# COMMONWEALTH OF VIRGINIA
# Meeting of the Board of Pharmacy

**Perimeter Center, 9960 Mayland Drive, Second Floor**
**Henrico, Virginia 23233**

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


## Tentative Agenda of Public Hearing and Full Board Meeting

***March 25, 2016***

**9:00AM**

**TOPIC** **PAGES**

**Call to Order of Public Hearing for Scheduling Certain Substances:** Cynthia Warriner, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

**Call for Public Comment:**

- Possible scheduling of the following substances:
  - N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (Other name: butyryl fentanyl)
  - Flubromazolam
  - 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)
  - 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)

**Adjournment of Public Hearing**

**Call to Order of Full Board Meeting:** Cynthia Warriner, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - November 23, 2015, Special Conference Committee 1-2
  - December 1, 2015, Full Board Meeting 3-10
  - December 1, 2015, Public Hearing for Hours of Continuous Work by Pharmacists 11-12
  - December 15, 2015, Special Conference Committee 13-14
  - December 29, 2015, Pilot Informal Conference Committee 15-19
  - January 5, 2016, Regulation Committee 20-25

**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

- Report on Pharmacy Benefit Manager Workgroup 26-35

**Regulatory Actions:**

- Legislative Update - Elaine Yeatts 36-41
- Regulatory Update - Elaine Yeatts 42

- Report from Regulation Committee – Ellen Shinaberry/Elaine Yeatts
  - Committee Recommendation regarding Adoption of NOIRA for Periodic Review of *Regulations Governing the Practice of Pharmacy*, chapter 20, and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, chapter 50 — 42A-48
- Consideration of Any Scheduling Action from Public Hearing - Elaine Yeatts — 49-53
- Petitions for Rulemaking: Elaine Yeatts — 54
  - Allow long term care facility to provide prescription information for Schedule VI drugs to a "back-up" pharmacy located near the facility — 55-61
  - Allow pharmacists in hospitals or free-standing emergency departments to adjust or order medications according to clinically accepted guidelines — 62-67
  - Allow bar code and RFID scanning to extend the pharmacist check, once bar code or RFID scan has been verified — 68-79
- Adoption of Proposed Regulations to Replace Emergency Regulations for Permitted Facilities used by Practitioners of the Healing Arts to Sell Controlled Substances - Elaine Yeatts — 80-90
- Adoption of Proposed Regulations to Replace Emergency Regulations for Outsourcing Facilities- Elaine Yeatts — 91-106
- Adoption of Proposed Regulations for a Prohibition on Incentives to Transfer Prescriptions- Elaine Yeatts — 107-116
- Adoption of Final Regulations on Setting Certain Conditions on Work Hours for Pharmacists- Elaine Yeatts — 117-126
- Adoption of Fast-Track Amendment for 18VAC110-20-540, Emergency Drug Kit — 127A-C
- Possible Topics for 2017 Legislative Proposals- Elaine Yeatts/Caroline Juran

**Old Business:**

- Guidance for Whether Nurses May Prepare Methadone Take-home Bottles - Jim Rutkowski — 6, 127-129

**New Business:** Caroline D. Juran

- Amend Healthcare Workforce Pharmacist Survey – Elizabeth Carter, Ph.D., Director, HWDC — 130-146
- Amend *Protocol for the Prescribing and Dispensing of Naloxone* — 147-149
- Consideration for "white bagging, brown bagging" and "specialty drugs" — 31,35
- Amend Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide — 150-162
- Amend Guidance Document 110-29 *Physicians Dispensing Drugs* — 163-169

**Reports:**

- Chairman's Report – Cynthia Warriner
- 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 & possible summary restrictions/suspensions, if any**

**Adjourn**

******The Board will have a working lunch at approximately 12pm and recognize former board members Dinny Li and Empsy Munden. ******

# VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES *(Draft/Unapproved)*

Monday, November 23, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy ("Board") was called to order at 9:30 a.m. |
| PRESIDING: | Jody Allen, Committee Chair |
| MEMBERS PRESENT: | Melvin Boone, Sr., Committee Member |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist<br>Loni Dickerson, Disciplinary Program Specialist |
| SAMANTHA WARREN<br>Registration No. 0230-015146 | Samantha Warren did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 18, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Warren's legal address of record. |
| Closed Meeting: | Upon a motion by Mr. Boone, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Samantha Warren. Additionally, he moved that Cathy Reiniers-Day, Mykl Egan, and Loni Dickerson 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 Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to offer an Order for the suspension of Ms. Warren's pharmacy technician registration. |

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| KWATU TUFFOUR<br>Registration No: 0230-017150 | Kwatu Tuffour did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 19, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Tuffour's legal address of record. |
| Closed Meeting: | Upon a motion by Mr. Boone, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Kwatu Tuffour. Additionally, he moved that Cathy Reiniers-Day, Mykl Egan, and Loni Dickerson 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 Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to offer an Order for the suspension of Mr. Tuffour's pharmacy technician registration. |
| Adjourn: | With all business concluded, the meeting adjourned at 1:25 p.m. |

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

DRAFT/UNAPPROVED

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF BOARD MEETING

December 1, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr. (arrived 9:18 a.m.)
Michael I. Elliott
Freeda Cathcart
Ryan K. Logan
Rafael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen
Sheila K. W. Elliott (arrived 9:18 a.m.)

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

STAFF ABSENT: J. Samuel Johnson, Jr., Deputy Executive Director

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

APPROVAL OF AGENDA: An amended agenda was provided as a handout for the members, staff, and the public. The following two topics were included on the amended agenda: under Old Business, a request from VPhA to amend guidance document 110-36 *Compliance with USP Standards for Compounding* and under new Business, consideration for mandatory continuing education for pharmacists on a specific topic in 2016.

**MOTION:** **The Board voted unanimously to approve the amended agenda as presented in the handout. (motion by Shinaberry, second by Saenz)**

APPROVAL OF MINUTES: The Board reviewed draft minutes in the agenda packet for:

- September 29, 2015, Public Hearing for Scheduling Certain Chemicals
- September 29, 2015, Full Board Meeting

- September 29, 2015, Panel Formal Hearings
- September 30, 2015, Inspection Special Conference Committee
- November 3, 2015, Regulation Committee

**MOTION:** **The Board voted unanimously to approve the minutes as presented for the meetings held between September 29, 2015 and November 3, 2015. (motion by Allen, second by Logan)**

PUBLIC COMMENTS: No comment was provided to the Board.

DHP DIRECTOR'S REPORT: Cynthia Warriner introduced the newly-appointed Chief Deputy Director of DHP, Lisa Hahn, who provided the Director's report in place of David Brown, D.C who was attending another meeting outside of the office. Ms. Hahn provided comment that the new board member training as well as board member development day went very well. Ms. Hahn elaborated on the additional training that DHP has been providing staff regarding employee hiring, employee work performance reviews, and supervisor training. Ms. Hahn also spoke of the Healthcare Workforce Data Center and the surveys conducted mainly during renewal of licensure and how they will be used in an aggregate manner in the near future to educate high school students about careers in healthcare.

REPORT ON APPALACHIAN COLLEGE OF PHARMACY: Susan Mayhew, Dean of Appalachian College of Pharmacy provided a report via Polycom to the board on recent school activities. A handout summarizing her report was also provided to the members, staff, and public. The College has graduated over 500 students who are practicing throughout the United States. Dean Mayhew indicated that between 40-50% of the graduates remain in the Appalachian region. In 2014 the College had Virginia's highest pass rate on the NAPLEX examination. The College has Virginia's only three-year accelerated Doctor of Pharmacy program.

The College recently opened its Mountain Care Center delivering pharmaceutical care to the indigent in the region. The College has begun a global health elective, started a community residency program as well as a post doctorate program. The school also just completed a re-accreditation through ACPE and has an upcoming accreditation visit from the Southern Association of Colleges of Pharmacy.

REPORT ON HAMPTON UNIVERSITY COLLEGE OF PHARMACY: Wayne Harris, Dean, and Anand Iyer, Assistant Dean of Academic and Student Affairs from Hampton University College of Pharmacy appeared in-person and provided a report to the board on recent school activities. Dean Harris reported that the College admitted its first class in 1998 and has graduated over 600 PharmD candidates. Current enrollment is approximately 250 students with possible growth in the future. The site visit for ACPE in November 2014 went well and the accreditation was continued for a time period of eight years. The school has an ongoing curriculum review to build for the future and includes establishing the Hampton University center of excellence which will focus on providing medication therapy management to medically underserved clinics.

Four faculty members at The College currently have research grants through the National Institutes of Health (NIH). He reported there is an interest in increasing the school's involvement in research. Dean Harris is currently a co-director of a minority men's health initiative, funded NIH to address minority health disparities.

REGULATORY ACTIONS:

- REGULATORY UPDATE:

Ms. Yeatts provided a chart of regulatory actions as a handout. Emergency regulations for outsourcing facilities and Practitioner of the Healing Arts are currently at the Governor's office. There are two actions that are at the Department of Budget and Planning and those are the collection sites for disposal of unused drugs and the repackaging at PACE sites. In addition there are two actions that are in a public comment period, one of which the public hearing was held just prior to this Board meeting. Those public comment period for the prohibition against incentives to transfer prescriptions ends 12/16/15 and the comment period for addressing hours of continuous work by pharmacists ends 1/29/16.

- REGULATION COMMITTEE REPORT ON ISSUANCE OF CSR TO MEDICAL OFFICE BUILDING:

Ms. Shinaberry reported that the Regulation Committee determined at its November 3, 2015 meeting to recommend that the board not issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. Based on concerns for oversight, it recommended that board staff continue to issue CSRs to individual clinics that maintain their own stock of drugs for their own use. Mr. Saenz recused himself from the discussion and voting since the request for a single CSR came from his employer.

**VOTE**

**The Board voted unanimously to accept the recommendation of the Regulation Committee and not authorize staff to issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. (Saenz recused)**

- REQUEST FOR RULEMAKING TO ALLOW "BACK-UP" PHARMACY TO DISPENSE FIRST FILL OF PRESCRIPTION WITHOUT NECESSITATING TRANSFER OF PRESCRIPTION:

Ms. Yeatts advised that this request should be treated as a petition for rulemaking which requires a publication of the request and a 21-day public comment period prior to the Board considering the matter. Therefore, this matter will be deferred to a later date.

OLD BUSINESS:

- REQUEST FROM VPHA TO AMEND GUIDANCE DOCUMENT 110-36:

Ms. Juran provided a handout on the issue and reminded the board members that this issue was discussed at the September board meeting and staff was tasked with researching the issue further. Ms. Juran contacted USP experts who confirmed that USP allows for alternative methods of sterility testing. Since Virginia law allows compliance with USP, alternative methods of sterility testing are allowable. Ms. Shinaberry pointed out that the first two sentences in the draft answer to #39 in the guidance document may need to be adjusted in the future based on proposed revisions to USP <797>. Ms. Allen agreed and pointed out that proposed revisions may take up to two years or longer to be adopted by USP.

**MOTION:**

**The Board voted unanimously to amend Guidance Document 110-36 as presented in the handout which provides guidance in a new question #39 regarding the use of a microbiological method alternative to compendial methods used. (motion by Cathcart, second by S. Elliott)**

NEW BUSINESS:

- NEED GUIDANCE FOR NURSES PUMPING METHADONE TAKE HOME BOTTLES:

Ms. Juran referenced the request from a narcotic treatment program (NTP) in the agenda packet. The NTP would like to know if nurses can pump, i.e., prepare methadone take home bottles for patients under pharmacist supervision. Board counsel advised he would need to research the statute regarding duties of a pharmacy technician and if these duties could be performed by a nurse in a NTP under pharmacist supervision.

**ACTION ITEM:**

**The Board recommended that the matter regarding a need for guidance for nurses pumping methadone take home bottles be deferred to the March board meeting to allow counsel time for researching the issue.**

- REQUEST TO AMEND GUIDANCE DOCUMENT 110-8, PRESCRIPTIVE AUTHORITY IN VIRGINIA:

Ms. Yeatts stated that there are two changes to this document on prescriptive authority. The first change is that optometrists may now prescribe hydrocodone in combination with acetaminophen products which are now Schedule II and a regulatory change for physician assistants regarding the co-signature of prescriptions in certain schedules. Since the change for optometrists is a legislative change that has already been passed and the second change for PA's prescribing rules is a regulatory change that is likely to be effective on January 15, 2016, Ms. Yeatts suggested that the Board either have two separate motions or one motion with two parts. The Board agreed to have two separate motions as this would be clearer in the event the regulatory change did not occur on January 15, 2016.

**MOTION:**

**The Board voted unanimously to amend Guidance Document 110-8 as presented to reflect the legislative change in 2015 that permits optometrists to prescribe hydrocodone in combination with**

**acetaminophen products. (motion by S. Elliott, second by Cathcart)**

**MOTION:**

**Contingent upon the Board of Medicine regulatory amendment becoming final January 15, 2016, the Board voted unanimously to amend Guidance Document 110-8 as presented which would advise that the name of the supervising physician be included on a Schedule II-V prescription written by a physician assistant. (motion by Allen, second by Boone)**

- AMEND GUIDANCE DOCUMENT 110-4, CONTINUING PHARMACY EDUCATION GUIDE:

Ms. Juran indicated that there are some exceptions in law that appear to create confusion for licensees as to when they must renew their license or registration and if they must obtain hours of continuing education. Staff has recently answered numerous questions on this subject and recommends that the board amend Guidance Document 110-4 to provide clarity on the subject. A handout was provided with staff's suggested amendments for the guidance document. Ms. Shinaberry recommended the question and answer on page 3 of the handout be changed to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." Prior to voting, a corrected version of the handout was also provided which included staff's draft language for two additional frequently asked questions.

**MOTION:**

**The Board voted unanimously to amend the question and answer on page 3 of the corrected handout to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." and to otherwise amend the guidance document as presented in the corrected handout provided during the meeting. (motion by Saenz, second by Shinaberry)**

- CONSIDER MANDATORY CE FOR PHARMACISTS ON A SPECIFIC TOPIC IN 2016:

Ms. Warriner discussed the possibility of continuing the opioid use and abuse CE topic or possibly choosing another pertinent topic for mandatory continuing education for pharmacists based on the allowance in §54.1-3314.1 J. Mr. Saenz asked the possibility of reaching out to the Department of Health or other agency to determine if there are other public health issues that may be problematic. Ms. Allen commented that we may want to see results from a continuing education audit from 2015 prior to choosing another mandatory topic for continuing education. Mr. Elliott agreed with Ms. Allen. Ms. Shinaberry stated that this one time mandatory CE was intended to educate on this specific topic and did not see a need to continue it in 2016.

**MOTION:**

**The Board voted unanimously to not have a mandatory topic of continuing education for pharmacists in 2016.**

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| • AMEND GUIDANCE DOCUMENT 110-27, PHARMACIST-IN-CHARGE RESPONSIBILITIES | Ms. Juran reported that staff occasionally receives questions on PIC responsibilities and recommends the board consider amending Guidance Document 110-27 to provide clarity on the subject. |
| **MOTION:** | **The Board voted unanimously to amend Guidance Document 110-27 as presented in the agenda packet which clarifies on page two of the document that the pharmacy permit application must indicate the effective date the pharmacist intends to assume the role as PIC, strikes the sentence regarding board approval of the signed application, and clarifies that the incoming PIC inventory must be taken prior to opening for business on the date the pharmacist first assumes the role as PIC. (motion by Logan, second by Saenz).** |
| • PRESENTATION ON THE HEALTH PRACTITIONERS' MONITORIN PROGRAM (HPMP): | Janet Knisely, Ph.D and Sherman Master, MD with the Virginia Commonwealth University presented to the Board information on the Health Practitioners' Monitoring Program including the mission of the program and the goals to achieve their mission. Some of the topics discussed during the presentation were the inception of the program, the intake process, toxicology testing process, case management, ongoing monitoring and reviewing the statistics of the program. A handout of their Power Point slides was provided. |
| • RECONSIDER DATE FOR MARCH 2016 FULL BOARD MEETING: | The Board unanimously agreed to change the date of the March 2016 Board meeting from March 29, 2016 to March 25, 2016 due to a scheduling conflict with Ms. Juran. |
| • SET DATES FOR JANUARY AND MARCH REGULATION COMMITTEE MEETINGS: | Ms. Juran indicated that the date for the Regulation Committee meeting had recently been scheduled for January 5, 2016 and that no further action was needed for that meeting. The Board unanimously agreed to schedule the March Regulation Committee meeting on March 24, 2016. |

REPORTS:

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| • Chairman's Report | Ms. Warriner informed the board that she had received a note from Dean DiPiro, Dean of the Virginia Commonwealth University School of Pharmacy congratulating the Board on receiving the NABP Fred T. Mahaffey award earlier this year. Additionally, she congratulated Ms. Logan for recently being appointed to the Board of Health Professions and thanked Ms. Shinaberry for her past participation on this board. Lastly, she thanked Ms. Thornbury for representing the board during the recent ACPE accreditation site visit at the Appalachian College of Pharmacy. |
| • Report on Board of Health Professions | Mr. Logan was appointed to the Board of Health Professions and since his appointment the board of health professions has not had a meeting. |

- Report on ACPE visit to Appalachian College of Pharmacy

Ms. Thornbury provided a report on the ACPE site visit to the Appalachian College of Pharmacy. Ms. Thornberry stated it was a very positive experience and very informative. She was thankful for the opportunity to attend this site visit and encouraged other board members to do so as the opportunity arises.

- Report on licensure program

In Mr. Johnson's absence, Ms. Juran provided the licensure report. She indicated the board currently licenses 36,838 individuals and facilities. The Board issued 763 licenses and registrations for the period of September 1, 2015 through November 29, 2015. Inspectors conducted 356 facility inspections including 154 routine inspections of pharmacies: 36 (23%) resulted in no deficiency, 53 (35%) with deficiencies and 65 (42%) with deficiencies and a consent order. Ms. Shinaberry commented that she noticed approximately 30% of all major deficiencies involved sterile compounding.

**ACTION ITEM:**

**Additionally, Ms. Shinaberry requested if staff could break out the hospital pharmacy from the community pharmacy statistics in the licensure report. Ms. Juran indicated this would have to be done manually, but that she would look into the feasibility of it.**

- Report on disciplinary program

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of March 24, 2015; June 12, 2015; September 28, 2015; and November 30, 2015. For the final date, she reported that there were no cases at the entry stage; 69 at the investigation stage; 158 at the probable cause stage; one at the administrative proceedings division stage; three at the informal stage; three at the formal stage; and 105 at the pending closure stage.

Further, Ms. Reiniers-Day discussed the importance of having the Special Conference Committees attend informal conferences on a monthly basis to avoid a backlog of informal conferences, but also cases for presentation. She thanked Ms. Allen and Mr. Boone for attending on November 23rd when two informal conferences were held and 54 cases were presented.

- Executive Director's report

Ms. Juran provided a handout which highlighted the meetings she or staff has attended since the last full board meeting. She reported Mr. Johnson and Ms. O'Halloran convened a job analysis meeting recently for the pharmacy technician exam. Additionally, Ms. O'Halloran attended training on sterile compounding offered by NABP for board staff and inspectors. She provided a brief update on staffing issues and mentioned two upcoming presentations that she will offer in the next month.

**CONSIDERATION OF CONSENT ORDERS**

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| Closed Meeting: | Upon a motion by Ms. Thornbury, and duly seconded by Ms. Elliott , the Board voted 10-0 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 two Consent Orders. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, James Rutkowski and Loni Dickerson 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. Elliott, the Board voted 10-0 in favor of accepting the Consent Orders as presented by Ms. Reiniers-Day in the matters of Denise A. Coffman and Sandy Rivers, pharmacy technicians. |
| ADJOURN: | With all business concluded, the meeting concluded at approximately 1:40 pm. |

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# PUBLIC HEARING FOR ADDRESSING HOURS OF CONTINUOUS WORK BY PHARMACISTS

December 1, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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| CALL TO ORDER: | The public hearing was called to order at 9:10a.m. |
| PRESIDING: | Cynthia Warriner, Chairman |
| MEMBERS PRESENT: | Michael I. Elliott<br>Freeda Cathcart<br>Ryan K. Logan<br>Rafael Saenz<br>Rebecca Thornbury<br>Ellen B. Shinaberry<br>Jody H. Allen |
| MEMBERS ABSENT: | Melvin L. Boone, Sr.<br>Sheila K. W. Elliot |
| STAFF PRESENT: | Caroline D. Juran, Executive Director<br>Cathy M. Reiniers-Day, Deputy Executive Director<br>Lisa Hahn, Chief Deputy Director, DHP<br>James Rutkowski, Assistant Attorney General<br>Elaine J. Yeatts, Senior Policy Analyst, DHP<br>Beth O'Halloran, Individual Licensing Manager<br>Sharon Davenport, Administrative Assistant |
| STAFF ABSENT: | J. Samuel Johnson, Jr., Deputy Executive Director |
| QUORUM: | With eight members present, a quorum was established. |
| CALL FOR COMMENT: | Ms. Warriner called for comment to the proposed amendments to Regulation 18VAC110-20-110 for addressing hours of continuous work by pharmacists. No public comment was provided.<br><br>A public comment period will remain open through January 29, 2016 on the Virginia Regulatory Townhall website. |
| ADJOURN: | The public hearing adjourned at 9:15am. |

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

**DRAFT/UNAPPROVED**
**VIRGINIA BOARD OF PHARMACY**
**SPECIAL CONFERENCE COMMITTEE MINUTES**

Tuesday, December 15, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy ("Board") was called to order at 9:30 a.m. |
| PRESIDING: | Jody Allen, Committee Chair |
| MEMBERS PRESENT: | Ryan Logan, Committee Member |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist |
| Alina D. Hunter<br>Registration No. 0230-023983 | Alina D. Hunter appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 13, 2015 Notice. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Alina D. Hunter. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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. Logan, and duly seconded by Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to issue an order that takes no action on Ms. Hunter's pharmacy technician registration. |

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| Julie N. Watson<br>Registration No: 0230-008511 | Julie N. Watson appeared to discuss the reinstatement of her pharmacy technician registration and allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the December 11, 2015, and July 15, 2015 Notices. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Julie N. Watson. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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. Logan, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order granting Ms. Watson's, reinstatement application for her pharmacy technician registration and that said registration be placed under terms and conditions. |
| Adjourn: | With all business concluded, the meeting adjourned at 1:00 p.m. |

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Tuesday, December 29, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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

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| CALL TO ORDER: | The meeting was called to order at 9:05 a.m. |
| PRESIDING: | Jodi Allen, Committee Chairperson |
| MEMBERS PRESENT: | Cynthia Warriner |
| STAFF PRESENT: | Caroline D. Juran, Executive Director<br>J. Samuel Johnson, Jr., Deputy Executive Director<br>Beth O'Halloran, Individual Licensing Manager<br>Anne Joseph, Deputy Executive Director, APD |
| University of Virginia Health System Pharmacy – Technology Check Technician Pharmacy System | The purpose of the informal conference was to act upon the Application of University of Virginia Health System (UVAHS) Pharmacy for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from UVAHS Pharmacy were Raphael Saenz, Administrator of Pharmacy Services and Pharmacist-In-Charge, Mathew Jenkins, Pharmacy Operations Manager, Matthew Allsbrook, PGY2 Pharmacy Administration Resident.<br><br>UVAHS Pharmacy, requested a waiver of Board of Pharmacy Regulations so that pharmacy technicians, rather than pharmacists, may perform the second medication check for first doses and drugs placed into automated drug dispensing cabinets. Additionally, UVAHS requested a waiver to allow a 1% random daily verification by a pharmacist of medications verified by pharmacy technicians rather than 5% verification.<br><br>Mr. Saenz and Mr. Jenkins provided an overview of the future process by which the pharmacy technician will be checking the technology in place indicating that medications go through four to five independent barcode scanning events prior to being dispensed to a patient. The pharmacy also dispenses medications to approximately 20 ambulatory care units using automated dispensing cabinets. UVAHS currently does not have the technology to perform barcode scanning of |

medications in its ambulatory clinics at the point of administration to the patients and plans to implement this in 2017. The request is for the pharmacist to perform a 1% check for medications dispensed for cart fill from the Talyst AutoCarousel system which is used also for first doses. Additionally, request was made for a 1% pharmacist check for medications dispensed for the intent to fill and stock the automated dispensing cabinets.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for UVAHS Pharmacy. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and Anne Joseph 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 § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen stated the Committee shall offer a consent order that approves the innovative (pilot) program for a period of three (3) years from the date the Order is entered by the Board with the following terms and conditions that were read by Ms. Joseph:

1. The requirement of 18VAC110-20-270(C), 18VAC110-20-420(A)(8)(d), 18VAC110-20-460(A), and 18VAC110-20-490(C)(1) of the Regulations shall be waived to allow pharmacy technicians to perform final verification for accuracy of all Schedule VI and over-the-counter products prior to leaving the pharmacy and to allow pharmacists to perform a daily random check of 5.0% of medications verified by pharmacy technicians. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all

discrepancies found.

2. Any technician performing such final verification shall hold current registration with the Board.
3. Pharmacists shall retain responsibility for maintaining the UVAHS Pharmacy medication barcode library.
4. This variance is allowed for inpatient settings and for ambulatory care settings in which patient barcode scanning is utilized at the final point of administration of medications. UVAHS Pharmacy shall notify the Board when barcode scanning is implemented in its ambulatory care units.
5. UVAHS Pharmacy shall comply with all other requirements of the Regulations Governing the Practice of Pharmacy.
6. At least one year after implementation of the program, UVAHS Pharmacy shall be subject to one unannounced inspection of the program and shall be responsible for the cost of said inspection.
7. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
8. UVAHS Pharmacy shall report any significant errors or problems to the Board immediately. The Executive Director of the Board, in consultation with the Committee Chair, is authorized to review the error report and require UVAHS Pharmacy to re-institute 100% pharmacist verification of all Schedule VI and over-the-counter medications leaving the pharmacy pending further review.
9. Any violation of this Order shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval shall be rescinded.

Virginia Oncology Associates Lake Wright In-Office Dispensary – Remote Prescription Approval

The purpose of the informal conference was to act upon the Application of Virginia Oncology Associates (VOA) Lake Wright In-Office Dispensary – Remote Prescription Approval for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-30-40. Present for the meeting from VOA Lake Wright were Mickey Dozier, Clinical Manager, Torrea Harris, Pharmacy

Manager, Jennifer Lee, Senior Manager Information Services, and Joel Andres, Government Relations Director from Kemper Consulting.

VOA Lake Wright, a practice of oncologists licensed to sell controlled substances, requested a waiver of 18VAC110-30-40 of the Regulations which require the practitioner who is licensed to sell controlled substances, prior to dispensing the controlled substance, to inspect the prescription product to verify its accuracy in all respects, and to place his initials on the record of sale as certification of the accuracy of and responsibility for the entire transaction. Ms. Dozier and Ms. Harris presented the future process for which the physicians licensed to dispense controlled substances would inspect and verify an electronic image of the prescription and drug via email.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for VOA Lake Wright. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and Anne Joseph 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 § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen stated the Committee denied the application. The Order is entered by the Board with the following conclusions of law that were read by Ms. Joseph:

1. The selling and storage area is locked and alarmed but has no additional security measures in place to prevent and detect the diversion of controlled substances. The proposed process would allow the pharmacy technician to practice

for extended periods of time within the storage and selling area without personal supervision by the practitioner during the hours of operation.

2. VOA Lake Wright presented a sample of the images that would be electronically transmitted to the prescriber for inspection and verification. The sample image does not appear to provide legible and sufficient information for safely verifying the accuracy of the drug product.
3. Based on the foregoing, the Committee concludes that the proposed waiver of the requirements of 18VAC110-30-40 (B)(2) of the Regulations for the VOA Lake Wright Remote Prescription Approval system does not adequately address the criteria enumerated in §54.1-3307.2 of the Code of Virginia.

ADJOURN: With all business concluded, the meeting adjourned at 4:00 p.m.

Jody Allen, Committee Chairman

Date

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

DRAFT/UNAPPROVED

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

January 5, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:15pm

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT: Ryan K. Logan
Cynthia Warriner
Melvin L. Boone, Sr.
Rebecca Thornbury

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

**APPROVAL OF AGENDA:** The agenda was approved as presented.

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

**PUBLIC COMMENT:** Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) provided further explanation of the written comments submitted to the Board requesting a strengthening of 18VAC110-20-270 to address concerns with pharmacists not being provided adequate pharmacy technician support.

**AGENDA ITEMS:** Ms. Yeatts reviewed the procedure with the Committee of this periodic review process. The Committee is to consider the public comment recently received and recommend regulations to the full board for its consideration which should be drafted or amended. If the full board agrees, a Notice of Intended Regulatory Action (NOIRA) will be adopted which simply identifies the areas of regulation the board may address. Once the executive branch review is completed and approval to publish



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the NOIRA is received, another public comment period will be opened for 30 days. Based on the comment received, the Board will then develop the proposed regulatory language. After review and approval by the Governor, the proposed regulations will be published and another public comment period will be opened for 60 days. Comment will be reviewed by the Board, final regulation will be adopted, and once the Governor approves the final regulation, a 30-day final adoption period will begin.

The Committee reviewed written comments, provided as a handout by staff, regarding areas of regulation to consider amending during the periodic review. The handout included comments from pharmacist Jon Horton and pharmacist Jamin Engel submitted to Regulatory Town Hall, an email from VPhA, and a letter from NACDS. The committee determined it would not recommend the drafting of a regulation to allow for pharmacy technicians checking pharmacy technicians when using unit dose dispensing systems since this process could be considered on a case-by-case basis through the submission of an innovative pilot program application. Additionally, the Committee determined it would not recommend an allowance for regionalization of hospital packaging and compounding as this does not appear to be permissible under federal or state law. The Committee recommended including 18VAC110-20-190 and 18VAC110-20-270 in the NOIRA and will ensure the rulemaking aligns with any federal changes resulting from the Drug Quality and Security Act.

- Review of Parts V - XII of *Regulations Governing the Practice of Pharmacy, Chapter 20*

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

- Review of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers, Chapter 50*

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

The Committee rejected staff's proposed amendment of 18VAC110-20-330 to require an expiration date on a prescription label.

- Draft regulatory language for NOIRA regarding unprofessional conduct to induce or incentivize a patient to transfer prescriptions.

Ms. Juran reviewed the excerpt of the Regulation Committee minutes from May 12, 2014 included in the agenda packet and the research summary presented at the time. The committee reviewed the proposed amendment prepared by staff for the Regulation Committee's review on May 12, 2014 as well as an excerpt from the full board meeting minutes from June 4, 2014.

**MOTION:**

**The Committee voted unanimously to approve the proposed amendment to 18VAC110-20-25 as presented which would add "#11. Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not limited to, incenting or inducing the transfer of a prescription absent professional rationale" to the regulation on unprofessional conduct. (motion by Warriner, second by Thornbury)**

**ADJOURN:**

Next Regulation Committee meeting is tentatively scheduled for March 24, 2016.

With all business concluded, the meeting adjourned at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

Below are regulations in *Regulations Governing the Practice of Pharmacy*, Chapter 20, Parts V-XII and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, Chapter 50 identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

**18VAC110-20-10**

- Review definition for "robotic pharmacy system".

**18VAC110-20-190**

- Consider amending physical requirements for a prescription department's enclosure.
- Consider amending A, 2 to not allow locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

**Part VI Drug Inventory and Records**

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

- Consider adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Consider deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Consider clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

**Part VII Prescription Order and Dispensing Standards**

**18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians**

- Consider separating subsections A and B from the rest of the regulation.
- Consider addressing VPhA's concern with pharmacists not being provided adequate pharmacy technician support in subsection B.
- Regarding subsection E, consider appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, Warriner questioned if a pharmacist is required to pull the originally filed prescription and refile it. Staff to review issue.
- Consider adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

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

- Consider amending to address delivery of Schedule II-VI drugs to a central desk at other facilities, e.g., assisted living facilities, hotels, places of employment, etc. Staff to consult DEA.
- Consider addressing concerns with white bagging and brown bagging.

*18VAC110-20-277 Prescription Requirements*

- Consider adding new regulation 18VAC110-20-277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

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

- Determined that staff's suggested amendments to clarify that signature must be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Consider whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

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

- Consider adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

**Part VIII Labeling and Packaging Standards for Prescriptions**

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

- Consider amending requirement for how to identity pharmacist verifying accuracy of the process.
- Consider reviewing all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

**Part X Unit Dose Dispensing Systems**

**18VAC110-20-425 Robotic Pharmacy Systems**

- Consider streamlining robotic pharmacy system regulations by striking #5 and simplifying #4. May also need to amend the definition of robot.
- Consider strengthening requirements for pharmacist accountability in assigning bar codes.

**Part XI Pharmacy Services to Hospitals**

**18VAC110-20-470 Emergency room**

- In #2, consider changing "practitioner" to "prescriber".

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

- Consider streamlining requirements for automated dispensing devices in hospitals.
- Consider clarifying that drug for emergency use may include drugs for first doses.
- Consider clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

**Part XII Pharmacy Services to Long-Term Care Facilities**

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

- Consider clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarify that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

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

- Consider whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

## REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

### Part I General Provisions

**18VAC110-50-40 Safeguards against diversion of drugs**

- Consider amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Consider amending 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 operable.

### Part II Wholesale Distributors

**18VAC110-50-60 Special or limited-use licenses**

- Consider expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

**18VAC110-50-70 Minimum required information**

- Consider placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

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

- Consider requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.
- For consistency, consider similar requirements in 18VAC110-20-80 for responsible party of manufacturers.

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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March 4, 2016

**MEMORANDUM**

TO: The Honorable William A. Hazel Jr. MD
Secretary of Health and Human Resources

FROM: David E. Brown, DC, Director
Department of Health Professions

RE: **Report on Pharmacy Benefit Managers**

A Workgroup was convened by the Department of Health Professions to look at issues involving Pharmacy Benefit Managers (PBMs) and to make recommendations regarding the need for additional oversight of PBMs. The Workgroup included representatives from the Virginia Boards of Pharmacy and Medicine, various state agencies (VDH, DHRM, DMAS), Virginia Bureau of Insurance, Medical Society of Virginia, Virginia Pharmacists Association, National Community Pharmacists Association, Virginia Association of Chain Drug Stores, Pharmaceutical Care Management Association, Virginia Association of Health Plans, Anthem Blue Cross and Blue Shield, and Express-Scripts.

The Workgroup concluded that there were five options but was able to reach a consensus on only two of them. There was consensus on the need to convene a meeting of key stakeholders to address concerns with the prior authorization process and for the Board of Pharmacy to review the practices of white bagging and brown bagging to address issues of concern.

A copy of the Workgroup's report is provided for your information. Please let us know if any additional information or assistance is needed.

cc: Dr. Jennifer Lee
Del. Keith Hodges
Del. Chris Jones
PBM Workgroup Members

DEB/lzr

# Report of the Pharmacy Benefit Managers Workgroup

## Virginia Department of Health Professions

**March 4, 2016**

### Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Association of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

### Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

### Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

## Introduction:

In a letter from United States Senator Mark R. Warner dated February 19, 2015, the Virginia Board of Pharmacy was requested to look into a constituent's concern involving pharmacy benefit managers (PBM) and provide an appropriate response. The constituent requested that Senator Warner assist him with concerns regarding pharmacy benefit manager oversight as the Virginia State Corporation Commission, Bureau of Insurance, and Board of Pharmacy had informed him that they did not have legal authority to oversee or act on his complaint. The constituent alleged CVS Caremark and other PBMs discriminate against independent pharmacies by requiring documentation during the credentialing and re-credentialing process that are not required of chain pharmacies. He stated refusing to provide the documentation will result in a termination of the contract with the PBM for reimbursement of prescriptions. The constituent indicated that the un-level playing field threatens the survival of independent pharmacies and their ability to conduct normal business.

In a letter dated February 24, 2015 on behalf of the Board Chairman, the Executive Director for the Board of Pharmacy, after speaking with a representative of the Bureau of Insurance, confirmed to Senator Warner that neither agency has the authority to license PBMs or address the concerns expressed by the constituent. The letter indicated that there appears to be a possible lack of oversight in state law in regulating pharmacy benefit managers and that the board would discuss the issue further at its next meeting in March 2015.

At the March 24, 2015 Board of Pharmacy full board meeting, the Board heard comment from the National Community Pharmacists Association, the Medical Society of Virginia, the Virginia Pharmacists Association, EPIC Pharmacies, and owners of two independent pharmacies. Concerns included: lack of oversight of PBMs; impact PBM decision-making may have on patient access to medications, particularly in a rural setting; burdensome credentialing and re-credentialing processes that lack standards and demand too much of the pharmacist's time; PBMs' ability to designate drugs as specialty drugs and requiring them to be dispensed by mail order pharmacies often owned by PBMs; concerns with mail order pharmacies complying with statutory requirement for a bona fide pharmacist-patient relationship; and, an exclusion of the Bureau of Insurance in HB 1942 and SB 1262 during the 2015 General Assembly session to adjudicate patient disputes or disagreements regarding denial of access to medications by insurance carriers or the PBMs with which the carriers contract. Commenters requested that the Regulation Committee of the Board of Pharmacy further review concerns with patient safety, medication access, and determine if registration or licensure of PBMs is warranted. A 2013 report of the National Association of Boards of Pharmacy which considered the issue of regulation of PBMs was provided by the Medical Society of Virginia for the Board's consideration. Following deliberation, the Board concluded that some of the concerns do not fall within the Board's jurisdiction, but that the issue should be referred to the Regulation Committee for a more thorough review.

The Regulation Committee of the Board of Pharmacy considered this matter on May 11, 2015. Public comments provided to the Committee addressed concerns with patient safety based on an inability to obtain prescribed drugs in a timely manner and an increasing number of drugs requiring prior authorizations or being classified as specialty drugs which require dispensing

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, David Brown, D.C., Director of the Department of Health Professions (DHP), and Caroline Juran, Executive Director of the Board of Pharmacy, recommended that Dr. Brown discuss with William A. Hazel Jr., MD, Secretary of Health and Human Resources, the possibility of forming a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

## Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human Resources Management. There is no state oversight for self-insured (Employee Retirement Income Security Act, aka ERISA) health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) has the authority to oversee the administration of benefits by fully-insured health plans but does not have authority to directly oversee the PBMs with which the health plans may contract to fulfill certain functions. Oversight of PBMs is indirect, through the contracting fully-insured health plan. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies but may not require it unless the health plan deems the drug a specialty drug which the health plan may require to be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to fully-insured health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, and a complaint system in place. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs as is the case with other subcontractors the health plan has contracted with to deliver health care benefits to beneficiaries, e.g., behavioral health, vision, and dental.

## Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last

decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Health plans make decisions as to formulary management, plan design, and cost-sharing. The PBM administers the plan per the contract with the client. PBMs' clients include the federal government, state governments, large employers, and health plans. Common approaches in the industry for PBMs to mitigate the high costs of drugs include requiring prior authorizations of certain drugs, requiring certain drugs to be dispensed from a specialty pharmacy or mail order pharmacy, the development of pharmacy networks, disease management, and claims processing. In the 2013 National Association of Boards of Pharmacy *Report of the Task Force on the Regulation of Pharmacy Benefit Managers*, which updated and broadened information from the 1999 Task Force on Licensing of Pharmacy Benefit Managers, the following activities performed by a PBM were identified as activities which may encompass the practice of pharmacy: disease state management; disease compliance management; drug adherence management; drug interaction management; drug utilization management; formulary management; generic alternative program management; generic incentive program management; medical and/or drug data analysis; patient drug utilization review services; prior authorization services; provider profiling and outcomes assessment; refill reminder program management; therapy guidelines management; stop therapy protocol management; wellness management; maintenance of confidential patient information; and, direction or design of the clinical programs for a pharmacy or a group of pharmacies.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. The plan design determines which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug; and the specialty pharmacies may have a financial relationship with the PBMs or may be operated by an independent pharmacy, chain pharmacy or a Health System.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the health plan or the PBM, unless the patient is willing to pay the cash price. The purposes of prior authorization are decreasing overall healthcare costs as well as managing health and safety by ensuring the patient is receiving the least expensive, yet most effective drug therapy. Health plans determine which drugs require prior authorization, and this status can vary based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are often informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

## Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

**"White bagging and brown bagging"**

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

**Parity regarding access to and requirements of plans**

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

**Prior authorizations**

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management.

e.g., identifying prescribing errors and mitigating the significant increase in drug costs imposed by pharmaceutical manufacturers, but that process improvements for prior authorization are needed.

The Workgroup also identified the current model as a reactive prior authorization process and acknowledged that patients, prescribers, pharmacists, health plans, and PBMs would benefit from a more proactive process. Online resources for prescribers to determine drug coverage at the point of prescribing was briefly discussed, but challenges with time and accuracy of information create barriers to this solution. The National Adoption Scorecard for Electronic Prior Authorization from covermymeds® was reviewed and discussed. There was general consensus that the proactive process with electronic prior authorizations would significantly reduce the amount of time for all involved in handling prior authorizations and reduce the time delay in patients having access to the prescribed drugs. The Workgroup acknowledged that electronic prior authorizations cannot be utilized until electronic prescribing is commonplace. New York will be the first state to require all prescriptions to be electronically transmitted as of March 2016, and there is interest in monitoring the success of this requirement. In the interim, there was consensus that the Medical Society of Virginia, along with the Virginia Pharmacists Association, should meet with Virginia Health Plans and other key stakeholders with appropriate technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and expanding the use of e-prescribing by prescribers.

**Credentialing process**

Comment was received from several independent pharmacy owners, including the pharmacist who wrote Senator Warner, that the credentialing process of the health plans is overly burdensome, lacks standards regarding the process and frequency at which they occur, and impacts patient care by reducing the pharmacist's time available for patient care. The process often involves verification of state licensure, DEA registration, National Provider Identification number, valid Medicare participation, valid pharmacist-in-charge, liability coverage, review of any disciplinary action, and review of state and federal tax files. In response to allegations in the letter to Senator Warner that CVS Caremark discriminated against an independent pharmacy by requesting information from it that CVS Caremark did not request from chain pharmacies, a representative from CVS Caremark indicated it requests the same information from all pharmacies. There was discussion regarding why CVS Caremark needed a pharmacy floorplan, as this information is maintained confidentially by the Board of Pharmacy to reduce security risks. Presently, no uniform standards exist in State law regarding information which can be requested by a PBM during the credentialing and re-credentialing process. It was suggested that such standards could possibly be enacted through the current oversight structure of health plans. Monitoring of the PBMs for compliance of such standards and any enforcement action against the PBM would then be the responsibility of the health plan, since the current oversight model provides health plans with the responsibility for their PBM contracts.

**PBM communication with patients**

Comment was received from independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacy Association regarding concerns with PBMs calling patients of specific pharmacies to encourage them to use a different pharmacy. Those

representing health plans and PBMs acknowledged that patients may be notified via different methods to maximize health benefits and reduce costs. Whether it is appropriate for PBMs, or health plans to require PBMs to use their access to patient identification information for this purpose was called into question. Additionally, there was some concern that such notifications may be confusing to patients.

**Filing complaints/Appeals Process**

There was concern expressed by some Workgroup members that both patients and providers are generally unaware of who to contact or how to file a complaint regarding concerns with their drug coverage or access. Those members associated with health plans reported that patients receive this information in the insurance documents provided by the employer or health plan; however, it was suggested that perhaps this information should be more prominent or user-friendly. It was noted that the health plan contact information for patients who have any issues is already on their health plan benefit identification card. However, it was suggested that the card should also include the number of the appropriate regulatory entity for escalating a complaint when the patient does not feel the issue has been satisfactorily resolved by the health plan. Regarding what entity is appropriate for receiving complaints, there was some discussion that complaints should be filed with the employer, but there was concern that many employers may not know how to address such complaints. It was noted that current law within Title 38.2 of Virginia Code, along with BOI regulations, require fully-insured health plans to make available an internal appeals process, but that the timeframe for resolution within such appeal processes may vary among the health plans. The law also currently addresses an external review of adverse determinations rendered by health carriers and the qualifying conditions for such review. Furthermore, as a self-insured health plan, the insurer for state employers has an ombudsman to receive complaints; however, Virginia does not have a designated ombudsman for addressing concerns with fully-insured health plans. VDH OLC and the BOI investigate matters after identifying a pattern of complaints but do not generally investigate individual complaints.

**Impact on rural communities**

Independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacists Association expressed concern that current PBM practices impact their ability to dispense prescriptions and are resulting in the closing of many independent pharmacies. One pharmacist indicated that four (4) pharmacies have closed recently in his rural area and should he be forced to close, patients would then have to drive 40 miles roundtrip to the nearest pharmacy. Because pharmacists are often the most accessible, if not the only, healthcare professional in rural settings, it was stated that healthcare questions may go unanswered, and compliance with optimal drug therapy may suffer. Independent pharmacies do not believe the current practices allow for a level playing field, as they feel PBMs are incentivized to drive business to the mail order and specialty pharmacies that have a financial relationship with the PBMs. During Workgroup discussions, those representing health plans and PBMs noted that other factors may also be impacting pharmacy care in rural settings such as current requirements of the Centers for Medicare and Medicaid Services (CMS), increased competition with chain pharmacies, and the willingness of other pharmacies to accept certain reimbursement rates. Additionally, they recommended that the viability of the business prior to closure should be taken into consideration, as some closures may result from the selling of a successful business.

**Recent actions regarding additional oversight**

An antitrust attorney commented that the Federal Trade Commission (FTC) is not adequately reviewing anticompetitive standards with current PBMs. He felt additional oversight of PBMs is warranted, because no one is currently looking after the patients' rights and that what the Workgroup is considering is very basic. Those representing health plans and PBMs indicated the FTC has repeatedly opined that PBMs operate in a competitive environment. There was also discussion of the passing of an Iowa law impacting PBMs and a federal court judge's decision that ERISA does not preempt states from regulating PBMs. The decision is currently under appeal. Those representing health plans and PBMs noted that there have been other cases that uphold the ERISA preemption, and that this case is not in the Virginia circuit. During public comment, it was stated that many states are taking reasonable reform action of PBMs and that recently 26 transparency bills and 34 audit reform bills were introduced across the states. Those representing health plans and PBMs noted that the Virginia General Assembly has already addressed and enacted bills on these subjects. The public commenter also stated that simply licensing PBMs does not equal oversight and that enforcement powers are necessary.

The National Association of Boards of Pharmacy convened a task force in 2014 to review oversight of PBMs. It identified several tasks that may constitute the practice of pharmacy for which licensure and Board of Pharmacy oversight is appropriate. Presently, the Mississippi Board of Pharmacy is the only board of pharmacy to directly oversee PBMs. Based on Virginia's current model, there was discussion that it may be more appropriate to place potential oversight with the VDH OLC. While VDH OLC does not have a formal position on this matter, it is willing to assume this oversight if resources are provided.

**Establishment of drug formularies**

Title 38.2 of the Code of Virginia authorizes a health plan to apply a formulary to the prescription drug benefits if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics (P&T) committee consisting of practicing licensed pharmacists, physicians, and other licensed health care providers. While it was stated a PBM may elect to use an independent P&T committee for the clinical review of drugs, there is no express requirement in law for an independent review. The law does not address the role of PBMs in the establishment of drug formularies; however, during discussions it was stated that PBMs may negotiate costs with drug manufacturers and may offer drug formulary recommendations to health plans who determine the drug formularies. The PBMs and health plans stated that ultimately the employer determines what drugs will be covered. It was noted that one pharmacy employer commented that he has never been asked to provide input into the process.

**Drug waste**

Because mail order pharmacies typically dispense 90-day supplies, a concern was expressed by the National Community Pharmacists Association that requiring or incentivizing patients to use mail order pharmacies may result in wasted drugs if the patient does not complete the entire course of medication. During discussion it was noted that sources for drug waste other than mail order pharmacies may exist and that this issue should be discussed more broadly to include discussions on the appropriateness of current benefit design and if the Boards of Pharmacy or Medicine should consider restrictions on prescribing or dispensing.

**Specialty drugs**
There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

## Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

**Other Possible Policy Options/Considerations:**
Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

# Board of Pharmacy

## Report of the 2016 General Assembly

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**HB 314 Drugs; administration by certain school employees.**

*Chief patron:* Orrock

*Summary as passed House:*

**Administration of drugs by certain school employees.** Provides that a prescriber may authorize an employee of a school for students with disabilities licensed by the Board of Education, or a private school accredited pursuant to § 22.1-19 of the Code of Virginia as administered by the Virginia Council for Private Education, who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia pursuant to a written order or standing protocol and provides immunity from civil damages to such employees for ordinary negligence in acts or omissions resulting from the rendering of such treatment, provided that the insulin is administered in accordance with the child's medication schedule or such employee has reason to believe the individual receiving the glucagon is suffering or about to suffer life-threatening hypoglycemia. The bill also allows nurse practitioners and physician assistants to provide training programs on the administration of drugs to students of private schools accredited pursuant to § 22.1-19 of the Code of Virginia as administered by the Virginia Council for Private Education.

**HB 319 Health regulatory boards; continuing education for certain individuals.**

*Chief patron:* Rasoul

*Summary as passed House:*

**Volunteer health care providers.** Requires health regulatory boards to promulgate regulations providing for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. The bill has a delayed effective date of January 1, 2017.

**HB 527 Nonresident medical equipment suppliers; registration with Board of Pharmacy**

*Chief patron:* Hodges

*Summary as passed House:*

**Registration of nonresident medical equipment suppliers.** Requires any person located outside the Commonwealth other than a registered nonresident pharmacy that ships, mails, or delivers to a consumer in the Commonwealth any hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled

device, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, sterile water and saline for irrigation, or solutions for peritoneal dialysis pursuant to a lawful order of a prescriber to be registered with the Board of Pharmacy. The bill requires registrants to renew registration by March 1 of each year and to notify the Board of Pharmacy of any substantive change in information previously submitted to the Board within 30 days. The bill also requires nonresident medical equipment suppliers to maintain a valid, unexpired license, permit, or registration in the state in which it is located, if required by the resident state, or to furnish proof that it meets the minimum statutory and regulatory requirements for medical equipment suppliers in the Commonwealth if the state in which the nonresident medical equipment supplier is located does not require a license, permit, or registration. The bill also requires nonresident medical equipment suppliers to maintain records of distribution of medical equipment into the Commonwealth in such a manner that they are readily retrievable from records of distribution into other jurisdictions and to provide the records to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

**HB 528 Prescription drugs; manufacture and distribution in the Commonwealth.**

*Chief patron:* Hodges

*Summary as passed:*

**Manufacture and distribution of prescription drugs in the Commonwealth.** Eliminates the requirement that the Board of Pharmacy establish and implement a pedigree system for recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer to a dispenser or person who will administer the controlled substance; defines "co-licensed partner" as a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law, and specifies that a co-licensed partner may be a manufacturer of a controlled substance; and defines "third-party logistics provider" as a person who provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product. The bill specifies that bulk drug substances used for compounding drugs distributed by a supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board of Pharmacy as well as the federal Food and Drug Administration and requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed. The bill authorizes the Board of Pharmacy to deny, revoke, suspend, or take other disciplinary actions against holders of a third-party logistics provider permit, manufacturer permit, or nonresident manufacturer permit; applies the inspection and audit requirements that apply to wholesale distributors to nonresident wholesale drug distributors, third-party logistics providers, manufacturers, and nonresident manufacturers; creates a permitting process for third-party logistics providers; allows holders of a manufacturer permit to distribute the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit; and creates a process for registration of nonresident manufacturers of prescription drugs.

**HB 586 Health regulatory boards; confidentiality of certain information obtained by boards.**

*Chief patron:* Yost

*Summary as passed House:*

**Confidentiality of certain information obtained by health regulatory boards in disciplinary proceedings.** Provides that in disciplinary actions involving allegations that a practitioner is or may be unable to practice with reasonable skill and safety to patients and the public because of a mental or physical disability, a health regulatory board shall consider whether to disclose and may decide not to disclose in its notice or order the practitioner's health records or his health services, although such information may be considered by the board in a closed hearing and included in a confidential exhibit to a notice or order. The bill provides that the public notice or order shall identify, if known, the practitioner's mental or physical disability that is the basis of its determination.

**HB 629 Prescription drugs; pharmacies may participate in voluntary drug disposal programs.**

*Chief patron:* Hodges

*Summary as passed House:*

**Prescription drug disposal.** Provides that pharmacies may participate in voluntary drug disposal programs, provided that such programs are operated in accordance with state and federal law by a pharmacy, and requires the Board of Pharmacy to maintain a list of such pharmacies on a website maintained by the Board. The bill also provides that no person that participates in a drug disposal program shall be liable for any theft, robbery, or other criminal act related to participation in the pharmacy drug disposal program or for any acts of simple negligence in the collection, storage, or destruction of prescription drugs collected through such pharmacy drug disposal program, provided that the pharmacy practice site is acting in good faith and in accordance with applicable state and federal law and regulations.

**HB 657 Prescription Monitoring Program; indicators of misuse, disclosure of information.**

*Chief patron:* O'Bannon

*Summary as passed House:*

**Prescription Monitoring Program; indicators of misuse; disclosure of information.** Directs the Director of the Department of Health Professions to develop, in consultation with an advisory panel that shall include representatives of the Boards of Medicine and Pharmacy, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and authorizes the Director to disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions.

**HB 829 Prescribers of covered substances; continuing education.**

*Chief patron:* Stolle

*Summary as passed House:*

**Prescribers of covered substances; continuing education.** Authorizes the Director of the Department of Health Professions to disclose information to the Board of Medicine about prescribers who meet a certain threshold for prescribing covered substance for the purpose of requiring relevant continuing education.

The threshold shall be determined by the Board of Medicine in consultation with the Prescription Monitoring Program. The bill also directs the Board of Medicine to require prescribers identified by the Director of the Department of Health Professions to complete two hours of continuing education in each biennium on topics related to pain management, the responsible prescribing of covered substances, and the diagnosis and management of addiction. Prescribers required to complete continuing education shall be notified of such requirement no later than January 1 of each odd-numbered year. The provisions of the bill will expire on July 1, 2022.

**HB 1044 Prescription Monitoring Program; disclosure of certain information.**

*Chief patron:* Landes

*Summary as passed House:*

**Prescription Monitoring Program; disclosures.** Provides that the Director of the Department of Health Professions may disclose information in the possession of the Prescription Monitoring Program about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia Medicaid managed care program to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. The bill also requires the Prescription Monitoring Program advisory committee to provide guidance to the Director regarding such disclosures.

**HB 1077 Drug Control Act; adds certain chemical substances to Schedule I.**

*Chief patron:* Garrett

*Summary as introduced:*

**Drug Control Act; Schedule I.** Adds certain chemical substances to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to SB 480.

**HB 1292 Schedule IV drugs; adds eluxadoline to list.**

*Chief patron:* Pillion

*Summary as passed House:*

**Schedule IV drugs; eluxadoline.** Adds eluxadoline to the list of Schedule IV drugs.

**SB 287 Prescription Monitoring Program; reports by dispensers shall be made within 24 hours or next day.**

*Chief patron:* Wexton

*Summary as passed Senate:*

**Prescription Monitoring Program.** Provides that, beginning January 1, 2017, reports by dispensers to the Prescription Monitoring Program (the Program) shall be made within 24 hours or the dispenser's next business day, whichever comes later. The bill also allows the Director of the Department of Health Professions to disclose information about a specific recipient to a prescriber for the purpose of establishing the treatment history of the specific recipient when the prescriber is consulting on the treatment of such recipient; allows the Director to disclose information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in providing clinical consultation on the care and treatment of the recipient; removes the requirement that information disclosed to a dispenser for the purpose of determining the validity of a prescription be disclosed only when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices; and provides that a prescriber may include information obtained from the Program for the purpose of establishing the treatment history of a specific recipient in the recipient's medical record.

**SB 513 Prescription Monitoring Program; requirements of prescribers of opiates.**

*Chief patron:* Dunnavant

*Summary as passed Senate:*

**Prescription Monitoring Program; requirements of prescribers opioids.** Requires a prescriber to obtain information from the Prescription Monitoring Program at the time of initiating a new course of treatment that includes the prescribing of opioids anticipated to last more than 14 consecutive days. Currently, a prescriber must request such information when a course of treatment is expected to last 90 days. The bill also eliminates the requirement that a prescriber request information about a patient from the Prescription Monitoring Program when prescribing benzodiazepine; allows a prescriber to delegate the duty to request information from the Prescription Monitoring Program to another licensed, registered, or certified health care provider who is employed at the same facility under the direct supervision of the prescriber or dispenser who has routine access to confidential patient data and has signed a patient data confidentiality agreement; and creates an exemption from the requirement that a prescriber check the Prescription Monitoring Program for cases in which (i) the opioid is prescribed to a patient currently receiving hospice or palliative care; (ii) the opioid is prescribed to a patient as part of treatment for a surgical procedure, provided that such prescription is not refillable; (iii) the opioid is prescribed to a patient during an inpatient hospital admission or at discharge; (iv) the opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy; (v) the Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or (vi) the prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record. The bill requires the Director of the Department of Health Professions to report to the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health on utilization of the Prescription Monitoring Program and any impact on the prescribing of opioids. The provisions of the bill expire on July 1, 2019.

**SB 701 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.**

*Chief patron:* Marsden

*Summary as passed Senate:*

**Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.** Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil. The bill requires the Board of Pharmacy to adopt regulations establishing health, safety, and security requirements for permitted processors. The bill also requires that a practitioner who issues a written certification for cannabidiol and THC-A oil and the patient or his primary caregiver to register with the Board and requires a permitted pharmaceutical processor, prior to providing the patient or his primary caregiver and the practitioner who issues a written certification have registered with the Board. Finally, the bill provides criminal liability protection for pharmaceutical processors. An enactment clause provides that except for provisions requiring the Board of Pharmacy to promulgate regulations, the provisions of the bill do not become effective unless reenacted by the 2017 Session of the General Assembly.

**Agenda Item:** **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of March 1, 2016

Action: None – provided for information only

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

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Outsourcing facilities [Action 4452]<br>Emergency/NOIRA - *Register*<br>*Effective: 12/7/15 to 6/6/17*<br>*Comment on NOIRA ended: 1/27/16* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>NOIRA - *Register Date: 11/16/15*<br>*Comment on NOIRA ended: 12/16/15* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Addressing hours of continuous work by pharmacists [Action 3755]<br>Proposed - *Register Date: 11/30/15*<br>*Comment on proposed ended: 1/29/16* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Collection sites for disposal of unused drugs [Action 4337]<br>Fast-Track - *Register Date: 2/8/16*<br>*Effective: 3/24/16* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Repackaging at PACE sites [Action 4453]<br>Fast-Track - *Register Date: 3/7/16*<br>*Effective: 4/21/16* |
| [18 VAC 110 - 30] | Regulations for Practitioners of the Healing Arts to Sell Controlled Substances | Permits for facilities [Action 4451]<br>Emergency/NOIRA - *Register*<br>*Effective: 12/7/15 to 6/6/17*<br>*Comment on NOIRA ended: 1/27/16* |

**Agenda Item:** **Adoption of Notice of Intended Regulatory Action**

**Staff Note:**

The Board issued a Notice of Periodic Review with comment requested from 11/30/15 to 12/30/15. Subsequently, the Regulation Committee held two meetings to review Chapters 20 and 50 – Regulations Governing the Practice of Pharmacy and Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers.

**Included in your package are copies of:**

- Copy of Notice of Periodic Review
- Copies of comments on the Review
- Draft substance of the Notice of Intended Regulatory Action identifying the sections for which the Board is considering amendments.

**Action:**

Motion to adopt the Notice of Intended Regulatory Action as recommended by the Regulation Committee.

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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]**

Edit Review

## Periodic Review of this Chapter

Includes a Small Business Impact Review

**Date Filed:** 11/3/2015

**Review Announcement**

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Board of Pharmacy is conducting a periodic review and small business impact review of VAC citation: 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy and 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers.

The review of this regulation will be guided by the principles in Executive Order 17 (2014). http://dpb.virginia.gov/regs/EO17.pdf

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins November 30, 2015, and ends on December 30, 2015.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Name: Elaine Yeatts, Title: Agency Regulatory Coordinator, Address: 9960 Mayland Drive, Suite 300, City: Henrico, State: Virginia, Zip: 23233, FAX: 804-527-4434, email address: elaine.yeatts@dhp.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

**Public Comment Period**

Begin Date: 11/30/2015 End Date: 12/30/2015

**Comments Received: 2**

**Review Result**

Pending

**Attorney General Certification**

Pending

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Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Previous Comment Back to List of Comments

**Commenter:** Jon Horton, Sentara Norfolk General * 12/24/15 12:16 pm

**Tech-Check-Tech**

Please thoughtfully consider the addition of Tech-Check-Tech within Part X regulating Unit Dose Dispensing Systems.

Tech-Check-Tech programs have been in existence since 1978 and are currently approved for use in 12 states. In a 2009 NABP survey California, Colorado, Idaho, Iowa, Kansas, Kentucky, Michigan, Minnesota, Montana, North Dakota, South Carolina, and Washington indicated that they allowed pharmacy technicians to check the work of other technicians in hospital and institutional or community settings. Studies have demonstrated the value of these programs in providing safe and effective care in the institutional setting. They have demonstrated that a technician's accuracy of final dispensing checks is comparable to a pharmacist's accuracy in performing final dispensing checks. Allowance for implementation of Tech-Check-Tech programs would maintain the accuracy of the checking process and facilitate a pharmacists' involvement in providing direct patient care services.

Please consider addition to the Virginia Board of Pharmacy regulations the allowance for Tech-Check-Tech processes within Part X. Language found in Kansas law clearly identifies the requirements for technicians who would qualify as a checking technician as well as a process for training technicians and evaluating their competency once they have met the criteria to qualify ( http://www.sos.ks.gov/pubs/kar/2013/068_68-Board%20of%20Pharmacy,%202013%20KAR%20Supp.pdf ):

*"...a pharmacy technician in a medical care facility may check the work of another pharmacy technician in filled floor stock, a crash cart tray, a unit dose cart, or an automated dispensing machine if the checking pharmacy technician meets each of the following criteria:*

*(1) Has a current certification issued by the pharmacy technician certification board or a current certification issued by any other pharmacy technician certification organization approved by the board. Any pharmacy technician certification organization may be approved by the board if the board determines that the organization has a standard for pharmacy technician certification and recertification not below that of the pharmacy technician certification board;*

*(2) has either of the following experience levels:*

*(A) One year of experience working as a pharmacy technician plus at least six months experience working as a pharmacy technician in the medical care facility at which the checking will be performed; or*

*(B) one year of experience working as a pharmacy technician in the medical care facility at which the checking will be performed; and*

*(3) has successfully completed a written training program and related examination designed by the*

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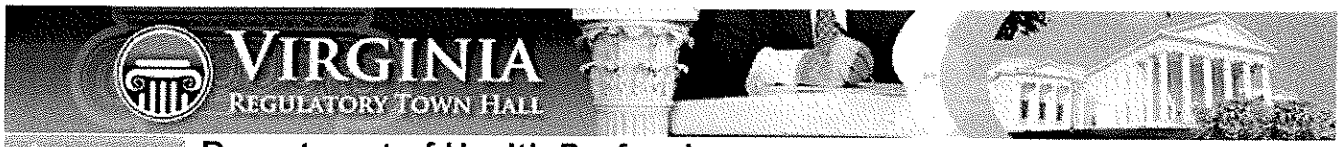
*pharmacist-in-charge of the medical care facility pharmacy to demonstrate competency in accurately checking whether floor stock, a crash cart tray, and an automated dispensing machine have been properly filled."*

Respectfully submitted for your consideration!

* Nonregistered public user

42 D

Virginia.gov Agencies | Governor




Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Next Comment Back to List of Comments

**Commenter:** Jamin Engel, Pharmacy Manager at Sentara RMH Medical Center * 12/11/15 3:47 pm

**Regionalization of Hospital Packaging**

Please thoughtfully consider the addition of regionalization of hospital packaging within Part XI regulating Pharmacy Services to Hospitals.

ASHP Pharmacy Forecast for 2015-2019 indicates that the pharmacy departments in at least 50% of hospitals will be responsible for preparing nearly all compounding sterile products needed for the hospital's patients. An increasing amount of facilities are moving away from outsourcing facilities due to unresolved FDA 483's and subsequent warning letters.

The increasing demand on internal sterile compounding operations is exponentiated by changes in USP guidelines and CETA regulations that continue to increase demands on facility controls and compounding competencies. As health systems continue to merge and acquire additional facilities to mitigate changing financial and quality measures, there is an opportunity to utilize and capitalize sterile compounding skilled labor internally and centrally for these systems.

Insourcing through regionalization allows centralized compounding to ensure quality standards are met and consistency is established throughout the continuum of care within the system. In comparison to a manufacturing facility, consistency is established through ISO standardization that improves the quality of the end-product. As facilities and individual sites increase, the risk for inconsistency increases, thus putting our patients at risk. In addition, sterile compounding continues to involved technological resources, advances in engineering, and specific competency that is better established and implemented at a centralized location for better controls.

California board of Pharmacy 2015 Lawbook for Pharmacy Article 7.6:4128 allows "a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership"

Wisconsin Chapter Phar 7.01 (2) does not "prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems"

New Jersey also allows health system regionalization of sterile compounding under section 503A.

Please consider addition to the Virginia Board of Pharmacy regulations the allowance for regionalization of compounded products under a common ownership entity. The prescription data may be collected by the site of requisition, and can be recalled by the site of distribution allowing for receipt of a valid order prior to dispensing and administration to the end-user to comply with 503A Traditional Compounding.

Recommended addition for consideration:

42 E

*E. Centralized Hospital Packaging*

*A centralized hospital packaging pharmacy may prepare medications, unit dose packaging and compounded medications, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and share a common medical information system.*

Thank you for your thoughtful consideration!

* Nonregistered public user

42 F

## Yeatts, Elaine J. (DHP)

**From:** Tim Musselman <Tim@virginiapharmacists.org>
**Sent:** Wednesday, December 30, 2015 9:12 PM
**To:** Yeatts, Elaine J. (DHP)
**Cc:** Juran, Caroline (DHP)
**Subject:** Periodic Review Comments

Elaine,

See below for regulations that VPhA members have suggested the Board of Pharmacy consider reviewing:

- **Prescription department enclosures for locations where the pharmacy and business open and close at the same time**
  - 18VAC110-20-190. Prescription department enclosures; access to prescription department.
    - A few pharmacies have been cited recently for not locking their prescription department. In some these cases, the pharmacy department is only open when the entire location is opened (or closed) by the pharmacist and thus do not operate the front of the store with the pharmacy department closed. The Board should consider reviewing the requirement for a secure prescription department in instances where the department and the entire location are closed and secured at the same time.
- **Lack of adequate technician help**
  - 18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.
    - We hear too often that pharmacists are not provided with adequate technician help. While Section B clearly states that "a pharmacist shall determine the number...." we have heard from many pharmacists who are not willing to approach their employer about the lack of staffing support due to fear of retribution including losing their job. Thus, the decision to determine their technician support does not lie in the hands of the pharmacist on duty. We encourage the Board to consider strengthening this regulation as pharmacists are placed in unsafe staffing situations that ultimately fall out of their control.

Please feel free to contact me if you have any questions.

- Tim

**Timothy S. Musselman, Pharm.D.**
Executive Director
Virginia Pharmacists Association
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Visit us online at:
www.virginiapharmacists.org
www.twitter.com/VPhARx



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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

December 15, 2015

Elaine Yeatts
Agency Regulatory Coordinator
9960 Mayland Drive
Suite 300
Henrico, VA 23233
*Via email:* elaine.yeatts@dhp.virginia.gov

**Re: Periodic Regulatory Review: 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers**

Dear Ms. Yeatts:

On behalf our members that operate approximately 1,126 chain pharmacies in the Commonwealth of Virginia, the National Association of Chain Drug Stores ("NACDS") is writing to comment to the Virginia Board of Pharmacy ("Board") on the periodic regulatory review of 18VAC110-50-10 et seq. regarding wholesale distributors, manufacturers and warehousers and requirements for pedigree. We are concerned that the current rules are inconsistent with and preempted by provisions of the Federal Drug Quality and Security Act (DQSA) that outline requirements for an electronic, interoperable system to identify and trace drugs that are distributed in the United States.

The new federal track and trace law implements various approaches designed to promote a secure drug supply chain, including: product identification, tracing and verification; detection and response to quarantine and investigate suspect drug products; notification systems; wholesaler licensing; and third-party logistics provider licensing. There are numerous instances where the existing and proposed rule language in 18VAC110-50-10 et seq. regarding drug pedigree and recordkeeping requirements is inconsistent with the new requirements of DQSA.

Notably, the Food and Drug Administration (FDA) gave a presentation at the 2015 National Association of Boards of Pharmacy Annual Meeting on the topic of drug supply chain integrity. During this session, representatives from FDA explained how DQSA preempts states' laws and regulations on drug distribution recordkeeping.

For these reasons, NACDS urges the Board amend 18VAC110-50-10 et seq. to mirror the federal law.

Thank you for considering our comments on the periodic regulatory review of 18VAC110-50-10 et seq. Please do not hesitate to contact me with any questions or for further assistance.

Sincerely,

Jill K. McCormack

Jill McCormack, Director
State Government Affairs

42 I

# DRAFT Substance for Notice of Intended Regulatory Action

## Substance

*Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.*

---

As part of the periodic review, 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 to the following sections of Chapter 20 (or the new chapter 25) will be considered in the promulgation of proposed regulations:

**PART I. General Provisions.**

**18VAC110-20-10. Definitions**

- Modifying definition for "robotic pharmacy system."

**18VAC110-20-20 Fees**

- Changing the renewal for pharmacist licenses and pharmacy technician registrations to a date different from December 31st, but retain the facility renewal dates for facilities. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

**18VAC110-20-21 Public address**

- Adding requirement for notification to the board if there is a name change and specify documentation that must be submitted. Consider a specific timeframe for notification.

**18VAC110-20-25 Unprofessional conduct**

- Adding failure to submit corrective action related to inspection deficiency within a specified time frame.
- Adding dispensing any controlled substance with the intent or knowledge that it will be used otherwise than medicinally, for accepted therapeutic purposes, or with the intent to evade any law with respect to the sale or use of such drug.

**PART II. Licensure Requirements for Pharmacists.**

**18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination**

- Specifying a timeframe for validity of law exam score to 3 years, consistent with requirements for record retention.

**18VAC110-20-80 Renewal and reinstatement of license**

- Clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee rather than the current active renewal fee.
- Revising terms "reactivate" and "reinstate" for correct and consistent usage.

**18VAC110-20-90 Requirements for continuing education (CE)**

- Accepting additional inter-professional continuing education.
- Changing wording in (B) (2) from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of continuing education.
- Requiring a portion of the 15 required hours to be live or real-time interactive continuing education.

**18VAC110-20-100 Approval of continuing education programs**

- Deleting ability for board to approve CE programs.

**PART III. Requirements For Pharmacy Technician Registration.**

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

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

**18VAC110-20-106 Requirements for continued competency**

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

**PART IV. Pharmacies.**

**18VAC110-20-110 Pharmacy permits generally**

- Specifying minimum number of hours pharmacist-in-charge (PIC) must practice at the location listed on the pharmacy permit application
- Requiring minimum number of years of experience for pharmacist-in-charge eligibility.

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

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Requiring an inspection during change of ownership.

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

- Clarifying requirements for acquisitions with regard to inspection and inventory

- Allowing Board to rescind pharmacy permit if not opened within 60 days of issuing permit.

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

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

**18VAC110-20-180 Security system**

- Requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient.

**18VAC110-20-190**

- Amending physical requirements for a prescription department's enclosure.
- Amending requirement for locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

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

- Adding language from Guidance Document 110-40 regarding dispersion of Schedule II drugs.

**PART VI. Drug Inventory and Records.**

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

- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

**PART VII. Prescription Order and Dispensing Standards.**

**18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians**

- Separating subsections A and B from the rest of the regulation.
- Addressing concern in subsection B by the Virginia Pharmacist Association with pharmacists not being provided adequate pharmacy technician support.
- Reviewing appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, revising requirement for pharmacy to pull the originally filed prescription and refile it.
- Adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

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

- Addressing concerns with white bagging and brown bagging.
- Revising section 275 for more clarity.

**18VAC110-20-277 Prescription Requirements**

- Adding new regulation in section 277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

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

- Clarifying that a requirement for a signature to be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Considering whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

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

Adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

**PART VIII. Labeling and Packaging Standards for Prescriptions.**

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

Amending requirement for how to identity pharmacist verifying accuracy of the process.

**PART X. Unit Dose Dispensing Systems.**

**18VAC110-20-425 Robotic Pharmacy Systems**

- Streamlining robotic pharmacy system regulations by striking #5 and simplifying #4.
- Strengthening requirements for pharmacist accountability in assigning bar codes.

**Part XI Pharmacy Services to Hospitals**

**18VAC110-20-470 Emergency room**

In #2, consider changing "practitioner" to "prescriber"

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

- Streamlining requirements for automated dispensing devices in hospitals.
- Clarifying that drug for emergency use may include drugs for first doses.
- Clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

**Part XII Pharmacy Services to Long-Term Care Facilities**

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

- Clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarifying that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

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

Considering whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

**PART XIII Other Institutions and Facilities**

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

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

**PART XV Medical Equipment Suppliers (MES)**

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

- Adding requirement that applications must include name of responsible party
- Requiring MES to notify the Board within 14 days of a change in the responsible party

**18VAC110-20-680 Medical equipment suppliers**

- Adding language from Guidance Document 110-19 for MES to transfer prescriptions.
- Adding requirement to provide Board with hours of operation and notification to board and public when hours change.

**PART XVI Controlled Substance Registration for Other Persons or Entities**

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

- Amending schedules to include Schedule I

The Board considered whether there is a better method for identifying the responsible pharmacist as initials are required 23 times throughout regulations of the Board. It is likely the Board review all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

**REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS**

**Part I General Provisions**

**18VAC110-50-40 Safeguards against diversion of drugs**

- Amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Amending 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 operable.

**Part II Wholesale Distributors**

**18VAC110-50-60 Special or limited-use licenses**

- Expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

**18VAC110-50-70 Minimum required information**

- Placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

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

- Requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.
- For consistency, considering similar requirements in 18VAC110-20-80 for responsible party of manufacturers.

**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

**Board action:**

Adoption of amendments to section 18VAC110-20-322. Placement of chemicals in Schedule I. (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 March 25, 2016** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to March 23, 2016 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified six (6) compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. A brief description and chemical name for each compound is as follows:

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

   Butyryl fentanyl is a powerful synthetic opioid similar in structure to fentanyl and has been identified in DFS laboratories. Butyryl fentanyl has not been approved for medical use in the United States. DFS recommends placing butyryl fentanyl into Schedule I (§ 54.1-3446(6)).

2. **Flubromazolam**

   Flubromazolam is classified as a benzodiazepine which is a central nervous system depressant. Flubromazolam has been identified in DFS laboratories found on blotter paper and candy. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(4)).

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

   5-MeO-MIPT is classified as a research chemical and has been identified in DFS laboratories. 5-MeO-MIPT is similar in structure to 5-MeO-DIPT which is currently a schedule I compound. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

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

   ADB-FUBINACA is classified as a cannabimimetic agent, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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

   MDMB-FUBINACA is classified as a cannabimimetic agent, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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

   5-fluoro-ADB is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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

# Scheduling of Chemicals in Schedule I

**18VAC110-20-322. Placement of Chemicals in Schedule I.**

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

1. Cannabimimetic agents:

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

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

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

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

2. Substituted cathinones:

a. 4-bromomethcathinone (other name: 4-BMC); and

b. 4-chloromethcathinone (other name: 4-CMC).

The placement of drugs in this subsection shall remain in effect until February 11, 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. Acetyl fentanyl (other name: desmethyl fentanyl).

2. Etizolam.

3. 4-Iodo-2, 5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH).

4. Cannabimimetic agent:

1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201).

5. Substituted cathinones:

a. Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP); and

b. Alpha-Pyrrolidinoheptiophenone (other name: PV8).

The placement of drugs listed in this subsection shall remain in effect until June 1, 2017, 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. 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)

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 (18 months from the effective date), unless enacted into law in the Drug Control Act.

**Agenda Item: Petitions for rulemaking**

**Included in your package are:**

3 petitions for rulemaking

Copies of the *Requests for Comment*

Copies of comment on petitions

Copies of applicable regulations

**Board action: The Board will consider each petition separately:**

1) Irwin – allow long term care facility to provide prescription information for Schedule VI drugs to a "back-up" pharmacy located near the facility (3 comments)
2) Gilley – allow pharmacists in hospitals or free-standing emergency departments to adjust or order medications according to clinically accepted guidelines (0 comments)
3) Merryfield – allow bar code and FRID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified (0 comments).

The Board may reject the petition's request. If rejected, the Board must state their reasons for denying the petition.

OR

The Board may initiate rulemaking by adoption of an amendment by publication of a Notice of Regulatory Action.

## Request for Comment on Petition for Rulemaking

Promulgating Board: **Board of Pharmacy**


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

Agency Contact: Caroline Juran
Executive Director
caroline.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233


Chapter Affected:

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

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

Petitioner Bill Irvin, for Omnicare

Petitioner's Request

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 located near the facility enabling the "back-up" pharmacy to provide the first dispensing of the prescription without the act constituting a transfer of the prescription.

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on December 28, 2015. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until January 27, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016.

**Comments may be posted on the Virginia Regulatory Townhall at:**
**www.townhall.virginia.gov**

Publication Date 12/28/2015 *(comment period will also begin on this date)*

Comment End Date 01/27/2016

**From:** Irvin, William [mailto:William.Irvin@omnicare.com]
**Sent:** Wednesday, October 14, 2015 2:51 PM
**To:** Juran, Caroline (DHP)
**Cc:** mark.johnston@cvscaremark.com
**Subject:** Follow Up Omnicare Meeting - First Fill Discussion

Good Afternoon Caroline,

During our recent meeting, we discussed Omnicare's protocol for handling "first fill" doses for patients residing in long term care facilities. In consultation with Mark Johnston, we respectfully share the language used by the Idaho Board of Pharmacy that governs this issue. We believe it is most representative of Omnicare's current process as well as those conducted in other pharmacies engaged in providing long term care pharmacy services. The specific language is noted below along with a link to the full suite of Idaho Rules. Please let me know if I can provide any additional information that may further assist with the regulation review. Last, would it be possible to participate in the regulation review meeting as a key stakeholder?

Thank you gain for your time and consideration.

All the best

Bill

http://adminrules.idaho.gov/rules/current/27/0101.pdf

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY. A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13) 01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13) 02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13) 03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13) 04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required.

Bill Irvin, R.Ph.
Director, Pharmacy Regulatory Affairs
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CVSHealth

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Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

**All comments for this forum**

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**Commenter:** Amy Hewett, Virginia Health Care Association * 1/20/16 2:31 pm

**Support for the petition for rulemaking**

The Virginia Health Care Association (VHCA), which represents over 270 long term care facilities in the Commonwealth of Virginia, supports this petition for rulemaking. Allowing a "back-up" pharmacy to initially dispense a prescription without that constituting a prescription transfer would help ensure patients receive their medication in a timely manner. This efficiency is especially important in circumstances when the patient is beginning a new, clinically critical medication. Changing the regulations as proposed would also improve the continuity of care when patients are transferred from hospitals to nursing facilities and the on-site pharmacy may not have the new prescription on-hand.

**Commenter:** Hope Spencer * 1/25/16 11:28 am

**Support for change in backup pharmacy requirement for LTC**

I work in a LTC, mail order pharmacy which handles many backup requests for our consumers. The vast majority of these requests are for antibiotics and other emergency meds which patients need quickly. We have been handling these requests as transfers per the Board requirement, which means we have to transfer the medication to another (local to the patient) pharmacy and then transfer it back to us if it is not a one time order or a control. This process is very time consuming and frequently results in more of a delay for start of treatment. Additionally, some of the pharmacies our patients' caregivers would like to utilize as backup pharmacies consider the extra work to be too prohibitive and refuse to accept our transfers, which causes even more of a delay in start of treatment.

**Commenter:** Kimberly White, Pharmacy Alternatives * 1/27/16 1:47 pm

**Support for backup requirement change**

I support the change for backup requirement for long term care pharmacies. I currently work at a long term care pharmacy, and we send many prescriptions to backup pharmacies every day. Our patients typically need acute care meds or new prescriptions/dose changes to begin immediately. It is very time-consuming for both us and the retail pharmacy to do a transfer of each of these prescriptions, negatively impacting patient care. In fact, many of the retail pharmacies we call will refuse to serivce our patients any longer due to the time/effort of transferring the prescription back and forth when they may only be filling a three day supply. My patients and their caregivers cannot

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always go the the backup pharmacy of their choice because the backup pharmacy will not fill these prescriptions. I strongly feel if change the requirements, we can benefit our patients and their caregivers.

* Nonregistered public user

**Idaho.** A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. IA ADC 27.01.641

http://adminrules.idaho.gov/rules/current/27/0101.pdf

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY. A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13) 01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13) 02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13) 03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13) 04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required.

**Colorado.** Pharmacist at prescription drug outlet may dispense up to 72-hour supply of non-controlled substance prescription drug pursuant to a duplicate copy of an LTCF chart order . 3 CCR 719-3.00.25

**Montana.** In an emergency, Montana allows a pharmacy to "transfer" original prescription order for a non-controlled substance to a second pharmacy for dispensing up to a seven day supply without adhering to the states formal prescription transfer requirements. See Mont. Admin. R. 24.174.514(6).

**Florida.** Florida allows a pharmacy to transmit a starter dose to another pharmacy provided that the originating pharmacy: (1) has a written authorization from the LTC facility; (2) has a written contract with the starter dose pharmacy; (3) has written authorization from the prescriber to act as the prescriber's agent for the purpose of transmitting a starter dose prescription; (4) has a valid prescription from the prescriber p; (5) maintains a record of each starter dose prescription; and (6) maintains policies and procedures regarding starter dose prescriptions. Fla. Admin. Code Ann. r. 64B 28.503(2)(a)-(f).

Virginia

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

### 18VAC110-20-520. Drugs in long-term care facilities.

Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat drug box or emergency drug box or as provided for in 18VAC110-20-560 within this chapter.

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

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.

## Request for Comment on Petition for Rulemaking

Promulgating Board: Board of Pharmacy


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

Agency Contact: Caroline Juran
Executive Director
caroline.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233


Chapter Affected:

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

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

Date Petition Received 12/28/2015

Petitioner Angela Gilley

Petitioner's Request

Within a Hospital or free-standing Emergency Department setting, the medical staff may approve guidelines that are clinically accepted as the standard of care, or are approved by the Medical Staff of the hospital through the typical approval process (such as the Pharmacy and Therapeutics Committee), which allow pharmacists to change, discontinue, adjust, monitor, order pertinent labs, and make subsequent adjustments to medications as applicable to the approved guideline without requiring a physician order to implement the guideline. In addition, a practitioner may write an order for "pharmacy to dose" a medication which allows the pharmacist to dose, monitor, order pertinent labs, and make subsequent adjustments to any medication specified in the order based on the pharmacist's clinical judgment.

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on January 25, 2016. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 24, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. It will also be reviewed by the Assistant Attorney General who can advise the Board on whether the request requires a change in the Code of Virginia. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016.

Publication Date 01/25/2016 *(comment period will also begin on this date)*

Comment End Date 02/24/2016

# COMMONWEALTH OF VIRGINIA
# Board of Pharmacy

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

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

## Petition for Rule-making

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

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

| | | |
|---|---|---|
| **Petitioner's full name (Last, First, Middle initial, Suffix,)**<br>Gilley, Angela | | |
| **Street Address**<br>5377 Blackwater Loop | **Area Code and Telephone Number**<br>757-421-3132 | |
| **City**<br>Virginia Beach | **State**<br>VA | **Zip Code**<br>23457 |
| **Email Address (optional)** | **Fax (optional)** | |

**Respond to the following questions:**

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

This is a request to amend Part XI. Pharmacy Services to Hospitals. There is a need for language in the Regulations that addresses pharmacists adjusting medication regimens per medical staff approved guidelines.

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

The Centers for Medicare & Medicaid Services (CMS) updated the State Operations Manual (SOM) Appendix A (October 30, 2015) with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP), clarifying their interpretive guidance in Appendix A for existing regulations in 42 CFR Part 482.25(b)(8) as follows.
§482.25(b)(8) - Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.
Interpretive Guidelines §482.25(b)(8)
The pharmacy must be a resource for medication-related information to the hospital's health-care practitioners and other health care personnel to optimize therapeutic outcomes and minimize adverse drug events. Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration.
The pharmacy may also assist other health care professionals with the following medication-related functions:
• Identification of the presence of medication-therapy problems, both potential and actual, such as drug-drug interactions, excessive doses;
• Identification and specification of pharmaco-therapeutic goals;
• Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health-care professionals;
• Monitoring the effects of the pharmacotherapeutic regimen – could include adjusting doses based on lab values (i.e.: Coumadin dosing);
• Redesigning the regimen and monitoring plan as indicated.
For example, practitioners may write an order for "pharmacy to dose" an antibiotic. The pharmacist would then take patient-specific information, review the patient's current medication therapies for any problems, and then calculate the dose required to meet therapeutic goals.

The proposed language would read as follows:
Within a Hospital or free-standing Emergency Department setting, the medical staff may approve guidelines that are clinically accepted as the standard of care, or are approved by the Medical Staff of the hospital through the typical approval process (such as the Pharmacy and Therapeutics Committee), which allow pharmacists to change, discontinue, adjust, monitor, order pertinent labs, and make subsequent adjustments to medications as applicable to the approved guideline without requiring a physician order to implement the guideline. In addition, a practitioner may write an order for "pharmacy to dose" a medication which allows the pharmacist to dose, monitor, order pertinent labs, and make subsequent adjustments to any medication specified in the order based on the pharmacist's clinical judgment.

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

**Signature:** *Angela Gilley* **Date:** 12-23-15

## Part XI. Pharmacy Services to Hospitals

### 18VAC110-20-440. Responsibilities of the pharmacist-in-charge.

A. The PIC in a pharmacy located within a hospital or the PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to non-pharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;

2. Irrigation solutions;

3. Contrast media;

4. Medical gases;

5. Sterile sealed surgical trays that may include a Schedule VI drug; and

6. Blood components and derivatives, and synthetic blood components and products.

### 18VAC110-20-450. After-hours access to the pharmacy.

A. When authorized by the PIC, an authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, provided that such drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist

and provided further that a separate record shall be made and left at the location of the stock of drugs on a form prescribed by the PIC and such records are maintained within the pharmacy for a period of one year showing:

1 The date of withdrawal;

2. The patient's name;

3. The name of the drug, strength, dosage form and dose prescribed;

4. Number of doses removed; and

5. The signature of the authorized nurse.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

**18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.**

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI 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. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

**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.

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.

**18VAC110-20-480. (Repealed)**

**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.

## Request for Comment on Petition for Rulemaking

Promulgating Board: **Board of Pharmacy**


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

Agency Contact: Caroline Juran
Executive Director
carolin.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233


Chapter Affected:

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

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

Date Petition Received 12/31/2015

Petitioner David Merryfield

Petitioner's Request

To allow bar code and RFID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified once for each product by a pharmacist.

Agency Plan

Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 24, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016, and the petitioner will be informed of the Board's decision on his request after that meeting

Publication Date 01/25/2016 *(comment period will also begin on this date)*

Comment End Date 02/24/2016

# COMMONWEALTH OF VIRGINIA
# Board of Pharmacy

RECEIVED
DEC 29 2015

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

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

## Petition for Rule-making

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

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

| Petitioner's full name (Last, First, Middle Initial, Suffix,) | | |
|---|---|---|
| Merryfield, David W. | | |
| **Street Address** | **Area Code and Telephone Number** | |
| 1332 Meadow Lake Road | 757-934-4699 | |
| **City** | **State** | **Zip Code** |
| Virginia Beach, VA 23454 | VA | 23454 |
| **Email Address (optional)** | **Fax (optional)** | |
| | | |

**Respond to the following questions:**

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

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

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

**Signature:** [signature] **Date:** 12/29/15

July 2002

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December 29, 2015

Virginia Board of Pharmacy
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

RE: Periodic review of Chapter 20: Regulations Governing the Practice of Pharmacy (18 VAC 110-2—10 et seq.)

This is a request to amend Part X Unit Dose Dispensing Systems and Part XI Pharmacy Services to Hospitals.

18 VAC 110-20-420
8.d. currently requires "...the initials of the pharmacist checking and certifying the contents of the drug cart..."
18 VAC 110-20-425
3 requires "Pharmacists shall verify and check...and the verifying pharmacist shall initial the record..."
5 requires "Pharmacists shall perform a daily random check...Documentation of this check shall include the pharmacist's initials...:
6 requires "All manual picks shall be checked by pharmacists."
18 VAC 110-20-460
A requires "A pharmacist shall check all Schedule II-VI drugs..."
18 VAC 110-20-490
C.1. requires "...initials of the pharmacist checking the drugs to be removed from the pharmacy..."

The purpose of this periodic review is to determine whether these regulations should be amended or retained in their current form, including whether they are necessary for the protection of public health, safety, and welfare.

Bar coding technology has been available in pharmacy for several decades. RFID technology has become available somewhat more recently. These technologies are in wide use within pharmacy. Bar code scanning is recognized by Boards of Pharmacy in most other states. This is no longer innovative practice; this is usual and customary practice. A pharmacist should be required to verify that the bar code or RFID code assigned to a drug product is correct, but once that has been verified by the pharmacist, bar code or RFID scanning is well-established as safe for the protection of public health, safety, and welfare. Requiring a pharmacist to continue to physically check these items, each time they are dispensed, seriously limits the time that the pharmacist should be spending in other, much more valuable, contributions to the care and safety of patients.

Under the authority of the Code of Virginia 12.3-45 to promulgate regulations, this is a petition for new or amended regulations as described in the Code of Virginia Section 2.2-4007. Please give serious consideration to allowing bar code and RFID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified once for each product by a pharmacist. This will be a boon to the profession of pharmacy in Virginia, freeing pharmacists to improve patient care and safety.

Although each of the above provisions could be modified separately, another way to approach this update would be to add in 18VAC110-20-10. Definitions. A new definition. (and the terms "certify" and "verify" above changed to "check"):

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"check" means the pharmacist check that the product prepared by the technician or robotic technology is the correct medication, dosage form, and strength, as ordered for the patient. If electronic bar code or RFID scanning technology is used to perform the check in lieu of visual inspection by the pharmacist, the electronic scanning system must record a record of the scan. A pharmacist must have verified that each product's scan matches the correct product in the scanning database.

Sincerely,

David W. Merryfield
Pharmacist in Charge
Sentara Obici Hospital

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## Part X. Unit Dose Dispensing Systems

### 18VAC110-20-420. Unit dose dispensing system.

A. A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long-term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications:

1. Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system shall be fitted with a locking mechanism and locked at all times when unattended.

2. A signed order by the prescribing practitioner shall accompany the requests for a Schedule II drug, except that a verbal order for a hospital patient for a Schedule II controlled substance may be transmitted to a licensed nurse or pharmacist at the hospital who shall promptly reduce the order to writing in the patient's chart. Such an order shall be signed by the prescriber within 72 hours.

3. Properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system provided these are done under the personal supervision of a pharmacist.

4. All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.

5. The patient's individual drug drawer or tray shall be labeled in a manner to identify the patient and his location without violating health privacy laws.

6. All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.

7. A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area provided that the dose is maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.

8. A record shall be made and maintained within the pharmacy for a period of one year showing:

a. The date of filling of the drug cart;

b. The location of the drug cart;

c. The initials of the person who filled the drug cart; and

d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C.

9. A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions:

a. The record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.

b. In the case of Schedule II through V drugs, after the patient profile record or medication card has been completed, the card must be maintained for two years.

c. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18VAC110-20-460 B will be accepted for drugs distributed as floor stock.

B. In providing unit dose systems to hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall dispense not more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.

C. In addition to the requirements listed in subsection A of this section, the following requirements apply to those long-term care facilities in which unlicensed persons administer drugs:

1. The pharmacy providing medications to such facility shall dispense no more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time.

2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used.

3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations.

4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration.

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

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 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 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;

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. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. 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 doses or compliance packages 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. 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.

## Part XI. Pharmacy Services to Hospitals

### 18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI 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. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

**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 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.

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 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.

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 administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records from 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.

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

**Included in your agenda package are:**

A copy of the 2015 legislation mandating issuance of permits to facilities in which practitioners of the healing arts dispense drugs

A copy of the emergency regulations in effect from December 7, 2015 through June 6, 2017

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

**Board action:**

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

## CHAPTER 117

*An Act to amend and reenact § 54.1-3304.1 of the Code of Virginia, relating to Board of Pharmacy; practitioners dispensing controlled substances.*

[H 2192]

Approved March 16, 2015

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

**1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:**

**§ 54.1-3304.1. Authority to license and regulate practitioners; permits.**

*A.* The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. *Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.*

*B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.*

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

**BOARD OF PHARMACY**

**Permits for physician selling drugs facilities**

**Emergency Regulations Effective: 12/7/15 to 6/6/17**

**18VAC110-30-15. Fees.**

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

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

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

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

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

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

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

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

D. Late fees.

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

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

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

E. Reinstatement fees.

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

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

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

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

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit.

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

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

Part II

Licensure Requirements

**18VAC110-30-20. Application for licensure.**

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 4, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

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

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

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

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

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

A. After June 4, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner shall make application for the facility permit on a form provided by the board.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Part III

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

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

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

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

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

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

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

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

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

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

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

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

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

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

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

**18VAC110-30-90. Physical standards.**

Physical standards for the controlled substance selling and storage area:

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

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

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

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

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

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

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

**Agenda Item: Adoption of Proposed [redacted] Regulations for Outsourcing Facilities and Compounding**

**Included in your agenda package are:**

A copy of the 2015 legislation mandating issuance of permits to resident and non-resident outsourcing facilities

A copy of the emergency regulations which are effective from December 7, 2015, through June 6, 2017

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

**Board action:**

Adoption of proposed regulations to replace emergency regulations as currently in effect

## CHAPTER 300

*An Act to amend and reenact §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5, relating to outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration.*

[H 1737]

Approved March 17, 2015

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

**1. That §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5 as follows:**

**§ 54.1-3401. Definitions.**

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a

single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or " dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or

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prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions

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of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

*"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.*

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or " produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not

include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

**§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.**

*A.* No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

*B. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with §54.1-3410.2.*

**§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.**

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to

commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may ~~also~~ provide *a reasonable amount of* compounded products to practitioners of medicine, osteopathy, podiatry, *or* dentistry~~, or veterinary medicine~~ to administer to their patients ~~in the course of their professional practice~~, either personally or under their direct and immediate supervision*, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.*

Pharmacists *who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations* shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid

prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

***§ 54.1-3434.05. Permit to act as an outsourcing facility.***

*A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.*

*B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.*

*C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.*

*The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.*

*D. Every outsourcing facility shall compound in compliance with the requirements of state and*

*federal law and regulations except §54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.*

*E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.*

**§ 54.1-3434.4. Prohibited acts.**

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy ~~which~~ *or compounding services of an outsourcing facility that* has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy *or outsourcing facility* to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

***§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.***

*A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.*

*B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.*

*C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.*

*The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.*

*D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.*

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

**BOARD OF PHARMACY**

**Outsourcing facilities**

**Emergency Regulations Effective: 12/7/15 to 6/6/17**

**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.

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

D. Annual renewal fees.

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

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.

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|---|---|
| 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 |

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| 7. Humane society permit | $5 |
| 8. Outsourcing facility permit | $90 |
| ~~8.~~9. Nonresident pharmacy registration | $90 |
| 10. Nonresident outsourcing facility registration | $90 |
| ~~9.~~11. Controlled substances registrations | $30 |
| ~~10.~~12. Approval of a pharmacy technician training program | $15 |

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.

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|---|---|
| 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 |

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| 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.

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

**18VAC110-20-215. Outsourcing facilities.**

A. Any facility in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient shall obtain a permit as an outsourcing facility from the board in accordance with § 54.1-3434.05. Any outsourcing facility located outside of the Commonwealth that delivers in any manner Schedule II through VI drugs or devices into the Commonwealth without a prescription for a specific patient shall be registered with the board in accordance with § 54.1-3434.5.

B. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV and VI, with the following exceptions:

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

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

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

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

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

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

1. Pharmacist supervision.

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

2. Records.

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

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

assigned, or lot number; and an appropriately assigned expiration date or beyond use date.

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

3. Renewal.

a. Upon initial application and at each renewal, outsourcing facilities shall submit to the board documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

b. Upon initial registration and at renewal, outsourcing facilities shall submit to the board a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5.

c. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations and requirements, except it shall compound in compliance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

d. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5 shall not meet the requirements for renewal of registration.

Part VIII

Labeling and Packaging Standards for Prescriptions

**18VAC110-20-321. Compounding.**

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

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

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

**Included in your agenda package are:**

A copy of the Notice of Intended Regulatory Action

Copies of comment on the NOIRA

Draft proposed regulation based on language from other states

**Board action:**

Adoption of proposed regulations as drafted or as amended

## Notice of Intended Regulatory Action

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

Promulgating Board: **Board of Pharmacy**

| | |
|---|---|
| NOIRA Notice: | Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending the following regulations |
| Chapters Affected: | |
| 18 vac 110 - 20: | Virginia Board of Pharmacy Regulations |
| Action Title: | Prohibition against incentives to transfer prescriptions |
| Agency Summary: | The purpose of the proposed action is summarized as follows:<br><br>The new provision would prohibit advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing a patient to transfer a prescription absent professional rationale by use of coupons, rebates, etc. The action responds to a petition for rulemaking from a Virginia pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews. |

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

Is a public hearing planned for the proposed stage? Yes

**Public comments may be submitted until 5:00 p.m. on 12/16/2015.**
**Link to Regulatory Action on Townhall:**
**http://townhall.virginia.gov/L/viewstage.cfm?stageid=6973**

Agency Contact: Caroline Juran, RPh
Executive Director

(804)367-4416
(804)527-4472
caroline.juran@dhp.virginia.gov

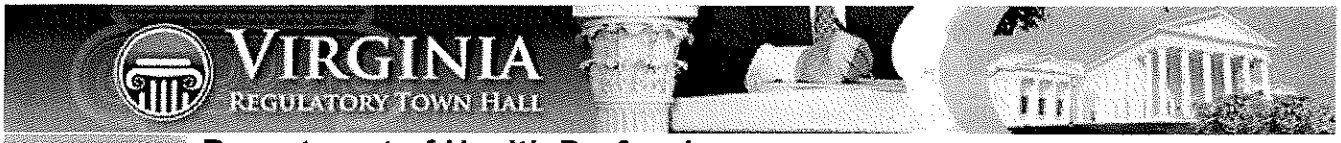
Contact Address: Department of Health Professions

9960 Mayland Drive

Suite 300
Richmond, VA23233-1463

APA Compliance: This regulation has been adopted in accordance with the Administrative Process Act.

Virginia.gov Agencies | Governor




Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

| | |
|---|---|
| **Action** | **Prohibition against incentives to transfer prescriptions** |
| **Stage** | **NOIRA** |
| **Comment Period** | Ends 12/16/2015 |

**All comments for this forum**

**Back to List of Comments**

**Commenter:** Lauren Caldas * 11/20/15 11:22 pm

**Against Transfer Incentives**

To whom it may concern,

Please consider the banning of transfer incentives. This practice of incentivizing patients to change pharmacies multiple times solely based on coupon accumulation, is not only embarrassing for the profession but also opens us to unsafe medication practices. There is a potential for transcribing errors and also patients may accumulate unnecessary prescriptions solely based on financial outcome (ex. A patient buys unneeded $4 prescription because can get $25 coupon). The burden it places on pharmacies continues to create an unsafe working place. I cannot think of any other medical practice that give incentives for switching practices.

Please consider that this practice continues the public impression that pharmacies are equivalent to Cellular plans or Car insurance instead of as hospitals or medical practices. We should behave as professionals if we hope to be thought of as such in the public eye. Please end the gimmicks of transfer coupons.

Thank you.

**Commenter:** Katie Clasen * 11/21/15 12:11 am

**Ban prescription transfer incentives**

Patient safety is jeopardized by incentivizing prescription transfers. Patients end up with multiple pharmacies, each with a partial list of medications, and without a complete list, pharmacies can miss drug interactions and duplications of therapy. Although every attempt is made to ensure accurate transfer of information, each transfer does introduce an opportunity for

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transcription error. In addition, transfers done solely for the sake of a coupon add a significant and unnecessary burden to an already heavy workload.

We know that the best practice is to have coordinated care where all the players (doctors, pharmacists, nurses, patients, etc) have complete and accurate information, and the practice of encouraging prescription transfers through coupons and other incentives completely undermines this ideal.

**Commenter:** Brian Quigley R.PH. * 11/28/15 8:25 pm

**PROHIBITION AGAINST INCENTIVES TO TRANSFER PRESCRIPTIONS**

**I am against incentives to transfer prescriptions. Pharmacist are here to help protect the public by looking for interactions of drugs and by knowing the patient and the medications they are taking. Every time you transfer a prescription you are adding another layer of chance that a interaction with some of the medicine they are already taking will be missed. Also, the prescription being transfered may be misinterpreted by the other pharmacy. To have people move prescriptions around from pharmacy to pharmacy because of a coupon offer is just adding another layer for mistakes to happen. Please consider that coupons put an added stess level on the Pharmacists, who are here to protect the public.**

**Commenter:** Robert M. Rhodes, Pharmacist * 11/30/15 4:38 pm

**Transfer coupons**

This is one of the most dangerous things that are allowed and endorsed by the Virginia State Board of Pharmacy.

It has patiienrs transfereing prescriptions that they really d not need just to get a gift certificate and encourages patients to poly- pharmacy. Many of these prescriptions are not run on insurance because they are cheaper on the store plan so therefore no record of what the patient is taken is available to the pharmacy.

The duty of the Board is to protect the welfare and safety of the consumer. I beleive that the NABP does not endorse coupons .

Coupons and gift cards also can not be used for prescriptions only on other store goods so no real bendfit that out weighs the danger.

Coupons have no place in our profession and should have been addressed long ago.

**Commenter:** Robert M. Rhodes, Pharmacist * 11/30/15 5:20 pm

**transfer coupons**

## Promotions end for consumers who transfer prescriptions


By Laura Gunderson | The Oregonian/OregonLive
Email the author | Follow on Twitter
on July 21, 2012 at 3:00 PM, updated July 21, 2012 at 3:22 PM

Reddit Email

View full size*Laura Gunderson/The Oregonian*Pharmacies in Oregon can no longer offer deals to customers who transfer prescriptions. Such promotions, offering free gas, groceries and gift cards, gained popularity in recent years. However, local pharmacists said that when customers constantly switched prescriptions it became difficult for them to track what drugs they were taking and how they would interact.

In the past few years, many consumers have become expert pharmacy hoppers.

If Walgreens offered a $25 gift card for transferring a prescription, off they'd trot to Walgreens. When Safeway made a similar deal a few months later, they'd switch their regular prescription to the grocer. The promotions were plentiful, offered by such big players as Fred Meyer, Target and Rite Aid -- each offering a range of extras, from free groceries to gasoline gift cards.

But in Oregon, such hopping has been halted.

The Oregon Board of Pharmacy voted last month to fine or revoke the licenses of pharmacies that offer promotions encouraging prescription-holders to switch. It also forbids retailers from guarantees on how quickly prescriptions will be ready -- programs that sometimes resulted in

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varying "punishments" for pharmacy employees when deadlines weren't met.

The changes were spurred by a survey the state board offered to its 5,700 licensed pharmacists last summer. The board was surprised when 1,300 responded online and another 500 sent in written responses, all sharing their concerns about unsafe working conditions that they felt put patients at risk.

"Every time a pharmacist dispenses a prescription, they review the patient's list of drugs to be sure there are no inconsistencies and that the new drug won't interact with another," said Gary Schnabel, executive director of the Oregon Pharmacy Board and past president of the National Association of Boards of Pharmacy.

"Every time a consumer switches pharmacies it breaks that chain," he said. "And every time you break that chain, a patient is more at risk."

Transfer offers became common and quite popular over the past few years, although Schnabel said he's not seen any data outlining the number of consumers who participated in them locally.

As with other deals through the recession, cash-strapped consumers welcomed ways to offset prescription costs with the variety of bonuses. So-called "mommy bloggers," who often share money-saving tips, regularly highlighted prescription-switching deals. One site that collects information geared for women readers recently included this "tip":

"Whenever Target runs their prescription promotion, my mom gets extra coupons from her friends and family. She has their prescriptions filled using the coupon, which gives her a $10 gift card for each prescription... The promotions are a great way to help your dollars go further."

Schnabel said that during hearings on the issue he heard of a consumer who kept filling a prescription that was no longer needed to take advantage of the promotions.

In general the programs were offered at larger retail pharmacies. Independents, which make up about 200 of the 750 retail pharmacies statewide, didn't typically offer the transfer deals, Schnabel said.

Signs went up recently at Walgreens warning pharmacy customers that it could no longer honor its $25 transfer coupons. Other retailers such as Fred Meyer, which offered such deals a few times a year, will simply stop the promotions.

Fred Meyer spokeswoman Melinda Merrill said the grocer will continue its practice of rewarding loyalty-card holders with points toward gas discounts each time they fill prescriptions.

"These retailers are creative and they can still do all kinds of marketing around rewarding those who stick around," Schnabel said. "The point of this rule is not to rein in what businesses are doing, we want them to be healthy, too -- just not at the expense of the public interest."

* Nonregistered public user

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VIRGINIA PHARMACISTS ASSOCIATION

2530 Professional Road ~ Richmond, Virginia 23235
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@virginiapharmacists.org www.virginiapharmacists.org

December 9, 2015

Caroline Juran, R.Ph.
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Henrico, VA 23233
caroline.juran@dhp.virginia.gov

Comments on NOIRA: "Prohibition against incentives to transfer prescriptions"

Dear Ms. Juran,

The Virginia Pharmacists Association (VPhA) is pleased to provide comments in support of the NOIRA: "Prohibition against incentives to transfer prescriptions". These comments echo the comments we provided to the Board in January 2014 in response to the original petition for rulemaking.

The Virginia Pharmacists Association has the following policy concerning the use of pharmacy coupons and transfer incentives:

> **12-B01 Use of Pharmacy Coupons and Transfer Incentives**
> The Virginia Pharmacists Association recognizes the use of pharmacy competitor prescription coupons and other transfer incentives may encourage poly pharmacy. The use of these incentives does not facilitate the goal of a concise medical home or complete medication record for review by the pharmacist(s). Whereas the use of prescription coupons in the form of manufacturer coupons can assist patients with compliance to their medication regimen, VPhA discourages the use of transfer coupons and transfer incentives among pharmacies. Transfer coupons and other transfer incentives fragment the medication record of patients which leads to inaccuracies in the medication records and is detrimental to patient care. VPhA advocates for the use of a single pharmacy for pharmaceutical services and promotes the prescriber-pharmacist-patient relationship.

We encourage the Board to develop strong regulations that will eliminate these dangerous incentives from being offered in the Commonwealth.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

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# DRAFT Proposed Regulation

## Prohibition on Incentives to Transfer Prescriptions

**18VAC110-20-25. Unprofessional conduct.**

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

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

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

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

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

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

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

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

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

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

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

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

**Agenda Item: Adoption of Final Regulations on setting certain conditions on work hours for pharmacists**

**Included in your agenda package are:**

A copy of the Notice of Comment on Proposed Regulations

Copies of comments

Proposed regulation as published

**Board action:**

Adoption of final regulations as proposed or as amended

# Notice of Public Comment: Proposed Action on Regulations

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

Promulgating Board: **Board of Pharmacy**

| Chapters Affected | | Action Type |
|---|---|---|
| 18VAC110 - 20: | Virginia Board of Pharmacy Regulations | Amend |

Action Title: Addressing hours of continuous work by pharmacists

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

Is a public hearing planned for the proposed stage? Yes

Public Hearing Dates: 12/1/2015: 09:00 am
Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA 23233

**Public comment deadline: 1/29/2016.**

Previously Published: The NOIRA was previously published on 9/10/2012
Register Issue: Volume: 29 1

Agency Contact: Caroline Juran, RPh
Executive Director
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(804)527-4472

caroline.juran@dhp.virginia.gov
Department of Health Professions

Contact Address: 9960 Mayland Drive
Suite 300
Richmond, VA23233-1463

APA Compliance: This regulation has been adopted in accordance with the Administrative Process Act.

Virginia.gov Agencies | Governor


Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

| | |
|---|---|
| **Action** | **Addressing hours of continuous work by pharmacists** |
| **Stage** | **Proposed** |
| **Comment Period** | Ends 1/29/2016 |

**All comments for this forum**

**Back to List of Comments**

**Commenter:** Robert Rhodes, Pharmacist * 12/1/15 8:58 pm

**Continuous hours worked**

First let me say , I have worked 10-12 hours shifts in my career. I was fortunate to have partners and staff that allowed us to take lunch breaks and dinner breaks away from the counter.

With that said, I think that breaks should be at least 15 minutes long and lunch or dinner breaks should be a minimum 30 minutes away from the pharmacy . To insure public safety is the duty of the Board of Pharmacy.

It is a proven fact that long hours and reduced help can contribute to errors and cause harm to patients.

I also feel that if you work a 10 or 12 hour shift having only a 6 hour rest between turn around. It should be at least 8 hours at a minimum

**Commenter:** T Barksdale * 12/3/15 12:45 pm

**Pharmacy Hours**

As a 2016 graduate who has worked for a major retail chain as a pharmacy technician, intern, and signed as a future staff pharmacist. I have seen pharmacists pull thirteen hour days with no overlap or extra pharmacist help. I have seen it done successfully and done not so successfuly. I think the main issue isn't necessarily telling pharmacist that they get a 30minute break evry 6 hours... because most companies "tell" them that and to utilize their breaks, but these pharmacist sacrifice those "breaks" because they have goals, times, and script deadlines etc. imposed by their companies and non-patient customers to meet. I feel that in order to protect all pharmacists. Pharmacy's should be required to have a 2 thirty minute windows in which no prescriptions will be filled so a pharmacist can have a true break. It's hard to sit down for your lunch, when you can't stop patient from dropping off prescritions. Once they drop them off and are filled by technicians, someone has to check them. So the pharmacist who is on "break" still has to get up, run over to the counter, verify the prescriptions, and check it. But then, another patient spots the pharmacist and asks a question, needs a recommendation, the phone rings, and basically that break is over.

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Pharmacies should be required to shut down at least 30 minutes to 1 full hour a day for a lunch. This would give everyone a time to PAUSE and regroup. I don't believe it's the long 13 hour days that are the issue. It's pharmacist feeling that if they take that 30minute to 1 hr break that they will be so behind and can't recover for the day. It's patients and consumers not understanding that retail pharmacy is not a McDonald's restaurant we can NOT premake all their orders an just hand it to them. It's medicine and can be deadly if mixed up incorrectly or wrong drug is given to the wrong patient.

All retail chain stores with pharmacies opperating more than 12 hours a day should be closed to the public for atleast 30 minutes to 1 hour. A lot of docotors offices have a 30 minute to 1 hour break for lunch, so the medication centers for a community should do.

Monday through Friday most retail stores are open from 8am to 9pm, these shifts are doable and if the company was required to pause for 30 minutes, what a difference that would make for the whole team. Now on weekends, there are normally sortened hours and I don't think that a mandatory shut down would be needed. But, yes, lunch breaks should be required for all pharmacists and in order to protect these pharmacist from abusing themselves while trying to meet employer goals, the companies should be held to a mandatory 30 minute or 1 hour (they can choose) lunch shutdown. This could count to their employees lunch breaks as well, so if everyone took lunch at same time it would save them from having dips in production etc. when people have to keep switching out for breaks. Everyone would win and pharmacists can still keep their flexible shifts and have a day or two off for the week if they are completing longer shifts each day.

**Commenter:** anonymous, former Pharmacy Tech, Current Intern & PharmD. Candidate * 12/3/15 2:39 pm

**Pharmacist Hours**

The hours in healthcare are not easy by any means and requires a certain type of individual with passion and precision for their field. This seems to be aimed more towards retail pharmacy, which I am glad to see. I do approve of the message being sent by this regulation, however it is flawed. A previous commenter made a solid point in which yes many corporations give or even require pharmacists to have an adequate break. However, those that have actually worked in retail know that customers that are regulars, or impatiently waiting for a medication, in a critical state etc can see the pharmacist during their break and ask for the service. A pharmacist is rarely going to say " I'm currently on my break, can you come back later." I believe that there needs to be a separate/ floater/ oncall pharmacist to cover for the pharmacist on break ( I've worked for places where there is only one for the 12 hr day) or that the pharmacy shuts down for the 30 min break ( less patient friendly option and more prone to robbery/ diversion) and that the pharmacist needs to vacate the premises during break with the white coat OFF. I also believe that if a pharmacist wants to work, or is basically forced to work more than 12 hours due to unforseen causes etc, that the break should be 30 mins every 4 hours and be paid time and a half for those not on salary and some type of equivalent for those on salary.

**Commenter:** Wendy Klein, MD * 12/3/15 4:16 pm

**Common sense**

I am writing in staunch support of 18 VAC110-20-110, which would limit continuus work hours for pharmacists to not more than 12 continuous hours in a a work day and which would offer a 30 minute break after 6 hours. It is unconscionable that this even needs to mandated. Decent

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standards such as these are simple common sense, and will increase productivity by reducing fatigue and improving concentration. These rules should apply to all, but especially to those in a field such as this that demands intense attention to detail.

**Commenter:** anonymous, pharm.D. candidate * 12/5/15 12:24 am

**how to implement this?**

This law has no meaning unless pharmacists are 'required' to leave their stores for that 30 minutes. As a pharmacy technician, I often don't get to take the 30 minutes break althought there is a law that mandates it and my company does not provide any compensation for that 30 minutes of my work. Many companies are cutting technician hours and do not provide enough tech helps for pharmacists. Knowing how busy my pharmacist is, often times I cannot just leave the pharmacy to get my lunch break alone. It is shocking how many pharmacists are not eating anything and standing on feet for whole 12 hour shift, but this is reality. This should be changed.

**Commenter:** Ifeanyi Ogbonna, Shenandoah University School of Pharmacy * 12/5/15 12:32 pm

**Pharmacists 30 Minutes Break**

As a student pharmacist and pharmacy intern at CVS pharmacy, I have seen what it is with pharmacists not allowed to take a 30 minutes break in a 13 hours shift. In my opinion, this is not the best way to go about the proffession because the body as we all know needs some rest at some point. Working for 12 hours without break may affect the pharmacist parformance with can indirectly affect the treatment/services patients get from pharmacists.

**Commenter:** 2016 Pharm D candidate * 12/24/15 2:43 pm

**Pharmacist 12 hour/d restriction**

I do not think that limiting a pharmacist to a 12 hour day will fix the issue that they are not taking breaks. Pharmacies should be allowed to break/shut down for at least 30 minute a day and not be obligated to take waiters, or fill prescriptions during this time unless there was an emergency situation to arise. However, most emergencies would land the patient in the ER and not their local retail chain store. Pharmacists whether working 8,10,or 13 hours a day shouldn't be limited.The hours worked isn't the problem, it's pharamcist not being allowed in "real life" to take a 30 minute break although their cooporations, etc. tell them to. Many community pharmacists (unless completely caught up or are priviledged to work in a store with overlap) feel too burdened to actually take the time and this is the problem. The problem is the community pharmacy system and the catering to unnecessary customer complaints due to their "fast food" concept of pharmacy drive-thru and dispencing services. Pharmacists need the Board to back them up and legally profess that all pharmacies must halt production for at least 30 minutes each day if the work day is 12 hours or more to insure that a pharmacist can truly rest and restore in order to increase patient safety.

**Commenter:** Tiffany Johnson, pharmacist * 1/1/16 4:52 pm

**Mandatory break after 6 hours**

Thank you for bringing the topic of 12-hour+ work days to our attention. As a pharmacist that works 12-hour shifts In a community setting, I would truly appreciate the break to reduce mental and

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physical fatigue. I feel that with a break I would be more confident in keeping public safety at the forefront of my profession. Knowing that I am the final check during the 12-hour shift leaves an immense burden that could safely be minimized through mandatory breaks. Thank you again for your consideration. Please favorably find the proposed regulation for increasing public safety.

**Commenter:** Drug Topics * 1/4/16 12:40 pm

**How Pharmacy Metrics Affect Our Profession**

Anonymous Jan 2, 2016

All that I know was that where I live the 2 CVS pharmacy managers with > 20 years each with the company were fired on the same day rumored to be due to "metrics". A recent graduate I know had an interview with CVS and was told "they are slowly weeding out the old guys". After double-digit years of above average reviews with my company I was given a poor rating by a new supervisor (no longer with the company) and demoted from my position to fast-track another employee to a supervisor position (that didn't happen). A pharmacist locally in a third company spoke his mind to a supervisor (no such thing as an open door policy) and was subsequently transferred to a more remote location from where he lives. All levels of management live on metrics only. Work hard, do your job, take care of your patients but don't completely trust your management at any level.

**Commenter:** Drug Topics * 1/4/16 12:41 pm

**How Pharmacy Metrics Affect Our Profession**

Anonymous May 6, 2015

I worked for Walgreens for 12 years in San Diego and 2 years at CVS between 2010 and 2014. CVS in San Diego create an extremely hostile working environment for ALL store and pharmacy employees especially pharmacists. I have been a floater pharmacist for CVS since 2008 and I have seen it all. In 2008, they hired a 30 year old Pharmacy District Supervisor who came in and fired and harassed numerous of older pharmacists INSIDE the pharmacy, using derogatory term regarding their age and performance based on CVS metrics. Terms like you are too old to work or too slow. They wrote up numerous counselings on pharmacists, pharmacist techs daily, weekly and fired them at their wish. They keep moving pharmacists around against their will to other stores and keep replacing with new pharmacy graduates and FORCED them to be pharmacist managers or get fired. They took advantage of the 2007 economic crisis and the abundance of pharmacists to keep threaten pharmacists to comply with their metrics or else face the ultimate penalty of getting fired. I have personally seen numerous of firings of pharmacists, techs on the job without any justifications. The average lifespan of a pharmacy manager is 6 months. Pharmacists are leaving CVS at an alarming rate. The 'don't care" and "it' s me or the "highway" altitude display CVS' arrogance and disrespect for human dignity is beyond imagination.

**Commenter:** Drug Topics * 1/4/16 12:44 pm

**Age Discrimination and the Use of Pharmacy Metrics**

Anonymous Apr 3, 2015

I am 68 years old and after 6 months working at a CVS pharmacy that had been open for 10 months I was given a choice of having my hours cut from 30 hours/week to 5-10 hours/week. This store has never met it's metric goals. This was part of their solution!? I was told that my job

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performance was fine. Also at a earlier date we were told that we could only take at most a 15 minute break to eat something or eat while working or not at all. This is when working 10-14 hour shifts. The possibity for med errors increase under these conditions. It is my opinion that CVS does not care about employee or patient health. I do not understand how stopping the sale of tobacco but continue to sell alcohol shows real concern over a persons health.

**Commenter:** Drug Topics * 1/4/16 12:45 pm

**Metrics equal Corporate Bullying**

AnonymousApr 1, 2015

Oh yeah? And I can present to the clown DeAngelis the write ups that led to the termination of my partner(who was about 60)and me(nearly 40). The write ups specifically say, and I quote"on performance warning for failing to exhibit the ability to deliver and drive various business results. Some of which include" PCI(AO, NSPU) KPM and Service targets" This write up was copied and pasted by my DM 3 times. I was explicitly told to my face that they have a big line of new grads willing to take my job. More, according to my DM running a store dispensing 400-500 prescriptions per day with 1 pharmacist and 1-2 techs is perfectly fine, as long as you can manage your techs.

**Commenter:** Drug Topics * 1/4/16 12:47 pm

**Metrics are More Important than Patient Health**

AnonymousMar 31, 2015

...the same unfair criminal practice happened to me back in Las Vegas 2010,the vice president of operations for the whole District made up a special metric system just for me because I questioned in a big meeting when he he announced all pharmacist are expected to, on their days off, to go out, no reimbursement ,procure and work to generate flu shot clinics saying it was part of the job description when we got hired. He then forced me to sign a special document, that no other R.Ph had to sign, saying I had to meet metrics of 95% across the board, and that I was going to be reevaluated every two weeks and if I did not meet those metrics, I would than be rated as "not meeting expectations". I than got ahold of HR who got the document dismissed, but I was forced to quit because superiors started coming in once a week 'writing' me up, for example a dirty sink, due to a few smudges. Doing more than 600 rx's a day as well as immunizing,no overlap coverage, they than cut my tech grid weekly from 325 hr to 175,20% reduction every week. Unfair labor practices permeate this whole organization.

**Commenter:** Concerned Pharmacist * 1/4/16 1:03 pm

**Pharmacy Metrics Define the Future of Pharmacy Not Patient Health**

What other health care profession can you go into that will guarantee you work long hours, without a formal break, and expected to fullfill dispensing quotas and a failure to do so WILL cost you your job------PHARMACY. The state of retail pharmacy has changed for the worse. Due to all time low 3rd party reimbursement practices and an inability to compete with mail order pricing guidelines. The current retail pharmacy outlet faces EXTINCTION. Your conventional drug stores like CVS, Walgreens, and Rite Aid have employed Pharmaceutical Metrics to "justify" eliminating older pharmacist in exchange for lower paid pharmacists, right out of school, so they can pay them less money and overall inject Millions if not Billions of dollars into an industry to satisfy financial goals of the company while putting more veteran/skilled pharmacists out of work. They set up dispensing metrics which directly contradict what they say they want us to do, which is spend more time

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counseling and managing patients health care challenges and less time dispensing YET many of the company metrics are time sensitive in reference to completing the dispensing process, which endangers public safety and health. Pharmacist's today have to choose between taking care of patients needs or satisfying company metrics. If the company metrics aren't satisfied the company will surely seek retribution including no raises, working on days off without pay, or ultimately TERMINATION! The time is now for the governing board of our great profession to stand up and put a STOP to this corporate bullying and greed!

**Commenter:** Concerned Pharmacist * 1/9/16 3:59 pm

**In support of mandatory breaks for pharmacists...**

As pharmacists have moved from being employers to being employees, we have not been able to take some of the "luxuries" like bathroom breaks and lunch breaks with us. The pharmacy metric driven corporate philosophy has removed much of the pharmacists ability to be able to sit down for 30 minutes to refresh themselves. I have worked for an employer before that shut the phones off for 30 minutes each day so that the pharmacist could have a break and that was a great time to step away and gather yourself for the rest of the day. Patients got used to the lunch concept and were for the most part respectful of it. People could still drop off and pick up during this time but nothing would be checked during this time. We need the board to step in and require this for patient safety because without board support the corporations will never implement it.

* Nonregistered public user

**Project 3337**

## BOARD OF PHARMACY

### Addressing hours of continuous work by pharmacists

Part IV

Pharmacies

**18VAC110-20-110. Pharmacy permits generally.**

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

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

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

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

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

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

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

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

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

**Agenda Item: Adoption of Amendment by a Fast-track Action**

**Staff Note:**

This recommended regulatory action arises from the following request:
Omnicare, a CVS Health Company, provides Long Term Care pharmacy services to a diverse population of skilled nursing patients in Virginia to include sub-acute care for children. Specifically, the children in these facilities suffer from complex physical and neurological diseases and experience frequent seizures. As a result, nurses assigned to these pediatric units need immediate access to Diastat Rectal gel in their stat boxes. Limiting the access to this critical medication will most certainly threaten a successful patient outcome up to and including the survival of the patient(s). Unfortunately, current pharmacy regulation 18VAC110-20-550 does not allow a CIV rectal gel to be included in the contents allowed in the stat box. We respectfully request 18VAC110-20-550.5.b be amended to include this dosage form (gel) to allow our pharmacists and others to meet the needs of this fragile population.

The recommendation is for an amendment to 18VAC110-20-540 for the emergency drug kit to include diazepamrectal gel.

**Included in your agenda package are:**

Information about diazepamrectal gel

A draft amendment to section 540

**Board action:**

To amend section 540 by a fast-track action or to deny such an amendment.

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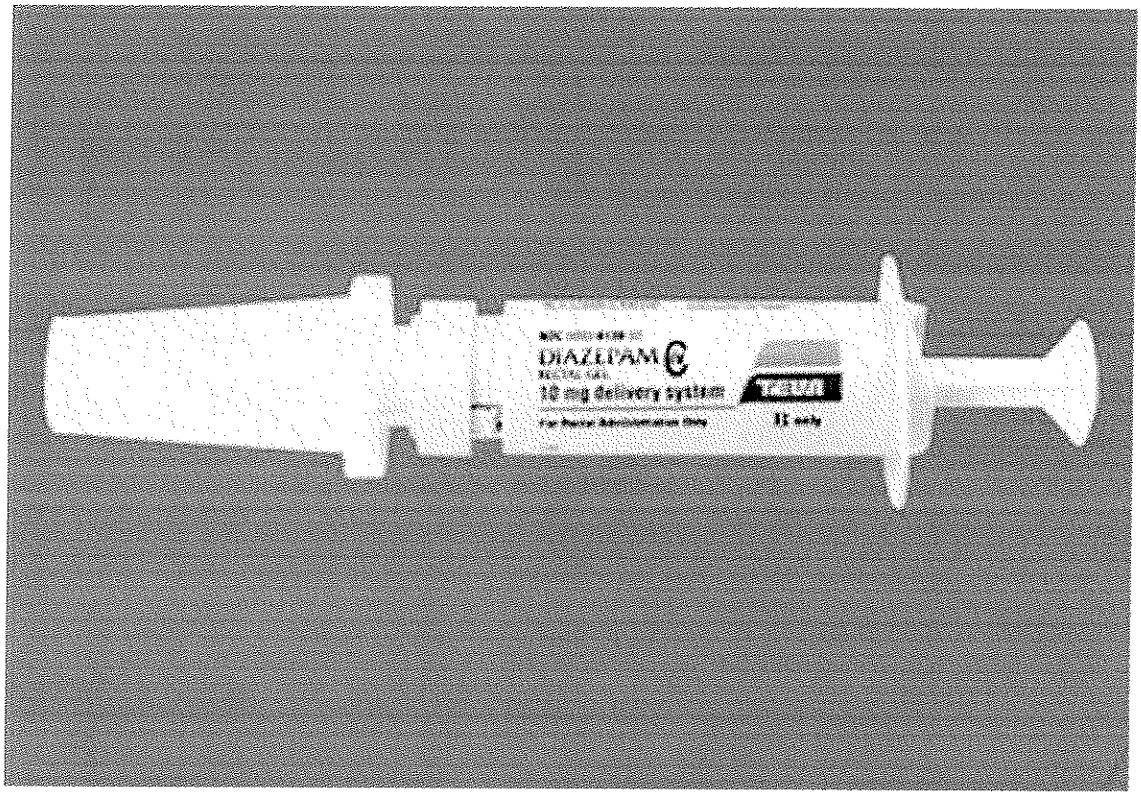
## Yeatts, Elaine J. (DHP)

**From:** Lincoln, Michelle <Michelle.Lincoln@omnicare.com>
**Sent:** Wednesday, March 09, 2016 9:28 AM
**To:** Juran, Caroline (DHP); Irvin, William
**Cc:** Yeatts, Elaine J. (DHP)
**Subject:** RE: VA Board of Pharmacy - Request for Regulatory Review meeting on 3/24/16
**Attachments:** Diastat Rectal gel #2.JPG

Caroline,




Diastat Acudial is available in varying mg delivery systems . The pharmacist dials the dose and locks it using the ring shown on the delivery system. The manufacturer actually supplies these in a twin pack in order to give a subsequent dose within 4 hours as needed (picture attached). Below are the delivery system units available and the doses that are available from each system.

Please let me know if you need more clarification.

Michelle

Diastat AcuDial is available in the following delivery system units: 2.5 mg, 10 mg, and 20 mg. The available doses from the 20 mg delivery system are 10 mg, 12.5 mg, 15 mg, 17.5 mg, and 20 mg. The available doses from 10 mg delivery system are 5 mg, 7.5 mg, and 10 mg. The 2.5 mg dose may also be used as a partial replacement dose for patients who may expel a portion of the first dose.



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**Proposed Amendment by Fast-track Action**

**18VAC110-20-540. Emergency drug kit.**

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

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

2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.

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

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

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

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

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

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

127C

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

A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

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

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.

2. The PIC shall be notified prior to each entry and give permission for the designated, specific individuals to enter.

3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.

4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The PIC shall ensure that the alarm access code is changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for one year.

**§ 54.1-3320. Acts restricted to pharmacists.**

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations.

(2001, c. 317; 2005, c. 403; 2006, c. 626; 2010, c. 90.)

**§ 54.1-3321. Registration of pharmacy technicians.**

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

F. The Board shall waive the initial registration fee and the first examination fee for the Board-approved examination for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

**From:** CHAD W TOUSSANT [mailto: ]
**Sent:** Tuesday, December 22, 2015 7:08 AM
**To:** Board of Pharmacy
**Subject:** Informatics as practice specialty

To whom it may concern:

When recently renewing my license, I was disappointed to find that Informatics is completely absent from the PGY2 residency and current pharmacy practice choices. We should certainly be represented as a practice specialty.

Please consider adding Informatics as a practice choice. Currently at Sentara Healthcare, we have 5 full time pharmacists in Informatics (up to the director level) and 1 pharmacy (PGY2) resident. With electronic medical records, this is a growing field and I'm sure the other health systems also have informatics pharmacists as well.

Thank you,
Chad Toussant, RPh
Sentara Healthcare

# What Types of Residencies are Available?

Postgraduate Year 1—or **PGY1**—residencies provide training for "generalists" in health systems, managed care, or community settings.

Postgraduate Year 2—or **PGY2**—residencies provide advanced training in a focused area of patient care, including:

- Ambulatory care,
- Cardiology,
- Critical care,
- Drug information,
- Emergency medicine,
- Geriatrics,
- Immunology,
- Infectious diseases,
- Informatics,
- Internal medicine,
- Managed care pharmacy systems,
- Nuclear pharmacy,
- Nutrition support,
- Oncology,
- Pediatrics,
- Pharmacotherapy,
- Practice management or administration,
- Psychiatry, or
- Transplantation.

***Note: You must complete a PGY1 (general practice) residency before going on to a PGY2 (specialized) residency.***

For more information on the types of residencies available in programs across the U.S., check **www.ashp.org**.

# Pharmacist Survey

**Instructions:**

**The following survey will assist policymakers at the state, federal and local levels assess the adequacy of the current pharmacist workforce and project future workforce trends in relation to Virginia's changing population and health needs. It will help us advance the practice of pharmacy and to improve the health of all Virginians. By law, information collected as part of this survey is confidential. License numbers and other individually identifying information are removed from Healthcare Workforce Data Center data sets. The Healthcare Workforce Data Center only releases information in the aggregate or to qualified research organizations who meet our strict confidentiality standards. You may exit the survey at any time by scrolling to the bottom and pushing the "Submit" button or by clicking on the "Finish" button at the bottom of the left sidebar. Note: Clicking "Finish" will finalize your renewal application.**

**The survey questions are designed to allow comparisons across professions, and among state and federal data collection efforts. Some of the questions, particularly demographic questions, match Federal data collection standards.**

| | | |
|---|---|---|
| | | |
| **Education and Background** | | |
| | | |
| 1) | Year of Birth: | *Dropdown: 2000 to 1920 (reverse order)* |
| | | |
| 2) | Sex: | *Dropdown: Male/Female* |
| | | |
| | Please select the items that best describe your race/ethnicity. Please answer both question 3a about Hispanic origin and 3b about race/ethnicity. | |
| 3a) | Select one: | *Check one* |
| | | Hispanic, Latino or Spanish Origin |
| | | Not Hispanic, Latino or Spanish Origin |
| | | |
| 3b) | Select all that apply: | *Check all that apply* |
| | | White |
| | | Black or African American |
| | | American Indian or Alaska Native |
| | | Asian |
| | | Native Hawaiian or Pacific Islander |
| | | Some other race |
| | | |
| 3c) | If some other race, please specify: | *Fill in the blank* |
| | | |
| 4) | Where did you graduate from high school (Secondary School)? | *Dropdown* |
| | | Outside of the US or Canada |
| | | Canada |
| | | 57 US States and Territories |

| | | |
|---|---|---|
| 5) | Was your childhood spent mostly in rural, urban or suburban areas? | *Dropdown: urban, rural, suburban* |
| | | |
| 6) | Where did you obtain your undergraduate degree? | *Dropdown* |
| | | Did not obtain an undergraduate degree |
| | | Outside of the US or Canada |
| | | Canada |
| | | 57 US States and Territories |
| | | |
| 7) | Where did you obtain the degree that initially qualified you to practice pharmacy? | *Dropdown* |
| | | Outside of the US or Canada |
| | | Canada |
| | | 57 US States and Territories |
| | | |
| 8) | Please indicate the highest level of pharmacist education you have completed as of today: | *Dropdown* |
| | | BS Pharm |
| | | PharmD |
| | | |
| 9) | Do you hold an active license to practice pharmacy in any other jurisdiction? | *Check all that apply* |
| | | District of Columbia |
| | | Kentucky |
| | | Maryland |
| | | North Carolina |
| | | Tennessee |
| | | West Virginia |
| | | One or more other US states |
| | | |
| | Please indicate any residencies you have completed as of today: | |
| | Note: The list here is structured to match the current ASHP residency structure. General and clinical residencies were consolidated in 1993 into "pharmacy practice". The current PGY1/PGY2 structure was adopted in 2005. For those who completed residencies prior to these dates, please select the residency from either PGY1 or PGY2 that best matches your residency. | |
| 10a) | PGY1: | *Dropdown* |
| | | Community Pharmacy |
| | | Managed Care Pharmacy |
| | | Pharmacy Practice (Post 1993) |
| | | Pharmacy Practice (Pre-1993--Health Systems, Ambulatory Care, Clincal, etc.) |

| | | |
|---|---|---|
| | | Other |
| | | |
| 10b) | PGY2: | *Dropdown* |
| | | Ambulatory Care |
| | | Cardiology |
| | | Critical Care |
| | | Drug Information |
| | | Emergency Medicine |
| | | Geriatrics |
| | | Health-system Pharmacy Administration |
| | | Infectious Disease |
| | | Informatics |
| | | Internal Medicine |
| | | Managed Care Pharmacy Systems |
| | | Medication Safety |
| | | Nuclear |
| | | Nutrition Support |
| | | Oncology |
| | | Palliative Care |
| | | Pediatrics |
| | | Pharmacogenetics |
| | | Pharmacotherapy |
| | | Psychiatry |
| | | Solid Organ Transplant |
| | | Other |
| | | |
| 10c) | If you selected "other" for either residency, please provide a brief description and indicate whether the residency was PGY1 or PGY2: | *Open-ended* |
| | | |
| 11a) | Please indicate any Board Certifications for pharmacists you hold that are current as of today: | *Check all that apply* |
| | | ABAT-Applied Toxicology |
| | | BPS- Pharmacotherapy |
| | | BPS-Ambulatory Care |
| | | BPS-Nuclear Pharmacy |
| | | BPS-Nutrition |
| | | BPS-Oncology |
| | | BPS-Psychiatric |
| | | CCGP-Geriatrics |
| | | Other |

| | | |
|---|---|---|
| | | |
| 11b) | Please choose any self-designated specialty areas in which you practice and have advanced education, training, certification or experience: | *Check all that apply:* |
| | | Ambulatory Care |
| | | Anticoagulation |
| | | Applied Toxicology |
| | | Community Pharmacy |
| | | Compounding |
| | | Diabetic Educator |
| | | Geriatrics |
| | | Health Systems-Pharmacy Administration |
| | | Immunization |
| | | Managed Care |
| | | Nuclear Pharmacy |
| | | Nutrition |
| | | Oncology |
| | | Pharmacotherapy |
| | | Psychiatric |
| | | Other |
| | | |
| 11c) | If you have any other specialty areas or credentials, please provide short description: | *open ended* |
| | | |
| | | |
| **Current Employment Status** | | |
| | | |
| 12) | Which choice best describes your *current* employment or work situation? | *Dropdown* |
| | | Employed in a pharmacy related capacity. |
| | | Employed, NOT in a pharmacy related capacity. |
| | | I am retired. |
| | | Voluntarily unemployed (including for medical reasons). |
| | | Involuntarily unemployed. |
| | | |
| 13) | Overall, and taking into account all positions you fill, how satisfied are you with your *current* employment or work situation? | *Dropdown* |
| | | Very satisfied |
| | | Somewhat satisfied |
| | | Somewhat dissatisfied |

| | | |
|---|---|---|
| | | Very dissatisfied |
| | | |
| 14) | How many positions do you *currently* hold? | *Dropdown* |
| | *Note: There is no legal standard for part-time work, and each employer defines part-time work differently. Part-time work generally refers to workweeks of 35-hours per week or less. Per diem, temporary, contract, self-employed and seasonal workers, and workers subject to annual limits on hours should consider average hours spent working over the term of employment.* | One part-time position |
| | | One full-time position |
| | | Two part-time positions |
| | | position |
| | | Two full-time positions |
| | | More than two positions |
| | | |
| 15) | Considering all postions you *currently* fill, how long is your average workweek? | *Dropdown* |
| | | I am not currently working |
| | | 1 to 4 hours |
| | | 5 to 9 hours |
| | | 10 to 14 hours |
| | | 15 to 19 hours |
| | | 20 to 24 hours |
| | | 25 to 29 hours |
| | | 30 to 34 hours |
| | | 35 to 39 hours |
| | | 40 to 44 hours |
| | | 45 to 49 hours |
| | | 50 to 54 hours |
| | | 55 to 59 hours |
| | | 60 to 64 hours |
| | | 65 to 69 hours |
| | | 70 to 74 hours |
| | | 75 to 79 hours |
| | | 80 or more hours |
| | | |
| ***Unless otherwise noted, the rest of the questions draws on your experiences over the past 12 months. If you did not work in the past 12 months in a capacity that drew on your pharmacy background, please skip to question 39.*** | | |
| | | |
| **Primary Work Location** | | |

*Questions 16 to 22 refer to your primary place of employment, work or practice (volunteer or paid) over the past 12 months. This is the location where you spend the most work hours during an average workweek or where you spent the most weeks working in the past 12 months. You do not need to currently work at this location. These questions refer to a location, not an employer. Persons who consistently work in multiple locations (e.g. temporary workers, home health, multi-facility rounds) should choose the location where they are based.*

| | | |
|---|---|---|
| 16) | Please select the Virginia County or Independent City, or other location, of your primary place of employment, work or practice: | *Dropdown:* |
| | | Outside of US |
| | | Virginia Border State/DC |
| | | Other US State |
| | | List of Virginia's Cities and Counties |
| | | |
| 17) | How long have you worked at this particular location? | Dropdown |
| | | I do not currently work at this location |
| | | Less than 6 months |
| | | 6 months to 1 year |
| | | 1 to 2 years |
| | | 3 to 5 years |
| | | 6 to 10 years |
| | | More than 10 years |
| | | |
| 18a) | Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc): | *Dropdown: 1 week - 52 weeks* |
| | | |
| 18b) | How many hours do you (or did you) work in an average workweek at this location? | *Dropdown* |
| | | 1 to 4 hours |
| | | 5 to 9 hours |
| | | 10 to 14 hours |
| | | 15 to 19 hours |
| | | 20 to 24 hours |
| | | 25 to 29 hours |
| | | 30 to 34 hours |
| | | 35 to 39 hours |
| | | 40 to 44 hours |
| | | 45 to 49 hours |
| | | 50 to 54 hours |
| | | 55 to 59 hours |
| | | 60 to 64 hours |
| | | 65 to 69 hours |

| | | |
|---|---|---|
| | | 70 to 74 hours |
| | | 75 to 79 hours |
| | | 80 or more hours |
| | | |
| 19) | In the average workweek at this location, roughly what percentage of your working hours were spent in the following roles: **(Answers should roughly equate to 100%)**. | *Dropdown: (for each sub-question)* |
| 19a) | Patient Care (including medication dispensing, direct patient care, patient education, reviewing charts, etc.) | None |
| 19b) | Administration (including recordkeeping, third-party billing, business management, wholesale distribution, manufacturing, etc) | 1% to 9% |
| 19c) | Formal Research (including practice-based research) | 10% to 19% |
| 19d) | Education (including preceptoring) | 20% to 29% |
| 19e) | Other | 30% to 39% |
| | | 40% to 49% |
| | | 50% to 59% |
| | | 60% to 69% |
| | | 70% to 79% |
| | | 80% to 89% |
| | | 90% to 99% |
| | | 100% |
| | | |
| 20a) | Please select the choice that best describes this location's organizational sector: | *Dropdown* |
| | | For-profit (e.g. private practice, corporate) |
| | | Non-profit (including religious affiliated) |
| | | State/local-government |
| | | US military |
| | | Veterans Administration |
| | | Other federal government |
| | | |
| 20b) | Please select the choice that best describes this practice setting: | *Dropdown:* |
| | | Independent Community Pharmacy (1-4 store |
| | | Small Chain Community Pharmacy (5-10 store |
| | | Large Chain Community Pharmacy (11+ store |
| | | Mass Merchandiser (i.e. Big Box Store) |
| | | Supermarket Pharmacy |
| | | Clinic-Based Pharmacy |
| | | Mail Service Pharmacy |
| | | Hospital / Health System, Inpatient |
| | | Hospital / Health System, Outpatient |
| | | Nursing Home, Long Term Care |

| | | |
|---|---|---|
| | | Home Health / Infusion |
| | | Pharmacy Benefit Administration (e.g. PBM, m |
| | | Academic Institution |
| | | Wholesale Distributor |
| | | Manufacturer |
| | | Other |
| | | |
| 20c) | If you selected "other practice setting" please provide a brief description: | *Open-ended* |
| | | |
| 21) | Please choose the option that best describes how you are (or were) personally compensated for activities at this location: | *Dropdown* |
| | | Business/Practice income (including salary as owner/partner) |
| | | Salary/Commission (excluding salary as owner/partner) |
| | | Hourly wage |
| | | By contract, per diem, traveling |
| | | Volunteer, unreimbursed |
| | | |
| 22) | Do you provide any of the following services at this location? | *Check all that apply* |
| | *Telepharmacy: Off-site collaboration using telephone, video or other telecommunications devices.* | Central filling |
| | | Collaborative Practice Agreement |
| | | Compounding |
| | | Medication Therapy Management |
| | | Remote consulting/telepharmacy |
| | | Remote order processing |
| | | |
| **If you only had one practice location in the past 12 months, please skip to question 33. If you had additional practice locations, please continue.** | | |
| | | |
| **Secondary Work Location** | | |
| *Questions 23 to 30 refer to your secondary place of employment, work or practice (volunteer or paid) over the past 12 months. This is the location where you spend the second most work hours during an average workweek or where you spent the second most weeks working in the past 12 months. You do not need to currently work at this location. These questions refer to a location, not an employer. Persons who consistently work in multiple locations (e.g. temporary workers, home health, multi-facility rounds) should choose the location where they are based.* | | |
| | | |

| | | |
|---|---|---|
| 23) | Is this location with the same employer or practice as your primary location, or a different employer/practice? | *Dropdown* |
| | | Same employer or practice |
| | | Different employer or practice |
| | | |
| 24) | Please select the Virginia County or Independent City, or other location, of your secondary place of employment, work or practice: | *Dropdown:* |
| | | Outside of US |
| | | Virginia Border State/DC |
| | | Other US State |
| | | List of Virginia's Cities and Counties |
| | | |
| 25) | How long have you worked at this particular location? | Dropdown |
| | | I do not currently work at this location |
| | | Less than 6 months |
| | | 6 months to 1 year |
| | | 1 to 2 years |
| | | 3 to 5 years |
| | | 6 to 10 years |
| | | More than 10 years |
| | | |
| 26a) | Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc): | *Dropdown: 1 week - 52 weeks* |
| | | |
| 26b) | How many hours do you (or did you) work in an average workweek at this location? | *Dropdown* |
| | | 1 to 4 hours |
| | | 5 to 9 hours |
| | | 10 to 14 hours |
| | | 15 to 19 hours |
| | | 20 to 24 hours |
| | | 25 to 29 hours |
| | | 30 to 34 hours |
| | | 35 to 39 hours |
| | | 40 to 44 hours |
| | | 45 to 49 hours |
| | | 50 to 54 hours |
| | | 55 to 59 hours |
| | | 60 to 64 hours |
| | | 65 to 69 hours |
| | | 70 to 74 hours |

| | | |
|---|---|---|
| | | 75 to 79 hours |
| | | 80 or more hours |
| | | |
| 27) | In the average workweek at this location, roughly what percentage of your working hours were spent in the following roles: **(Answers should roughly equate to 100%).** | *Dropdown: (for each sub-question)* |
| 27a) | Patient Care (including medication dispensing, direct patient care, patient education, reviewing charts, etc.) | 1% to 9% |
| 27b) | Administration (including recordkeeping, third-party billing, business management, wholesale distribution, manufacturing, etc) | 20% to 29% |
| 27c) | Formal Research (including practice-based research) | 30% to 39% |
| 27d) | Education (including preceptoring) | 40% to 49% |
| 27e) | Other | 50% to 59% |
| | | 60% to 69% |
| | | 70% to 79% |
| | | 80% to 89% |
| | | 90% to 99% |
| | | 100% |
| | | |
| 28a) | Please select the choice that best describes this location's organizational sector: | *Dropdown* |
| | | For-profit (e.g. private practice, corporate) |
| | | Non-profit (including religious affiliated) |
| | | State/local-government |
| | | US military |
| | | Veteran's Administration |
| | | Other federal government |
| | | |
| 28b) | Please select the choice that best describes this practice setting: | *Dropdown:* |
| | | Independent Community Pharmacy (1-4 store |
| | | Small Chain Community Pharmacy (5-10 store |
| | | Large Chain Community Pharmacy (11+ store |
| | | Mass Merchandiser (i.e. Big Box Store) |
| | | Supermarket Pharmacy |
| | | Clinic-Based Pharmacy |
| | | Mail Service Pharmacy |
| | | Hospital / Health System, Inpatient |
| | | Hospital / Health System, Outpatient |
| | | Nursing Home, Long Term Care |
| | | Home Health / Infusion |
| | | Pharmacy Benefit Administration (e.g. PBM, m |
| | | Wholesale Distributor |

| | | |
|---|---|---|
| | | Manufacturer |
| | | Academic Institution |
| | | Other |
| | | |
| 28c) | If you selected "other practice setting" please provide a brief description: | *Open-ended* |
| | | |
| 29) | Please choose the option that best describes how you are (or were) personally compensated for activities at this location: | *Dropdown* |
| | | Business/Practice income (including salary as owner/partner) |
| | | Salary/Commission (excluding salary as owner/partner) |
| | | Hourly wage |
| | | By contract, per diem, traveling |
| | | Volunteer, unreimbursed |
| 30) | Do you provide any of the following services at this location? | *Check all that apply* |
| | *Telepharmacy: Off-site collaboration using telephone, video or other* | Central filling |
| | | Collaborative Practice Agreement |
| | | Compounding |
| | | Medication managment |
| | | Remote consulting/telepharmacy |
| | | Remote order processing |
| | | |
| **If you had only two locations in the past 12 months, please skip to question 31. If you had additional practice locations, please continue.** | | |
| | | |
| 31) | How many **total** work locations have you had *over the past 12 months?* | *Dropdown* |
| | | 3 |
| | | 4 |
| | | 5 |
| | | 6 or more |
| | | |
| 32) | How many work locations do you have *currently?* | *Dropdown* |
| | | 3 |
| | | 4 |
| | | 5 |
| | | 6 or more |
| | | |

| | | |
|---|---|---|
| **Employment Information** | | |
| *The Healthcare Workforce Data Center collects compensation information to assess the balance of supply and demand in the state and in localities, and to assist students in planning health careers and choosing specialties. Information from these questions will only be presented in the aggregate. The confidentiality of information for these and all questions is protected by law. All questions are voluntary.* | | |
| | | |
| 33) | Within the past 12 months, have you experienced any of the following: | *Check all that apply* |
| | | Voluntary unemployment (including for medical reasons)? |
| | | Involuntary unemployment? |
| | | Switched employers/practices? |
| | | Worked part-time or temporary positions, but would have preferred a full-time or |
| | | Worked two or more positions at the same time? |
| | | |
| 34) | What is your estimated annual income (before taxes, net of business expenses) from pharmacy-related activities? | *Dropdown:* |
| | | Volunteer work only |
| | | Less than $40,000 |
| | | $40,000-$49,999 |
| | | $50,000-$59,999 |
| | | $60,000-$69,999 |
| | | $70,000-$79,999 |
| | | $80,000-$89,999 |
| | | $90,000-$99,999 |
| | | $100,000-$109,999 |
| | | $110,000-$119,999 |
| | | $120,000-$129,999 |
| | | $130,000-$139,999 |
| | | $140,000-$149,999 |
| | | $150,000-$159,999 |
| | | $160,000-$169,999 |
| | | $170,000 or more |
| | | |
| 35) | Do you receive any of the following benefits from any *current* employer? | *Check all that apply:* |
| | | Paid Vacation Leave |
| | | Paid Sick Leave |
| | | Health Insurance |
| | | Dental Insurance |

| | | |
|---|---|---|
| | | Retirement (401k, Pension, etc.) |
| | | Group Life Insurance |
| | | Signing/retention bonus |
| | | |
| 36) | What is your estimated current educational debt? | *Dropdown:* |
| | | None |
| | | Less than $10,000 |
| | | $10,000-$19,999 |
| | | $20,000-$29,999 |
| | | $30,000-$39,999 |
| | | $40,000-$49,999 |
| | | $50,000-$59,999 |
| | | $60,000-$69,999 |
| | | $70,000-$79,999 |
| | | $80,000-$89,999 |
| | | $90,000-$99,999 |
| | | $100,000-$109,999 |
| | | $110,000-$119,999 |
| | | $120,000-$129,999 |
| | | $130,000-$139,999 |
| | | $140,000-$149,999 |
| | | $150,000-$159,999 |
| | | $160,000-$169,999 |
| | | $170,000-$179,999 |
| | | $180,000-$189,999 |
| | | $190,000-$199,999 |
| | | $200,000 or more |
| | | |
| 37) | At what age do you plan to retire from pharmacy? | *Dropdown* |
| | | Under age 50 |
| | | 50 to 54 |
| | | 55 to 59 |
| | | 60 to 64 |
| | | 65 to 69 |
| | | 70 to 74 |
| | | 75 to 79 |
| | | 80 or over |
| | | I do not intend to retire |
| | | |
| 38) | Within the next two years do you plan to do any of the following: | *Check all that apply* |

| | | |
|---|---|---|
| | | Retire |
| | | Cease working in pharmacy |
| | | Continue working in pharmacy, but cease working in Virginia |
| | | Increase patient care hours |
| | | Decrease patient care hours |
| | | Increase time spent teaching pharmacy |
| | | Decrease time spent teaching pharmacy |
| | | Pursue additional pharmacy education |
| | | |
| **End of Questionnaire for active practitioners-Thank you!** | | |
| | | |
| 39) | If you did not practice, teach or otherwise work in pharmacy within the past twelve months, did/are you. . .? | *Check all that apply:* |
| | | I am retired. |
| | | Work occasionally for charity/consultation/special patients? |
| | | Pursue pharmacy education or certifications? |
| | | Pursue education not related to pharmacy? |
| | | Work in another profession or field? |
| | | Experience temporary **voluntary** unemployment (including for medical reasons)? |
| | | Experience temporary **involuntary** unemployment? |
| | | |
| 40) | Do you provide any pharmacy-related volunteer, mentoring or other services in Virginia? If so, approximately how many hours in the past year? | *Dropdown:* |
| | | None |
| | | 1-25 hours |
| | | 26-50 hours |
| | | 51-75 hours |
| | | 76-100 hours |
| | | Over 100 Hours |
| | | |
| 41) | Do you expect to begin working in Pharmacist in Virginia? If so, when? | *Dropdown:* |
| | | Not currently planning to practice/work in Virginia |

| | | |
|---|---|---|
| | | Plan to practice/work in a volunteer capacity |
| | | Yes, within the next year |
| | | Yes, within 1-2 years |
| | | Yes, within 3-5 years |
| | | Yes, in more than 5 years |
| | | Yes, do not know when |
| | | |
| **End of Questionnaire-Thank you!** | | |

# Protocol for the Prescribing and Dispensing of Naloxone

*Pharmacists shall follow this protocol when dispensing naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opiate overdose as authorized in §54.1-3408.*

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling, unless pharmacist is able to verify successful completion of REVIVE! training program.
   b) The pharmacist shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://dbhds.virginia.gov/library/document-library/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

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

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order, a pharmacist may dispense naloxone pursuant to a standing order. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   a) Name of pharmacy authorized to dispense naloxone pursuant to standing order;
   b) Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration, to include quantity of drug and directions for administration;
   c) Prescriber's signature; and
   d) Date of issuance.

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

| Intranasal | Auto-Injector | Intranasal |
|---|---|---|
| Naloxone 2mg/2ml prefilled syringe, # 2 syringes<br><br>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.<br><br>Mucosal Atomization Device (MAD) # 2<br>SIG: Use as directed for naloxone administration.<br><br>Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration. | Naloxone 0.4 mg/0.4 ml #1 twin pack<br><br>SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.<br><br>~~Kit is commercially available as a twin pack with directions for administration included.~~<br>No kit is required. Product is commercially available. | Narcan Nasal Spray 4mg, #2<br><br>SIG: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br><br>No kit is required. Product is commercially available. |

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

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

**5) Labeling and Records:**

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation.

## Protocol for Dispensing to Law-Enforcement Officers and Firefighters

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

6) **Resources:**
   a) REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dbhds.virginia.gov/library/document-library/osas-revive-02-revive-training-curriculum.pdf
   b) Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
   c) Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
   d) Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

# Virginia Board of Pharmacy
# Pharmacy Inspection Deficiency Monetary Penalty Guide

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

5

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

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

| ~~Major~~ Deficiency | Law/Reg Cite | Conditions | $ Penalty |
|---|---|---|---|
| 18. Records of dispensing not maintained as required | 54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425 | | 250 |
| 19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions | 18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425 | 10% threshold for documentation | 500 |
| 20. Pharmacist not checking and documenting repackaging or bulk packaging | 54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425 | Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant. | 250 |
| 20a. Pharmacist not documenting final verification of non-sterile compounding | 54.1-3410.2, 18VAC110-20-355 | 10% threshold | 500 |
| 20b. Pharmacist not documenting final verification of sterile compounding | 54.1-3410.2, 18VAC110-20-355 | | 5000 |
| 21. No clean room | 54.1-3410.2 | | 10000 |
| 21a. Performing sterile compounding outside of a clean room. | 54.1-3410.2 | Compliant clean room present but not utilized for preparation of compounded sterile drug products. | 3000 |

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

| ~~Major~~ Deficiency | Law/Reg Cite | Conditions | $ Penalty |
|---|---|---|---|
| 25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved finger tip testing for persons performing high-risk level compounding of sterile preparations. | 54.1-3410.2 | Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated. | 5000 |
| 25b. High-risk compounded sterile preparations intended for use are improperly stored | 54.1-3410.2 | | 5000 |
| 25c. Documentation that a person who failed a media-fill test or gloved finger tip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved finger tip test | 54.1-3410.2 | | 5000 |
| 26. No documentation of initial and annual (12 months) media-fill testing or gloved finger tip testing for persons performing low and medium-risk level compounding of sterile preparations. | 54.1-3410.2 | Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated. | 500 |
| 26a. Documentation that a person who failed a media-fill test or gloved finger tip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved finger tip test | 54.1-3410.2 | | 500 |

| ~~Major~~ Deficiency | Law/Reg Cite | Conditions | $ Penalty |
|---|---|---|---|
| 27. Compounding using ingredients in violation of 54.1-3410.2. | 54.1-3410.2 | | 1000 |
| 28. Compounding copies of commercially available products | 54.1-3410.2 | per Rx dispensed up to maximum of 100 RX or $5000 | 50 |
| 29. Unlawful compounding for further distribution by other entities | 54.1-3410.2 | | 500 |
| 30. Security of after-hours stock not in compliance | 18VAC110-20-450 | | 500 |
| 31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist. | 18VAC110-20-555 | Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C) | 250 |
| 32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling | 54.1-3410.2 | | 2000 |
| 33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD) | 54.1-3410.2 | | 1000 |
| 34. Combined with ~~Minor~~ Deficiency 142 – 12/2013. | | | |
| 35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner | 18VAC110-20-395 | | 250 |

## ~~Minor~~ Other Deficiencies

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

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

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

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

| ~~Minor~~ Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained | 54.1-3410.2 | |
| 132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements | 54.1-3410.2 | |
| 133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2 | 54.1-3410.2 | |
| ~~Hospital specific or long-term care specific:~~ | | |
| 134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured | 18VAC110-20-440 | |
| 135. Policies and procedures for drug therapy reviews not maintained or followed | 18VAC110-20-440 | |
| 136. After hours access to a supply of drugs or records not in compliance | 18VAC110-20-450 | 10% threshold |
| 137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done | 18VAC110-20-460 | 10% threshold |
| 138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance | 54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555 | Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements. |
| 139. Emergency medical services procedures or records not in compliance | 18VAC110-20-500 | 10% threshold |

| ~~Minor~~ Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 140. Emergency kit or stat-drug box procedures or records not in compliance | 18VAC110-20-540 and 18VAC110-20-550 | 10 % threshold |
| 141. Maintaining floor stock in a long-term care facility when not authorized | 18VAC110-20-520 and 18VAC110-20-560 | |
| 142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance | 18VAC110-20-418 | 20% Threshold.<br>Do not cite deficiency until July 1, 2015 |
| 143. Exceeds pharmacist to pharmacy technician ratio | 54.1-3320 | Per each technician over the ratio<br>First offence – ~~Minor~~ Deficiency 143 ~~deficiency~~<br>Second Offense – ~~Major~~ Deficiency 6 ~~deficiency~~ |
| 144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. | 18VAC110-20-180 | ~~Minor~~ Deficiency 144 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action.<br>~~Major~~ Deficiency 9a if drug loss. |
| 145. Insufficient enclosures or locking devices | 18VAC110-20-190 | ~~Minor~~ Deficiency 145 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application.<br>~~Major~~ Deficiency 11 if drug loss. |
| 146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. | 18VAC110-20-200 | ~~Minor~~ Deficiency 146 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. |

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| ~~Minor~~ Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| | | ~~Major~~ Deficiency 12a if drug loss. |
| 147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. | 54.1-3410.2 | |

# Virginia Board of Pharmacy

## Physicians Dispensing Drugs

Dispensing by a physician means the providing of drugs to patients to take with them away from the physician's place of practice. Physicians in Virginia may dispense under certain circumstances without being required to obtain a license to dispense from the Board of Pharmacy. Those circumstances include the dispensing of manufacturer's samples appropriately labeled as samples and not for sale, dispensing in a bona fide medical emergency, and dispensing when pharmaceutical services are not otherwise available. Any other type of dispensing by a physician requires the physician to obtain a license from the Board of Pharmacy. The Board offers two types of license to physicians.

**Permitted Physicians – Practice as a pharmacy**

One type of license, pursuant to § 54.1-3304 authorizes the Board to license a physician to practice pharmacy when good cause is shown that pharmacy services are not otherwise readily available. This type of license is usually granted to physicians working in rural areas where there is not a pharmacy within at least 15 to 20 miles and there are only a handful of these types of licenses still current. With this type of license, a physician may also fill prescriptions of other practitioners.

**Physicians Selling Drugs**

The second and more common type of dispensing license for physicians is the license for a practitioner of the healing arts to sell controlled substances. The term "controlled substances" in Virginia includes any drug in Schedule I through VI which is all prescription drugs, not just those drugs which are DEA controlled substances. Another confusing term is the term "sell" or "sale". Many physicians question why they are required to have this license if they do not charge a patient for the drugs dispensed. The term "sale" is defined in the Drug Control Act as "gift, barter, or exchange". Therefore a charge is not required in order for dispensing to become a "sale". With this license a physician ~~may only dispense to his own patients,~~ must comply with a set of regulations which relate specifically to this license~~, and dispensing under this license may not be delegated to anyone else, such as to a nurse practitioner, physician assistant, nurse, or pharmacy technician~~. If there is more than one physician dispensing within a single practice, each dispensing physician must obtain this license ~~and may only dispense to his own patients.~~ Effective June 4, 2016, a permit from the Board of Pharmacy must also be obtained for the facility from which practitioners of the healing arts dispense controlled substances and it shall meet compliance with the regulations for practitioners of the healing arts to sell controlled substances. Physicians licensed to sell controlled substances may dispense from any facility permitted for this purpose.

A physician licensed to sell controlled substances may only dispense to his own patients. However, with this license the physician may dispense pursuant to a prescription written by a nurse practitioner or physician assistant under the following conditions:

- The physician has a bona fide practitioner-patient relationship with the patient whom the nurse practitioner or physician assistant has prescribed a drug; and,
- The physician is the supervising physician of the physician assistant or the physician who has entered into a practice agreement with the nurse practitioner.

A physician may also dispense a refill of a prescription written by another physician licensed to sell controlled substances if the physician has a bona fide practitioner-patient relationship with the patient.

While the regulation allows for a pharmacy technician, or trained nurse or trained physician assistant to assist the licensed physician in preparing the drug for dispensing, the physician is responsible for conducting a prospective drug review, offering to counsel the patient, inspecting the prescription product to verify its accuracy in all respects, and placing his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. The physician may not delegate the responsibility of dispensing a drug to a nurse practitioner or physician assistant; hence, no drug may be dispensed when a physician is not on-site.

Within this category of licensure, it is possible to request a **limited-use license.** Pursuant to Regulation 18VAC110-30-20 and the delegation of authority to the Executive Director as set forth in Bylaws of the Board, a physician may apply for a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. Under a limited-use license, a waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

There is one other exception to the pharmacy act which allows physicians acting on behalf of the state or a local health department to dispense without having to obtain licensure from the Board of Pharmacy. It has been interpreted that this authority can be delegated to other persons authorized to prescribe within the health department system, such as nurse practitioners, since there is no direct prohibition against such delegation, as is the case with the physician selling drugs license.

***Excerpts from the Code of Virginia—Pharmacy Act and Medical Practice Act related to physician dispensing***

~~**§ 54.1-3301. Exceptions.**~~

~~This chapter shall not be construed to:~~

~~1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;~~

~~2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408;~~

~~3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;~~

~~6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;~~

~~7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in §/n 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing manufacturers' samples of these drugs to his own patients;~~

~~8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;~~

~~9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written agreement with a physician;~~

~~10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;~~

~~11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or~~

~~12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other~~

~~jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.~~

~~This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.~~

**§ 54.1-3301. Exceptions.**

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;

4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;

5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to

prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written or electronic agreement with a physician;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the

limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

**§ 54.1-3302. Restrictions on practitioners of the healing arts.**

A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.

**§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.**

For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.

~~**§ 54.1-3304.1. Authority to license and regulate practitioners.**~~

~~The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts.~~

**§ 54.1-3304.1. Authority to license and regulate practitioners.**

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

**§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.**

A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall

not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

B. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

C. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision A 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.

D. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.

Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.