



# 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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### Tentative Agenda of Meeting

*October 1, 2012*

9:00AM

#### TOPIC

#### PAGE(S)

#### Call to Order: David C. Kozera, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

#### Approval of Agenda

**Call for Public Comment:** The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

#### Approval of Minutes:

- June 12, 2012, Full Board Meeting 1-9
- June 29, 2012, Special Conference Committee and Informal Conference Committee 10-11
- July 24, 2012, Formal Hearing 12-16
- August 22, 2012, Special Conference Committee and Informal Conference Committee 17-21
- September 18, 2012, Special Conference Committee and Informal Conference Committee handout

#### Reports:

- DHP Director's Report - Diane Reynolds-Cane, M.D.
- Report on Enforcement Activities – Faye Lemon, Director of Enforcement
- Report on Health Practitioner Monitoring Program (HPMP) - Dr. Penelope Ziegler, Medical Director, VCU-HPMP and Peggy Wood, Program Manager, HPMP
- Report on Implementation of PARE Examination – Elizabeth Scott (Scotti) Russell, NABP Government Affairs Manager
- Chairman's Report – David C. Kozera
- Report on Licensure Program – J. Samuel Johnson, Jr., Deputy Executive Director
- Report on Disciplinary Program – Cathy M. Reiniers-Day, Deputy Executive Director

- Executive Director's Report - Caroline D. Juran

**Regulatory Actions:** Elaine Yeatts

- Regulatory Update 22
- Adoption of proposed regulations for changes to run-dry requirement for automated counting devices 23-34

**New Business:** Caroline D. Juran

- Request to offer comment to Board of Health Professions (BHP) regarding pharmacist scope of practice review – Elizabeth Carter, Executive Director BHP 35-116
- Adopt guidance document for dispensing authorized generics 117-118
- Amend Guidance Document 110-36 regarding USP standards 119
- Consider request for member to participate telephonically at certain full board meetings
- Guidance from Counsel regarding leadership roles in a professional association and appearances of a possible conflict of interest confidential
- Scheduling of 2013 dates for full board meetings handout

**Consideration of consent orders (if any)**

**Adjourn**

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

(DRAFT/UNAPPROVED)

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

June 12, 2012  
Second Floor  
Board Room 2

Perimeter Center  
9960 Mayland Drive  
Henrico, Virginia 23233-1463

**CALL TO ORDER:** The meeting was called to order at 9:10 AM.

**PRESIDING:** Gill B. Abernathy, Chairman

**MEMBERS PRESENT:** R. Crady Adams  
Jody H. Allen  
David C. Kozera  
Dinny Li  
Empsy Munden  
Robert M. Rhodes  
Pratt P. Stelly  
Brandon K. Yi

**MEMBERS ABSENT:** Ellen B. Shinaberry

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Howard M. Casway, Senior Assistant Attorney General  
Dianne Reynolds-Cane, Director, DHP  
Arne Owens, Chief Deputy Director, DHP  
Elaine J. Yeatts, Senior Policy Analyst, DHP  
Heather Hurley, Administrative Assistant

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

**APPROVAL OF AGENDA:** An amended agenda was provided and approved as presented.

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for the March 13, 2012 (Full Board Meeting), April 12, 2012 (Telephone Conference Call), April 30, 2012 (Special Conference Committee and Informal Conference Committee), May 2, 2012 (Panel Formal Hearing), May 2, 2012 (Regulation Committee- Pharmacy Working Conditions), and May 15, 2012 (Special Conference Committee and Informal Conference Committee).

**MOTION:** **The Board voted unanimously to approve the minutes as presented. (motion by Stelly, second by Allen)**

**PUBLIC COMMENTS:** There were no public comments offered at this time.

**DHP DIRECTOR'S REPORT:** Dr. Cane reported that suggestions for legislative proposals will need to be submitted to the Secretary's Office by August. She also reported that she has been conducting a weekly progress check of the regulations that are currently at the Governor's Office. Arne Owens, Chief Deputy

Director, DHP, and Ralph Orr, Director, Prescription Monitoring Program (PMP), visited the Department of Health and Human Resources in Washington, DC to discuss the PMP with regards to interoperability between states (interstate data sharing between PMP programs). Dr. Cane also spoke on new policies being set forth by the agency that will help decrease traveling expenses.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that the comment period for the changes to the “run-dry” requirement for automated dispensing devices is now closed. Emergency regulations for Continuous Quality Improvement Programs (CQI) are at the Governor’s Office. The proposed amendments to address on-hold prescriptions and the final regulations for repackaging in the Community Service Boards and Behavioral Health Authorities are also at the Governor’s Office (emergency regulations for CSB’s and BHA’s expire 6/18/12). The proposed regulation for administrative fees for duplicate licenses and verification are at the Secretary’s Office.

- Re-adoption of the proposed regulations for automated dispensing devices:

Ms. Yeatts indicated that staff did not make any substantive changes, but did reorganize the proposed regulations for automated dispensing devices to improve readability. Therefore, she requested that the Board review the changes. Ms. Yeatts stated that the Board would need to re-adopt the proposed regulations.

MOTION:

**The Board voted unanimously to adopt the proposed regulations as presented for automated dispensing devices.  
(motion by Yi, second by Allen)**

REGULATORY COMMITTEE REPORT:

- Recommendation on Petition for Rulemaking, Kristen Barratt, Pharmacist

Ms. Yeatts presented to the Board Ms. Barratt’s Petition for Rulemaking concerning professional work environment. Ms. Yeatts stated that the Board could either deny the petitioner’s request for amendments and state the reason why the request was denied, or accept the request and initiate rulemaking by adopting a Notice of Intended Regulatory Action (NOIRA). Ms. Juran discussed the research that staff conducted and provided to the Regulation Committee. The Regulation Committee’s motion was for the Board to accept the request and adopt a NOIRA.

MOTION:

**The Board voted unanimously to approve the Regulation Committee’s recommendation to accept the petition for rulemaking and adopt a Notice of Intended Regulation Action regarding the number of continuous hours a pharmacist may work and required breaks.**

- Recommendation regarding request from *The Pharmacy Alliance* on pharmacy working conditions

Ms. Allen discussed with the Board the request from The Pharmacy Alliance concerning pharmacy working conditions and the Regulation Committee’s recommendation. The Committee recommended the following: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and other pharmacists to submit evidence to the Board that the identified practices referred to

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the Committee can or have created patient harm; publish an article in the Board's e-newsletter expressing concerns for contemporary practices and restating the relevant sections of §54.1-3434 and Regulation 18 VAC 110-20-110(B) which state that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

**MOTION:**

**The Board voted unanimously to approve the Regulation Committee's recommendation regarding *The Pharmacy Alliance's* request concerning pharmacy working conditions.**

**MISCELLANEOUS:**

- Request to discuss length of time associated with and access to final orders:

Mr. Adams presented to the Board his concerns regarding pharmacists who have past disciplinary actions on their licenses and are having a difficult time getting employment as a result. Notices and Orders are public information and kept on record for eighty-five years. Mr. Casway explained that changes would necessitate the General Assembly amending the Administrative Process Act, Freedom of Information Act, title 54.1 and possibly other sections of law. Additionally, changes to the state record retention requirements and agency policy would be necessary. Mr. Kozera commented that many violations are also reportable to the National Practitioner Databank and therefore, a violation would also exist in its records.

**MOTION:**

**A motion was presented and subsequently withdrawn by Mr. Adams for the Board to consider a process to expunge certain case violations from a pharmacist's license.**

**MOTION:**

**A new motion was made that the Department of Health Professions reconsider how it displays public information on its website with a focus of discussion on violations occurring in excess of twenty years. (motion by Adams, died for lack of a second)**

- Define "annual" and "semiannual" in guidance document 110-36

To further clarify the Board's expectations regarding when media fill testing must be performed, Ms. Juran requested that the Board review staff's suggested changes to Guidance Document 110-36 concerning the definitions of "annual" and "semiannual". It was suggested the terms "annual" and "semiannual" be defined to mean every twelve and six months, respectively. Additionally, she indicated that the information in the document was somewhat outdated and the other suggested changes as presented in the draft document were to simply update the information.

**MOTION:**

The Board voted unanimously to adopt the amended Guidance Document 110-36 as presented. (motion by Rhodes, second by Munden)

- Establish threshold for compliance in guidance document 110-9

The Board discussed whether a threshold was appropriate when determining compliance with annual and semiannual requirements for media fill testing found in Major Deficiencies 25 and 26 in Guidance Document 110-9. Mr. Adams believed a 60-day threshold was too long.

**MOTION:**

A motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9, but without the suggested 60-day threshold. (motion by Adams, died for lack of second)

**MOTION:**

A new motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9 which included the suggested 60-day threshold. (motion by Yi, died for lack of second)

**MOTION:**

The Board voted unanimously to amend Major Deficiencies 25 and 26 in Guidance Document 110-9 to include the following thresholds when determining compliance:

- Major Deficiency 25 = 14-day threshold added, i.e., inspector will not cite deficiency until 15 days after the required due date of the semi-annual media fill testing for high-risk level CSPs;
- Major Deficiency 26 = 30-day threshold added, i.e., inspector will not cite deficiency until 31 days after the required due date of the annual media fill testing for low and medium-risk levels. (motion by Rhodes, second by Adams)

- Evaluation and revision of Sanction Reference Point System:

Neal Kauder presented to the Board a slide presentation reviewing the suggested evaluation and revision process of the Sanction Reference Point System (SRPS). The Board adopted the SRPS in guidance document 110-21 in September 2007 and he recommended that it may be time to evaluate its effectiveness and determine if it remains consistent with Board policies. He stated that other boards such as Medicine and Nursing have recently concluded this evaluation process which did result in some changes.

**MOTION:**

The Board voted unanimously that the Board of Health Professions evaluate the effectiveness of the Board of Pharmacy's Sanction Reference Point System. (motion by Kozera, second by Yi)

**REPORTS:**

- Report on Workforce Survey

Dr. Elizabeth Carter, Director, DHP's Healthcare Workforce Data Center, presented the draft workforce survey results. The survey was conducted of pharmacists during the recent licensure renewal cycle. Dr. Carter reported that 90% of online renewing pharmacists responded to the survey. This survey included various questions that were responded

to by pharmacists located in all regions of Virginia. Data and percentages were compiled based off of the number of pharmacists who participated in the survey and location of these individuals. While draft results were shared with the Board members, these results remain embargoed and will not be available for the public until the full analysis is completed. Dr. Carter indicated that it is anticipated that final results of the pharmacist workforce survey will be released to the public in the next few months. A release date for the draft results of the pharmacy technician workforce survey was not indicated.

- Report on Board of Health Professions

Mr. Rhodes stated that the full board meeting of the Board of Health Professions scheduled for May was cancelled, and therefore, he did not have anything to report at this time.

#### LICENSURE PROGRAM

Mr. Johnson reported that the Board issued 918 licenses and registrations for the period of March 1, 2012 through May 31, 2012, including 129 pharmacists, 82 pharmacy interns, and 538 pharmacy technicians. Inspectors performed 300 facility inspections including 110 routine inspections of pharmacies: 28 resulted in no deficiency, 25 with deficiencies, and 57 with deficiencies and a consent order. There are currently two active innovative (pilot) programs, one pilot program pending approval, and three pilot programs to be renewed for an extension.

#### DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of September 19, 2011; December 12, 2011; March 12, 2012; and June 8, 2012. For the final date, open cases are 37 at the investigation stage; 50 at the probable cause stage; 31 at the administrative proceedings division stage; five at the informal stage; one at the formal stage; and 89 at the pending closure stage.

Further, Ms. Reiniers-Day informed the Board that one case received the previous week had already accrued the 250 business days while at the enforcement level. The case was already at the APD level to draft an informal notice.

Ms. Reiniers-Day also stated that Rose Dematteo, the new Compliance Case Manager, was quickly reviewing all the compliance cases so that all the cases could be current.

#### EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran thanked Ms. Abernathy and Mr. Kozera for serving as Chairman and Vice-Chairman, respectively, during the past year. Additionally, she acknowledged Ms. Abernathy whose second full term as board member expires June 30, 2012 and Mr. Brandon Yi whose first full term expires June 30, 2012. Ms. Juran then reported that Dave Kozera, Leo Ross, and she attended the 108<sup>th</sup> NABP Annual Meeting held in Philadelphia in May and highlighted several presentations offered at the meeting. She reminded the members that the 2012 General Assembly passed a law to implement the National Precursor Log Exchange (NPLEx) effective January 1, 2013. She has been working

with the Virginia State Police (VSP) and Appriss to coordinate implementation efforts. She indicated that a letter from the VSP will be sent within the next two months to all pharmacies and retailers selling pseudoephedrine informing them of the law and the process for implementing this free technology. Additionally, Ms. Juran briefly reported that Elaine Yeatts, Sammy Johnson, and she participated on the anaphylaxis workgroup for drafting anaphylaxis guidelines for schools that must stock epinephrine for anaphylaxis treatment. She then reported that a new part-time employee has been hired, Laura Rothrock. She is assisting Mr. Johnson with the handling of possible disciplinary matters resulting from the inspection program or continuing education audit. Additionally, she stated that the pharmacist inspector for the northern Virginia region, Scott Arnott, is retiring as of July 1. Lele Pallavi, pharmacist investigator, has been transferred into this position and is currently training with Mr. Arnott. Additional meetings in which Ms. Juran will be participating or offering presentations include the Pharmacy Workforce Center meeting to be held June 18<sup>th</sup> and the 131<sup>st</sup> VPhA Annual Convention this August.

**ELECTION OF OFFICERS:**

**MOTION:**

**The Board voted unanimously to elect Mr. Kozera as Chairman for the term July 1, 2012 through June 30, 2013. (motion by Rhodes, second by Allen)**

**MOTION:**

**The Board voted unanimously to elect Ms. Allen as Vice-Chairman for the term July 1, 2012 through June 30, 2013. (motion by Adams, second by Munden)**

**NEW BUSINESS:**

- Request from staff for guidance regarding nine-month allowance in regulations 18 VAC 110-20-101(D) and 18VAC 110-20-111(C)

Board staff requested the Board to confirm its understanding that the nine month allowance for pharmacy technicians as stated in regulations 18 VAC 110-20-101(D) and 18 VAC 110-20-111(C) is restricted to nine continuous months from the date of enrollment in a Board-approved pharmacy technician training program.

**MOTION FOR CLOSED MEETING:**

**The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(7) of the Code of Virginia for the purpose of obtaining advice from Board Counsel that is excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Elaine Yeatts and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.**

**MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:**

**The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for**

closed meeting were heard, discussed or considered during the closed meeting.

**MOTION:**

The Board voted unanimously to adopt a Guidance Document that clarifies regulations 18 VAC 110-20-101(D) and 18 VAC 110-20-111© in that the nine-month allowance to perform tasks restricted to a pharmacy technician prior to obtaining registration as a pharmacy technician begins on the first enrollment date in a Board-approved pharmacy technician training program and ends nine consecutive months later, regardless of whether the person completes the program or enrolls in a different program during those nine months. (motion by Kozera, second by Adams)

- Request for guidance regarding when more than one pharmacist is involved with the dispensing process

Counsel advised staff that a conflict may exist between Regulations 18 VAC 110-20-270 and 18 VAC 110-20-276 and advised that the Board provide guidance to staff as to which pharmacist should be held responsible for an error when the dispensing involved more than one pharmacist. Al Carter with Walgreens addressed the Board concerning remote processing allowances in Regulation 18 VAC 110-20-276 and explained that several pharmacists are involved in the dispensing process as allowed in regulation. Each pharmacist is assigned a duty and if an error is made during the dispensing, the pharmacist responsible for that individual task can be identified. However, Regulation 18 VAC 110-20-270 indicates that the pharmacist shall verify accuracy in all respects and take responsibility for the entire transaction. Three dispensing scenarios were discussed: one pharmacist performing all dispensing functions and taking responsibility for the entire transaction; two pharmacists involved at one pharmacy location, one performing data entry verification and one performing drug product verification; and, two pharmacists involved at multiple pharmacy locations performing central or remote processing. Ms. Juran also discussed that recordkeeping requirements of 18 VAC 110-20-255 may apply to some of these scenarios.

**MOTION FOR CLOSED MEETING:**

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(7) of the Code of Virginia for the purpose of obtaining advice from Board Counsel that is excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Elaine Yeatts and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.

**MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:**

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for

closed meeting were heard, discussed or considered during the closed meeting.

MEMBERS ABSENT FROM  
CLOSED SESSION:

Jody H. Allen

MOTION:

The Board voted unanimously that, for remote processing, each individual pharmacist is responsible for their dispensing role as stated in 18 VAC 110-20-276 and that this motion is retroactive for any open disciplinary matters. Further, staff should draft a guidance document to include information on: the three dispensing scenarios discussed; identifying which pharmacist would be held responsible for a dispensing error in each scenario; suggested best practices for complying with Regulations 18 VAC 110-20-270, 18 VAC 110-20-276, and 18 VAC 110-20-255. Potential conflicts with the regulations during the next periodic regulatory review should be further clarified. (motion Kozera, second by Adams, Allen abstained)

REQUESTS FOR  
EXAMINATION  
ACCOMMODATION:

MOTION FOR CLOSED  
MEETING:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia for the purpose of consideration and discussion of medical/mental health records contained in an accommodation request that are excluded from the Freedom of Information Act by Virginia Code Section 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.

MOTION TO CERTIFY THE  
PURPOSE OF THE CLOSED  
MEETING:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

MOTION:

The Board voted unanimously to approve the following examination requests of Hope Pierpoint: extended time by one and a half times the normally allotted time; a pop-up calculator provided on the computer at the testing center; and, a room with limited distractions for completing the exams with a proctor appropriately monitoring her testing experiences. (motion by Adams, second by Stelly)

**APPROVAL OF CONSENT  
ORDERS**

**Motion for a closed meeting**

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding two Consent Orders. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Sammy Johnson, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Kozera, second by Rhodes)

**MOTION TO CERTIFY THE  
PURPOSE OF THE CLOSED  
MEETING:**

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Kozera, second by Rhodes)

**Motions**

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Rachel J. Mitchell, pharmacy technician. (motion by Kozera, second by Stelly)

Further, eight Board members voted affirmatively with one abstaining to accept the Consent Order as presented by Ms. Reiniers-Day and amended in the matter of Morgan R. Tripke, pharmacy technician. (motion by Yi, second by Allen)

**ADJOURN:**

With all business concluded, the meeting adjourned at 3:35pm.

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Gill Abernathy, Board Chairman

\_\_\_\_\_  
Caroline D. Juran, Executive Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Friday, June 29, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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

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CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 11:00 a.m.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: Pratt P. Stelly, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director  
Mykl D. Egan, DHP Adjudication Specialist

ROBERT D. MCKENNEY  
Pharmacist  
Reinstatement Applicant  
License No. 0202-010726  
Robert D. McKenney appeared to discuss his petition 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 June 13, 2012, Notice.

Closed Meeting: Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, 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 Robert D. McKenney. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and

unanimously voted to issue an Order to deny Mr. McKenney's application for the reinstatement of his pharmacist license.

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

ADJOURN:

With all business concluded, the meeting adjourned at 2:10 p.m.

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David C. Kozera, Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Date



(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY MINUTES

Tuesday, July 24, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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

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

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

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT: Crady Adams  
Jody H. Allen  
Empsy Munden  
Robert M. Rhodes  
Cynthia Warriner

STAFF PRESENT: Caroline Juran, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
Eusebia L. Joyner, Disciplinary Program Specialist  
Howard Casway, Senior Assistant Attorney General  
Wayne T. Halbleib, Senior Assistant Attorney General  
Corie E. Tillman Wolf, Assistant Attorney General  
Mykl Egan, DHP Adjudication Specialist

BOARD: With six (6) members participating and four (4) unable to participate, it was established that a Board of the Board of Pharmacy ("Board") was called to order.

**SUMMARY SUSPENSION:**

JENNIFER R. CAMPBELL  
Pharmacy Technician  
Registration Number 0230-010990

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

Motion to certify the purpose for the closed meeting:

The Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Informal Act and only such public matters as were identified in the motion for closed meeting were

heard, discussed or considered during the closed meeting. (Motion by J. Allen, second by C. Adams).

Motion:

The Board voted unanimously in favor of the motion that, according to the evidence presented the continued practice by Jennifer R. Campbell as a pharmacy technician poses a substantial danger to the public; and therefore, Ms. Campbell's registration to practice as a pharmacy technician be summarily suspended. (Motion by J. Allen and second by C. Adams).

The Board unanimously voted that, in lieu of a hearing, a Consent Order be offered to Ms. Campbell for the indefinite suspension of her registration for a period not less than two years. (Motion by J. Allen, second by C. Adams).

**RESCISSION OF STAY OF  
INDEFINITE SUSPENSION:**

JAMES T. MORROW  
Pharmacist  
License Number 0202-012984

Wayne T. Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in this case for the Board to consider a rescission of the stay of indefinite summary suspension on Mr. Morrow's pharmacist license. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Motion to certify the purpose for the closed meeting:

The Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Informal Act and only such public matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. (Motion by J. Allen, second by C. Warriner).

Motion:

The Board unanimously voted to rescind the stayed indefinite suspension that was placed on Mr. Morrow's pharmacist license on May 22, 2006. Mr. Morrow shall be noticed to appear at a Formal Hearing however, the Board determined that a Consent Order shall be offered that indefinitely

suspends his license but stays the suspension conditioned upon entry into the Health Practitioners Monitoring Program. (Motion by J. Allen, second by C. Adams).

**APPROVAL OF CONSENT  
ORDER:**

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (Motion by J. Allen, second by C. Adams).

**MOTION TO CERTIFY THE PURPOSE  
OF THE CLOSED MEETING:**

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (Motion by J. Allen, second by E. Munden).

Motion:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Ronald W. Shifflett, pharmacy technician. (Motion by C. Adams, second by C. Warriner)

**PANEL FORMAL  
ADMINISTRATIVE HEARINGS:**

SHADAI A. MERRITT  
Registration # 0230-011054

Ms. Merritt was not present at the hearing. The Board proceeded with the hearing in Ms. Merritt's absence as the Notice of Formal Hearing dated June 25, 2012, was mailed to her legal address of record, both by regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Ms. Merritt.

Corie E. Tillman Wolf, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

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Sherry Foster, DHP Investigator, testified in person on behalf of the Commonwealth; Dave Inman, CVS District Pharmacy Supervisor; and Mitch Fletcher, CVS Regional Loss Prevention Manager, testified by telephone on behalf of the Commonwealth.

Closed Meeting:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Shadai A. Merritt. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (Motion by J. Allen, second by C. Warriner).

Reconvene:

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

Decision:

The Board voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Tillman Wolf, amended by the Board and read by Mr. Casway. (Motion by J. Allen, second by C. Warriner).

The Board voted 6-0 that Ms. Merritt's registration to practice as a pharmacy technician be revoked. (Motion by J. Allen, second by C. Warriner).

SHANNON C. WHITE  
Registration Number 230-017782

Ms. White was not present at the hearing. The Board proceeded with the hearing in Ms. White's absence as the Notice of Formal Hearing dated March 16, 2012, was mailed to Ms. White's legal address of record, both by regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Ms. White.

Corie E. Tillman Wolf, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Jennifer Challis, DHP Senior Investigator, testified in person on behalf of the Commonwealth; and Mitch

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Fletcher, CVS Regional Loss Prevention Manager, testified by telephone on behalf of the Commonwealth.

Closed Meeting:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Shannon C. White. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (Motion by J. Allen, second by C. Warriner).

Reconvene:

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

Decision:

The Board voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Tillman Wolf and amended by the Board and read by Mr. Casway. (Motion by J. Allen, second by C. Warriner).

The Board voted 6-0 that Ms. White's registration to practice as a pharmacy technician be indefinitely suspended for a period of not less than two years. (Motion by J. Allen, second by C. Warriner).

Adjourn:

With all business concluded, the meeting adjourned at 2:55 p.m.

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David C. Kozera, Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, August 22, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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

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CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 10:00 a.m.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: Pratt P. Stelly, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director  
Shevaun Roukous, DHP Adjudication Specialist

JENNIFER L. HUGGINS  
Registration No. 0230-004045  
Jennifer L. Higgins appeared with W. McMillan Powers, her attorney, and Nancy Rogerson, a pharmacist, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 25, 2012, Notice.

Closed Meeting: Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, 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 Jennifer L. Huggins. Additionally, she moved that Cathy Reiniers-Day and Shevaun Roukous 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 Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and

unanimously voted to issue Ms. Huggins an Order imposing a reprimand and placing her pharmacist technician registration on probation.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Huggins, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Huggins 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.

FERESHTEH EJTEMAI  
License No. 0202-008014

Fereshteh Ejtemai appeared with Hossein Ejtemai, her brother and Melody Korrami, her daughter, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 19, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, 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 Fereshteh Ejtemai. Additionally, she moved that Cathy Reiniers-Day and Shevaun Roukous 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 Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Ejtemai an Order imposing a reprimand.

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

ADJOURN:

With all business concluded, the meeting adjourned at 2:20 p.m.

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David C. Kozera, Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Date

19

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Wednesday, August 22, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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

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CALL TO ORDER: A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 2:20 p.m.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: Pratt P. Stelly, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director  
Shevaun Roukous, DHP Adjudication Specialist

MARTINSVILLE FAMILY PHARMACY  
Permit No. 0201-003742

Robert A. Pratt, Pharmacist-in-Charge, Martinsville Family Pharmacy, appeared on behalf of Martinsville Family Pharmacy to review allegations that Martinsville Family Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 19, 2012, Notice.

Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, 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 Martinsville Family Pharmacy. Additionally, she moved that Cathy Reiniers-Day and Shevaun Roukous attend the closed meeting because their presence in the closed meeting 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.

Decision: Upon a motion by Ms. Stelly, and duly seconded by Mr. Kozera, the Committee made certain Findings

of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Martinsville Family Pharmacy with no sanction being imposed.

(This Consent Order shall be effective upon endorsement by Martinsville Family Pharmacy and the Board).

ADJOURN:

With all business concluded, the meeting adjourned at 3:40 p.m.

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Cathy M. Reiniers-Day  
Deputy Executive Director

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David C. Kozera, Chair

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Date

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

Staff Note: Attached is a chart with the status of regulations for the Board as of September 18, 2012

Action: None – provided for information only

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Continuous quality improvement programs</p> <p><u>Stage:</u> Emergency/NOIRA – approved by the Governor on 9/18/12; regulations effective 10/1/12 to 9/30/13 Comment on NOIRA: 10/8/12 to 11/7/12</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Modifications to requirements for automated dispensing devices</p> <p><u>Stage:</u> Proposed regulation – At the Secretary's office for 10 days</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Change to run-dry requirement for automated counting devices</p> <p><u>Stage:</u> Comment closed April 25, 2012 Board to adopt proposed regulations 10/1/12</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Administrative fees for duplicate licenses and verification</p> <p><u>Stage:</u> Proposed - At Secretary's Office for 411 days</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Amendments to address on-hold prescriptions</p> <p><u>Stage:</u> Proposed - At Governor's Office for 123 days</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Addressing hours of continuous work by pharmacists</p> <p><u>Stage:</u> NOIRA - Register Date: 9/10/12 Comment closes on 10/8/12</p>

**Emergency regulation – Effective October 1, 2012 to September 30, 2013**

**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:

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. Therapeutic duplication;
- b. Drug-disease contraindications, if known;
- c. Drug-drug interactions, if known;
- d. Incorrect drug dosage or duration of drug treatment;
- e. 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;

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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

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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.

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"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.

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"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.

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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 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.

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B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 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.

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b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, 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.

**22-K**

**Agenda Item: Adoption of Proposed Regulations  
Run-Dry Requirements for Automated Counting Devices**

**Included in your agenda package are:**

An excerpt from Regulation Committee minutes of 11/29/11

A copy of the Notice of Intended Regulatory Action in *Register of Regulations*

A copy of comment on the NOIRA

A DRAFT of proposed amendments

**Staff note:**

There was a comment period on the petition from March 26, 2012 to April 25, 2012

**Board action:**

Consideration of the comment on NOIRA and regulation drafted by staff.

Adoption of proposed amendments to section 355.

(FINAL/APPROVED)

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF REGULATION COMMITTEE FOR AUTOMATED COUNTING DEVICES,  
AUTOMATED DISPENSING DEVICES, AND DEFINITION OF "LOW VOLUME"**

November 29, 2011  
Second Floor  
Conference Center

Perimeter Center  
9960 Mayland Drive, Suite 300  
Richmond, VA 23233-1463

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**CALL TO ORDER:** The meeting was called to order at 1:15 PM.

**PRESIDING:** Ellen Shinaberry, Chairman

**MEMBERS PRESENT:** Gill Abernathy  
David C. Kozera  
Cradly Adams  
Empsy Munden  
Robert M. Rhodes

**MEMBER ABSENT:** Jody Allen

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Elaine J. Yeatts, Senior Policy Analyst, DHP

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

**PUBLIC COMMENTS:** Comments were received at the time the issue was taken up by the committee.

The regulation committee met to discuss the following three topics; "Run Dry" requirements for automated counting devices, the definition of "low volume" as used in USP 797 and automated dispensing devices. These regulations were referred to the committee for further review by the Board at the September 20, 2011 meeting.

**"RUN DRY" REQUIREMENT FOR AUTOMATED COUNTING DEVICES:** The committee discussed information in the agenda packet and concerns regarding devices not currently being able to guarantee that the first tablets placed in the device will be the first tablets dispensed from the device. Therefore, the committee remained concerned that a recalled drug could potentially remain in the device longer than anticipated. Alan Friedman with Kaiser Permanente was present and offered public comment urging the committee to eliminate or extend the current run dry requirement.

**MOTION:** The committee voted unanimously to recommend to the full board on December 14, 2011 that Regulation 18VAC110-20-355 be amended to eliminate the run dry requirement and include the

following statement, "In the event of drug recall involving one of multiple lots placed in a cell in the last four months, all drug will be removed from the cell and not used for patient care." (motion by Abernathy, second by Adams.)

DEFINITION OF "LOW  
VOLUME" AS USED IN USP  
CHAPTER 797:

Ms. Juran explained that board counsel had recently advised that the Board cannot define "low volume" in a guidance document, because it would go beyond Regulation 18VAC110-20-321 which simply adopts USP-NF compounding standards by reference. Should the board wish to define the term, counsel advised that it could amend the regulation and gather expert testimony to determine the appropriate number of hazardous sterile compounds that may be performed in the same space as non-hazardous sterile compounds. Additionally, Ms. Juran stated USP was currently convening an expert panel and is scheduled to review the term "low volume" in the near future.

MOTION:

The committee voted unanimously to recommend to the full board that it remove from Major Deficiency 24 in guidance document 110-9 the definition of "low volume," as advised by board counsel, and take no further action, understanding that USP may define the term in the future. (motion by Adams, second by Kozera)

AUTOMATED DISPENSING  
DEVICES:

Ms. Yeatts reminded the committee of the three petitions for rulemaking submitted on this subject and stated that the Notice of Intended Regulatory Action was prepared on September 23, 2011. She further explained that the committee needed to develop draft language to recommend to the full board for consideration to potentially amend Regulation 18VAC110-20-490. Members of the public present and offering comment included Karen Dunavant, Assistant Pharmacy Director, Reston Hospital Center, Annette Reichenbaugh, Pharmacy Director, Reston Hospital Center, Courtney Fuller, Director of Pharmacy, Retreat Doctors' Hospital, Stephen LaHaye, Bon Secours St. Francis Medical Center and representing VSHP, and Noel Hodges, Division Director of Pharmacy, HCA Central Atlantic Supply Chain Services. Those offering comment believed the current auditing requirements for automated dispensing devices only provide a snapshot of information during the month, and that current software that use standard deviations and compare peer-to-peer practices during the month is more likely to identify suspicious activity or issues of concern. The committee then reviewed a draft of the regulation prepared by staff which incorporated the changes as suggested in the three petitions for rulemaking. While reviewing the entire draft several edits were made. Because a public comment period on the NOIRA does not expire until December 21, 2011, the first opportunity for the committee's suggested changes to regulation to be presented and considered by the full board is the March 2012 full board meeting. (Attachment 1)

Ms. Yeatts departed at approximately 4:15pm.

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# NOTICES OF INTENDED REGULATORY ACTION

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## TITLE 4. CONSERVATION AND NATURAL RESOURCES

### VIRGINIA SOIL AND WATER CONSERVATION BOARD

#### Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Virginia Soil and Water Conservation Board intends to consider amending **4VAC50-60, Stormwater Management Regulations**. The purpose of the proposed action is to consider amendments to the applicable portions of the Virginia Soil and Water Conservation Board's Virginia Stormwater Management Program (VSMP) Permit Regulations in order to reauthorize and amend the general permit for stormwater discharges from small municipal separate storm sewer systems (small MS4s). The existing five-year general permit became effective on July 9, 2008; thus, a new general permit must be adopted before the July 8, 2013, expiration date.

The changes may include, but are not limited to, (i) incorporation of water quality requirements for impaired waters and total maximum daily loads (TMDLs) including monitoring requirements, consistency requirements with other regulations such as erosion and sediment control, chemical application, and handling requirements; and (ii) minimum prescriptive measures regarding public notification and reporting. The permit will also consider implementation of new stormwater management technical criteria for post development (including compliance with water quality and quantity standards set out in Part II (4VAC50-60-40 et seq.) and compliance with Part III (4VAC50-60-100 et seq.)) and permit requirements for compliance with the Chesapeake Bay TMDL.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: §§ 10.1-603.2:1 and 10.1-603.4 of the Code of Virginia.

Public Comment Deadline: April 25, 2012.

Agency Contact: David C. Dowling, Policy and Planning Director, Department of Conservation and Recreation, 203 Governor Street, Suite 302, Richmond, VA 23219, telephone (804) 786-2291, FAX (804) 786-6141, or email david.dowling@dcr.virginia.gov.

VA.R. Doc. No. R12-3136; Filed March 6, 2012, 1:25 p.m.

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## TITLE 9. ENVIRONMENT

### STATE WATER CONTROL BOARD

#### Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board intends to consider amending **9VAC25-860, General Virginia Pollutant Discharge Elimination System (VPDES) Permit for Potable Water Treatment Plants**. The purpose of the proposed action is to establish appropriate and necessary permitting requirements for discharges of wastewater from potable water treatment plants. The existing general permit expires on December 23, 2013, and must be reissued to be available after that date. The proposed regulation will contain standard language for effluent limitations and monitoring requirements necessary to regulate this category of dischargers.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 62.1-44.15 of the Code of Virginia.

Public Comment Deadline: April 25, 2012.

Agency Contact: Elleanore M. Daub, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4111, FAX (804) 698-4032, or email elleanore.daub@deq.virginia.gov.

VA.R. Doc. No. R12-3134; Filed March 6, 2012, 1:23 p.m.

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## TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

### BOARD OF PHARMACY

#### Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending **18VAC110-20, Regulations Governing the Practice of Pharmacy**. The purpose of the proposed action is to modify or eliminate the current requirement that bulk bins in an automated counting device be "run dry" every 60 days. The requirement to allow the bins to "run dry" every 60 days to prevent expired drugs from dispensed is probably not necessary to protect public health and safety. In modifying the regulation, the board will consider safeguards that would ensure expired or recalled drugs are not being dispensed to patients. If the technology of the device can ensure drugs in a particular lot have been cleared out of the machine, it might not be necessary to dispose of all drugs in a bin to which a recalled lot has been added. If not, and if multiple lots are in a bin, the drugs may have to be removed

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## Notices of Intended Regulatory Action

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and not used for patient care if there is a recall on any of the lots. Additionally, the regulation may require regular emptying and cleaning of the device to avoid an accumulation of drug residue that might affect the efficacy of the drugs or the accuracy of the dispensing. In considering modification to or elimination of the "run-dry" regulation, the board will include requirements in the best interest of public health and safety in prescription medications.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

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

Public Comment Deadline: April 25, 2012.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4416, FAX (804) 527-4472, or email [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov).

VA.R. Doc. No. R12-3083; Filed February 23, 2012, 2:06 p.m.



2101 East Jefferson Street  
Department of Pharmacy Services, 3-West  
Rockville, MD 20852

April 25, 2012

Elaine J. Yeatts, Senior Policy Analyst  
Department of Health Professions  
9960 Mayland Drive  
Henrico, VA 23233

Dear Ms. Yeatts,

Thank you for the opportunity to provide comment on the Notice of Intended Regulatory Action (NOIRA) to modify or eliminate the requirement for bulk bins in an automated counting device to be "run dry" every sixty days as outlined in 18VAC110-20-355.

As the profession of pharmacy continues to evolve and progress, so does the technology used to support the practice. Historically, automated counting devices utilized a rotating mechanism that sifted thru the cell to count tablets or capsules, resulting in a continuous mixing of the medication placed into the cell, analogous to a cement mixer. The previous means of technology was also limited in scope and functioned only as a counting device, requiring manual intervention by the pharmacist or technician to place the counted medication into a vial and attach the corresponding prescription label. Furthermore, the tracking of lot numbers and expiration dates had to be maintained in a written log as the system was incapable of recording this information. Due to the inability to track lot numbers and expiration dates, coupled with the mechanism of action which continuously mixed the medication in the cells, a "run dry" requirement was created to provide a means of tracking the entry and removal of specific lot numbers and expiration dates from the cells.

Modern automated counting devices utilize the concept of gravity to create technology that no longer requires the continuous mixing of medications to provide an accurate count. The cells are replenished from the top and medication is dispensed from the bottom of the cell, in essence dispensing the medication in the order it was added to the cell. While there may not be a fool-proof guarantee that the first lot of medication added is dispensed in its entirety prior to dispensing a subsequently added lot number, the technology is designed to support first in and first out flow.

Modern automated counting devices are no longer limited to counting functionality only, and are developed to deliver medications efficiently, safely, and economically. Technology advances now include a verification system which allows for comprehensive bar code scanning and software-driven checks for all initial NDC assignments and dispenser replenishment. The systems display photo images of the medication to assist the pharmacy team ensure the correct medication has been counted and dispensed. Most importantly, the system is capable of tracking

and storing useful information for all prescriptions counted by the device, including the electronic management of lot numbers and expiration dates. For each prescription medication dispensed, the system is capable of pinpointing which lot numbers and expiration dates a patient may have received based upon the contents of the cell at the time of dispensing. The ability to track which patient received what lot number is a sophisticated functionality that is not captured if a prescription was prepared manually.

In light of modern automation capability that utilizes gravity to count medications and capture pertinent prescription information, including the tracking of lot numbers and expiration dates, the "run dry" requirement appears unnecessary for the safe and efficient management of pharmacy operations. No other jurisdiction in the United States has a "run dry" requirement. For most pharmacies, the primary purpose of investing in costly automation is to improve patient safety and enhance efficiencies in workflow allowing for additional time to interact directly with patients and other healthcare providers. The "run dry" requirement is counterproductive to this philosophy as it prevents proactive replenishment of cells when they reach a critical inventory level, and instead require a pharmacist or technician to remove themselves from the workflow when a cell empties to replenish it at that time. In addition, the need to "run dry" results in wastage of medications and creates an undue financial burden on pharmacies as they must discard any remaining product in the cell if not used within a sixty day period to comply with the regulations. Therefore, we strongly urge the Virginia Board of Pharmacy to eliminate the requirement for bulk bins in an automated counting device to be "run dry" every sixty days as outlined in 18VAC110-20-355.

While technology supports the elimination of the "run dry" requirement, there is still a need to consider safeguards to ensure expired or recalled drugs are not dispensed to a patient. Since automated counting devices are used primarily for fast-moving products and the dispensing mechanism closely resembles first in and first out, the probability of a tablet or capsule from a particular lot number remaining in the cell after an extended period of time is extremely unlikely. Thus, Kaiser Permanente would like to suggest the Board of Pharmacy consider instituting regulations to require the emptying and disposal of all product in a cell in the event of a drug recall where the involved lot number was placed into the cell within the previous three months. Based on informal survey of our automation systems, we firmly believe extending beyond a three month time frame seems unreasonable and unnecessary. However, an exception to this requirement should exist if the technology of the device can ensure drugs in a particular lot have been cleared or if the cell has "run dry" since the addition of the lot number to avoid unnecessary disposal and wastage of medications.

With the elimination of a "run dry" requirement, there remains a need to prevent accumulation of drug residue that may affect the efficacy of the drugs or the accuracy of the dispensing. The need to clean and calibrate each individual cell of an automated counting device is dependant upon the type of medication placed into the cell, for example how powdery or dusty the medication is, and how often the cell is used to dispense medication. Manufacturers of modern automated counting devices typically recommend periodic maintenance. In addition, our systems are programmed to alert the user when a particular cell requires cleaning due to medication dust or frequency of use. Thus, Kaiser Permanente would like to suggest the Board of Pharmacy consider including a provision to require the cleaning and maintenance of automated counting devices according to

manufacturer guidelines and specifications to alleviate concerns about drug residue affecting functionality and quality assurance.

To protect the safety and efficacy of the drugs dispensed to patients in a manner that is reasonable and the least burdensome to pharmacies that use such devices, Kaiser Permanente would like to suggest the language in 18VAC110-20-355(C) be amended as follows:

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

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

- a. The drug name and strength, if any;*
- b. The name of the manufacturer or distributor;*
- c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;*
- d. Any assigned lot number;*
- e. An expiration date determined according to USP guidelines for repackaging;*
- f. The date of filling; and*
- g. The pharmacist's initials verifying the accuracy of the process.*

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

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

*4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed; AND the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, ~~and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.~~*

**5. IN THE EVENT OF A DRUG RECALL INVOLVING ONE OF MULTIPLE LOTS PLACED IN A BIN OF AN AUTOMATED COUNTING DEVICE IN THE LAST THREE MONTHS, ALL DRUGS SHALL BE REMOVED FROM THE BIN AND NOT USED FOR PATIENT CARE. THE REMOVAL OF DRUGS FROM THE BIN IS NOT REQUIRED IF:**

- A. THE TECHNOLOGY OF THE AUTOMATED COUNTING DEVICE CAN ENSURE DRUGS IN A PARTICULAR LOT HAVE BEEN CLEARED;**
- OR**

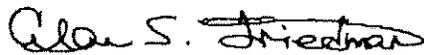
**B. THE BIN HAS BEEN "RUN DRY" SINCE THE ADDITION OF THE RECALLED LOT NUMBER WHERE ALL PRODUCT WAS COMPLETELY REMOVED PRIOR TO FILLING WITH A SUBSEQUENT LOT NUMBER.**

**6. AN AUTOMATED COUNTING DEVICE SHALL BE CLEANED AND MAINTAINED ACCORDING TO RECOMMENDED MANUFACTURER GUIDELINES AND SPECIFICATIONS.**

Kaiser Permanente appreciates the willingness of the Virginia Board of Pharmacy to recognize technological advances within the profession of pharmacy, and to work with stakeholders to determine a means of increasing efficiency while protecting the safety of our patients. It is important that as technology advances to increase efficiencies and patient safety, barriers are not in place that make it more difficult to use automation, potentially causing stakeholders to resort to manual processes which are less burdensome but also have less tracking functionality and safety mechanisms in place.

Thank you again for the opportunity to offer remarks on the proposed revisions to the "run dry" requirement in 18VAC110-20-355. Should you have any questions, please do not hesitate to contact us.

Sincerely,



Alan Friedman, RPh  
Regulatory, Quality and Professional  
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cc: Caroline D. Juran, Executive Director, Virginia Board of Pharmacy  
Kristin Bear, Senior Legal Counsel, Kaiser Permanente

# DRAFT Proposed Amendments

## BOARD OF PHARMACY

### Change to run-dry requirement for automated counting devices

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

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

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

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

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

a. The drug name and strength, if any;

- b. The name of the manufacturer or distributor;
  - c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;
  - d. Any assigned lot number;
  - e. An expiration date determined according to USP guidelines for repackaging;
  - f. The date of filling; and
  - g. The pharmacist's initials verifying the accuracy of the process.
2. If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.
3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.
4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, ~~and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.~~
5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:
- a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

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

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

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

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

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

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

**Agenda Item: Request from Board of Health Professions to offer comment regarding pharmacist scope of practice review**

<b>Included in your agenda package are:</b>	<b>pages</b>
BHP Study Workplan Draft	35-41
Response to Study Workplan Draft submitted by Virginia Pharmacy Congress	42-97
Summary of Public Comment as of August 17, 2012	98-103
Individual comments submitted as of August 17, 2012	104-116

**VIRGINIA BOARD OF HEALTH PROFESSIONS  
VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

**STUDY WORKPLAN DRAFT**

**Review of Potential Pharmacist and Pharmacy Technician Scope of Practice Barriers  
to the Development of Effective Team Approaches to Healthcare Delivery in Virginia**

**May 8, 2012**

**Background and Authority**

At the February 15, 2011 meeting of the Virginia Board of Health Professions, the Secretary of Health and Human Resources requested the Board's assistance in addressing Virginia's health reform issues. The Secretary's request followed the publication in December 2010 of the Virginia Health Reform Initiative Advisory Council's (VHRI) latest findings and recommendations.

Led by Secretary Hazel and commissioned in August of 2010 by Governor Robert F. McDonnell, VHRI's charge is to develop recommendations for implementing health reform in Virginia and to search for innovative solutions to meet Virginia's needs in 2011 and beyond. To date, six VHRI task forces have been formed to address the following key interrelated issues: Medicaid Reform, Service Delivery and Payment Reform, Technology, Insurance Reform, Purchaser Perspectives, and, of greatest relevance to the Department and Board, Capacity.

The Capacity Task Force noted in the December VHRI report that health workforce capacity must be increased to ensure all Virginians have access to affordable and high quality care. Even now before increased coverage from federal health reform takes effect, there are many medical, dental, and mental health underserved areas throughout across the state. And, looming shortages are predicted for most health service providers due to increases in Virginia's population size and age, alone. With increase coverage slated to go into effect in 2014, the gap between supply and demand can be expected to only worsen without help.

The Capacity Task Force viewed that effective capacity could be reached with increases in health professional supply, expanded use of technology to reach underserved areas, optimizing efforts to re-organize health care delivery through teams that effectively deploy non-physicians, and permitting health professionals to practice up to the evidence-based limits of their education and training in ways not currently possible with existing scope of practice and supervisory restrictions. To inform these approaches, the Task Force further recommended multi-dimensional studies which include reviews of promising team practice approaches and examination of how current scope of practice limits may needlessly restrict Virginia's ability to take full advantage of best practice team models of care delivery.

The Board of Health Professions is authorized by the General Assembly with a variety of powers and duties specified in §§54.1-2500, 54.1-2409.2, 54.1- 2410 *et seq.*, 54.1-2729 and 54.1-2730 *et seq.* of the *Code of Virginia*. Of greatest relevance here is §54.1-2510 (1), (7), and (12) enable the Board to evaluate the need for coordination among health regulatory boards, to advise on matters relating to the regulation or deregulation of health care professions and occupations, and to examine scope of practice conflicts involving professions and advise on the nature and degree of such conflicts.

Thus, the Board determined at its May 3, 2010 meeting that it can most effectively assist VHRI and the Capacity Task Force by objectively examining the aforementioned current scope of practice limits in light of the latest evidence-based policy research and available data related to safety and effectiveness. With the assistance of member Boards and invited input from experts and public and private stakeholders, this review will aim to identify barriers to safe healthcare access and effective team practice that may exist due to current scope of practice limits and will determine the changes, if any, that should be made to scope of practice and regulatory policies to best enable effective team approaches for the care of Virginia's patients. The goal is not to replace physicians with non-physicians but to lessen unnecessary restrictions to ease the burden on practitioners and better ensure access to healthcare through strengthened health professional teams.

The Board referred the project to the Regulatory Research Committee and directed that the first review address scope of practice issues in Virginia relating to Nurse Practitioners and this second study to focus on Pharmacists and Pharmacy Technicians. All reviews are to consider scope of practice issues in the perspective of their potential role in team health care delivery models that have evidence of effectiveness in helping to address workforce shortage. Subsequent to this review, the Committee will determine future professions to be highlighted based upon the evolving evidence related to effective team models and the workforce research findings for professions under review by the DHP Healthcare Workforce Data Center and Virginia Health Workforce Development Authority.

## **Methods**

Throughout the review, it is understood that the Board will strive to work in concert with the efforts of its member Boards, the VHRI Capacity Task Force, the Department's Healthcare Workforce Data Center, the Health Care Workforce Development Authority, and others working to assist the Secretary in these matters.

In keeping with constitutional principles, Virginia statutes, and nationally recognized research standards, the Board has developed a standard methodology to address key issues of relevance in gauging the need for regulation of individual health professions. The specifics are fully described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions*, available from the Board's website: [http://www.dhp.virginia.gov/bhp/bhp\\_guidelines.htm](http://www.dhp.virginia.gov/bhp/bhp_guidelines.htm)) under Guidance Document 75-2 Appropriate Criteria in Determining the Need for Regulation of Any Health Care Occupation or Professions, revised February 1998. (Hereinafter this is referred to as "the Policies and Procedures"). The Policies and Procedures will be employed in this study and modified as deemed appropriate by the Committee. It is understood that the Policies and Procedures'

seven evaluative criteria apply most directly to determining *whether* a profession should be regulated and to what degree. But, they also provide a standard conceptual framework with proscribed questions and research methods that have been employed for over two decades to successfully address key policy issues related to health professional regulation. The seven Criteria typically used in sunrise review studies are as follows:

1. **Risk of Harm to the Consumer**
2. **Specialized Skills and Training**
3. **Autonomous Practice**
4. **Scope of Practice**
5. **Economic Costs**
6. **Alternatives to Regulation**
7. **Least Restrictive Regulation**

Since Pharmacists and Pharmacy Technicians are already licensed, the first five Criteria will chiefly guide the study. This study will provide background information on the qualifications and scopes of practice of Pharmacists and Pharmacy Technicians in Virginia and elsewhere and on major existing and described emerging health delivery models.

The following provide the chief questions recommended to be addressed:

### **Background**

1. What are the current qualifications that Virginia's Pharmacists and Pharmacy Technicians must demonstrate to become licensed? Do they differ from other states?
  - a. What are the educational or training requirements for entry into each profession? (sample curricula) Which programs are acceptable? How are these programs accredited? By whom?
  - b. What are the minimal competencies (knowledge, skills, and abilities) required for entry into the profession? As determined by whom?
  - c. Which examinations are used to assess entry-level competency?
    - i. Who develops and administers the examination?
    - ii. What content domains are tested?
    - iii. Are the examinations psychometrically sound – in keeping with *The Standards for Educational and Psychological Testing*?
2. How do Pharmacists and Pharmacy Technicians maintain continuing competency? Does it differ in other states?
3. What is the Scope of Practice in Virginia for Pharmacists? For Pharmacy Technicians? How does it differ from other states?
4. Describe existing team delivery models of care that utilize Pharmacists and Pharmacy Technicians in Virginia and elsewhere.

5. Based upon the emerging literature, describe existing and anticipated team delivery models that may evolve as a result of the federal health reform and the potential role(s) for Pharmacists and Pharmacy Technicians in those models.

### **Risk of Harm to the Consumer**

1. What are the typical functions performed and services provided by Pharmacists and Pharmacy Technicians in Virginia and elsewhere?
2. Is there evidence of harm from either Pharmacists or Pharmacy Technicians with expanded scopes of practice relative to that in Virginia? If any,
  - a. To what can it be attributed (lack of knowledge, skills, characteristics of the patients, etc)?
  - b. How is the evidence documented (Board discipline, malpractice cases, criminal cases, other administrative disciplinary actions)?
  - c. Characterize the type of harm (physical, emotional, mental, social, or financial)
  - d. How does this compare with other, similar health professions, generally?
3. Does a potential for fraud exist because of the inability of the public to make informed choice in selecting a competent practitioner?
4. Does a potential for fraud exist because of the inability for third party payors to determine competency?
5. Is the public seeking greater accountability of this group?

### **Specialized Skills and Training**

NOTE: The following are in addition to the qualification-related questions previously posed for the "Background" section of the evaluation.

1. Are there currently recognized or emerging specialties/levels within this profession?
  - a. If so what are they? How are they recognized? By whom and through what mechanism?
  - b. Are they categorized according to function? Services performed? Characteristics of clients/patients? Combination? Other?
  - c. How can the public differentiate among these specialties or levels?

### **Autonomous Practice**

1. What is the nature of the judgments and decisions that Pharmacists and Pharmacy Technicians currently entitled to make in practice in Virginia? Does this differ in states with more expanded scope of practice? If so, how?

2. Which functions typically performed by Pharmacists and, separately, Pharmacy Technicians in Virginia are **unsupervised** (i.e., neither directly monitored nor routinely checked)?
  - a. What proportion of the practitioner's time is spent in unsupervised activity?
  - b. Who is legally accountable or civilly liable for acts performed with no supervision?
3. Which functions are performed **only under supervision** in Virginia?
  - a. Is the supervision *direct* (i.e., the supervisor is on the premises and responsible) or *general* (i.e., the supervisor is responsible but not necessarily on the premises)?
  - b. How frequently is supervision provided? Where? And for what purpose?
  - c. Who is legally accountable or civilly liable for acts performed under supervision?
4. Describe the nature of supervision.
5. Describe the typical work settings, including supervisory arrangements and interactions of the practitioner with other regulated and unregulated occupations and professions.
6. Are patients/clients **referred to** these professions for care or other services? By whom? Describe a typical referral mechanism.
7. Are patients/clients **referred from** these professions to other practitioners? Describe a typical referral mechanism. How and on what basis are decisions made to refer?

### Scope of Practice

1. Which existing functions of this profession in Virginia are **similar** to those performed by other professions? Which profession(s)?
2. What additional functions, if any, are performed by these professions in other states?
3. Which functions of this profession are **distinct from** other similar health professions in Virginia? Which profession(s)? In other states?

### Economic Costs

1. What are the range and average incomes of members of each of these professions in the Commonwealth? In adjoining states? Nationally?

2. If the data are available, what are the typical fees for service provided by these professions in Virginia? In adjoining states? Nationally?
3. Is there evidence that expanding the scope of practice would
  - a. Increase the cost for services?
  - b. Increase salaries for those employed by health delivery organizations?
  - c. Restrict other professions in providing care?
  - d. Other deleterious economic effects?
4. Address issues related to supply and demand and distribution of resources including discussion of insurance reimbursement.

The following steps are recommended for this review

1. Conduct a comprehensive review of the pertinent policy and professional literature.
2. Review and summarize available relevant empirical data as may be available from pertinent research studies, malpractice insurance carriers, and other sources.
3. Review relevant federal and state laws, regulations and governmental policies.
4. Review other states' relevant experiences with scope and practice expansion and team approaches to care delivery.
5. Develop a report of research findings, to date, and solicit public comment on reports and other insights through hearing and written comment period.
6. Publish second draft of the report with summary of public comments.
7. Develop final report with recommendations, including proposed legislative language as deemed appropriate by the Committee..
8. Present final report and recommendations to the full Board for review and approval.
9. Forward to the Director for review and comment.
10. Upon approval from the Director forward to the Secretary for final review and comment.
11. Prepare the final report for publication and electronic posting and dissemination to interested parties.

### **Timetable and Resources**

This study will be conducted with existing staff and within the budget for the remainder of FY2012 and half of FY2013.

The following timeline is submitted for the Committee's consideration:

May 8, 2012	Committee Review of Workplan and Progress to Date
July 13, 2012	1st Draft Report to Committee Members & Posted to the Website
July 23, 2012	Public Hearing/Committee Meeting
August 17, 2012	2 <sup>nd</sup> Draft Report to Committee Members & Posted to the Website
September 17, 2012	Committee Meeting/Recommendations
October 2, 2012	Committee Report to the Full Board/Final Recommendations

**VIRGINIA PHARMACY CONGRESS  
STUDY WORKPLAN DRAFT**

**for submission to**

**VIRGINIA BOARD OF HEALTH PROFESSIONS  
VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

**Review of Potential Pharmacist Scope of Practice Barriers to the Development of Effective  
Team Approaches to Healthcare Delivery in Virginia**

**REVISED January 30, 2012**

**Background**

- 1. What are the current qualifications that Virginia's Pharmacists must demonstrate to become licensed? Do they differ from other states?**

The **qualifications for licensure** as a pharmacist in the Commonwealth of Virginia are outlined in the Code of Virginia and further defined in the Regulations Governing the Practice of Pharmacy.<sup>1,2</sup> In order to be eligible for licensure, applicants must be at least 18 years and be in good moral character. A minimum of 1500 hours of practical experience in the practice of pharmacy is required for licensure. To gain pharmacy practical experience in Virginia, pharmacy students must first register with the board to become a pharmacy intern. On and after June 1, 1964, the applicant must have graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded from a school that meets the standards of the Accreditation Council for Pharmaceutical Education. The applicant must achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy. The approved licensing examination is The North American Pharmacist Licensure Examination™ (NAPLEX®).<sup>3</sup> An applicant must also achieve a passing score on a board-approved examination assessing the knowledge of the federal and state laws relevant to pharmacy practice. The board-approved law examination is the Virginia Federal and State Drug Law Examination.<sup>3</sup> Once these requirements are met, applicants may submit an application and fee to become licensed. Pharmacists must complete continuing pharmacy education in approved programs for each annual renewal of licensure.<sup>2</sup>

**The qualifications for licensure as a pharmacist vary among states.** For example, states have different requirements for practical experience prior to applying for licensure. While many states require a minimum of 1500 hours, certain states require more hours or have more stringent requirements for the experience. The practical experience

requirements for licensure in Pennsylvania include a maximum of 750 hours attained from school of pharmacy internship experience.<sup>4</sup> Differences exist in examination requirements for licensure among states. The specific examination assessing the applicants' law knowledge may be different. The Multistate Pharmacy Jurisprudence Examination (MPJE™) is utilized by 47 states, but Virginia uses a contracted administrator to administer its own psychometrically sound jurisprudence examination. Other states that do not utilize MPJE as part of licensure requirements are Arkansas and California.<sup>5</sup> Some states require examinations beyond the NAPLEX and law examination. For example, some states such as West Virginia require that pharmacists also pass The Errors and Omissions examination for licensure.<sup>6</sup> Requirements for continuing education and renewal of licenses also vary across states.

Pharmacists licensed in other states who wish to obtain licensure in Virginia must comply with the same minimal educational and practical experience requirements as pharmacists initially licensed in Virginia. Additionally, NABP serves as the clearinghouse for identifying any disciplinary action taken by another state for the Virginia board to take into consideration prior to issuance of the license.

Foreign graduates must also comply with obtaining the same number of years of educational experience from a school that is equivalent to an ACPE-approved school. In addition to obtaining the same number of hours of practical experience and passing the NAPLEX and Virginia Federal and State Drug Law Exam, this person must also pass the test of English as a foreign language and the Foreign Pharmacy Graduate Equivalency Examination.

In two states, New Mexico and North Carolina, licensed pharmacists can seek advanced-practice designations that broaden their scope of practice including and prescribing privileges. To gain these designations, licensed pharmacists must have additional qualifications and training. In order to be recognized as a Pharmacist Clinician in New Mexico, one must be a licensed pharmacist who meets one of the following criteria: 60 hours of physical assessment training with either 9 months of clinical experience or physician-supervised preceptorship of 150 hours and 300 patient contacts, plus passing of a Board-approved examination; OR certification by the Indian Health Service Pharmacist Practitioner Program with 600 patient contacts within the last 2 years and an affidavit from a supervising physician.<sup>7</sup> The state of North Carolina has its own requirements for the Clinical Pharmacist Practitioner designation. The pharmacist must be licensed to practice pharmacy, have a collaborative practice agreement with a physician, and meet one of the following criteria: a BS degree, five years experience, and completion of two approved Certificate Programs; OR a PharmD degree, three years experience, and completion of one approved Certificate Program; OR a Board of Pharmaceutical Specialties (BPS) Certification or Geriatric Certification or completion of an ASHP accredited residency program and two years clinical experience.<sup>8</sup>

- a. **What are the educational or training requirements for entry into this profession? (sample curricula) Which programs are acceptable? How are these programs accredited? By whom?**

The accreditation of colleges and schools of pharmacy are under the purview of the Accreditation Council for Pharmacy Education (ACPE). State boards of pharmacy require that licensure applicants from the United States have graduated from an accredited pharmacy degree program to be eligible to sit for the North American Pharmacist Licensure Examination™ (NAPLEX®). ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. ACPE was established in 1932 and in 1975 its scope of activity was broadened to include accreditation of providers of continuing pharmacy education. ACPE is an autonomous and independent agency whose Board of Directors is derived through the American Association of Colleges of Pharmacy (AACP), the American Pharmacists Association (APhA), the National Association of Boards of Pharmacy (NABP) (three appointments each), and the American Council on Education (ACE) (one appointment).

After decades of debate, the transition to the Doctor of Pharmacy (PharmD) as the sole professional practice degree for pharmacy in the United States was initiated when ACPE adopted its *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* on June 14, 1997.<sup>9</sup> The implementation timeline for the new standards required transition for the entering professional classes in academic year 2000-2001, and the transition was completed in academic year 2004-2005 with the graduation of the last student from an ACPE-accredited baccalaureate in pharmacy program. Many pharmacy colleges and schools converted to the PharmD well in advance of the implementation deadline, and all programs met the implementation timetable. This dramatic action added an additional year to the entry-level curriculum and established clinical/direct patient care as a foundational element of the practice. Subsequently, the ACPE issued new standards in 2007 and 2011 that explicitly address the curricular content of educational programs.

A joint publication by the American Pharmacists Association and American Association of Colleges of Pharmacy highlights the strategies utilized by 18 schools and colleges of pharmacy to incorporate medication therapy management (MTM) into the curriculum. The goal of including MTM in the curriculum is to increase students' knowledge and experiences, therefore empowering graduates with the skills to develop and implement MTM services.<sup>10</sup>

**Sample curricula from the four pharmacy schools in Virginia can be found in Appendix A.**

A complete listing of all accredited colleges and schools of pharmacy can be found at [http://www.acpe-accredit.org/shared\\_info/programsSecure.asp](http://www.acpe-accredit.org/shared_info/programsSecure.asp). The pre-

requisites for acceptance into colleges and schools of pharmacy are variable however there is a strong trend toward requirement that students have previously earned an undergraduate degree.

**b. What are the minimal competencies (knowledge, skills, and abilities) required for entry into the profession? As determined by whom?**

The minimum competencies required for entry into the profession are set by ACPE. The ACPE standards and guidelines, taken together, ensure the development of students who can contribute to the care of patients and to the profession by practicing with competence and confidence in collaboration with other health care providers. The revision has placed greater emphasis on the desired scientific foundation and practice competencies, the manner in which programs need to assess students' achievement of the competencies, and the importance of the development of the student as a professional and lifelong learner. The standards focus on the development of students' professional knowledge, skills, attitudes, and values, as well as sound and reasoned judgment and the highest level of ethical behavior.

The AACP Center for the Advancement of Pharmaceutical Education (CAPE) published their CAPE Educational Outcomes in 1997 shortly after the ACPE established the new doctor of pharmacy accreditation standards. These outcomes were intended to be the target toward which the evolving pharmacy curriculum should be aimed. These outcomes, which were revised in 2004 and are articulated in points 1-3 below, now serve as the minimal competencies that student pharmacists must demonstrate in order to graduate from an ACPE accredited college or school of pharmacy. The revised *CAPE Educational Outcomes*<sup>11</sup> employ similar language to other competency/outcomes documents in the health professions (e.g., Institute of Medicine, Accreditation Council for Graduate Medical Education, Pharmacy's Framework for Drug Therapy Management, Medical School Objectives Project). The Outcomes include:

1. Provide pharmaceutical care in cooperation with patients, prescribers, and other members of an inter-professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving pharmaceutical, biomedical, sociobehavioral, and clinical sciences that may impact therapeutic outcomes.
  - a. Provide patient-centered care.
    - i. Design, implement, monitor, evaluate, and adjust pharmaceutical care plans that are patient-specific and evidence-based.
    - ii. Communicate and collaborate with prescribers, patients, care givers, and other involved health care providers to engender a team approach to patient care.

- iii. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to patients, their families, and other involved health care providers.
  - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact patient-specific therapeutic outcomes.
- b. Provide population-based care.
- i. Develop and implement population-specific, evidence-based disease management programs and protocols based upon analysis of epidemiologic and pharmaco-economic data, medication use criteria, medication use review, and risk reduction strategies.
  - ii. Communicate and collaborate with prescribers, population members, care givers, and other involved health care providers to engender a team approach to patient care.
  - iii. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to other health care providers and to the public.
  - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact population-based, therapeutic outcomes.
2. Manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- a. Manage human, physical, medical, informational, and technological resources.
- i. Apply relevant legal, ethical, social, economic, and professional principles/issues to assure efficient, cost-effective utilization of human, physical, medical, informational, and technological resources in the provision of patient care.
  - ii. Communicate and collaborate with patients, prescribers, other health care providers, and administrative and supportive personnel to engender a team approach to assure efficient, cost-effective utilization of human, physical, medical, informational, and technological resources in the provision of patient care.
  - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.

- iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact management of human, physical, medical, informational, and technological resources in the provision of patient care.
- b. Manage medication use systems.
    - i. Apply patient and population-specific data, quality assurance strategies, and research processes to assure that medication use systems minimize drug misadventuring and optimize patient outcomes.
    - ii. Apply patient and population-specific data, quality assurance strategies, and research processes to develop drug use and health policy, and to design pharmacy benefits.
    - iii. Communicate and collaborate with prescribers, patients, caregivers, other involved health care providers and administrative and supportive personnel to identify and resolve medication use problems.
    - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
    - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact medication use systems, to develop use and health policy, and to design pharmacy benefits.
- 3. Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.
    - a. Assure the availability of effective, quality health and disease prevention services.
      - i. Apply population-specific data, quality assurance strategies, and research processes to develop identify and resolve public health problems.
      - ii. Communicate and collaborate with prescribers, policy makers, members of the community and other involved health care providers and administrative and supportive personnel to identify and resolve public health problems.
      - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
      - iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may affect the efficacy or quality of disease prevention services to amend existing or develop additional services.

- b. Develop public health policy.
  - i. Apply population-specific data, quality assurance strategies, and research processes to develop public health policy.
  - ii. Communicate and collaborate with prescribers, policy makers, members of the community and other involved health care providers and administrative and supportive personnel to develop public policy.
  - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may affect public health policy, to amend existing or develop additional policies.

**c. Which examinations are used to assess entry-level competency?**

**i. Who develops and administers the examination?**

The NAPLEX is issued by the National Association of Boards of Pharmacy (NABP) and is utilized by the state Boards of Pharmacy as part of their assessment of competence to practice pharmacy.<sup>12</sup> Each state requires applicants to pass the NAPLEX examination in order to obtain a license to practice as a registered pharmacist. The purpose of the NAPLEX is to determine whether or not it is safe for individuals to practice as an entry-level pharmacist. The examination is a computer-adaptive, competency-based examination. The examination is administered by Pearson VUE.

The Commonwealth of Virginia utilizes the Virginia Federal and State Drug Law Examination to test candidates' knowledge of Federal Drug Law and Virginia Pharmacy laws and regulations.<sup>13</sup> The examination is developed Virginia pharmacists under the direction of a contracted psychometrician and administered by Iso-Quality Testing. The test incorporates simulations of prescriptions, labels, and refill records to evaluate a candidates' ability to apply pharmacy laws in real-life situations.

**ii. What content domains are tested?**

The NAPLEX examination evaluates applicants' ability to apply knowledge learned in pharmacy school to real life situations. The NAPLEX competency statements are a blueprint of the areas covered.<sup>12</sup> These competencies include: assess pharmacotherapy to assure safe and effective therapeutic outcomes (56% of test), assess safe and accurate preparation and dispensing of medications (33% of test), and assess, recommend, and provide healthcare information that promotes public

health (11% of test). Further details on specific objectives are listed on the complete NAPLEX Blueprint.

The Virginia Federal and State Drug Law Examination evaluates applicants' knowledge of federal and state laws with more emphasis on state law.<sup>13</sup> The areas applicants' must be competent in include the laws and regulations pertaining to licensing, registration, and inspection (24% of test), ordering, receiving, and managing drug inventory (21%), review of prescriptions (30% of test), and dispensing and distribution (25%). Further details including specific behavioral objectives are in the study guide posted on the Board of Pharmacy's website.

iii. **Are the examinations psychometrically sound – in keeping with *The Standards for Educational and Psychological Testing*?**

Yes, the examinations required for licensure are psychometrically sound.

2. **How do Pharmacists maintain continuing competency? Does it differ in other states?**

**Pharmacists complete continuing pharmacy education (CPE) to maintain competencies.** The Accreditation Council for Pharmacy Education defines CPE for the profession of pharmacy as a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. CPE should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.<sup>14</sup> The five core areas pharmacists should develop and maintain proficiency in are delivering patient care, working as part of interdisciplinary teams, practicing evidence-based medicine, focusing on quality improvement, and using information technology. Pharmacists may complete CPE sessions in three formats including live activities, home study, or activities that contain both live and home study.

**To be eligible for annual license renewal, pharmacists licensed in Virginia are required to complete at least 15 contact hours of continuing pharmacy education.**<sup>2</sup>

**The CPE requirements differ in other states.** States range from requiring 10 hours in a year (New Jersey and New Mexico) to 20 hours in a year (Ohio). The majority of states require 15 hours in a year, however 31 states require pharmacists to renew their license every 2 years and 2 (New York and Ohio) are every 3 years. Certain states place requirements on the number of live continuing pharmacy education courses whereas others may specify required topic areas.

**In the past, documenting and reporting of CPE has also varied across states.** In Virginia, pharmacists are required to attest to compliance with CPE requirements at the time of annual license renewal. The Board of Pharmacy has the authority to conduct audits to verify compliance. Pharmacists selected for an audit must submit original

documents of completion to the board for review. Since auditing all licensed pharmacists is not practical and the current self-reporting system is subject to fraud, boards of pharmacy needed an improved system for assessing CPE compliance. Recently, NABP and ACPE created the CPE Monitor, an electronic system for tracking CPE credits for pharmacists and technicians. This will improve CPE reporting and compliance verification.<sup>15</sup>

**CPE requirements also differ in states with advanced-practice designations for pharmacists, such as the Clinical Pharmacist Practitioner (CPP) in North Carolina and the Pharmacist Clinician in New Mexico.** Similar to the additional training and requirements to obtain these designations, additional continuing education is required. North Carolina's CPE requirement for licensed pharmacists is 15 hours of CPE annually, however the requirement for Clinical Pharmacist Practitioners is 35 hours annually.<sup>8,16</sup> Similarly, Pharmacist Clinicians must complete 20 additional hours of CPE beyond those required in New Mexico law.<sup>7</sup>

### 3. What is the Pharmacist Scope of Practice in Virginia? How does it differ from other states?

The scope of pharmacy practice in Virginia and elsewhere encompasses functions that serve to improve public health through the safe and effective use of medications, and as such involves almost every aspect of the medication use process. Traditionally, pharmacist roles revolved mainly around the medication product: processing prescriptions or drug orders, preparing the pharmaceutical product, and dispensing or delivering the medication or device. Increasingly, pharmacist roles also encompass clinical and cognitive services that help promote safe and appropriate medication use. Pharmacists are responsible for assessing the appropriateness of prescribed therapies, ensuring patient understanding and adherence to treatment plans through counseling and education, monitoring and reporting patient outcomes, and preventing drug-related problems and adverse effects.<sup>17</sup>

In many settings across Virginia, including hospitals and health systems, pharmacists are responsible for managing medication use within the system, working with physicians and other health professionals to ensure optimal pharmacotherapy for patients, and delivering clinical services that promote wellness and disease prevention. These responsibilities are increasingly being performed within interdisciplinary team-based models that promote collaboration with other health care practitioners in acute care, primary care, and long-term care settings.<sup>17</sup>

Additionally, many state boards (including Virginia) have taken steps to incorporate expanded clinical services into the scope of practice for pharmacists by authorizing Collaborative Drug Therapy Management (CDTM) through collaborative practice arrangements with physicians, osteopaths, and podiatrists. In addition to the federal pharmacy sector, 44 states have enacted legislation to support some form of Collaborative Practice Agreements (CPAs) between physicians and pharmacists that

provide the opportunity for pharmacists to deliver high-level clinical services that extend beyond the usual scope of pharmacists practice.<sup>18</sup>

Although Virginia has established regulations for the creation of collaborative practice agreements, other states have been more progressive in expanding the scope of practice for pharmacists. Several state Medicaid programs, including Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina had waivers approved to allow for contract pharmacist-related compensation for clinical services. Pharmacists in these states are recognized as providers and may be reimbursed for medication therapy management services.<sup>19</sup> The National Clinical Pharmacy Specialist (NCPS) program expanded the functions of Indian Health Service pharmacists by recognizing them as primary care providers with prescriptive authority.<sup>20</sup> Similar expanded functions exist for Veterans Affairs pharmacists.<sup>21</sup> Currently, in both North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.<sup>7,8</sup> Since 1993, New Mexico pharmacists have the opportunity to pursue additional training and earn the designation Pharmacist Clinician. Pharmacist Clinicians may obtain personal DEA numbers and have prescriptive authority under a supervising physician. In North Carolina, the Clinical Pharmacist Practitioner Act of 2000 established the designation Clinical Pharmacist Practitioners (CPP).<sup>8</sup> A CPP provides disease therapy management and can initiate, modify, or substitute therapies under a broad collaborative practice agreements.

**4. Describe existing team delivery models of care that utilize Pharmacists in Virginia and elsewhere.**

In Virginia and other states, there are many avenues for pharmacists to practice within team delivery models. In institutional settings, pharmacists often round in treatment teams alongside physicians, nurses, dietitians, occupational therapists, and social workers in areas like acute care, cardiology, oncology, emergency department, pediatrics, psychiatry, critical care, and infectious disease. Pharmacists on these teams are responsible for assessing patients' medication regimens, evaluating laboratory values and diagnostic results, making recommendations regarding appropriate pharmacotherapy, and communicating information to other members of the team. Pharmacists in the acute setting also provide drug selection and dosing consultations, lead team-based antibiotic stewardship programs, manage anticoagulation therapy, and perform medication counseling services.<sup>22,23</sup> In the community setting, pharmacists provide care within the team delivery model by communicating with physicians (via phone or electronically) to discuss appropriate therapy, answer questions, and make recommendations as indicated. Pharmacists are also active in providing immunizations to patients for influenza, pneumococcal disease, meningococcal disease, hepatitis A and B, and herpes zoster (shingles).

Team-based patient care is also the cornerstone of collaborative practice agreements between physicians and pharmacists. Through this type of practice, pharmacists may engage in collaborative medication therapy management and chronic disease

management based on protocols agreed upon by the pharmacist and physician. Examples of disease states that can be managed using this team-based approach include hypertension, diabetes, hypercholesterolemia, asthma, anticoagulation, and pain.

There are numerous examples in the literature of collaborative practice arrangements and team-based care models that have been successfully implemented in various settings across the country. For example, in a study published in 2010, Carter, et al<sup>24</sup> evaluated the effect of a physician-pharmacist collaborative model in community-based medical offices on blood pressure (BP) control. The study demonstrated BP control in 63.9% of patients in the collaborative practice (intervention) group compared to 29.9% of patients in the control group ( $p < 0.001$ ), and a 55.4% increase in adherence to treatment guidelines in the intervention group.<sup>24</sup>

The effectiveness of group medical clinics (GMC) for managing patients with comorbid diabetes and hypertension was compared to usual care in a study conducted by Edelman and colleagues.<sup>25</sup> This study was conducted in two Veterans Affairs Medical centers in Durham, North Carolina and Richmond, Virginia. A “group medical clinic” included seven to eight patients managed by a care team that consisted of a primary care general internist, a pharmacist, and a nurse or other certified diabetes educator. The visits, conducted every two months, included various interactive educational sessions and the development of individualized plans for medication or lifestyle management created by the pharmacist and physician to improve diabetes control (reduction in HbA<sub>1C</sub>) and blood pressure. At the study conclusion, the mean systolic blood pressure decreased by 13.7 mm Hg in the GMC group and 6.4 mm Hg in the usual care group ( $P = 0.011$ ). Blood pressure control was achieved in 22% of patients in the GMC group and 12% in the usual care group [odds ratio [OR], 2.0 [CI, 1.0 to 4.2]. Diabetes control did not differ significantly between the groups.<sup>25</sup>

Examples of team-based patient care models in Virginia have been described both in the literature and through personal communication with participating pharmacists. In a study published in 2011, Moczygemba, et al<sup>26</sup> evaluated the effect of integrating a collaborative medication therapy management model into medical and mental health clinics serving homeless individuals. The study found that in the mental health clinic, pharmacists identified an average of 2 drug-related problems per patient, while in the medical clinic they identified an average of 5 per patient.<sup>26</sup> The study also found that up to 89% of pharmacist recommendations were accepted by providers and/or patients, indicating successful integration of pharmacist services into the patient care model.<sup>26</sup>

Another example of a team-based delivery model in Virginia can be found at Buford Road Pharmacy in Bon Air.<sup>27</sup> While the pharmacy does perform a dispensing and counseling role, there is a clinic located within the facility where pharmacists perform and evaluate point of care measurements, including cholesterol, glucose, bone density, blood pressure, and INR. Through protocols established as part of collaborative practice agreements with physicians, pharmacists at Buford Road Pharmacy communicate these measurements to the physicians and use them to make appropriate drug therapy recommendations.

As stated, there are many other studies that have evaluated these practice models and have shown improved clinical outcomes for patients as a result of team-based care with integration of pharmacists' clinical services. A summary of some of these studies can be found in Appendix B of the Report to the U.S. Surgeon General titled "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice."<sup>28</sup>

**5. Based upon the emerging literature, describe existing and anticipated team delivery models that may evolve as a result of the federal health reform and the potential role(s) for Pharmacists in those models. (Note: This section contains commentary)**

Pharmacists in progressive practices provide direct patient care in acute and chronic care settings by employing chronic disease state management and medication therapy management principles, which directly supports health reform by increasing patient access to high quality affordable care. One of the most pressing issues with the U.S. health system is that millions of patients do not have access to a healthcare provider, regardless of insurance coverage. The increasing number of uninsured Americans since the economic downturn of the last few years has added to this burden on the health system. Rural areas have fewer doctors and thus health provision is limited more so than in suburban and urban communities. Through the provision of chronic disease state management on collaboration with physicians, pharmacists can use their skills and expertise to expand patient access to care. In addition to improved health outcomes, the inclusion of a pharmacist as one of the primary care team members would help to ease the burden of too many patients and too few providers. A study in 2000 estimated that approximately 275 million people visited pharmacies each week and thus pharmacists are well posed to enhance patient access to care.<sup>29</sup> Primary care physicians are overburdened, and the aging of 'baby-boomer' generation will exacerbate this problem since it is projected that by 2030, one in five Americans will be over the age of 65.<sup>30,31</sup>

***Physician Shortages and Reduced physician burden.***

Several reports have identified an shortage in primary care physicians.<sup>32,33,34,35</sup> The American medical system is threatened by this severe shortage of primary care physicians, which could lead to restricted access to health care.<sup>35</sup> Implementation of the Affordable Care Act of 2010 will provide insurance to an additional 30 million Americans in 2014 will not solve the problem of access to services in and of itself if there are too few physicians. A recent and comprehensive report from the Association of American Medical Colleges Center for Workforce Studies projected a physician shortage of 85,000 to 200,000 by 2020,<sup>36</sup> and a 38% increase in demand for general internists is projected by the year 2020.<sup>31</sup> These data indicate that if current physician utilization patterns remain as they are, a physician shortage is imminent. If the relationship between economic growth and physician demand holds true – the demand for physicians will likely increase beyond what supply could possibly meet.

At least 12 states have already reported or projected physician shortages (AZ, CA, FL, GA, KY, MA, MI, MS, NC, TX, OR, and WI).<sup>34</sup> These findings suggest that physician workforce alone will not be able to provide primary care to the burgeoning population of

insured individuals in 2014 and beyond. Currently many health systems utilize non-physician providers, such as physician assistants (PA) and nurse practitioners (NP), to increase the productivity of physicians by assisting with patient care and directly providing patient care under collaborative agreements. If given similar primary care roles – and additional ones such as focused chronic disease state management – the health system can optimally utilize pharmacists to enhance access to care. Pharmacists who have demonstrated their competence in disease management, allows them to serve as a point of triage and referral to optimize the utilization of the health care system.<sup>37</sup>

There are other benefits of involving a pharmacist in the primary care setting. In the UK, it has been estimated that there are about 57 million primary care physician consultations per year. About 51.4 million out of those are for minor ailments, many of which could be handled by a pharmacist.<sup>38</sup> A model similar to the UK's has been in place in the Indian Health Service since the early 1970s and in Ontario, Canada for over 7 years. The Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project involved the inclusion of a pharmacist into primary care office practices in seven sites in Ontario.<sup>39</sup> Pharmacists provided comprehensive medication assessments, and collaborated with the physician and other team members to resolve identified drug therapy problems. The IMPACT project paved the way for the development of multidisciplinary teams known as Family Health Teams that include a full-time pharmacist member. As illustrated, pharmacists are increasingly providing clinical services to supplement physician care through inter-professional practice arrangements, and therefore pharmacists can directly affect health determinants outlined in the Healthy People 2020 Action Model.<sup>40</sup>

### ***Support to Healthcare Reform.***

The US healthcare system is poised to include expanded health coverage for millions, and access to high quality primary care is paramount. Indeed there are many provisions in the Affordable Care Act of 2010 that clearly delineate expanded roles for pharmacists who are willing to enhance access to care as well as reduce the cost of care.<sup>41</sup> De Maeseneer et al.<sup>42</sup> argued that primary care contributes to public health by improving access; however they added that it also is through a contribution to social cohesion and empowerment of people, so that they become less vulnerable. This only occurs when quality of care is optimized. Accessibility without quality may even be dangerous. The pharmacy profession is uniquely situated to contribute to our healthcare system's changing needs. Pharmacists have the clinical and pharmacological education, training, scope and support from many providers of care and are in the best position of any health professional to effectively address the changing needs of the healthcare system. The cost to the system to implement this change is minimal as it is more a change in policy and perception than it is in fiscal resources.

Dramatic changes are needed to improve the U.S. health care system. The health reform that we are now in the midst of implementing will need to use existing providers and resources in order to achieve the goal of making health insurance more available, affordable, and accessible to all. Professional organizations, academia, the health care

industry, community and tertiary hospitals, and primary care practitioners must step to the plate if the implementation of these new initiatives is to be successful. The U.S. Surgeon General's endorsement of the PHS report "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice" addresses the many attributes that pharmacists can contribute to health care reform and improve patient outcomes.<sup>43</sup> The Surgeon General specifically calls for the following:

1. Health leadership and policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the healthcare team. These collaborative pharmacy practice models can be implemented to manage and prevent disease, improve health care delivery and address some of the current demands on the health care system.
2. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.
3. Recognition of pharmacists as health care providers, clinicians and an essential part of the health care team is appropriate given the level of care they provide in many health care settings.
4. Compensation models, reflective of the range of care provided by pharmacists, are needed to sustain these patient oriented, quality improvement services. This may require further evolution of legislative or policy language and additional payment reform considerations.

Well in line with the Surgeon General's recommendations, a 2010 report of the Virginia Health Reform Initiative (VHRI) Advisory Council supports the "team" delivery model to improve access to care for patients in Virginia.<sup>44</sup> The report states that pharmacists are currently underutilized in the standard care model, despite their expertise in drug therapy. It recommends that state scope of practice laws be updated to permit more health care professionals, such as pharmacists, to practice to the evidence-based limit of their training. By reorganizing into multidisciplinary teams, increasing the scope of more health care professionals, utilizing information technology to extend care, and by increasing the supply of health professionals the Commonwealth of Virginia will be prepared to increase access to care for Virginians.

The recommendations of the VHRI report directly support the process outlined in the 2010 resource guide developed by the Patient-Centered Primary Care Collaborative (PCPCC) for the establishment of a patient-centered medical home.<sup>45</sup> The guide explicitly mentions that optimizing medication use is a critical component of achieving the vision of patient-centered medical homes. The report goes on to discuss in detail the specific procedures that should be incorporated into comprehensive medication management services, including:

1. An assessment of the patient's medication-related needs
2. Identification of the patient's medication-related problems

3. Development of a care plan with individualized therapy goals and personalized interventions
4. Follow-up evaluation to determine actual patient outcomes

Pharmacists have the expertise and training to perform each of these functions and be the key providers of medication management services. As outlined in the Surgeon General's letter, the VHRI report, and the PCPCC resource guide, pharmacists should be afforded the opportunity to practice at the top of their scope to more effectively provide those services and coordinate their efforts with all other members of the health care team.

The right thing to do now is to empower and compensate pharmacists providing the level of care described in this report, and integrate them into patient-centered medical homes and accountable care organizations to benefit this nation's health reform. This can only come to fruition if those in decision-making positions acknowledge the value of these services with appropriate policy and compensatory actions.

## Risk of Harm to the Consumer

### 1. What are the typical functions performed and services provided by Pharmacists in Virginia and elsewhere?

Pharmacists in Virginia and elsewhere are charged with improving public health through the safe and effective use of medications, and as such are involved in almost every aspect of the medication use process. Traditionally, pharmacist roles revolved mainly around the medication product: processing prescriptions or drug orders, preparing the pharmaceutical product, and dispensing or delivering the medication or device. Increasingly, pharmacist roles also encompass clinical and cognitive services that help promote safe and appropriate medication use. Pharmacists are responsible for assessing the appropriateness of prescribed therapies, ensuring patient understanding and adherence to treatment plans through counseling and education, monitoring and reporting patient outcomes, and preventing drug-related problems and adverse effects.<sup>17</sup>

The Code of Virginia specifies in §54.1-3320 those acts and functions that are restricted to and must be performed by a pharmacist.<sup>46</sup> They include:

1. The review of a prescription, in conformance with the chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;
2. The receipt of an oral prescription from a practitioner or his authorized agent;
3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;
4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;
5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;
6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;
7. The supervision of pharmacy interns and pharmacy technicians; and
8. Any other activity required by regulation to be performed by a pharmacist.

In many settings across Virginia, including hospitals and health systems, pharmacists are also responsible for managing medication use within the system, working with physicians and other health professionals to ensure optimal pharmacotherapy for patients, and delivering clinical services that promote wellness and disease prevention. These responsibilities are increasingly being performed within interdisciplinary team-based models that promote collaboration with other health care practitioners in acute care, primary care, and long-term care settings.<sup>17</sup>

Additionally, many state boards (including Virginia) have taken steps to incorporate expanded clinical services into the scope of practice for pharmacists by authorizing Collaborative Drug Therapy Management (CDTM) through collaborative practice arrangements with physicians, osteopaths, and podiatrists. In addition to the federal pharmacy sector, 44 states have enacted legislation to support some form of Collaborative Practice Agreements (CPAs) between physicians and pharmacists that provide the opportunity for pharmacists to deliver high-level clinical services that extend beyond the usual scope of pharmacists practice.<sup>18</sup> [NOTE: Same findings in 2012 *Survey of Pharmacy Law*.]

**2. Is there evidence of harm from Pharmacists with expanded scopes of practice relative to that in Virginia?** [NOTE: Committee to determine if e-mail survey of all the states' boards of pharmacy is in order.]

No, there is not currently any evidence to suggest harm from pharmacists with expanded scopes of practice as compared to pharmacists with more traditional scopes of practice in Virginia or elsewhere.

One systematic review of 36 published studies evaluating interventions by clinical pharmacists in hospitalized adults found no interventions that led to worse clinical outcomes or increased risk of harm to patients.<sup>47</sup> Additionally, personal correspondence with a representative from Pharmacists Mutual Insurance Company revealed no documented claims over the last 15 years that were related to the initiation or modification of therapy by a pharmacist working under a collaborative practice agreement.<sup>48</sup>

**a. If any, to what can it be attributed (lack of knowledge, skills, characteristics of the patients, etc)?**

There is currently no evidence to suggest increased risk of harm from pharmacists with expanded scopes of practice relative to other pharmacists in Virginia. Therefore, there is no information to suggest potential contributing factors such as lack of knowledge or others.

**b. How is the evidence documented (Board discipline, malpractice cases, criminal cases, other administrative disciplinary actions)?**

While there is currently no evidence to suggest harm to patients, such evidence could potentially be obtained by contacting Boards of Pharmacy for information regarding complaints or disciplinary action taken against pharmacists with expanded scopes of practice. The National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB) house information on all malpractice payments paid on behalf of practitioners in the US and could serve as additional sources of evidence for harm. The Institute for Safe Medication Practices (ISMP) does not currently have documented evidence of harm related to

expanded scopes of practice for pharmacists but may serve as a potential source if such evidence were documented in the future.

**c. Characterize the type of harm (physical, emotional, mental, social, or financial).**

As with any other field in health care, the scope of harm that a pharmacist could potentially inflict on a patient would encompass physical, emotional, mental, social, and/or financial harm. There is no evidence to suggest that the type of harm would be any different between pharmacists with expanded scopes of practice and pharmacists with traditional roles.

**d. How does this compare with other, similar health professions, generally?**

The potential for such harm from a pharmacist with an expanded scope of practice is not expected to be any different from that of physicians or other practitioners who provide clinical services in primary care and other settings.

**3. Does a potential for fraud exist because of the inability of the public to make informed choice in selecting a competent practitioner?**

There should be no potential for fraud in the ability of the public to choose a competent pharmacist who can perform the functions outlined within the scope of practice for a pharmacist. The licensing process of each state Board of Pharmacy ensures that all pharmacists have achieved a standard level of education and competence required for general practice. (Details of the licensure process are found in an earlier section of this document.)

Pharmacists who have entered into collaborative practice agreements and thereby expanded their scope of practice currently do not receive any state recognition/identification of the new responsibilities and activities involving direct patient care that they have taken on. Thus there may exist a potential for pharmacists who have not been authorized through their becoming a party to a collaborative practice agreement to represent themselves to the public fraudulently. In part to prevent this and to define through regulation pharmacists who have demonstrated competency in direct patient care, several states – namely, North Carolina and New Mexico – have taken progressive measures to ensure that there is an adequate credentialing process in place that may alert patients and other practitioners to the qualifications and competence of a pharmacist providing direct patient care clinical services.

In the mid-1990s, the State of New Mexico Board of Pharmacy and Medical Examiners pioneered a program that developed an advanced practice license designated as a Pharmacist Clinician (Ph.C).<sup>49</sup> In order to be recognized as a Pharmacist Clinician, one must be a licensed pharmacist who meets specifically outlined criteria, which are detailed in the Background section of this document. These specific requirements ensure that only pharmacists with adequate experience who have demonstrated their competency may be