COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

(804) 367-4456 (Tel)
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Amended Agenda of Public Hearing and Full Board Meeting

June 4, 2014

9:00AM

TOPIC	PAGES

Call to Order of Public Hearing on Regulations 18VAC110-20-10 et seq.:
Jody H. Allen, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Proposed Regulations for Administrative Fees for Duplicate Licenses and Verification — 1-7

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Jody H. Allen, Chairman

- Approval of Agenda
- Approval of previous Board meeting minutes:
  - March 25, 2014, Informal Conference Committee – Innovative Pilot Application — 8-11
  - March 26, 2014, Full Board Meeting — 12-20
  - April 22, 2014, Panel Formal Hearing — 21-26
  - April 24, 2014, Special Conference Committee — 27-30
  - May 6, 2014, Informal Conference Committee – Innovative Pilot Application — 31-33
  - May 12, 2014, Regulation Committee — 33A-E

Call for Public Comment: The Board will receive all public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

Regulatory Actions: Elaine Yeatts

- Regulatory Update
- Report from Regulation Committee — 34
  - Replacement of emergency regulations for CQI programs — 35-49
  - Re-consideration of a fast-track regulation on EMS — 50-61
  - Adoption of NOIRA prohibiting offering incentives or inducements to transfer prescriptions — 62-69

- 2015 Draft Legislative Proposals:
  - Scheduling bill – alfaxalone 70-76
  - Authority to license facilities of practitioner of the healing arts to sell controlled substances 77
  - Requirement for wholesale distributors to notify Board when ceasing distribution to dispenser 78-79
  - Authority for pharmacists to possess and administer epinephrine and oxygen 80-85
  - Virginia licensure for outsourcing facilities, pharmacies that compound human drugs 86-106

Miscellaneous: Caroline D. Juran

- Summary of Healthcare Workforce Surveys Handou
- Staff request to amend Guidance Document 110-38 regarding inspections from nonresident pharmacies 107-108
- Board member request to amend 18VAC110-20-200 B to allow Schedule II drugs to be dispersed, securely locked, or a combination of both 109
- Staff request to amend 18VAC110-20-20 to allow staggering renewal of nonresident pharmacies 110-112
- Staff request to amend 18VAC110-20-190 to prohibit suspended or revoked pharmacists, pharmacy interns, and pharmacy technicians from accessing prescription department and controlled substances 113-114
- Board member request to discuss possibility of a "pharmacy assistant" 115

Reports:

- Chairman's Report
- Report on Board of Health Professions – Robert M. Rhodes
- Report on Prescription Monitoring Program – Ralph Orr 116
- Report on Licensure Program – J. Samuel Johnson, Jr. Handou
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handou
- Executive Director's Report - Caroline D. Juran

Election of Officers – Chairman and Vice-Chairman

New Business:

Consideration of consent orders (if any)

Adjourn

******The Board will have a working lunch at approximately 12pm and recognize former board member, David Kozera and former board counsel, Howard Casway. ******

******At 2:30pm or immediately following adjournment of the meeting, whichever is later, an ad hoc inspection committee will convene.******

Proposed Regulations for Public Hearing

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Chapter 20

Proposed Regulation

Titles of Regulations: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-20).**

18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (amending 18VAC110-50-20).

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information:

June 4, 2014 - 9 a.m. - Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA 23233

Public Comment Deadline: July 18, 2014.

Summary:

The amendments to 18VAC110-20 and 18VAC110-50 impose an administrative fee of $10 for providing duplicate licenses (including permits and registrations) and a fee of $25 for verification of licensure (including permits and registrations).

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	$180

2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90
10. Innovative program approval.	$250

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.

11. Approval of a pharmacy technician training program	$150
12. Approval of a continuing education program	$100
13. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy permit – due no later than April 30	$270
5. Physician permit to practice pharmacy – due no later than February 28	$270
6. Medical equipment supplier permit – due no later than February 28	$180
7. Humane society permit – due no later than February 28	$20
8. Nonresident pharmacy – due no later than April 30	$270

9. Controlled substances registrations – due no later than February 28	$90
10. Innovative program continued approval based on board order not to exceed $200 per approval period.	
11. Approval of a pharmacy technician training program	$75 every two years
12. Approval of a repackaging training program	$30 every two years

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

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

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

following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

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

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

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

6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

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

18VAC110-50-20. Fees.

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

B. Initial application fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270

6. Controlled substances registration	$90

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. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90
5. Nonresident wholesale distributor	$90
6. Controlled substances registration	$30

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date 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.

2. 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. 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.

3. 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. Nonrestricted manufacturer permit	$240

b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240
d. Warehouser permit	$240
e. Nonresident wholesale distributor	$240
f. Controlled substances registration	$180

F. Application for change or inspection fees.

1. Reinspection fee	$150
2. Inspection fee for change of location, structural changes, or security system changes	$150
3. Change of ownership fee	$50
4. Change of responsible party	$50

G. The fee for a returned check shall be $35.

~~H. For the annual renewal due on February 28, 2010, the following fees shall be imposed for a license or permit:~~

~~1. Nonrestricted manufacturer permit~~	~~$210~~
~~2. Restricted manufacturer permit~~	~~$140~~
~~3. Wholesale distributor license~~	~~$210~~
~~4. Warehouser permit~~	~~$210~~
~~5. Nonresident wholesale distributor~~	~~$210~~

H. The fee for verification of license or permit shall be $25.

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE REVIEW OF INNOVATIVE PILOT APPLICATION

March 25, 2014
Second Floor
Board Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 10:00 AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT: Empsy Munden

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director

RIVERSIDE REGIONAL MEDICAL CENTER: The purpose of the informal conference was to act upon the Application of Riverside Regional Medical Center for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulation 18VAC110-20-490 C and 18VAC110-20-460 A. Rebecca Schulkowski, pharmacist-in-charge of Riverside Regional Medical Center, John Campbell, Product Leader for CardinalASSIST, and Micah Siegmund, Operations Manager for CardinalASSIST appeared in person at the informal conference.

Riverside Regional Medical Center requested a waiver of 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from the pharmacy to be placed in an automated dispensing device to include the initials of the pharmacist checking. Riverside Regional Medical Center requested that the 5% check allowance in Regulation 18VAC110-20-425 for robotic pharmacy systems also apply to medications that are refilled into an automated dispensing device when utilizing CardinalASSIST technology. Riverside Regional Medical Center is currently utilizing the CardinalASSIST replenishment technology which uses individual product barcode scanning throughout the entire process.

Mr. Campbell provided an overview of the CardinalASSIST operation and Ms. Schulkowski answered questions regarding the pharmacy operations at Riverside Regional Medical Center, in particular regarding its use of bar code technology.

CLOSED MEETING: Upon a motion by Ms. Munden, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to Section 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 the use of Pharmacist 100% Check Variance for CardinalASSIST Delivery by Riverside Regional Medical Center. Additionally, she moved that Caroline D. Juran and J. Samuel Johnson, Jr. 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: Ms. Shinaberry announced the committee's decision to accept and approve an amendment of the request within the application to remove the requirement for pharmacist verification of Schedule VI drugs received from CardinalASSIST to be placed in an automated dispensing device for a period of three (3) years from the date the Order is entered by the Board and the pharmacy informs the Board it has reached a 90% restocking bar code scanning rate. The following terms and conditions also apply and were read by Ms. Juran:

1. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from the pharmacy to be placed in an automated dispensing device to include the initials of the pharmacist checking shall be waived for those Schedule VI drugs received from CardinalASSIST.
2. The requirement in 18 VAC 110-20-460 A of the Regulations for a pharmacist to check all Schedule 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 shall be waived for those Schedule VI drugs received from CardinalASSIST.
3. Riverside Regional Medical Center shall maintain a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices is less than 90% for any quarter, the pharmacy shall immediately reinstitute a 100% pharmacist verification process until the Board approves Riverside Regional Medical Center resuming the allowances within the innovative (pilot) program.
4. Riverside Regional Medical Center shall maintain a closed loop system throughout the entire ordering, replenishment of automated dispensing devices, and administration process.
5. The assignment of the Med ID to the national drug code (NDC) shall be performed by a pharmacist employed by Riverside Regional Medical Center.
6. Riverside Regional Medical Center shall submit to the Board a quarterly report which indicates the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from CardinalASSIST. The reports shall be submitted in March, June, September, and December.
7. CardinalASSIST shall deliver the drugs directly to the pharmacy.
8. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
9. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

INOVA LOUDOUN HOSPITAL:

The purpose of the informal conference was to act upon the Application of INOVA Loudoun Hospital for approval of an innovative (pilot) program ("Application") at the emergency rooms at INOVA Loudoun's main campus and its Cornwall site with a waiver of compliance of certain provisions of Board of Pharmacy Regulation 18VAC110-20-470. Specifically, the application requested the ability for emergency department physicians to dispense drugs, repackaged by the hospital pharmacy and stored in an automated dispensing device, to discharged patients from the emergency department. The application stated the proposed program would ensure medication compliance, reduce re-admission rates, increase patient satisfaction and begin INOVA Loudoun's efforts to meet new accountable care organization standards. Cathleen Cowden, pharmacist-in-charge of INOVA Loudoun Hospital Pharmacy appeared in person at the informal conference.

During the discussion and review of the application, Ms. Cowden indicated there is a pharmacy on-site at the Loudoun Hospital that operates twenty-fours a day, 7 days a week. However, she maintained that it was not feasible for the pharmacy to dispense the drugs for emergency department patients due to the inability to properly label the drug and insufficient staffing. Additionally, Ms. Cowden indicated that Loudoun County has only one community pharmacy with 24 hours operations and that it is 7.2 miles from the main hospital in Leesburg and 13.7 miles from the off-site Cornwall emergency department in Leesburg. INOVA Loudoun will operate a retail pharmacy at its Lansdowne campus in the 2014-2015 timeframe. In addition to the 24-hour on-site pharmacy, Ms. Shinaberry noted that the information provided by Ms. Cowden indicates the main campus in Loudoun issues 55% of the emergency department prescriptions issued by the INOVA Loudoun Hospitals and that this location is only 7.2 miles from the 24-hour community pharmacy.

CLOSED MEETING:

Upon a motion by Ms. Munden, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to Section 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 the use of Profiled Dispensing of Medications from the Emergency Room by INOVA Loudoun Hospital. Additionally, she moved that Caroline D. Juran and J. Samuel Johnson, Jr. 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:

Ms. Shinaberry announced the committee's decision to deny the application to allow physicians to dispense from the emergency departments because pharmaceutical services are otherwise available and the request did not appear to justify the waiving of regulation and possible statutory provisions.

ADJOURN: With all business concluded, the meeting adjourned at 2:45PM.

Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 26, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:05 a.m.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Ellen B. Shinaberry, Vice-Chairman
Crady R. Adams
Ryan K. Logan
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner
Dinny Li - arrived at 10:19 a.m.

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

WELCOME: Ms. Allen welcomed David E. Brown, D.C., newly appointed Director of the Department of Health Professions; Ryan K. Logan, newly appointed member of the Board of Pharmacy; and James Rutkowski, Assistant Attorney General, recently assigned as counsel for the Board of Pharmacy. Ms. Allen also welcomed two pharmacy students in the audience from Hampton University and Virginia Commonwealth University

APPROVAL OF AGENDA: Ms. Allen indicated that the conflict of interest training program would not be shown following adjournment of the business portion of the meeting because the audio-visual equipment was currently inoperable. The tentative agenda was otherwise approved by the Board as presented.

APPROVAL OF MINUTES: The Board reviewed the draft minutes. It was noted that the December 12, 2013 Full Board Meeting minutes had two corrections. On page 4, "pan" should be changed to "plan" and on page 11, "Rhoades" was misspelled.

MOTION:

The Board voted unanimously to amend the December 12, 2013 full board meeting minutes by changing "pan" to "plan" on page 4 and changing "Rhoades" to "Rhodes" on page 11 and to approve the minutes as otherwise presented for the following meetings: December 12, 2013 (Public Hearing on Regulations for Continuous Quality Improvement Programs); December 12, 2013 (Full Board Meeting); December 12, 2013 (Panel of the Board Formal Hearing); December 17, 2013 (Special Conference Committee and Informal Conference Committee); January 21, 2014 (Special Conference Committee and Informal Conference Committee); January 27, 2014 (Telephone Conference Call); February 5, 2014 (Special Conference Committee and Informal Conference Committee); February 18, 2014 (Telephone Conference Call); February 20, 2014 (Informal Conference Committee); February 26, 2014 (Panel Formal Hearing); and March 7, 2014 (Ad Hoc Committee on Guidance for Suggested Disciplinary Action and Monetary Penalties Resulting from Routine Inspections of Physicians Licensed to Dispense). (motion by Warriner, second by Stelly)

The Board was provided an additional handout of the draft minutes from the March 11, 2014, Informal Conference Committee for an Innovative (Pilot) Program.

MOTION:

The Board voted unanimously to approve as presented the minutes of the March 11, 2014 Informal Conference Committee for an Innovative (Pilot) Program. (motion by Munden, second by Shinaberry)

RECONSIDERATION OF PREVIOUSLY APPROVED MINUTES:

Ms. Juran stated she had recently been made aware of an inaccuracy in the previously approved minutes from the November 25, 2013, Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense and asked that the Board consider the suggested changes on page 39A of the agenda packet.

MOTION:

The Board voted unanimously to amend the previously-approved minutes for the November 25, 2013 "Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense" by replacing the sentence "He indicated that VPhA is not happy with the routine pharmacy inspection process and that it has decayed the relationship between VPhA and the Board" with the sentence "Speaking as an individual, Mr. Davis stated that he is currently not happy with the routine pharmacy inspection process and he feels that it has decayed the relationship between Virginia pharmacists and the Board." (motion by Shinaberry, second by Warriner)

PUBLIC COMMENTS:

There were no public comments received at this time.

DHP DIRECTOR'S REPORT: Dr. Brown introduced himself and provided the board members with his background information. He also expressed his pleasure at being appointed Director of the Department of Health Professions.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2014 General Assembly session that may potentially impact the board or the profession of pharmacy.

- Regulatory Update

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 45 of the agenda packet. She stated the modifications to regulatory requirements for automated dispensing devices for a less burdensome process became effective February 27, 2014, as did the regulatory amendments for less restrictive and burdensome record-keeping for on-hold prescriptions. She also reported the regulatory amendments to conform to changes in the Code for collaborative practice agreements will likely become effective April 23, 2014.

- Adoption of Final Regulations for CQI

Ms. Yeatts stated that the Board needs to adopt the proposed final regulations for continuous quality improvement (CQI) regulations to replace the emergency regulations that expired on September 30, 2013. She explained the request for an extension was never approved and therefore, there are currently no regulations in place. The Board had a lengthy discussion regarding suggested changes provided in the one written comment received during the public comment period. It was unclear to the Board what, if any, ramifications would result by adopting the proposed final regulations with the suggested change.

MOTION: **A motion to amend and adopt the proposed final regulations for continuous quality improvement programs by changing the definition of "actively report" to mean "<u>documenting as collected for</u> reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error" was made by Shinaberry and seconded by Warriner, but then was rescinded by both.**

MOTION: **The Board voted unanimously to table the discussion and refer the adoption of the final proposed regulations for continuous quality improvement programs to the regulation committee with direction to specifically consider whether documenting as collected for reporting affords protections under federal regulations and the appropriateness of requiring errors to be reported to a patient safety organization within 30 days of identifying the error. (motion by Stelly, second by Adams)**

- Reconsideration of Regulation 18 VAC 110-20-500 regarding EMS

Ms. Yeatts stated that there were several comments from Virginia EMS agencies requesting that the Board reconsider the previously adopted draft of fast-track regulatory action to amend Regulation 18 VAC 110-20-500. She indicated the draft language has not yet been submitted for Executive

branch review and Board Chairman has referred the matter to the Regulation Committee. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, offered brief comments and stated she would provide more detailed comments at the upcoming regulation committee meeting. Sam Dahl, Executive Director for the Northern Virginia EMS Council, introduced himself and indicated he will provide comments to the Regulation Committee. Joey King with the Northern Virginia EMS Council provided his insight on the needs of EMS agencies throughout Virginia and looks forward to working with the Board to achieve 1:1 exchange of Schedule VI drugs.

- Request from the Department of Corrections to Amend 18 VAC 110-20-590 to Allow Floor Stock of Certain Drugs

Ms. Yeatts discussed with the Board the request from the Department of Corrections to amend 18 VAC 110-20-590 to allow floor stock of certain drugs in the correctional facilities similar to allowances in other types of facilities, e.g., long term care. She reviewed the suggested amendments provided by staff. Ms. Yeatts stated the amendments could be adopted as a fast-track regulatory process.

MOTION:

The Board voted unanimously to amend Regulation 18 VAC 110-20-590 as presented to allow floor stock of certain drugs in correctional facilities and that the amendments be adopted under the fast-track regulatory process. (motion by Munden, second by Rhodes)

- Action on Petition for Rulemaking – Pharmacy Coupons

Ms. Yeatts reviewed with the Board the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Ms. Yeatts referenced the action taken by the Board in 2010 when a similar petition was received and board counsel advised that a prohibition of coupons may be a possible restraint of trade. The Virginia Pharmacist Association and the Academy of Managed Pharmacy Care submitted comment in favor of the recently received petition. Ms. Yeatts stated the Board could reject the petition and give the petitioner a reason as to why it was rejected; accept and adopt a Notice of Intended Regulatory Action (NOIRA), or reject the petition but refer the matter to the regulation committee for further consideration. Ms. Warriner and Mr. Rhodes expressed concern for the practice. Ms. Shinaberry referenced ISMP's position of concern for the practice and a recent review of this practice by the Department of Justice.

MOTION:

A motion was made to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration. (motion by Warriner, second by Adams)

MOTION:

A motion was made to table the discussion regarding the petition for rulemaking to prohibit pharmacy coupons until the June full board

meeting. (motion by Adams, second by Munden) (5 :5 vote, motion failed)

MOTION:

As previously motioned by Warriner and seconded by Adams, the Board voted unanimously to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration.

MISCELLANEOUS:

- Request from Containment Technologies Group, Inc. to Amend Guidance Document 110-36

Ms. Juran reviewed a letter that was received from Hank Rahe, Director Technology with Containment Technologies Group, Inc. that requests the Board to amend the response to question #24 in Guidance Document 110-36. Within the letter, Mr. Rahe provided information from the United States Pharmacopeia (USP) confirming that the current USP chapter <797> does not specifically require certifying companies to comply with guidelines published by the Controlled Environment Testing Association (CETA). Rather, chapter <797> states certifying companies shall comply with certification procedures "such as" those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006).

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented on page 103 of the agenda packet. (motion by Stelly, second by Shinaberry)

- Request from Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to Accept their Accreditation or Assessment In Lieu of Inspection Report from Regulatory or Licensing Agency of the Jurisdiction

Ms. Juran discussed the requests from the Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to accept their accreditation in lieu of the inspection report from the regulatory board or licensing agency of the jurisdiction. She indicated the Board Chairman has referred this matter to the Ad Hoc Committee for Inspections for further consideration.

- DEA Open Public Comment Period for Proposed Rule to Move Hydrocodone Combination Products to Schedule II

Ms. Juran reviewed DEA's notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II. She stated that in January 2013 an FDA Advisory Committee recommended the drugs be moved to Schedule II based on an 8-factor analysis and the potential for severe psychological and physical abuse. Ms. Juran asked if the Board would like to offer comment to DEA during the open comment period which ends April 28, 2014. David Creasy, pharmacist-owner of Poquoson Pharmacy, stated his concerns for patient care and access to the drug if moved to Schedule II. He indicated he is not in favor of the change at this time but perhaps down the road when e-prescribing is more fully utilized.

MOTION:

A motion was made to provide comment to DEA in support of rescheduling hydrocodone combination products from Schedule III to II. (motion by Adams, second by Stelly) (3 in favor, 7 opposed; motion failed)

No further action was taken on the subject.

- Ad Hoc Committee Report on Guidance for Suggested Disciplinary Action and Monetary Penalties Resulting from Routine Inspections of Physicians Licensed to Dispense

Ms. Shinaberry provided a report of the ad hoc committee's recommendations. The committee met on March 7, 2014, to discuss a ticketing program for practitioners of the healing arts to sell controlled substances that would mirror the pharmacy inspection guidance within Guidance Document 110-9. Ms. Shinaberry discussed the consensus of the committee and Mr. Johnson briefly reviewed the committee's recommended major and minor deficiencies and associated monetary penalties in the draft guidance document. Ms. Warriner noted a minor deficiency regarding the lack of equipment for non-sterile compounding in compliance with USP standards should be added to the draft guidance document.

MOTION:

The Board voted unanimously to adopt the guidance document as amended to establish suggested disciplinary action for major and minor deficiencies cited during routine inspections of practitioners of the healing arts to sell controlled substances. (motion by Warriner, second by Adams)

MOTION:

The Board voted unanimously to accept the following recommendations made by the ad hoc committee:

- **The Board will pilot this process for approximately 12 months beginning this summer, if possible;**
- **Strongly recommend that the physicians be present during the pilot inspection for educational purposes;**
- **No monetary penalties will be imposed by the inspector for any deficiencies cited during the pilot;**
- **The Board is to send written notification to all licensed practitioners of the healing arts to sell controlled substances prior to the implementation of the pilot to alert them of the pilot and educating them of ways to avoid being cited deficiencies.**

(motion by committee, second by Warriner)

- Board Member Request to Consider 24-Hour Advanced Notice of Routine Pharmacy Inspections

In lieu of unannounced routine inspections, Ms. Shinaberry requested the Board consider directing inspectors to provide a 24- hour notice prior to performing a routine inspection, similar to processes used by accrediting bodies. Ms. Shinaberry explained that providing advance notice would allow the pharmacist-in-charge an opportunity to be present during the inspection which may decrease the possibility of cited deficiencies as the PIC would be more aware of the location of required recordkeeping, allow the opportunity to schedule additional staff which could facilitate the inspection process and minimize distractions for the pharmacist practicing pharmacy that day, and possibly make the inspection process more palatable to the licensees. Ms. Yeatts stated that the agency has had

a longstanding policy to conduct unannounced inspections and that inspection policies should be uniform within the agency. A request made many years ago by the Board of Veterinary Medicine to announce inspections was denied by the agency director at that time. Paul Dalby, Deputy Director, Enforcement Division, stated that providing advance notice for a specific timeframe may shackle the inspectors and unplanned events may prevent the inspector from performing the inspection within the specified time. He agreed that providing notice may help improve compliance at that moment, but that unannounced inspections may create a culture of compliance. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, commented that a 30-day window notice could be helpful, but not really if it prevents staff from taking time off during that time period. Hunter Jamerson, Esquire, Macaulay & Burtch, P.C., stated he has noticed the informal conference hearings often deal with location of records and believes a quarterly notification could be helpful, more efficient, and make the inspection process more palatable for licensees. Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA), stated the ability to schedule additional staffing may prevent risk to patient care.

ACTION ITEM:

Ms. Allen suggested that staff research whether a written or verbal policy exists within the agency to perform routine inspections unannounced and request Dr. Brown, Director, DHP, to consider a policy to provide advance notice when performing routine inspections.

- Staff Request to Amend Guidance Document 110-9 to Include Deficiency Regarding Gloved Fingertip Sampling

Ms. Allen advised the board members that she has already referred the matter to the ad hoc inspections committee.

- 2015 Possible Legislative Proposals

Ms. Allen advised the board members that she has already referred the matter to the Regulation Committee.

REPORTS:

- Report on Board of Health Professions

Mr. Rhodes gave an update of previous and upcoming meetings with the Board of Health Professions. He reported that February 25, 2014, was the last meeting held. Some of the topics discussed included the PMP pamphlet, sanction reference points, budget, healthcare workforce and military credentialing as part of the National Governors Association policy grant.

- Report on Planning of the NABP/AACP District 1 & 2 Meeting

As Chairman of NABP District 2, Ms. Warriner updated the Board on the progress of the planning for the NABP/AACP District 1 & 2 meeting that is being hosted by Virginia October 5-7, 2014, at the Williamsburg Lodge. She reported that Alan Dow, M.D., Assistant Vice President of Health Sciences for Interprofessional Education and Collaborative Care, Virginia Commonwealth University, is the scheduled keynote speaker. He will also participate in a panel discussion with a pharmacist and nurse

on interprofessional development. She stated a planning committee is holding telephone conference calls about every two weeks for the planning of the event.

- Report on Licensure Program:

Mr. Johnson reported the Board issued 859 licenses and registrations for the period of December 1, 2013, through February 28, 2014, including 121 pharmacists, 142 pharmacy interns, and 492 pharmacy technicians. He also reviewed the number of current active licenses and certifications. Mr. Johnson informed the Board that the renewal process has begun for nonresident pharmacies. The Virginia Code was amended effective July 1, 2014, requiring nonresident pharmacies to submit a current inspection report when renewing the registration. A nonresident pharmacy that engages in sterile or non-sterile compounding must provide an inspection report that indicates compliance with USP-NF standards for sterile and non-sterile compounding. Inspectors conducted 351 facility inspections including 196 routine inspections of pharmacies: 57 resulted in no deficiency; 74 with deficiencies; and 65 with deficiencies and a consent order. Guidance Document 110-9, which was amended at the December 12, 2013, Board Meeting, modified several major deficiencies and established new minor deficiencies. Mr. Johnson stated that 33% of the inspections for the current period resulted in a consent order compared to 41% for the prior reporting period. He reviewed the report of Major & Minor Inspection Deficiencies.

- Report on Disciplinary Program:

- Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of June 14, 2013; September 9, 2013; December 10, 2013; and March 25, 2014. For the final date, open cases were none at the entry stage; 74 at the investigation stage; 89 at the probable cause stage; 11at the administrative proceedings division stage; ten at the informal stage; five at the formal stage; and 176 at the pending closure stage.

Further, Ms. Reiniers-Day provided the Board with the agency's Patient Care Disciplinary Case Processing Times for the Quarterly Performance Measurement for the Second Quarter 2014. Specific to the Board of Pharmacy, the clearance rate was 78%, the Pending Caseload older than 250 days was 18%, and the percent closed within 250 business days was 89%.

- Executive Director's Report:

Ms. Juran stated that DEA will host another prescription drug take-back event on Saturday, April 26, 2014. Additionally, she reported that she and board counsel attended a two-day intergovernmental meeting hosted by FDA on March 20-21, 2014, to discuss the new federal compounding requirements found in the Drug Quality and Security Act signed by the President in November 2013. She reported that it was a very informative meeting and that the Board may need to consider a possible legislative proposal on the subject at the upcoming Regulation Committee meeting. She also reminded the members of their legal obligation to complete conflict of interest training every two years. Members were asked to provide staff with certificates of completion of the training program by

April 15, 2014. She stated she is planning to attend the NABP Annual Meeting in Phoenix, AZ this May and that she has been awarded a travel grant of $1500. Mr. Rhodes and Ms. Warriner indicated they hope to attend the meeting as well.

CONSIDERATION OF CONSENT ORDERS: There were no consent orders to be considered at this time.

NEW BUSINESS: There was no new business.

ADJOURN: With all business concluded, the Board adjourned at 2:01 p.m.

Jody H. Allen, Chairman

Date: _____

Caroline D. Juran, Executive Director

Date: _____

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, April 22, 2014
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:10 a.m.

PRESIDING: Ellen B. Shinaberry, Chair

MEMBERS PRESENT:
R. Crady Adams
Dinny Li
Empsy Munden
Pratt P. Stelly
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
James E. Schliessmann, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With six (6) members of the Board present, a panel was established.

TANIA K. DOMINIQUE
Registration No. 0230-019822

A formal hearing was held in the matter of Tania K. Dominique, following the summary suspension of her pharmacy technician registration on February 27, 2014, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Dominique was not present at the hearing. The Board proceeded with the hearing in Ms. Dominique's absence as the Notice of Hearing dated February 27, 2014, was mailed to her legal address of record, both

by regular and certified mail. Ms. Shinaberry ruled that adequate notice was provided to Ms. Dominique.

James E. Shiliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Debra Hay-Pierce, DHP Senior Investigator testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Warriner, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Tania K. Dominique. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Warriner, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and read by Mr. Rutkowski.

Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the panel voted 6-0 to accept that Ms. Dominique's registration to practice as a pharmacy technician be revoked.

SAMIKA HAYMORE
Registration No. 0230-023067

A formal hearing was held in the matter of Samika Haymore, following the summary suspension of her pharmacy technician registration on February 27, 2014, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Haymore was not present at the hearing. The Board proceeded with the hearing in Ms. Haymore's

absence as the Notice of Hearing dated February 27, 2014, was mailed to her legal address of record, both by regular and certified mail. Ms. Shinaberry ruled that adequate notice was provided to Ms. Haymore. James E. Shiliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Debra Hay-Pierce, DHP Senior Investigator testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Warriner, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Samika Haymore. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Stelly, the panel voted 5-1 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and read by Mr. Rutkowski.

Upon a motion by Ms. Warriner and duly seconded by Ms. Munden, the panel voted 5-1 to accept that Ms. Haymore's registration to practice as a pharmacy technician be revoked.

MARCHEE JONES-ANDERSON
Registration No. 0230-018364

A formal hearing was held in the matter of Marchee Jones-Anderson, following the summary suspension of her pharmacy technician registration on February 27, 2014, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Jones-Anderson was not present at the hearing. The Board proceeded with the hearing in Ms. Jones-Anderson's absence as the Notice of Hearing dated February 27, 2014, was mailed to her legal address of record, both by regular and certified mail. Ms. Shinaberry ruled that adequate notice was provided to Ms. Jones-Anderson.

James E. Shiliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Debra Hay-Pierce, DHP Senior Investigator testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Warriner, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Marchee Jones-Anderson. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Stelly, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and read by Mr. Rutkowski.

Upon a motion by Ms. Warriner and duly seconded by Ms. Stelly, the panel voted 6-0 to accept that Ms. Jones-Anderson's right to renew her registration to practice as a pharmacy technician be revoked.

DOUGLAS A. HARRIS
License No. 0202-006176

A formal hearing was held in the matter of Douglas A. Harris, following the summary suspension of his

pharmacist license on December 16, 2013, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Sarah T. Melton, Clinical Psychiatric Pharmacist, Melton Healthcare Consulting; testified by telephone on behalf of the Commonwealth. Further, Karen McVay, a customer; Vicki G. Garrison, DHP Pharmacy Inspector; Joan McCormick, Pharmacy Technician; Joe Lumplin, Regional Director, Regulatory Affairs, McKesson Pharmaceutical North East Region; Bernadette Glenn, DEA Diversion Investigator; testified on behalf of the Commonwealth.

Mr. Harris was represented by Hunter W. Jamerson, Esquire and Lindsey Walton, Esquire.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Stelly, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Douglas A. Harris. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Li, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Mr. Rutkowski.

Upon a motion by Ms. Stelly and duly seconded by Ms. Li, the panel voted 6-0 that Mr. Harris' license to practice as a pharmacist be revoked and a monetary penalty of $15,000 be imposed.

Adjourn: With all business concluded, the meeting adjourned at 11:30 p.m.

Ellen B. Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Thursday, April 24, 2014
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	Jody H. Allen, Committee Chair
MEMBERS PRESENT:	Pratt P. Stelly, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
DAVID W. HALL Pharmacist Reinstatement Applicant License Number 0202-010394	David W. Hall appeared with John Beckner, his uncle, to discuss his application for reinstatement of his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 17, 2014, Notice.
Closed Meeting:	Upon a motion by Ms. Stelly, 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, for the purpose of deliberation to reach a decision in the matter of David W. Hall. Additionally, she 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 Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to Mr. Hall

to reinstate his license to practice pharmacy upon completion of the required 160 internship hours.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Hall, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Hall within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ELAINE K. TARDIFF
Pharmacist
License Number 0202-007487

Elaine K. Tardiff appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 25, 2014, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, 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, for the purpose of deliberation to reach a decision in the matter of Elaine K. Tardiff. Additionally, she 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 Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Tardiff an Order requiring her to obtain four (4) continuing education hours.

As provided by law, this decision shall become a final Order thirty (30) days after service of such

Order on Ms. Tardiff, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Tardiff within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

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

NORMA D. COOPER
Pharmacy Technician
Registration Number 0230-004523

Norma D. Cooper appeared to discuss her application for reinstatement of her registration to practice as a pharmacy technician and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the March 25, 2014, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, 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, for the purpose of deliberation to reach a decision in the matter of Norma D. Cooper. Additionally, she 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 Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to approve Ms. Cooper's application for the reinstatement of her pharmacy technician registration.

As provided by law, this decision shall become a final Order thirty (30) days after service of such

Order on Ms. Cooper, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Cooper within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 4:45 p.m.

Jody H. Allen

Cathy M. Reiniers-Day
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE REVIEW OF INNOVATIVE PILOT APPLICATION

May 6, 2014
Second Floor
Board Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:00 AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT: Jody Allen

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager

BLUE RIDGE PACE, DR. MARK A. NEWBROUGH, AND CAREKINESIS PHARMACY: The purpose of the informal conference was to act upon the Application of Dr. Mark A. Newbrough and CareKinesis Pharmacy for approval of an innovative (pilot) program ("Application") at the Blue Ridge PACE to operate in a manner similar to allowances in Regulation 18VAC110-20-276 wherein CareKinesis Pharmacy would provide remote order entry services for Dr. Newbrough who would be responsible for dispensing the drug product at the PACE facility. Dr. Newbrough, Medical Director, Blue Ridge PACE; Edward D. Rickert, Partner, Quarles & Brady, LLP; Cynthia Williams, RPh, System Director of Pharmacy, Riverside Health System; Michael Greenhalgh, RPh, Chief Operating Officer, CareKinesis; and, Sara T. Baughn, Director of Business Development, CareKinesis appeared in person at the informal conference. Requested waivers included: a waiver from the requirement that dispensing physicians are required to inspect the prescription product to verify its accuracy in all respects and a waiver from the requirement in 18VAC110-20-276 that a "pharmacy" can outsource prescription processing functions, to allow a dispensing practitioner to outsource those functions.

Mr. Greenhalgh provided an overview of the remote order entry process offered by CareKinesis and the dispensing cabinet to be located at the PACE facility which will select, label, and dispense the prescribed medication. The drug product would be dispensed pursuant to a practitioner of the healing arts to sell controlled substances license to be obtained Dr. Newbrough.

CLOSED MEETING: Upon a motion by Ms. Allen and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to Section 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 the use of Blue Ridge PACE Collaborative Prescription Medication Dispensing System by Dr. Newbrough and CareKinesis. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., and Beth O'Halloran attend the

closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of §2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

DECISION: Ms. Shinaberry announced the committee's decision to approve the innovative (pilot) program for a period of one (1) year contingent upon receipt of a policy and procedure manual consistent with Regulation 18VAC110-20-276 which identifies the roles and responsibilities of CareKinesis and Dr. Newbrough, implementation of the referenced dispensing cabinet, and the issuance of a practitioner of the healing arts to sell controlled substances license to Dr. Newbrough. The following terms and conditions also apply and were read by Ms. Juran:

1. All counseling provided to patients shall be provided by a pharmacist affiliated with CareKinesis or by Dr. Newbrough.
2. CareKinesis and Dr. Newbrough shall comply with all laws and regulations associated with licensure as a nonresident pharmacy and practitioner of the healing arts to sell controlled substances, respectively.
3. The innovative (pilot) program shall be subject to one unannounced inspection at the address of the Blue Ridge PACE program.
4. The dispensing cabinet shall be approved by the Board for the stocking and dispensing of drugs as outlined in the application, however, Dr. Newbrough shall be responsible for visibly verifying the accuracy of the drug in its entirety or the drug product, consistent with the policy and procedure manual.
5. Dr. Newbrough shall be responsible for ensuring quarterly reports are submitted to the Board. Information in the reports shall contain the number of drugs dispensed by Dr. Newbrough, any errors associated with the innovative (pilot) program, name and quantity of drugs dispensed.
6. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
7. Any additional physicians intending to dispense drugs pursuant to this innovative (pilot) program shall first obtain a practitioner of the healing arts to sell controlled substances license.
8. Errors associated with the innovative (pilot) program shall be immediately reported to the Board.
9. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

ADJOURN: The meeting adjourned at 12:35PM.

Ellen Shinaberry, Committee Chairman

Date

Caroline D. Juran, Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE FOR EMS, CQI, COUPONS, AND LEGISLATIVE PROPOSALS

May 12, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:05AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Dinny Li
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

PUBLIC COMMENT: Ms. Warriner announced that board counsel recently advised that the Board should accept all public comment at the beginning of the meeting and not throughout the meeting as individual agenda topics are discussed. Ms. Warriner then called for public comment.

Battalion Chief Jennie Collins with Prince William County Department of Fire & Rescue provided a handout of slides indicating there are 258 emergency boxes currently in- use in Prince William County. Currently the county exchanges Schedule VI drugs on a 1:1 basis as informally condoned by the Board for the past several years. She stated if the Board prohibits 1:1 exchange of Schedule VI drugs and requires box for box exchange, the county will need 645 boxes to meet demand. Concerns expressed by Chief Collins for a box to box exchange include: increase in pharmacy and EMS workload based on need to inventory contents of every box upon exchange; increase need for hospital storage of boxes awaiting exchange; increase demand of drug inventory amidst drug shortages; increase in time associated with exchanging boxes which will delay EMS ability to respond to 911 calls. Chief Collins requested Board allow a 1:1 exchange of Schedule VI drugs and that Schedules II-V drugs are exchanged box for box.

Sam Dahl, Executive Director of the Northern Virginia Emergency Medical Services Council emphasized the importance of EMS personnel spending as little time as necessary at the hospital when transporting patients, because the demand on EMS increases substantially when ambulances are out of service.

Gill Abernathy, Pharmacy Manager, Regulatory & Quality at Inova Health System expressed concern for pharmacy staffing and time constraints if the Board required box for box exchange of all drug schedules. Additionally, she requested the Board consider allowing a second EMS provider to witness the wasting of drugs and pleaded for ability to perform 1:1 exchange of Scheduled VI drugs. She is also concerned that stand-alone emergency departments must obtain a limited-use pharmacy permit to stock and exchange emergency kits, albeit she stated that she did not have a specific recommendation at this time.

Annette Reichenbaugh, Pharmacy Director at Reston Hospital Center expressed the following concerns for requiring box to box exchange of all drug schedules: currently facing drug shortages; insufficient space to currently store boxes; and, additional responsibility for pharmacy staff to monitor expiration dates of boxes.

Greg Rauch, President of the Northern Virginia Emergency Medical Services Council supported comments provided by others. Sam Dahl further stated that these concerns are not limited to northern Virginia.

Hunter Jamerson, Esq., representing EPIC Pharmacies expressed support for the petition recently submitted to the Board to prohibit incenting patients to transfer prescriptions as it creates polypharmacy. Additionally, he stated the practice creates difficulty for pharmacists to maintain a bona fide pharmacist-patient relationship and an inability for pharmacists to review a complete patient record. He suggested the Board consider reviewing current prohibitions in New York and New Jersey. He further stated that his comments were not intended to address the use of pharmaceutical manufacturer coupons.

EMS REGULATION:

After discussion, the motions below were offered.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend the proposed draft of Regulation 18VAC110-20-500 as follows:

- **Subsection A,10 - add "if the kit contents include Schedule II, III, IV, or V drugs" to the end of the second sentence;**
- **Subsection B – replace first sentence with "A licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices";**
- **Subsection B, 3 – replace "intravenous and irrigation fluids" with "Schedule VI drugs and devices". (motion by Thornbury, second by Adams)**

MOTION:

The Committee voted unanimously to recommend to the full board that it further amend the proposed draft of Regulation 18VAC110-20-500 subsection A, 6 by allowing a pharmacy technician or a second EMS provider to participate in the destruction of partially used Schedule II-V drugs and to adopt the amended EMS regulations as a fast-track regulatory change. (motion by Thornbury, second by Munden)

MOTION:

Mr. Adams moved to recommend to the full board that it consider requiring the printed name and signature when documentation is required within Regulation 18VAC110-20-500. (Motion died for lack of a second.)

CQI REGULATION:

The Committee discussed the proposed replacement regulations for continuous quality improvement programs. Ms. Juran reported that she had spoken with R. Brent Rawlings who submitted public comment on behalf of the Virginia Hospital and Healthcare Association during the last public comment period. Mr. Rawlings stated his clients had not expressed specific concerns regarding the proposed replacement regulations, however, he was slightly concerned that once the dispensing error is reported to a patient safety organization that it cannot be used to defend a possible lawsuit. He acknowledged to Ms. Juran that not requiring the submission of a dispensing error to a patient safety organization may not be consistent with the intent of the statute. Ms. Thornbury later questioned the intent of the proposed definition for "dispensing error" and whether an error that was corrected prior to the patient receiving it but after the pharmacist's final verification should be treated as a dispensing error. The consensus of the Committee was that such a "near miss" should be treated as a dispensing error since the error was not found during the pharmacist's final verification process.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend the proposed definition of "dispensing error" in Regulation 18VAC110-20-10 by adding "regardless of whether the patient received the drug" following the phrase "after the final verification by the pharmacist" and to adopt the proposed CQI regulations as amended. (motion by Thornbury, second by Adams)

PHARMACY COUPONS:

The Committee discussed the information contained in the agenda packet with a focus on whether a prohibition against incenting patients to transfer prescriptions could be construed as a restraint of trade. Ms. Juran reported that New York is currently defending a law suit for its current prohibitions against incenting patients. She also stated that the executive director of Oregon indicated its language prohibits pharmacies from incenting the transferring of prescriptions, but allows the incenting of patients to retain their prescriptions at a single pharmacy such as through loyalty programs. Board counsel stated that he did not believe Oregon's language could be construed as a restraint of trade. The Committee reviewed a proposed amendment to unprofessional conduct found in Regulation 18VAC110-20-25 that staff prepared using language similar to Oregon.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action regarding the use of coupons to incent patients to transfer prescriptions. (motion by Adams, second by Munden)

LEGISLATIVE PROPOSALS:

- WHOLESALE

33C

DISTRIBUTION NOTIFICATION REQUIREMENT

Ms. Yeatts and Ms. Juran provided an overview of the legislative proposal that was adopted by the Board in 2013 but not included in the administrative packet to the General Assembly. The proposal resulted from the Enforcement Working Group during the 2013 National Governor's Association Prescription Drug Abuse policy grant initiative in which Virginia participated.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal requiring wholesale distributors to notify the Virginia State Police and the Board of Pharmacy when ceasing or restricting distribution of controlled substances based on suspicious activity. (motion by Munden, second by Adams)

- AUTHORITY TO LICENSE PHYSICIAN DISPENSING FACILITIES

Ms. Yeatts explained that the Board has the authority to license individual physicians dispensing controlled substances, but not the facilities from where the drugs are dispensed. Because there has been a significant increase in the number of physician selling licenses issued by the Board in the past few years, it has become increasingly more difficult for staff to manage the oversight of these unlicensed facilities. Ms. Juran reminded the Committee of its desire to implement a routine inspection process for physician selling that is similar to the routine pharmacy inspection program. Currently, the pre-hearing consent order resulting from a routine inspection would have to be issued against the responsible physician as the Board does not have jurisdiction over the facility unlike its jurisdiction over a pharmacy. Ms. Yeatts stated the Board adopted this legislative proposal in 2013 but that it was not included in the administrative packet sent to the General Assembly.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal authorizing the Board to license the facility associated with the practitioners of the healing arts to sell controlled substances. (motion by Adams, second by Li)

- PHARMACIST POSSESSION AND ADMINISTRATION OF EPINEPHRINE AND OXYGEN

Ms. Juran explained that under a Board of Nursing-approved immunization protocol, pharmacists are required to recognize and administer epinephrine when warranted. This legislative proposal would provide the necessary authorization in law for pharmacists to possess and administer epinephrine and oxygen.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal authorizing pharmacists to possess and administer epinephrine and oxygen. (motion by Munden, second by Adams)

- PLACMENT OF ALFAXOLONE INTO SCHEDULE IV

Ms. Yeatts reported that effective March 31, 2014, DEA placed a new animal drug, alfaxalone, into Schedule IV. The proposed legislative proposal would place alfaxalone into Schedule IV of the Drug Control Act to conform to federal scheduling.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal to place alfaxalone into Schedule IV of the Drug Control Act. (motion by Munden, second by Adams)

- LICENSING AND REGULATING OF OUTSOURCING FACILITIES

Ms. Juran provided a brief overview of the compounding requirements in the recently passed federal legislation, the Drug Quality and Security Act. She then explained the concepts of the proposed legislative proposal acknowledging that she and Ms. Yeatts would need to continue editing the language. The proposal would create a new licensing category for outsourcing facilities and nonresident outsourcing facilities, require compliance with federal law, and require those outsourcing facilities that compound pursuant to patient-specific prescriptions to also obtain a pharmacy permit. There was discussion of whether §54.1-3410.2 should be amended to eliminate compounding for office use since the FDA has indicated the federal law prohibits pharmacies from compounding for office use. According to the FDA, compounding for office use must be performed by an outsourcing facility. The Committee did not reach consensus on this topic.

MOTION:

Based on the concepts of the proposed legislative proposal, the Committee voted unanimously to recommend to the full board that it adopt the legislative proposal to create a new licensing category for outsourcing facilities and nonresident outsourcing facilities, to regulate such facilities by requiring compliance with federal law and require those outsourcing facilities to also obtain a pharmacy permit prior to compounding pursuant to patient-specific prescriptions. (motion by Thornbury, second by Adams)

ADJOURN:

With all business concluded, the meeting adjourned at 1:05PM.

Cynthia Warriner, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

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

Staff Note: Attached is a chart with the status of regulations for the Board **as of May 25, 2014**

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Proposed - *Register Date: 5/19/14* *Comment period: 5/19/14 to 7/16/14* *Board to adopt final regulations on 9/9/14*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Continuous quality improvement programs [Action 3496] Proposed - *Register Date: 11/18/13* *Board to adopt final regulations on 6/4/14*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 381 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Floor stock for correctional facilities [Action 4157] Fast-Track – *At Department of Planning & Budget*
[18 VAC 110 - 40]	Regulations Governing Collaborative Practice Agreements	Conformity to changes in the Code [Action 4101] Final - *Register Date: 3/24/14* Errata published on May 19, 2014

Agenda Item: Adoption of Final Regulations

Replacement of Emergency Regulations for <u>Continuous Quality Improvement Programs</u>

Included in your agenda package are:

A copy of the 2011 legislation mandating continuous quality improvement programs for licensed pharmacies in Virginia

A copy of the Proposed Regulations replacing emergency regulations which were in effect from 10/1/12 to 9/30/13 (request for extension was never approved) – **including an amendment recommended by the Regulation Committee**

A copy of comment on the proposed regulations

Staff note:

There was a comment period on the proposed regulations which ended 1/17/14. At the public hearing on 12/12/13, there was no public comment.

Board action:

Consideration of the comment on proposed regulations

Adoption of final amendments to replace emergency regulations as recommended by the Regulation Committee

VIRGINIA ACTS OF ASSEMBLY -- 2011 SESSION

CHAPTER 124

An Act to amend and reenact § 54.1-3434.1 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 54.1-3434.03, relating to continuous quality improvement of pharmacies.

[H 2220]

Approved March 15, 2011

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434.1 of the Code of Virginia is 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 54.1-3434.03 as follows:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, 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.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a

prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

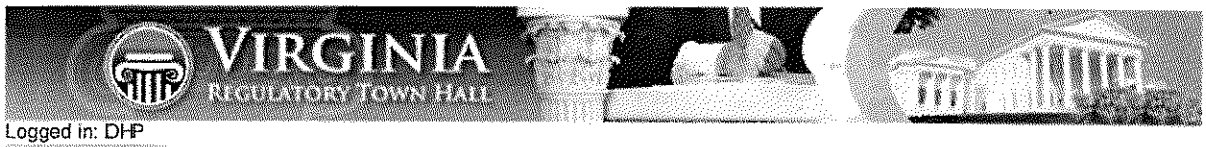
C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

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.

3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act.



Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]**

Action	**Continuous quality improvement programs**
Stage	**Proposed**
Comment Period	Ends 1/17/2014

Back to List of Comments

Commenter: Virginia Hospital & Healthcare Association * 1/7/14 12:50 pm

Continuous Quallity Improvement Programs

The Virginia Hospital & Healthcare Association submits these public comments in response to the Virginia Board of Pharmacy regulation at 18 VAC110-20, published in the Virginia Register, Volume: 30 Issue: 6, starting at page 753. The definition of "actively reports" should be modified to be consistent with federal regulations promulgated under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) (the "Act"). The Board of Pharmacy defines "actively reports" to mean "reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." However, the Agency for Healthcare Research and Quality regulations do not require information to be reported to a PSO in order to qualify for protections under the Act nor do they specify a timeframe for reporting patient safety work product. In issuing final regulations under the Act, AHRQ clarified that "information documented as collected within a patient safety evaluation system by a provider shall be protected as patient safety work product" and "would become patient safety work product upon collection." *See* 73 Fed. Reg. 70741. Accordingly, federal regulations do not require reporting in order for information to be protected as patient safety work product. There are several reasons why a provider would not report patient safety work product to a PSO within (30) days and the flexibility in the federal regulations was designed, in part, to avoid unintended consequences associated with a "race to report" and the need to develop dual systems for handling patient safety information. *Id.* Under the federal regulations, the act of documenting and collecting the information is sufficient.

One possible solution to address the apparent discrepancy between the Board's proposed regulations and the federal regulations would be to change the definition of "actively reports" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." This approach balances the need to encourage a timely process for identifying and analyzing errors with the need to extend the reporting timeframe beyond 30 days and is consistent with the federal regulations.

Thank you for this opportunity to comment. Please contact R. Brent Rawlings with any questions regarding these public comments by calling (804) 965-1228 or by email at brawlings@vhha.com.

* Nonregistered public user

38

DRAFT Final Regulations

As recommended by the Regulation Committee

BOARD OF PHARMACY

Continuous quality improvement programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist [,regardless of whether the patient received the drug] :

1. Variation from the prescriber's prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

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

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

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

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

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

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a

patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 Code of Virginia and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

Agenda Item: **Re-consideration of a fast-track action on EMS Regulations**

Staff Note:

There have been requests to re-consider provisions of section 500

Included in your packet:

A draft of fast-track regulations that incorporate comment from the EMS agencies and a board member

Board action:

Adoption of changes to EMS regulations as recommended by the Regulation Committee.

DRAFT Fast Track Regulations – as recommended by the Regulation Committee

BOARD OF PHARMACY

Emergency medical services programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

51

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

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

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

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

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

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

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is

considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a ~~drug~~ kit for a licensed ~~emergency medical services~~ EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this ~~drug~~ kit. A pharmacist shall check each ~~drug~~ kit after filling ~~the kit~~, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The ~~drug~~ kit is sealed, secured and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection ~~of such~~.

a. The hospital pharmacy shall have a method of sealing the drug kits such 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 kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an ~~emergency medical technician~~ EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the ~~technician~~ EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the ~~emergency medical services~~ EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The ~~emergency medical technician~~ EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV or V

controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. ~~An accurate record~~ Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year~~.~~:

a. The record of filling and verifying the kit to include the drug contents of kit, the initials of the pharmacist verifying the contents, date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician or a second EMS provider. Documentation shall be maintained for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the ~~drug~~ kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse or prescriber, if the kit contents include Schedule II, III, IV or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

Agenda Item: Adoption of Notice of Intended Regulatory Action

Included in your agenda package are:

A copy of the petition received from Daniel Colpo to amend regulation prohibiting offering incentives or inducements to transfer prescriptions

Copy of comments on the petition

A copy of Notice from the U. S. Department of Justice

Staff Note:

At its March meeting, the Board voted to reject the petition at that time but to refer the issue to the Regulation Committee for further information and advice from Counsel. (see minutes of Regulation Comm. of May 12th)

Board action:

Vote on the recommendation of the Regulation Committee to adopt a Notice of Intended Regulatory Action to move forward with a regulation to include offering inducements or incentives to transfer prescriptions in section 25 on unprofessional conduct.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, 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,) COLPO DANIEL C	
Street Address 13901 SHADOW RIDGE LANE	**Area Code and Telephone Number** (804) 744-5948
City MIDLOTHIAN	**State** VA / **Zip Code** 23112
Email Address (optional) DANCOLPO@AOL.COM	**Fax (optional)**

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18VAC110-20-240 MAINTAINING RECORDS
18VAC110-20-270C
FILLING OF PRESCRIPTIONS - INCENTIVING PATIENTS TO ROUTINELY CHANGE PHARMACIES

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. IN COMMUNITY PHARMACY WE INCENT PATIENTS TO PRACTICE POLY-PHARMACY THROUGH COUPONS TO TRANSFER PRESCRIPTIONS FROM ONE STORE TO ANOTHER. THIS PROMOTION LEADS TO OPENING PATIENTS UP TO POTENTIAL MEDICATION SAFETY CONCERNS THROUGH INCOMPLETE DUR/PROFILE DATA, TRANSCRIPTION ERRORS

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. 54.1-3307 - 1 MAINTENANCE & QUALITY, INTEGRITY AND SAFETY OF DRUGS DISTRIBUTED, DISPENSED OR ADMINISTERED

Signature: Daniel C Colpo **Date:** 12/10/13

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

February 11, 2014

Elaine Yeatts
Virginia Board of Pharmacy
Agency Regulatory Coordinator
9960 Mayland Drive
Henrico, VA 23233
elaine.yeatts@dhp.virginia.gov

Comments on Petition: "Coupons for dispensing prescriptions"

Dear Ms. Yates,

The Virginia Pharmacists Association (VPhA) is pleased to provide comments in support of the petition "Coupons for dispensing prescriptions". 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 consider implementing regulations in response to this petition.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

64

AMCP Academy of Managed Care Pharmacy®

February 12, 2014

Elaine Yeats
Agency Regulatory Coordinator
Department of Health Professions
9960 Maryland Drive
Henrico, VA 23233

Re: In support of petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns through incomplete DUR/profile data and transcription errors; would amend 18 VAC 110-20. Regulations Governing the Practice of Pharmacy

Dear Ms. Yeats:

The Academy of Managed Care Pharmacy (AMCP) writes in support of the petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns and the potential to undermine formulary development and utilization management that health plans utilize to provide evidence-based, cost-effective access to medications. AMCP would support patient assistance programs offered through either philanthropic or manufacturer-sponsored organizations that offer assistance based on economic need or to ensure appropriate patient access to high-cost medications, particularly specialty products with no therapeutic alternative with high-cost sharing.

AMCP is a national professional association of pharmacists, physicians, nurses and other managed care practitioners with nearly 7,000 members who provide services on behalf of the more than 200 million Americans served by managed care organizations, including health plans and pharmacy benefit management companies. Our members are responsible for managing prescription drug benefits on behalf of clients of the managed care organizations that employ them. They are responsible for implementing a broad and diversified range of clinical, quality-oriented services and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

AMCP opposes the use of manufacturer coupons because the net result of these coupons is additional, unnecessary costs to plans, employers, state and federal governments and other payers. These programs often encourage patients to utilize high-cost medications when other formulary alternatives may be available at lower-cost sharing rates. Manufacturer coupons often steer patients to more-expensive products, but not necessarily clinically better products by eliminating the patient's cost differential among preferred agents. The manufacturer then reimburses the pharmacy for the cost of the coupon, but plans, employers, and federal and state governments are still be responsible for paying higher costs associated with that medication in reimbursement to the pharmacy. In many cases, medication classes offering prescription drug coupons (including statin medications to lower high cholesterol, medications for high

100 North Pitt Street | Suite 400
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800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

blood pressure and other cardiovascular conditions) have multiple safe and effective alternatives available, including generics, at lower cost-sharing for patients. Medications included on a plan's formulary at more favorable cost sharing levels reduce patient, plan and payer costs by lowering overall medication spending.

Patients also often overlook that most coupon programs may only be used for a limited period of time and thus in the long run, may increase the cost of the medication for the patient. Many manufacturer programs limit the number of total prescription fills that qualify for the coupon, such as 12 total refills or 12 months total, and therefore, patients do not receive an indefinite benefit. Patients might then be forced to pay higher costs for the medication or change to a lower-cost, formulary alternative that would likely have been suitable at the beginning of therapy. In addition, additional costs incurred by plans and payers associated with providing the higher cost medications may also result in increased premium costs for patients.

AMCP also opposes the use of retail pharmacy coupons used to encourage patients to transfer prescriptions from a competing pharmacy. These coupons usually reward patients with store credit toward the purchase of non-pharmacy-related merchandise. When these coupons are used appropriately, patients may save money; however, patients who frequently transfer prescriptions among pharmacies to take advantage of such offers could see an increase in medication errors, duplicative therapy, and unnecessary medication-related problems. AMCP also opposes use of these coupons because of the safety concerns that result from pharmacies' and health plans' inability to access a full patient prescription record. This situation occurs because patients using the coupon may pay for the prescription in cash, rather than using their prescription drug benefit card, and thus the prescription would not be sent to the plan. While this might save the patient money, the plan has no record of the prescription and thus is unable to review the patient's record for duplicative claims, potential for adverse events, and for other medication-related problems. Therefore, if retail pharmacy coupons are used, at a minimum AMCP supports the requirement that cash claims be adjudicated to payers to ensure a medication record that allows for comprehensive drug utilization review and other safety checks used prior to dispensing.

AMCP thanks the Virginia Department of Health Professions for seeking comments on this important issue. AMCP reiterates support for programs that help patients afford prescription medications, but emphasizes that these programs should not be used when there is the potential to compromise patient safety and needlessly increase overall medication costs. If you have any questions, please contact me by email at erosato@amcp.org or by phone at 703-683-8416.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

Comments from Virginia Regulatory Townhall

Colpo Petition on Acceptance of coupons for prescriptions

Chapter

Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]

1/28/14 3:05 pm

Commenter: Travis Hale, Remington Drug Co *

Coupon Inflating Overall Costs

I am not a supporter of coupons as I feel they drastically add to the overall costs of the system as the patient, in many instances, does not see the true cost of the medication. Many times there is a generic alternative that would clinically provide the same benefit. I see this most often in dermatology as topical products come out under a new Brand Name with a slightly adjusted strength. Given the difference in cost of the medication, it is not necessarily cost effective to go with the Brand just because the doctors office has given the patient a coupon. Most patients will take the medication where the coupon has cut the price to $25 for example, when their normal copay would be $100. When that copay coupon is no longer active, they no longer want to get the product. They're willing to accept the generic at that point. This has resulted in a large dollar amount being applied to the overall system while they filled the Brand name with a coupon, when they would have been fine with a less expensive generic had they been responsible for their insurance copay. The pharmacy can also be stuck with a partial bottle of an expensive medication that they may or may not see another script for, resulting in drug expiration and a monetary loss.

2/12/14 12:27 pm

Commenter: Dave Jussen *

pharmacy coupons

I am not in support of pharmacy coupons. Tranferring prescriptions multiple times (for the benefit of cashing in on a coupon offer) increases the risk of potential mistakes and reduces the opportunity to perform a meaningful drug utilization review. (ie. compliance and interactions. Overall, we are contributing to the misconception that the service we perform is nothing more than putting a label on a smaller consumer-safe package.

2/12/14 5:50 pm

Commenter: big chain community pharmacist *

transfer coupons/incentive programs

Allowing transfer coupons and programs that encourage transfers only promotes poly-pharmacy. This breeds potiental for serious medication errors. The purpose of a pharmacist is to asses if a medication is safe for a patient to take or not. Patients have been taking advanage of these programs by transfering multiple scripts to multiple pharmacies that offer transfer gift cards. I personally had a patient ask me to transfer three of her prescriptions, one of which was a new presciption never filled, to three different chain pharmacies. Those pharmacists have no way of knowing if those prescriptions should or should not be filled without doctor intervention. I am concerned in this economy where every dollar counts patients will continue to fill their prescriptions at mulitple pharmacies leading a serious errors.

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Friday, April 20, 2012

Walgreens Pharmacy Chain Pays $7.9 Million to Resolve False Prescription Billing Case

Allegedly Offered Illegal Inducements to Government Health Care Programs Beneficiaries to Transfer Prescriptions to Walgreens

Walgreens, an Illinois-based corporation operating a national retail pharmacy chain, has paid the United States and participating states $7.9 million to resolve allegations that Walgreens violated the False Claims Act, the Justice Department announced today.

The settlement resolves allegations that Walgreens offered illegal inducements to beneficiaries of government health care programs, including Medicare, Medicaid, TRICARE and the Federal Employees Health Benefits Program (FEHBP), in the form of gift cards, gift checks and other similar promotions that are prohibited by law, to transfer their prescriptions to Walgreens pharmacies. The government investigation alleged that Walgreens had offered government health beneficiaries $25 gift cards when they transferred a prescription from another pharmacy to Walgreens. The company's advertisements that promoted gift cards and gift checks for transferred prescriptions typically acknowledged that the offer was not valid with Medicaid, Medicare or any other government program. Nevertheless, the government alleged that Walgreens employees frequently ignored the stated exemptions on the face of the coupons and handed gift cards to customers who were beneficiaries of government health programs, in violation of federal law.

"This case represents the government's strong commitment to pursuing improper practices in the retail pharmacy industry that have the effect of manipulating patient decisions," said Stuart F. Delery, Acting Assistant Attorney General for the Civil Division of the Department of Justice.

The allegations were brought to the government by two whistleblowers, known as relators, in two separate whistleblower lawsuits filed under the *qui tam*, or whistleblower, provisions of the False Claims Act and state False Claims Act statutes. The relators, Cassie Bass, a pharmacy technician formerly employed by Walgreens, and Jack Chin, an independent pharmacist, will receive $1,277,172 from the United States for their role in filing the *qui tam* actions. The federal share of the settlement is $7,298,124.

"This case vindicates and protects the interests of consumers throughout the nation by ensuring that they remain free from undue influence by large retail chains when making decisions about which pharmacies to entrust their own individual health care," said André Birotte Jr, U.S. Attorney for Central District of California.

"The law prohibits pharmacies from using their retail clout to lure patients whose prescriptions are subsidized by the government," said Barbara L. McQuade, U.S. Attorney for the Eastern District of Michigan. "Continuity with a pharmacist is important to detect problems with dosages and drug interactions. Patients should make decisions based on legitimate health care needs, not on inducements like gift cards."

"This settlement makes clear that corporations seeking increased profits over their patients' needs will pay a substantial price," said Daniel R. Levinson, Inspector General for the Department of Health and Human Services. "Violating Federal health care laws, as Walgreens allegedly did by offering incentives for new business, cannot be tolerated."

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Secretary of the Department of Health and Human Services Kathleen Sebelius in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $6.7 billion since January 2009 in cases involving fraud against federal

health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 are over $9 billion.

This case was investigated jointly by the Commercial Litigation Branch of the Justice Department's Civil Division, the U.S. Attorney's Offices for the Central District of California and the Eastern District of Michigan, the National Association of Medicaid Fraud Control Units and the Department of Health and Human Services, Office of Inspector General.

The claims settled by today's agreement are allegations only; there has been no determination of liability.

12-505 Civil Division

Agenda Item: **DRAFT Legislative Proposals**

Enclosed:

Copies of draft bill for:

Addition of alfaxalone to Schedule IV in DCA for consistency with federal rule

Authority for the Board to issue permits to facilities for physicians selling drugs

Requirement for wholesale distributors to notify Board if they cease distribution to a licensed dispenser for suspicious ordering

Authority for pharmacists to possess and administer epinephrine and oxygen

Virginia licensure for "outsourcing facilities," pharmacies that compound human drugs for office administration

Board Action:

Approval of legislative proposals to be distributed for comment and submitted for consideration for the 2015 General Assembly Session.

[Federal Register Volume 79, Number 39 (Thursday, February 27, 2014)]
[Rules and Regulations]
[Pages 10985-10989]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2014-04332]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-370]

Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance 5[alpha]-pregnan-3[alpha]-ol-11,20-dione (alfaxalone), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle alfaxalone and substances containing alfaxalone.

DATES: Effective Date: March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. **21 U.S.C. 801-971**. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), **parts 1300 to 1321**. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. **21 U.S.C. 812**. The initial schedules of controlled

substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at **21 CFR part 1308**.

Pursuant to **21 U.S.C. 811**(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [**21 U.S.C. 812**(b)] for the schedule in which such drug is to be placed . . . ." Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),\1\ or (3) on the petition of any interested party. **21 U.S.C. 811**(a). This action is based on a recommendation from the Assistant Secretary of the HHS and on an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle alfaxalone.

\1\ As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1995. In addition, because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

Background

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11,20-dione, previously spelled "alphaxalone"), a substance with central nervous system (CNS) depressant properties, is a neurosteroid that is a derivative of 11-alpha-hydroxy-progesterone. On October 23, 2012, the Food and Drug Administration (FDA) published a final rule to approve a New Animal Drug Application (NADA, 141-342) for alfaxalone (Alfaxan[supreg]), as an intravenous injectable anesthetic, for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance of anesthesia with an inhalant anesthetic, in cats and dogs (77 FR 64715). Alfaxalone primarily acts as an agonist at the gamma-aminobutyric acid (GABA) receptor-channel complex, with a mechanism of action at this site similar to that of barbiturates like phenobarbital (schedule IV) and methohexital (schedule IV), benzodiazepines such as diazepam (schedule IV) and midazolam (schedule IV), as well as the anesthetic agents

Virginia Board of Pharmacy
2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-3452 of the Code of Virginia, classifying alfaxalone as a Schedule IV substance with central nervous system (CNS) depressant properties under the Drug Control Act

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11,20-dione, previously spelled "alphaxalone") (including its salts, isomers, and salts of isomers)

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

73

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazapam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Virginia Board of Pharmacy
2014 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-3304.1 of the Code of Virginia authorizing issuance of permits for facilities where practitioners of the healing arts dispense controlled substances.

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; permit to sell controlled substances.

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 person to dispense controlled substances within this Commonwealth unless licensed by the Board as a practitioner of the healing arts 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.

Virginia Board of Pharmacy
2014 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia to require notification to the Board of Pharmacy and the State Police if a wholesale distributor ceases or restricts distribution to a licensed dispenser for reason of suspicious ordering.

Be it enacted by the General Assembly of Virginia:

1. **That §§ 54.1-3435 and 54.1-3535.01 of the Code of Virginia are amended and reenacted as follows:**

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases or restricts distribution of controlled substances to a licensed or permitted dispenser due to suspicious ordering shall notify the Board of Pharmacy and the Department of State Police within five days of this decision. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

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

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

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

D. A nonresident wholesale distributor that ceases or restricts distribution of controlled substances to a licensed or permitted dispenser due to suspicious ordering shall notify the Board of Pharmacy and the Department of State Police within five days of this decision. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

~~D.~~E. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

Virginia Board of Pharmacy

2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §54.1-3408 to authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

Be it enacted by the General Assembly of Virginia:

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

§ 54.1-3408. Professional use by practitioners.

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

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

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

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

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

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

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

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

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

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

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

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

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs, or to possess and administer epinephrine for use in emergency cases of anaphylactic shock.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the immediate and direct supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of a school board 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. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic under the direction of an operational medical director when the prescriber is not physically present. Emergency medical services personnel shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, as well as any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii)

a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, or (ii) a student at a private school that complies with the accreditation requirements set forth in § 22.1-19 and is accredited by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established

by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency or the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Virginia Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303 and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services, a person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose.

Summary: H.R.3204 — 113th Congress (2013-2014)

There are 2 summaries for this bill.

Public Law (11/27/2013)

GO

Bill summaries are authored by CRS.
Shown Here:
Public Law (11/27/2013)

(This measure has not been amended since it was introduced. The summary has been expanded because action occurred on the measure.)

Drug Quality and Security Act - **Title I: Drug Compounding** - Compounding Quality Act - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to the regulation of compounding drugs. Exempts compounded drugs from new drug requirements, labeling requirements, and track and trace requirements if the drug is compounded by or under the direct supervision of a licensed pharmacist in **a registered outsourcing facility** and meets applicable requirements.

Establishes annual registration requirement for any outsourcing facility. Requires a facility to report biannually to the Secretary of Health and Human Services (HHS) on what drugs are compounded in the facility and to submit adverse event reports. Subjects such facilities to a risk-based inspection schedule.

Requires the Secretary to: (1) publish a list of drugs presenting demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug, taking into account the risk and benefits to patients; and (2) convene an advisory committee on compounding before creating the list.

Requires the Secretary to assess an annual establishment fee on each outsourcing facility and a reinspection fee, as necessary.

(Sec. 103) Prohibits the resale of a compounded drug labeled "not for resale," or the intentional falsification of a prescription for a compounded drug. Deems a compounded drug to be misbranded if its advertising or promotion is false or misleading in any particular.

(Sec. 105) Requires the Secretary to receive submissions from state boards of pharmacy: (1) describing any disciplinary actions taken against compounding pharmacies or any recall of a compounded drug, and (2) expressing concerns that a compounding pharmacy may be violating the FFDCA.

(Sec. 106) Revises compounding pharmacy requirements to repeal prohibitions on advertising and promotion of compounded drugs by compounding pharmacies and repeal the requirement that prescriptions filled by a compounding pharmacy be unsolicited.

(Sec. 107) Requires the Comptroller General (GAO) to report on pharmacy compounding and the adequacy of state and federal efforts to assure the safety of compounded drugs.

Title II: Drug Supply Chain Security - Drug Supply Chain Security Act - (Sec. 202) Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.

Requires the Secretary to establish standards for the exchange of transaction documentation, which shall include transaction information, transaction history, and transaction statements.

Requires the Secretary to establish processes to: (1) provide waivers of requirements, including for undue economic hardship or emergency medical reasons; (2) provide exceptions to requirements relating to product identifiers if a product is packaged without sufficient space to bear the information; and (3) determine other products or transactions that should be exempt from the requirements of this Act.

Establishes requirements for drug manufacturers, wholesalers, dispensers, and repackagers to ensure that all prior transaction information is provided at each transfer of ownership.

Requires a manufacturer, wholesale distributor, dispenser, and repackager, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, to provide within a reasonable time the applicable transaction documentation upon request by the Secretary or other appropriate federal or state official.

Requires a manufacturer or repackager to affix or imprint a product identifier on each package and homogenous case intended to be introduced in a transaction into commerce. Excepts from this requirement with respect to unique device identifiers any products required to have a standardized numerical identifier.

Requires a manufacturer, wholesale distributor, dispenser, or repackager to ensure that each of its trading partners is authorized.

Requires a manufacturer, wholesale distributor, dispenser, and repackager to implement systems to: (1) investigate suspect products; and (2) handle illegitimate products, including through quarantine, disposal, and appropriate notice to the Secretary and, as necessary, trading partners.

Requires manufacturers, wholesale distributors, and repackagers to verify returned products before further distribution.

(Sec. 203) Prescribes additional requirements related to the tracing of products at the package level (enhanced drug distribution security) which shall go into effect ten years after enactment of this Act.

Authorizes a dispenser to enter into a written agreement with a third party, including an authorized wholesale distributor, that requires the third party to maintain confidentially any information and statements required to be maintained. Requires the Secretary to provide for alternative methods of compliance with such additional drug distribution security requirements.

Directs the Secretary to contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level.

Requires the Secretary to: (1) establish one or more pilot projects and hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain, (2) issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level, and (3) identify and make recommendations with respect to the standards necessary for adoption in order to support the secure interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

(Sec. 204) Requires the Secretary to establish standards for the licensing of wholesale distributors and third party logistics providers.

(Sec. 205) Preempts state and local requirements related to tracing drugs through the distribution system, and licensure of wholesale distributors and third party logistics providers.

(Sec. 206) Subjects violations of this Act to specified criminal and civil penalties.

Deems misbranded any drug failing to bear its required product identifier.

Virginia Board of Pharmacy

2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §§ 54.1-3401, 54.1-3410, 54.-3410.2, 54.1-3434, 54.1-3434.1, 54.1-3434.2, 54.1-3434.3, and 54.1-3434.4 of the Code of Virginia, relating to registration of outsourcing facilities that compound drug for human use.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3410, 54.-3410.2, 54.1-3434, 54.1-3434.1, 54.1-3434.2, 54.1-3434.3, and 54.1-3434.4 of the Code of Virginia are amended and reenacted 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.

"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,

90

mitigation, treatment, or 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 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 for human-use pursuant to state and federal law.

"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.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section. A pharmacist who practices at an outsourcing facility and dispenses or distributes drugs or devices shall label the drug or device in accordance with state and federal law.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

§ 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.

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 compounded products to practitioners of ~~medicine, osteopathy, podiatry, 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.

Pharmacists shall label all compounded products distributed to practitioners 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; and (v) 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 practicing in a facility other than an outsourcing facility shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding and when repackaging sterile products.

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. Permit to conduct pharmacy or outsourcing facility.

No person shall conduct a pharmacy or outsourcing facility without first obtaining a permit from the Board. Prior to obtaining a permit, an outsourcing facility is required to register as an outsourcing facility with the United States Food and Drug Administration.

An outsourcing facility shall compound in compliance with state and federal law. An outsourcing facility that compounds drugs for human use pursuant to a patient-specific prescription shall also obtain a pharmacy permit and shall comply with all requirements of this chapter for a pharmacy, except all compounding performed at an outsourcing facility shall be performed in compliance with current Good Manufacturing Practices pursuant to federal law. Compounding at an

outsourcing facility shall be performed by a registered pharmacy technician or licensed pharmacist.

The application for such permit 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 pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy or outsourcing facility will be open to provide pharmacy or compounding services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy or outsourcing facility, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records or the outsourcing facility's compounding and distribution records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a ~~pharmacy which~~ permit holder that has failed to designate a new pharmacist-in-charge shall not operate ~~as a pharmacy~~ nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy or outsourcing facility no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all

Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a ~~pharmacy~~ permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program.

No permit shall be issued or continued for the conduct of a pharmacy or outsourcing facility until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.01. Notice of pharmacy or outsourcing facility closing; change of ownership; penalty.

A. Prior to the closing of a pharmacy for more than one week, the owner shall either (i) post a conspicuous notice at least thirty days prior to the anticipated closing or (ii) ~~mail a~~ provide written or electronic notice, at least fourteen days prior to the anticipated closing, to every current pharmacy customer having refill authority. Each notice posted or ~~mailed~~ provided pursuant to this section shall indicate the date of such closing, if available, and the name of the pharmacy to which prescriptions and other required prescription dispensing records and individual patient records will be transferred unless patients indicate their preference to the contrary. The Board of Pharmacy shall promulgate regulations providing for a definition of "closing of a pharmacy" and exceptions to the requirements of this section.

B. Prior to the closing of an outsourcing facility for more than one week, the owner shall provide written or electronic notice, at least fourteen days prior to the anticipated closing, to every current customer and to the Board of Pharmacy. Each notice sent pursuant to this section shall indicate the date of such closing. The Board of Pharmacy shall promulgate regulations providing

for a definition of "closing of an outsourcing facility" and exceptions to the requirements of this section.

~~B.~~C. Upon any change of ownership of a pharmacy, regardless of how such change may be effectuated, the prescription dispensing records and other patient records for at least two years immediately prior to the change of ownership, shall be transferred, in accordance with Board regulations, to the new owner in a manner to ensure the confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records and the continuity of pharmacy services at substantially the same level as that offered by the previous owner.

Refusing to process a request for the prescription dispensing records and other patient records tendered in accordance with law or regulation shall constitute a closing and the requirements of this section shall apply. Such refusal may constitute a violation of § 54.1-111 A 9, depending on the circumstance.

§ 54.1-3434.1. Nonresident pharmacies or outsourcing facilities to register with Board.

A. Any pharmacy or outsourcing facility located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices ~~pursuant to a prescription~~ into the Commonwealth ~~shall be considered a nonresident pharmacy,~~ shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia, fully engaged and in full and actual charge of the pharmacy or outsourcing facility, and ~~is~~ responsible

for ~~the pharmacy's~~ compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy or outsourcing facility in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy or outsourcing facility shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section. An outsourcing facility shall also maintain registration with the United States Food and Drug Administration.

3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy or outsourcing facility shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding or

compliance with Good Manufacturing Practices for outsourcing facilities pursuant to federal law. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than ~~six months~~ one year prior to the date of submission of an application for registration with the Board or (ii) 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 nonresident pharmacy or outsourcing facility has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed 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.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. For a nonresident pharmacy, that ~~That~~ it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed; and for a nonresident outsourcing facility, that is maintains its compounding and distribution records of drugs delivered into the Commonwealth so that the records are readily retrievable from the records of other drugs compounded. ~~and provides a~~ A copy or report of such dispensing records shall be provided to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at

the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies or outsourcing facilities within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board. A nonresident outsourcing facility shall only deliver drugs directly to the consumer or his designated agent, or directly to a person or entity authorized to possess the drugs pursuant to regulations of the Board.

F. A nonresident outsourcing facility that also compounds drugs for human use pursuant to a patient-specific prescription shall obtain a nonresident pharmacy permit prior to shipping drugs into the Commonwealth and shall comply with all requirements of this chapter for a nonresident pharmacy, except all compounding performed at an outsourcing facility shall be performed in compliance with Good Manufacturing Practices pursuant to federal law.

~~F.~~G. Pharmacies subject to this section shall comply with the requirements set forth in § 54.1-3408.04 relating to dispensing of an interchangeable biosimilar in the place of a prescribed biological product.

§ 54.1-3434.2. Permit to be issued.

The Board shall only register nonresident pharmacies or outsourcing facilities that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy or outsourcing facility in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States. An outsourcing facility shall also maintain registration with the United States Food and Drug Administration.

Applications for a nonresident pharmacy or outsourcing facility registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy or outsourcing facility registration shall be renewed annually on a date determined by the Board in regulation. Renewal is contingent upon the nonresident pharmacy or outsourcing facility providing documentation of a current inspection report in accordance with subdivision A 3 of § 54.1-3434.1; continuing current, unrestricted licensure in the resident jurisdiction and registration with the United States Food and Drug Administration, if applicable ; and continuing certification if required in subdivision A 4 of § 54.1-3434.1.

§ 54.1-3434.3. Denial, revocation, suspension of registration, summary proceedings.

The Board may deny, revoke, suspend, or take other disciplinary actions against a nonresident pharmacy or outsourcing facility registration as provided for in § 54.1-3316.

The Board shall immediately suspend, without a hearing, the registration of any nonresident pharmacy or outsourcing facility upon receipt of documentation by the licensing agency in the jurisdiction where a nonresident pharmacy or facility registered with the Board is located, that the nonresident pharmacy or facility has had its license, certificate, permit, or registration as a pharmacy revoked or suspended by that agency and has not been reinstated, or if the Board has received notification from the licensing agency that the pharmacy or outsourcing facility in the resident state no longer holds a valid unexpired license, permit, certificate, or registration as a pharmacy or if the facility no longer maintains current registration as an outsourcing facility with the United States Food and Drug Administration. The Board shall provide written notice of the suspension to the nonresident pharmacy or outsourcing facility at the address of record on file with the Board and to the resident-state licensing agency. The nonresident pharmacy or outsourcing facility may apply for reinstatement of the registration only after it has been reinstated by and holds a current and unrestricted license, certificate, permit, or registration as a pharmacy or outsourcing facility from the licensing agency in the jurisdiction where it is located. Such nonresident pharmacy or outsourcing facility shall be entitled to a hearing not later than the next regular meeting of the Board after the expiration of 30 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify on its behalf.

The Board may summarily suspend the registration of any nonresident pharmacy or outsourcing facility without a hearing, simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial danger to the public health or safety that warrants such action. The Board may meet by telephone conference call when summarily suspending the registration if a good faith effort to assemble a quorum of the Board has failed and, in the judgment of a majority of the members of the Board, the continued dispensing by the nonresident pharmacy or outsourcing facility constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The Board may consider other information concerning possible violations of Virginia law at a hearing, if reasonable notice is given to such nonresident pharmacy or outsourcing facility of the information.

A nonresident pharmacy or outsourcing facility with a suspended registration shall not ship, mail, or deliver any Schedule II through VI drugs into the Commonwealth unless reinstated by the Board.

The Board may refer complaints concerning nonresident pharmacies or outsourcing facility to the regulatory or licensing agency in the jurisdiction where the pharmacy is located. The Board may take other disciplinary action against a nonresident pharmacy or outsourcing facility in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the opportunity for a hearing.

§ 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 or compounding services of an outsourcing facility which 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.

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

...

As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) 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 nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed 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.

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

An "opening" inspection report indicating compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an "operational" inspection report shall be provided during the subsequent renewal of the registration.

from *Regulations Governing the Practice of Pharmacy*, revised February 12, 2014

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

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

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

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

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

Draft Regulatory Amendment

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

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

D. Annual renewal fees.

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

12. Approval of a repackaging training program $30 every two years

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

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

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

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115
f. Controlled substances registration	$180
g. Approval of a pharmacy technician training program	$75
h. Approval of a repackaging training program	$50

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

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

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

Draft Regulatory Amendment

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

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.

2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.

3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. 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.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. Pharmacists, pharmacy interns, and pharmacy technicians whose license or registration to practice pharmacy is currently suspended or revoked shall not be permitted access to the prescription department or controlled substances.

~~D~~E. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that

have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Alternate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration; and

4. All requirements of subsection E of this section are met.

E. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

Discussion topic for June 2014 full board meeting as proposed by board member:

Pharmacist Assistant (PA)

A PA is a certified pharmacy technican who has completed a minimum of 2 years experience as a pharmacy technician, completed a Board of Pharmacy approved continuing education program and has no pending actions against their certification. Upon receipt of a letter of recommendation from the pharmacist in charge (PIC) responsible for technician supervision the Board may approve a Pharmacist Assistance endorsement to the pharmacy technician certification.

A PA may perform data entry from a chart order or written prescription and enter refills into a computer independently without pharmacist supervision. In the absence of pharmacist supervision, the computer used for data entry may not be located in a pharmacy department wherein medications are stored. The computer will be restricted to allow data entry only in such files as are directly related to processing prescription or chart orders. Files dealing with inventory control, financial management and personnel will be specifically excluded from PA access. The PIC shall attest to PA restricted computer access.

A pharmacist shall review original or electronic copies of documents and compare any labels generated by the PA data entry process prior to release of filled prescriptions. The pharmacist verifying order entry by a PA shall be directly responsible for any errors of interpretation or transcription.

The computer used by a PA shall be capable of capturing data related to all files accessed by the PA and actions taken by the PA to modify or update any files. A report shall be generated indicating files accessed by the PA and action taken on those files for pharmacist review. This report shall be reviewed and signed by the pharmacist prior to final review and release of prescriptions or chart orders processed by the PA. Reports shall be retained for Board inspection for 2 years.

The Board may designate a College of Pharmacy to create and administer an PA education program.

The Board may establish a separate annual fee for PA certification.

The Board will consider applications from any pharmacy that requests approval for an innovative practice program involving Pharmacist Assistant duties.

Prescription Monitoring Program Update:

A new reporting requirement of Virginia's Prescription Monitoring Program (PMP) becomes effective July 1, 2014.

House Bill 874 added "drugs of concern" as covered substances requiring the reporting of dispensing of such products to the PMP. A new section in the Drug Control Act, §54.1-3456.1 *Drugs of concern,* gives the Board of Pharmacy the authority to promulgate regulations designating specific drugs and substances as drugs of concern. The legislation specifically states that drugs and substances designated as drugs of concern shall include any material, compound, mixture, or preparation that contains any quantity of the substance **tramadol**, including its salts. (2014 Acts of Assembly Chapter 664: http://leg1.state.va.us/cgi-bin/legp504.exe?141+ful+CHAP0664)

The addition of **tramadol** as a drug of concern does not place restrictions applicable to Schedule II-V controlled substances to the dispensing of the product; it is still a Schedule VI controlled substance ("legend" drug) in Virginia. The only change is that the dispensing of these products is now required to be reported to the PMP.

Please contact your pharmacy software application vendor for instructions on actions you may need to take to start reporting the dispensing of **tramadol** prescriptions as of July 1, 2014.

Pharmacists in Virginia will be able to authorize delegates to make requests for prescription histories to the Prescription Monitoring Program (PMP) on their behalf beginning July 1, 2014.

House Bill 539 authorizes dispensers who are authorized to access the information in the possession of the PMP to delegate this authority to certain health care professionals employed at the same facility and under their direct supervision. The bill also changes the requirements for individuals to whom such authority may be delegated by prescribers or dispensers to include health care professionals licensed, registered, or certified by a health regulatory board in another state and employed at the same facility and under their direct supervision. (2014 Acts of Assembly Chapter 72: http://leg1.state.va.us/cgi-bin/legp504.exe?141+ful+CHAP0072)

Pharmacists who wish to authorize delegates may do so by using the form found on the PMP website: http://www.dhp.virginia.gov/dhp_programs/pmp/pmp_forms.asp and submitting to the program for review and approval. The delegate will receive their own username and password to access the program and pharmacists will be able to view reports requested by their delegates. (Accounts will not be activated until July 1, 2014)

For more information please go to www.dhp.virginia.gov, email the PMP at pmp@dhp.virginia.gov, or call 804-367-4566.