomers, salts and salts of isomers;~~

~~Acetyl fentanyl (other name: desmethyl fentanyl).~~

~~7.~~ Any substance that contains one or more cannabimimetic agents or that contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of one or more cannabimimetic agents.

a. "Cannabimimetic agents" includes any substance that is within any of the following structural classes:

2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent;

3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent;

3-(1-naphthoyl)pyrrole with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent;

1-(1-naphthylmethyl)indene with substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent;

3-phenylacetylindole or 3-benzoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent;

3-cyclopropoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the cyclopropyl ring to any extent;

3-adamantoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent;

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N-(adamantyl)-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent; and

N-(adamantyl)-indazole-3-carboxamide with substitution at a nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent.

b. The term "cannabimimetic agents" includes:

5-(1,1-Dimethylheptyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497);

5-(1,1-Dimethylhexyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C6 homolog);

5-(1,1-Dimethyloctyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C8 homolog);

5-(1,1-Dimethylnonyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C9 homolog);

1-pentyl-3-(1-naphthoyl)indole (other names: JWH-018, AM-678);

1-butyl-3-(1-naphthoyl)indole (other name: JWH-073);

1-pentyl-3-(2-methoxyphenylacetyl)indole (other name: JWH-250);

1-hexyl-3-(naphthalen-1-oyl)indole (other name: JWH-019);

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (other name: JWH-200);

(6aR, 10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a, 7,10,10a-tetrahydrobenzo[c]chromen-1-ol (other name: HU-210);

1-pentyl-3-(4-methoxy-1-naphthoyl)indole (other name: JWH-081);

1-pentyl-3-(4-methyl-1-naphthoyl)indole (other name: JWH-122);

1-pentyl-3-(2-chlorophenylacetyl)indole (other name: JWH-203);

1-pentyl-3-(4-ethyl-1-naphthoyl)indole (other name: JWH-210);

1-pentyl-3-(4-chloro-1-naphthoyl)indole (other name: JWH-398);

1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (other name: AM-694);

1-((N-methylpiperidin-2-yl)methyl)-3-(1-naphthoyl)indole (other name: AM-1220);

1-(5-fluoropentyl)-3-(1-naphthoyl)indole (other name: AM-2201);

1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole (other name: AM-2233);

Pravadoline (4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (other name: WIN 48,098);

1-pentyl-3-(4-methoxybenzoyl)indole (other names: RCS-4, SR-19);

1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (other names: RCS-8, SR-18);

1-pentyl-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: UR-144);

1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other ~~name~~ *names*: XLR-11, *5-fluoro-UR-144*);

N-adamantyl-1-fluoropentylindole-3-carboxamide (other name: STS-135);

N-adamantyl-1-pentylindazole-3-carboxamide (other ~~name~~ *names*: AKB48, *APINACA*);

1-pentyl-3-(1-adamantoyl)indole (other name: AB-001);

(8-quinolinyl)(1-pentylindol-3-yl)carboxylate (other name: PB-22);

(8-quinolinyl)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);

(8-quinolinyl)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide (other name: AB-FUBINACA);

1-(5-fluoropentyl)-3-(1-naphthoyl)indazole (other name: THJ-2201);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AB-PINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);

Methyl-2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);

1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);

1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);

1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (other name MAM-2201);

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

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

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

*Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other*

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*names: AMB-FUBINACA, FUB-AMB);*
*N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)*
*N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);*
*Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005);*
*N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA).*

**Agenda Item: Adoption of proposed amendments to complete Periodic Review of Chapters 20 and 50**

**Included in your agenda package is:**

Copy of sections reviewed by Regulation Committee on 5/10/17

A copy of comment on the NOIRA

**Staff note:**

A Notice of Periodic Review was published; 2 comments were received

A Notice of Intended Regulatory Action was published with comment from 7/11/16 to 8/10/16

The Regulation Committee reviewed regulations by sections and amendments adopted by the Board on the following dates:

| | |
|---|---|
| Committee: 11/29/16 | Board: 12/12/16 |
| Committee: 2/28/17 | Board: 3/21/17 |
| Committee: 5/10/17 | |

**Board action:**

1) To amend the sections of Chapter 20 and Chapter 50 as recommended by the Regulation Committee and presented in your agenda package or as amended by the Board.

2) To propose adoption of:

Chapter 16. Regulations Governing the Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate

Chapter 25. Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians

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VIRGINIA REGULATORY TOWN HALL

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:** Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25

Edit Action | Withdraw Action

## General Information

| | |
|---|---|
| **Action Summary** | The Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 25, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, Criteria for delegation of informal fact-finding proceedings to an agency subordinate, will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board. Amendments are being considered for Chapters 20 and 50 to address current issues with practice, to clarify certain requirements, and to incorporate provisions currently found in guidance documents. The intent is to update the regulations and to streamline requirements where possible. |

**Chapters Affected**

| | VAC | Chapter Name | Action Type |
|---|---|---|---|
| Primary | **18 VAC 110-20** | Regulations Governing the Practice of Pharmacy | Amend Existing Regulation |
| Other chapters | | | |
| | **18 VAC 110 - 16** | Regulations Governing the Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate [under development] | Promulgate New Regulation |
| | **18 VAC 110 - 25** | Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [under development] | Promulgate New Regulation |

| | |
|---|---|
| **Exempt from APA** | No, this action is subject to the *Administrative Process Act* and the standard executive branch review process. |
| **RIS Project** | Yes [004673] |
| **Associated Periodic Review** | **11/3/2015** |

## Stages

Stages associated with this regulatory action.

| Stage ID | Stage Type | Status |
|---|---|---|

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| | | |
|---|---|---|
| 7514 | NOIRA | Stage complete. Comment period ended 8/10/2016. |

**Create a new stage for this action** .. Create Stage

For guidance please see the following sections of our user guide:

**What type of regulatory action do I file?** **Flow charts of the regulatory process**

**Contact Information**

| | |
|---|---|
| **Name / Title:** | Caroline Juran, RPh / *Executive Director* |
| **Address:** | 9960 Mayland Drive<br>Suite 300<br>Richmond, VA 23233-1463 |
| **Email Address:** | caroline.juran@dhp.virginia.gov |
| **Phone:** | (804)367-4416 FAX: (804)527-4472 TDD: ()- |

*This person is the primary contact for this chapter.*

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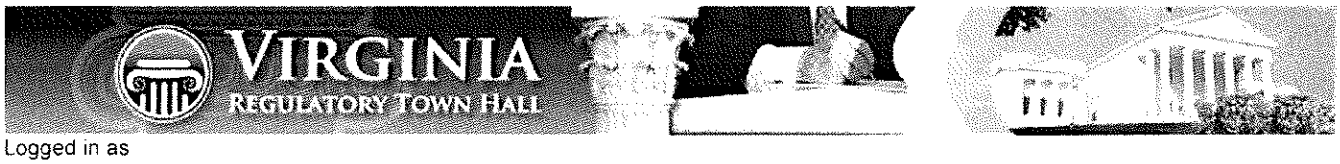


Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

| | |
|---|---|
| **Action** | Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 |
| **Stage** | NOIRA |
| **Comment Period** | Ends 8/10/2016 |

**All good comments for this forum** Show Only Flagged

Back to List of Comments

**Commenter:** Dale StClair, PharmD (Remedi SeniorCare) 8/9/16 4:12 pm

**NOIRA 18VAC110-20-240**

This comment is being made in regards to the Notice of Intended Regulatory Action posted regarding changes to VAC 18VAC110-20-10 et seq. Specifically as outlined, the proposed update to 18VAC110-20-240 "Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment." Currently Virginia regulations do not specifically require a quantity on any prescription regardless of it being considered a "Chart Order". The Board has already addressed this issue in Guidance Document 110-35 "While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances." Therefore, Remedi SeniorCare does not feel the proposed changes referenced above are necessary.

**Commenter:** Travain Sutphin, Pharm.D. 8/10/16 1:19 pm

**NOIRA 18VAC110-20-240**

This comment is being made regarding changes to 18VAC110-20-240 subsection C clarifying that chart order used in long term care facilities must include a quantity or duration of therapy. As a general rule, the current pharmacy practice for the skilled nursing setting uses chart orders in the form of 1) admission order/MD Plan of Care, or 2) individual chart orders (verbal orders). Most often the nurse contacts the Physician verbally to receive admission orders.

When the pharmacy dispenses the medications, the qty is generally driven by the payor source; shortened days supply for Medicare Part A Skilled residents and a full month supply for Medicare Part D or third party payer residents. Continual clinical oversight for medications is routinely occuring in the skilled facility settings. The skilled facility resident has licensed nursees monitoring

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the patients and there is a Consultant RPh reviewing medications monthly. The Physician also performs routine reviews through the recertification process (which could be monthly, every 3 or every 6 months) which are sent to the pharmacy with the physician signature once he has completed the review. The medication order is considered an active order until the pharmacy receives an order to modify or discontinue the order, or the patient is discharged from the LTC setting.

If this revision is adopted, admission orders received in the pharmacy without a qty or duration stipulated, will result in a delay of processing the medications until the requirements are met. The same would be true for ongoing orders or if new or changed orders were sent to the pharmcy without requirements. This has the potential to significantly delay therapy to residents, whom may have just been discharged from the hospital. This not only has the potential for significant harm to the patients, but it also has implications for the facility in regards to Federal CMS regulations specifically the following Federal Tags: F425 (Medication Availability is a recurring issues), F332 (Charting omissions/Med Errors per documetation/audit). This may also effect the CMS reimbursement and Five-Star Quality program ratings for the facility.

I would request that the board continue to allow Long Term Care pharmacies the use of chart orders without the requirement of quantity or duration of therapy, like hospitals and hospice programs, whom we are currently not facing this change. If you have any additional questions, please do not hesitate to contact me.

**Commenter:** Steve Ford, VHCA 8/10/16 4:04 pm

**Comment on NOIRA**

Please accept these comments to the NOIRA stage for the periodic review of pharmacy regulations on behalf of the Virginia Health Care Association-Virginia Center for Assisted Living (VHCA-VCAL), our members' 30,000 employees, and the 29,000 residents served in our over 280 nursing centers and assisted living facilities. VHCA-VCAL is proud of our role as the Commonwealth's largest association representing long term care. Our strength, effectiveness, and integrity are significantly enhanced by the diversity of our membership, which includes proprietary, non-profit, and government-operated facilities dedicated to providing the highest quality of care.

As this is only a NOIRA, it is difficult to interpret precisely what the Board intends to change. However, VHCA-VCAL wants to express our general concern that any changes made to 18VAC110-20-240 do not diminish the fact that chart orders remain a valid prescribing method and that regulatory changes do not obstruct the availability/timeliness of medications nor staff resources for direct clinical care of nursing facility residents and patients. As you are aware, regulations already require periodic order review for nursing facility residents which reconfirm any continued need for medication(s).

Thank you for the opportunity to comment. Please direct any questions to Steve Ford, SVP, Policy and Reimbursement, at steve.ford@vhca.org or (804) 212-1695.

**Commenter:** H. Otto Wachsmann 8/10/16 4:52 pm

**Comments on background document on upcoming proposals Board of Pharmacy**

To: Members and staff of the Virginia Board of Pharmacy

From: H. Otto Wachsmann, Jr

Subject: Comment period for proposed regulatory changes.

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Date: August 10, 2016

At this time I would like to express some concerns with the background document I received as a member of the Virginia Pharmacists Association. I regret my comments are at the very end of the comment period however my scheduled vacation and an inability to discuss with the document further with VPhA as their telephone lines were impacted by a storm, I am just now able to provide some hastily prepared thoughts on the document.

In reading the document, I find it is difficult to respond. While it provides subject material under consideration, it is difficult for me to have a full understanding on which direction many of these proposals are going.

An area that I initially agreed with was siting the CDC vaccine storage recommendations as the new guidelines for pharmacy refrigerators. I have googled CDC Vaccine Storage and discovered a CDC web page which provided various discussions on the subject but wasn't necessarily clear. For example, it discussed how dorm refrigeration units were less than ideal, but didn't exclude their use except for the freezer compartment. It discussed advantages and disadvantages of traditional household refrigerators vs especially made units but didn't necessarily exclude either one. When discussing certified recording thermometers I wasn't certain if there was a specific certification. In attempting to conduct an internet search for these devices, I saw prices ranging from $800.00 to $1800.00 for the thermometer. I am aware of one doctor's office that recent purchased a specialty refrigeration that cost thousands of dollars. I question with today's reimbursements how a small business such as a family owned pharmacy might be able to purchase something of this magnitude without adequate notice. It is also possible that I may have read a CDC recommendation/guideline page that was different than what the Board of Pharmacy is referencing. I also question the validity of using vaccine storage requirements and how they may or may not relate to a pharmacy such as mine that does not store vaccines. Then there is the question if we would need to have a complaint freezer if we do not stock zostavax?

In reading the section on the physical barrier for the pharmacy department and the front door, I am hopeful this will not require a complete barrier for the pharmacy floor to ceiling in the event the pharmacy department which is already secured and separately alarmed is only open when the rest of the building is open. The cost associated with constructing these barriers will be burdensome for family owned pharmacies. I anticipate this remodel will also require the pharmacy to pay for a re-inspection which further creates a financial burden.

Regarding the landline security system. This appears to be going backwards from the Board of Pharmacy requiring cell phone systems. I wonder how may alarm companies deactivated the old hard line phone system when pharmacies were required to install cell phone systems a few years ago. For pharmacies that fall into this category, this will require these small businesses to pay to have the alarm companies come back into the pharmacy to reattach the landline. I expect since this would be a change to the security system, will this not also require the pharmacy owner to have the pharmacy department re-inspected at an additional fee which may well be two inspections and two fees for those who will not be able to coordinate the alarm company at the same time period as the contractor installing the security barrier. Has the Board of Pharmacy seen a substantial number of cases where these items were an issue? My experience has been the existing alarm systems work effectively but the police response times cannot keep up with the professional burglars committing the crimes. Making it too difficult to gain access to a pharmacy after hours is also likely to create a more dangerous situation where the criminals increase the amount of armed robberies occur. This will results in pharmacy staff and our patients being placed in harms way.

I do not wish to complain about areas in which the Board of Pharmacy promotes to increase patient safety. That is certainly an important and complex task. I only wish to provide the perspective of a practicing community pharmacist of some unintended consequences that some of these areas may create. If I might suggest, it may be helpful to provide some discussion in the

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Board's quarterly newletter for additional thoughts and suggestions while providing a better understanding of the issues for practicing pharmacists. It's quickly becoming quite impossible to keep up with all the state/federal/PBM requirement changes that are going which practitioners are forced to keep up with. Add to that we are doing these at our expense in a market where stores are closing due to reimbursement issues. There is less and less time/resources left to actually take care of the patient.

Thanks

Otto Wachsmann

**Commenter:** Bill Irvin, CVS Health 8/10/16 5:39 pm

**NOIRA 18VAC110-20 Regulations Governing the Practice of Pharmacy**

CVS Health appreciates the opportunity to submit comments regarding the proposed Notice of Intended Regulatory Action (NIORA) regarding 18VAC110-20, Regulations Governing the Practice of Pharmacy. The goal of this communication is to provide the Board of Pharmacy (the "Board") with additional information regarding 18VAC110-20-240 and 18VAC110-20-280 for consideration and incorporation into the final proposal.

**Comments:**

**18VAC110-20-240(C), Manner of maintaining records, prescriptions, inventory records. The Board proposes to add language to clarify subsection (C) that chart orders used in long term care facilities must include a quantity or duration of treatment.**

CVS Health recommends the proposed change to 18VAC110-20-240(C) be removed from the proposal to afford the pharmacist the opportunity to continue leveraging good professional judgment as well as the guidance noted in 110-35. Pursuant to the Virginia Board of Pharmacy Guidance Documents 110-35, a chart order should contain directions for use as it relates to the quantity to be dispensed or authorized duration of therapy that the pharmacist can reference in calculating the quantity of medication to be dispensed to the patient. CVS Health believes that this guidance coupled with professional judgment provides pharmacists the best opportunity to serve the elderly population residing in long-term care facilities.

**18VAC110-20-280(A)(4)(C), Transmission of a prescription order by facsimile machine. The Board is considering whether there is value in the allowance for residents of long term care facilities and provider pharmacies or if it should be removed.**

CVS Health strongly opposes any consideration which would remove the ability for practitioners' authorized agents to transmit a written prescription from a long-term care facility to a pharmacy provider. Transmission of prescription information by a practitioner's authorized agent is a long-standing and commonly accepted pharmacy practice and legal principle recognized by the healthcare industry.

The current rule language in 18VAC110-20-280(A)(4)(C) is critical for long-term care facilities to successfully transmit chart orders to provider pharmacies and promotes the most expeditious dispensing and medication delivery model for the facility. The majority of long term care facilities in the state of Virginia still primarily rely on facsimile because more advanced technological solutions may be unattainable due to cost, available resources, IT integration challenges, or other operational barriers. Placing further restriction on the manner in which long term care facilities transmit prescription medication orders will create a significant burden on long term care facility providers, practitioners, and pharmacies. Removal of the facsimile transmission process by practitioners' authorized agents in the long-term care facility may lead to unintended consequences such as delays in processing chart orders, delays in medication administration, and

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jeopardize timely initiation of drug therapy.

As a leader in the long term care pharmacy industry and an advocate for increased patient access to prescription medication, CVS Health recommends the Board reconsider the proposal to 18VAC110-20-280(C) and allow the current language to remain as written.

In closing, CVS Health appreciates the opportunity to provide these comments to the Board of Pharmacy for their review and consideration regarding this proposal and look forward to a favorable outcome for the patients of the Commonwealth of Virginia.

Sincerely,

Bill Irvin, R.Ph.

Director, Pharmacy Regulatory Affairs

CVS Health

13 Commerce Avenue

Londonderry, NH 03053

(603) 339-7846

William.irvin@omnicare.com

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## Periodic Review – Suggested Draft Amendments for Chapter 20 Parts VI - VIII, X - XII and Chapter 50 Parts I -II

### 18VAC110-20-10. Definitions.

"Initial or initials" shall mean the first letters of a person's name or other unique personal identifier.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

### 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. Nonresident pharmacy | $270 |
| 9. Controlled substances registrations | $90 |
| 10. 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. Approval of a pharmacy technician training program | $150 |
| 12. Approval of a continuing education program | $100 |
| 13. 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. Nonresident pharmacy – due no later than the date of initial registration | $270 |
| 9. Controlled substances registrations – due no later than February 28 | $90 |
| 10. Innovative program continued approval based on board order not to exceed $200 per approval period. | |
| 11. Approval of a pharmacy technician training program | $75 every two years |
| 12. 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. Nonresident pharmacy | $90 |
| 9. Controlled substances registrations | $30 |
| 10. Approval of a pharmacy technician training program | $15 |
| 11. 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. Nonresident pharmacy | $115 |
| f. Controlled substances registration | $180 |
| g. Approval of a pharmacy technician training program | $75 |
| h. 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 |

**18VAC110-20-112. Supervision of pharmacy technicians.**

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.

B. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

## Part VI. Drug Inventory and Records

**18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.**

A. Each pharmacy shall perform and maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed which accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a ~~with~~ reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy. Inventories of drugs in Schedules III-V may be performed by estimating drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.

3. All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Invoices or other records showing receipts of Schedule VI drugs 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.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data

processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains and complies with a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard-copy prescription for those patients listed in subdivision 1 of this subsection. When a chart order is intended for out-patient dispensing, it shall comply with requirements for a prescription in 18VAC110-20-286.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with

records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

## Part VII. Prescription Order and Dispensing Standards

### 18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; ~~supervision of pharmacy technicians.~~

~~A. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.~~

~~B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.~~

In addition to the requirements in §54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature.

~~C.~~B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist ~~shall not~~ may refuse to return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

~~F.~~ E. An on-hold prescription shall be entered into the automated data processing system, if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

F. A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

**18VAC110-20-275. Delivery of dispensed prescriptions.**

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for

identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

**18VAC110-20-280. Transmission of a prescription order by facsimile machine.**

A. Unless otherwise prohibited by federal law, prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription.

3. An authorized agent, as defined in §54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

c. Forwarding a written prescription by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions, and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with §54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's manual signature or agent's name, and date of authorization.

**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.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the prescriber's signature or to make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

## Part VIII. Labeling and Packaging Standards for Prescriptions

### 18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Repacking of drugs shall be performed in compliance with USP-NF standards.

~~C.~~D. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

2. If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.

5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

6. An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.

~~D~~E. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

## Part X. Unit Dose Dispensing Systems

### 18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial ~~or otherwise identify himself on~~ the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and complied with, and shall include at a minimum, procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned bar codes;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

~~g~~h. Appropriately performing a root cause analysis to investigat~~e~~ing, identify~~ing~~ and correct~~ing~~ sources of discrepancies or errors associated with the robotic pharmacy system; and

~~h~~i. Maintaining quality assurance reports.

~~5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.~~

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all affected doses or compliance packages, perform a root cause analysis to investigate, identify, and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. ~~and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.~~

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.~~

~~c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.~~

~~d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.~~

~~9. All unanticipated downtime shall be immediately reported to the board.~~

~~10~~9. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or 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. Intravenous (IV) admixture robotics may be utilized to compound drugs in compliance with 54.1-3410.2 and 18VAC110-20-321, however, a pharmacist shall verify the accuracy all compounded drugs pursuant to 18VAC110-20-270 C.

## Part XI. Pharmacy Services to Hospitals

### 18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the ~~practitioner~~ prescriber.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

**18VAC110-20-490. Automated devices for dispensing and administration of drugs.**

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to 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; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. 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 pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports.

A discrepancy report for Schedule II through V drugs and any drugs of concern shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or 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.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution 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. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

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

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

b. 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.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections.

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. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which 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 records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. 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.

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

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

3. Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location 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.

## Part XII. Pharmacy Services to Long-Term Care Facilities

### 18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

A. The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both 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 long-term care 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.

d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

B. The pharmacy providing services to the long term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drug, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

1. The pharmacy providing services to the long term care facility has a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and,

2. The pharmacy providing services to the long term care facility provides a valid oral or written prescription or order to the other pharmacy.

**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 and/or resealing. 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 in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-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. The pharmacy may provide more than one stat-drug box to a long term care facility. Contents of the multiple boxes are not required to be uniform.

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

Nursing homes or hospices licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia or residential facilities in which only licensed nurses, pharmacists, or prescribers administer medications and which are licensed pursuant to Chapter 7 (§ 37.2-700 et seq.) of Title 37.2 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.

3. 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 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 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; and a unique identifier for the specific device receiving drugs; and initials of 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 properly reporting of a loss.

9. The PIC 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.

## Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers

### Part I. General Provisions

### 18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer or warehouser shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit~~, except for those distributors of only medical gases other than nitrous oxide,~~ shall install an operable device for the detection of breaking 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~~ One communication line installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards, to include wireless motion sensors.

3. The device shall be operable, centrally-monitored, ~~and~~ 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.

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

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, or warehouser, and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

## Part II. Wholesale Distributors.

### 18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license, nonresident wholesale distributor registration, restricted or nonrestricted manufacturer permit to entities that do not engage in the wholesale distribution of prescription drugs ~~except medical gases~~ or entities that engage in wholesale distribution or manufacturing but do not stock drugs and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

### 18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee;

3. The federal employer identification number of the applicant or licensee;

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility;
(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.

(4) The name, federal employer identification number, and state of incorporation of the parent company.

d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;

e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;

5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and

9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

**18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.**

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check ~~through the Central Criminal Records Exchange~~; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. Requiring any employee who has access to prescription drugs to attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs.

3. Maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. Maintaining proper security, storage and shipping conditions for all prescription drugs.

5. Maintaining all required records.

E. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record.

**18VAC110-50-90. Minimum requirements for the storage, handling, transport, and shipment of prescription drugs.**

A. All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

1. Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards;

2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

4. Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

5. Be maintained in a clean and orderly condition; and

6. Be free from infestation of any kind.

B. The facility shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.

C. The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

**18VAC110-50-100. Examination of drug shipments and accompanying documents.**

A. Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.

B. Upon receipt of drugs, a wholesale distributor must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

C. Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

**18VAC110-50-110. Returned, damaged and counterfeit drugs; investigations.**

A. Any drug or device returned to a manufacturer or another wholesale distributor shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer or wholesale distributor to which the drugs are returned.

B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.

C. When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer

through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor shall:

1. Provide notice to the board and the manufacturer, and to the other wholesale distributor if applicable, from which such drug or device was acquired within three business days of that determination.

2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.

D. The wholesale distributor shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device.

**18VAC110-50-120. Policies and procedures.**

All wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors shall include in their policies and procedures at least the following:

1. A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons;

2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;

3. A procedure for handling recalls and withdrawals of prescription drugs and devices;

4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor;

5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;

6. A procedure to ensure initial and ongoing training of all employees;

7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to the manufacture, distribution, or dispensing of prescription drugs; and

8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

**18VAC110-50-130. Recordkeeping.**

A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor. A wholesale distributor shall establish and maintain the following:

1. Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition;

2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;

3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;

4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;

5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs; and

6. Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia.

B. Records shall be either (i) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or (ii) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.

C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

**18VAC110-50-140. Due diligence.**

A. Prior to the initial purchase of prescription drugs from another wholesale distributor not residing and licensed in Virginia, a wholesale distributor shall obtain, and update annually, the following information from the selling wholesale distributor:

1. A copy of the license to wholesale distribute from the resident state;

2. The most recent facility inspection report, if available;

3. A list of other names under which the wholesale distributor is doing business, or was formerly known as;

4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation;

5. A list of all disciplinary actions by state and federal agencies;

6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution; and

7. A listing of any manufacturers for whom the wholesale distributor is an authorized distributor of record.

B. If the selling wholesale distributor's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor may conduct an inspection of the wholesale distributor's facility prior to the first purchase of drugs or devices from another wholesale distributor, to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor.

C. Prior to the first purchase of drugs from another wholesale distributor not residing in and licensed in Virginia, the purchasing wholesale distributor shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

## Part III. Manufacturers.

### 18VAC110-50-150. Good manufacturing practices.

A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference.

B. Each manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.

## Chapter 16. Regulations Governing the Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate

### 18 VAC 110-16-10. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

A. Decision to delegate. In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;

2. Drug diversion;

3. Impairment with an inability to practice with skill and safety;

4. Indiscriminate dispensing; and

5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

**Agenda Item:** **Legislative Proposal**

**Enclosed:**

**Copy of draft legislation for registration of non-resident third-party logistics provider and non-resident warehousers**

**Staff note:**

In addition to the legislative proposal included in your agenda, the Prescription Monitoring Advisory Committee met on June 7, 2017. It considered four possible legislative proposals:

- Authorize prescriber to request PMP report of parent or caregiver of child in certain cases (not recommended)
- Reporting of dispensing of naloxone to PMP (recommended)
- Reporting of Schedule V controlled substances to PMP (recommended)
- Reporting of information relating to person picking up controlled substances to PMP (referred to Board of Pharmacy for future consideration)

**It is not necessary for the Board to endorse the 2 legislative proposals recommended by the PMP Advisory Committee, but the Board may choose to add its approval, comment on the proposals, or take no action.**

**Board Action:**

Recommend that the Department submit a legislative proposal to authorize registration of non-resident third-party logistics provider and non-resident warehousers.

**Board of Pharmacy**

**2018 Draft Legislative Proposal**

**§ 54.1-3435.1. Denial, revocation, and suspension of license as wholesale distributor, registration as a nonresident wholesale distributor, or permit as a third-party logistics provider, nonresident third-party logistics provider, manufacturer, nonresident warehouser, or nonresident manufacturer.**

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, nonresident wholesale distributor registration, third-party logistics provider permit, nonresident third-party logistics provider registration, manufacturer permit, nonresident warehouser registration, or nonresident manufacturer permit as provided for in § 54.1-3316 or the following:

1. Any conviction of the applicant, licensee, or registrant under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Violations of licensing requirements under previously held licenses;

3. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs; or

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale drug distributors, third-party logistics providers, nonresident third-party logistics providers, manufacturers, nonresident warehousers, and nonresident manufacturers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

**§ 54.1-3435.4:01. Registration to act as a nonresident warehouser; regulations.**

A. Any warehouser, as defined in § 54.1-3401, located outside this Commonwealth who ships prescription drugs or devices into this Commonwealth shall be registered with the Board. The nonresident warehouser shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within thirty days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident warehouser shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located that authorizes the possession and distribution of such prescription drugs or devices and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs or devices distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

**§ 54.1-3435.4:2. Registration of nonresident third-party logistics provider; renewal.**

A. Any third-party logistics provider located outside this Commonwealth who ships prescription drugs or devices into this Commonwealth shall be registered with the Board. The nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within thirty days of any substantive change in the information previously submitted.

B. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a third-party logistics provider with the Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident third party logistics provider as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

D. Records of prescription drugs or devices distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

**Agenda item: Adoption of Guidance document on Categories of Facility Licensure**

**Enclosed:**

An amended draft of Guidance Document 110-1

**Staff note:**

Amendments are necessary to reflect recent changes in the issuance of a facility permit for distribution of medical gases and the addition of controlled substance registration following legislation passed in the 2017 General Assembly.

**Board action:**

Adoption of amendments to Guidance Document 110-1

# VIRGINIA BOARD OF PHARMACY
## CATEGORIES OF FACILITY LICENSURE

**PHARMACY:** This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. ~~Federal~~ State law, §54.1-3435.02, allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

**NONRESIDENT PHARMACY:** This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

**MEDICAL EQUIPMENT SUPPLIER:** This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

**NONRESIDENT MEDICAL EQUIPMENT SUPPLIER:** This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

**WHOLESALE DISTRIBUTOR:** This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user.

~~**LIMITED-USE WHOLESALE DISTRIBUTOR:** This license is a "carve-out" of a regular wholesale distributor restricted to those entities that only wholesale distribute medical gases, and in which the Board may waive some of the requirements of regulation. The Board typically waives some of the requirements for information required on initial application and some requirements related to the responsible party as well as some physical standards.~~

**NONRESIDENT WHOLESALE DISTRIBUTOR:** This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors.

**WAREHOUSER:** This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements. This permit may be preferable to the wholesale distributor license for those entities which distribute prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user.

**NON-RESTRICTED MANUFACTURER:** This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs.

**RESTRICTED MANUFACTURER:** This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use.

**CONTROLLED SUBSTANCES REGISTRATION (CSR):** This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouser, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs 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 or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration in order to dispense naloxone without charge or compensation. 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 may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

**OUTSOURCING FACILITY:** This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite, the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

**NONRESIDENT OUTSOURCING FACILITY:** This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

**Practitioner of the Healing Arts to Sell Controlled Substance Facility Permit**: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

DRAFT

* **§ 54.1-3455. Schedule VI.**

**The following classes of drugs and devices shall be controlled by Schedule VI:**

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.
2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

**Formation of Ad Hoc Committee to address HB1956, HB2046, and develop guidance on USP Chapter <800>**

**Included in agenda packet:**

- HB1956
- Letters from Del. Orrock, Del. Peace, and Del. Head
- HB2046

INTRODUCED

17102125D

**HOUSE BILL NO. 1956**

Offered January 11, 2017

Prefiled January 10, 2017

*A BILL to amend and reenact § 54.1-3420.2 of the Code of Virginia, relating to delivery of prescription drug order; shipping Schedule VI controlled substances.*

Patrons—Helsel and Peace

Referred to Committee on Health, Welfare and Institutions

**Be it enacted by the General Assembly of Virginia:**

**1. That § 54.1-3420.2 of the Code of Virginia is amended and reenacted as follows:**

**§ 54.1-3420.2. Delivery of prescription drug order.**

A. *Prescription drug orders may be delivered (i) directly to the patient or his legally authorized representative at the pharmacy; (ii) to the home of the patient, by hand delivery or by mail, common carrier, or delivery service; or (iii) to another delivery location, by hand delivery or by mail, common carrier, or delivery service, provided such delivery to such delivery location is authorized by federal law and regulations of the Board. The Board shall adopt regulations governing the delivery of prescription orders by mail, common carrier, or delivery service to a patient's home or to another delivery location, which shall include requirements related to access, accuracy, security, required records, storage, and accountability. Such regulations shall also include temperature control standards and shall require, for any drug requiring temperature control, a method approved by the United States Pharmacopeia by which the patient can detect temperature variances that could cause degradation of the drugs.*

*B.* Whenever any pharmacy permitted to operate in ~~this~~ *the* Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order *to a patient's home or another designated location* by mail, common carrier, or delivery service, ~~when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required~~ *each shipment so delivered shall include the following*:

1. Written notice ~~shall be placed in each shipment~~ alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice ~~shall be placed in each shipment~~ providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

~~B. If a prescription~~ *C. Prescription* drug ~~order~~ *orders* for ~~a~~ Schedule VI controlled ~~substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient,~~ *substances shall only be delivered to a delivery location other than the patient's home if* the delivery location ~~shall hold~~ *holds* a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. ~~The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems.~~ Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

~~C.~~ *D.* Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

~~D.~~ *E.* Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

~~E.~~ *F.* Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and

INTRODUCED



1/14/17 15:0

overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

ROBERT D. "BOBBY" ORROCK
POST OFFICE BOX 458
THORNBURG, VIRGINIA 22565

FIFTY-FOURTH DISTRICT

COMMITTEE ASSIGNMENTS:
HEALTH, WELFARE AND INSTITUTIONS (CHAIRMAN)
FINANCE
AGRICULTURE, CHESAPEAKE AND
NATURAL RESOURCES
RULES


February 17, 2017

The Honorable David Brown, Director
Virginia Department of Health Professions
9960 Mayland Drive
Richmond, VA 23233-1463

Dear Mr. Brown,

The Virginia Health, Welfare and Institutions Subcommittee voted to lay HB1956 on the table with a letter requesting the Virginia Board of Pharmacy to consider the issue related to any variances that may exist between mail-order and hand-delivered prescription medications.

I would appreciate your consideration of this and please inform me of any recommendations by November 2017.

Sincerely,

Robert D. (Bobby) Orrock, Sr.

RDO/rh

DISTRICT: (540) 891-1322 • RICHMOND: (804) 698-1054 • E-MAIL: DELBORROCK@HOUSE.VIRGINIA.GOV

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

CHRISTOPHER K. PEACE
POST OFFICE BOX 819
MECHANICSVILLE, VIRGINIA 23111

NINETY-SEVENTH DISTRICT

COMMITTEE ASSIGNMENTS:
GENERAL LAWS (VICE CHAIRMAN)
APPROPRIATIONS
HEALTH, WELFARE AND INSTITUTIONS

March 2, 2017

DIRECTOR'S OFFICE
MAR 07 2017
DEPT. HEALTH PROFESSIONS

The Honorable David Brown, Director
Virginia Department of Health Professions
9960 Mayland Drive
Richmond, VA 23233-1463

**RE: House Bill 1956 (Helsel): Delivery of prescription drugs orders**

Dear Dr. Brown,

On Tuesday, January 31, 2016, the Virginia Health, Welfare and Institutions Subcommittee voted to lay HB1956 on the table with a letter. I understand that the Chair has sent a letter asking the Board of Pharmacy to consider and provide recommendations regarding variances that may exist between mail-order and hand-delivered prescription medications.

As a member of the subcommittee which heard the bill, I heard conflicting claims about federal regulations related to the transportation of prescription drugs, including how the federal standards impact transit from the manufacturer to the pharmacy to the consumer. This matter is particularly important as more and more medications are delivered via mail-order or common carrier, including high-cost specialty pharmaceuticals such as biosimilars and biologics. I am interested in understanding how and whether mail-order shipment requirements have kept pace with changing pharmaceutical products, and whether Virginia's patients are obtaining the information they need to make informed decisions about their mail-order medications, especially those for which temperature control is vital to maintaining the efficacy of the drug.

As such, I would like to request that, as the Board studies the issues as requested by the Chair, that the Board consider specific questions that I, and other members have, regarding this matter. Information related to the following questions will be of great help as we consider this issue going forward:

1. What states have implemented rules, regulations or guidance regarding the shipment of prescription drugs directly to the consumer by mail or common carrier?

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2. Of the states that do have some form of regulation to govern shipping, which states require some form of notice or instruction to the consumer related to temperature? Do any states require a method by which consumers can detect temperature variation?

3. Which states collect data related to problems with the shipping of prescription drugs, either for all licensed pharmacies that ship drugs by mail or common carrier, or for any health plan that is overseen or implemented by the state (i.e. a state employee health plan, Medicaid, plan, etc.?) What kinds of data are collected?

4. What federal regulations or guidelines exist related to temperature controls of mail order prescription drugs? Is this really covered by "track and trace" as was claimed by some?

5. What part of the shipping process do the federal regulations control? (i.e. the oversight and monitoring of medications between the manufacturer and the pharmacy or between the pharmacy and the consumer?)

6. Does the Commonwealth track current losses related to fraud, waste and spoilage of mail order prescription drugs and if so, what are the associated costs to the Commonwealth?

7. What is the approximate number of Virginians (covered by commercial plans) who are required to obtain medication via mail-order?

I appreciate the work the Board of Pharmacy does to protect the public and I thank you for your consideration of this request.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Christopher K. Peace

CHRISTOPHER T. HEAD
POST OFFICE BOX 19130
ROANOKE, VIRGINIA 24019

SEVENTEENTH DISTRICT

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

DIRECTOR'S OFFICE
MAY 30 2017
DEPT. HEALTH PROFESSIONS

COMMITTEE ASSIGNMENTS:
FINANCE
HEALTH, WELFARE AND INSTITUTIONS
MILITIA, POLICE AND PUBLIC SAFETY

Received
VA Board of Pharmacy
MAY 31 2017

May 22, 2017

The Honorable David Brown
Director
Virginia Department of Health Professions
9960 Mayland Drive
Richmond, VA 23233-1463

**RE: House Bill 1956 (Helsel): Delivery of prescription drugs orders**

Dear Dr. Brown,

I understand that the Chair of the Health, Welfare and Institutions Committee has sent a letter asking the Board of Pharmacy to consider and provide recommendations regarding variances that may exist between mail-order and hand-delivered prescription medications.

This came as a result of a motion I made to Table HB 1959 with a letter. During the subcommittee meeting that heard the bill, a number of concerning points were made. One speaker even indicated that if members are concerned about temperature excursions with certain drugs shipped from a pharmacy through mail order, there should be just as much concern over the shipment of drugs on the way to the pharmacy from a manufacturer or distributor. We need the Board's expertise to help clarify this and other questions. As such, I would like to request that, as the Board studies the issue as requested by the Chair, the Board consider a few specific questions which I have outlined below:

1. §54.1-3420.2 requires that all medications shipped by mail order include a written notice "alerting the consumer that under certain circumstances chemical degradation of drugs may occur." Is this notice specific to the drug(s) being shipped? What guidelines does the Board have in place for the content of these notices?

2. How does the Board track compliance with the law requiring this notice?

3. How does a consumer know if his or her medicine has been subjected to circumstances that can affect the drug's efficacy?

4. Conflicting information was presented to the subcommittee as to whether or not the federal government already has regulations or guidelines in place regarding temperature variations of drugs shipped by mail or common carrier. Are such regulations or guidelines in place, and do the guidelines cover all aspects of medication shipments,

DISTRICT: (540) 283-2839 • RICHMOND: (804) 698-1017 • E-MAIL: DELCHEAD@HOUSE.VIRGINIA.GOV

including transit from the manufacturer/wholesaler to the pharmacy, as well as shipment from the pharmacy to the consumer?

5. What is the current process used by pharmacies to determine whether the drugs received by the pharmacy have been exposed to conditions that could compromise the efficacy of the drug(s)? Does Virginia have guidelines specific to this shipping scenario, or do the manufacturers/wholesalers rely on federal regulations or guidelines when shipping to a pharmacy?

6. If there are no state or federal guidelines that cover shipment from the manufacturer/wholesaler to the pharmacy or pharmacy to consumer, is this something Virginia can address?

I appreciate your consideration of this request. If you have any questions, please do not hesitate to contact me.

Sincerely,

Christopher T. Head
Virginia House of Delegates

# VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

## CHAPTER 114

*An Act to require the Board of Pharmacy to develop guidelines for the provision of counseling and information regarding disposal of unused drugs.*

[H 2046]

Approved February 21, 2017

**Be it enacted by the General Assembly of Virginia:**

**1.** *§ 1. That the Board of Pharmacy shall 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 participates pursuant to § 54.1-3411.2, by pharmacists to patients for whom a prescription is dispensed.*

**NABP**
National Association of Boards of Pharmacy

## *NABP e-Profile*

**Presented by: Neal Watson**
**Member Relations and Government Affairs Liaison**

## NABP e-Profile

What is it?

NABP E-PROFILE

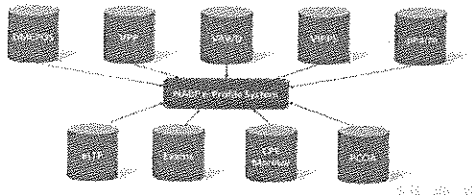
- A unique identifier
  - Assigned to licensed or registered Individuals and Facilities
- Links licensees to all NABP programs and services
- Links Licensees to state pharmacy boards

*"I thought that was only for CPE Monitor?"*

## National Association of Boards of Pharmacy®

- **501(c)(3) charitable and educational organization**
  - **Founded in 1904**
- **Members are the state boards of pharmacy** for 50 states, District of Columbia, and United States territories.
- **NABP's mission is to assist member boards in public protection.**
  - License Transfer Program
  - Examinations
  - Accreditations

## How are e-Profiles established?



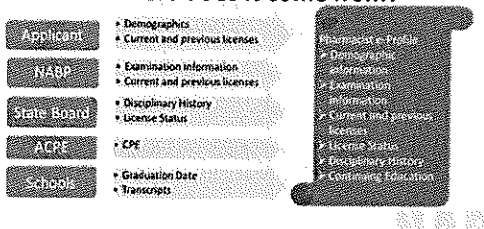
| Examinations | Accreditations | Assessments | Licensure |
|---|---|---|---|
| NAPLEX | NABP | PCOA | e-LTP |
| Pre-NAPLEX | NAAPP | PAPE | CPE Monitor |
| FPGEE | VIPPS | FPGEC | VPP |
| FPLEX | i-VIPPS | | |
| MPJE | | | |

**Other Services**

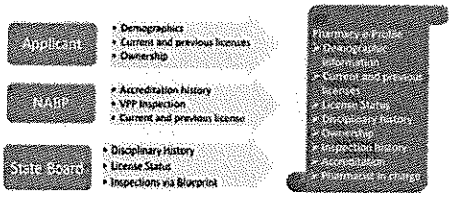
NABP*LAW*
*Eligibility Service*
Disciplinary Clearinghouse

PMP INTERCONNECT
AWA

## What data is in a *Pharmacist e-Profile* and where does it come from?



## What data is in a *Pharmacy e-Profile* and where does it come from?



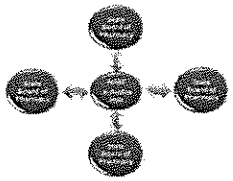

## How do we implement the NABP e-Profile?

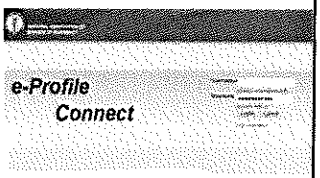
- First Step
  - Require the NABP e-profile on initial/renewal licensure applications for pharmacist and technicians
    - Facilities coming in 2018

- Next Step
  - Sync board data to NABP data utilizing the e-Profile Identifier
- Future Step
  - Real-time data exchange and integration

## e-Profile Connect

- State board data sharing
- Real-time secure access






## Questions

- Contact Information

Neal Watson
Phone: 847/391-4481
Email: nwatson@nabp.pharmacy

## NABP e-Profile

**Why should we require the e-Profile?**

- Quality assurance
- Streamlines the licensure process
  - Expedite NABP reporting for:
    - Exam eligibility, exam scores, discipline, inspections, etc.
  - Enhances board members and staff ability to make informed licensing decisions
- Reduce administrative burden – data exchange and integration
- Eliminate the necessity to identify licensees using sensitive data
- No additional cost to the boards
- No additional cost or burden to licensed individuals or facilities

**Expert admissibility standards to consider:**

Traditional Virginia Standard:

To qualify to serve as an expert witness, an individual:

> must possess sufficient knowledge, skill, or experience regarding the subject matter of the testimony to assist the trier of fact in the search for the truth. Generally, a witness possesses sufficient expertise when, through experience, study or observation the witness acquires knowledge of a subject beyond that of persons of common intelligence and ordinary experience.

Virginia Medical Malpractice Standard:

To qualify to serve as an expert witness, an individual:

> [a]ny health care provider who is licensed to practice in Virginia shall be presumed to know the statewide standard of care in the specialty or field of practice in which he is qualified and certified....A witness shall be qualified to testify as an expert on the standard of care if he demonstrates expert knowledge of the standards of the defendant's specialty and of what conduct conforms or fails to conform to those standards and if he has had active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action.