



# COMMONWEALTH OF VIRGINIA

## Meeting of the Board of Pharmacy

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

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

### Tentative Agenda of Meeting

*December 12, 2012*

9:00AM

#### TOPIC

#### PAGE(S)

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

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda
- Approval of previous Board meeting minutes:
  - October 1, 2012, Full Board Meeting 1-8
  - October 24, 2012, Special Conference Committee and Informal Conference Committee 9-12
  - November 6, 2012, Special Conference Committee and Informal Conference Committee 13-17
  - November 20, 2012, Telephone Conference Call 18-19
  - November 28, 2012, Informal Conference Committee for Innovative (Pilot) Programs handout
  - November 29, 2012, Panel Formal Hearing handout

**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.

#### **DHP Director's Report:** Dianne Reynolds-Cane, M.D.

#### **Regulatory Actions:** Elaine Yeatts

- Regulatory Update handout
- Discuss Regulation Committee's recommendations regarding:
  - Adoption of proposed regulations for CQI to replace emergency regulations 20-35
  - Adoption of proposed regulations for working conditions for pharmacists 36-55
  - Adoption of fast-track regulations resulting from regulatory reform handout

#### **Update on Action Items:** Caroline D. Juran

- Discussion of "authorized generics" 56-59

**Miscellaneous:** Caroline D. Juran

- Update on actions taken regarding pharmacies performing sterile compounding; additional guidance for staff requested handout
- Consideration of possible legislative amendments regarding licensure and renewal process of nonresident pharmacies and compounding handout
- Adoption of amended Guidance Document 110-9 60-68

**Reports:**

- Report on Board of Health Professions – Robert M. Rhodes
- Report on Licensure Program – J. Samuel Johnson, Jr. handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day handout
- Executive Director's Report - Caroline D. Juran

**New Business:**

**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**

October 1, 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:** David C. Kozera, Chairman

**MEMBERS PRESENT:** R. Crady Adams  
Jody H. Allen  
Dinny Li  
Empsy Munden  
Robert M. Rhodes  
Ellen B. Shinaberry  
Pratt P. Stelly  
Rebecca Thornbury  
Cynthia Warriner

**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 ten members present, a quorum was established.

**INTRODUCTION OF NEW BOARD MEMEBERS:** Mr. Kozera welcomed two new members to the Board of Pharmacy, Rebecca Thornbury and Cynthia Warriner.

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

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for the June 12, 2012 (Full Board Meeting), June 29, 2012 (Special Conference Committee and Informal Conference Committee), July 24, 2012 (Formal Hearing), August 22, 2012 (Special Conference Committee and Informal Conference Committee), and September 18, 2012 (Special Conference Committee and Informal Conference Committee).

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

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

DHP DIRECTOR'S REPORT:

Dr. Cane commended those who participated in the collaboration of the National Governors Association's (NGA) policy grant application for \$45,000 to reduce prescription drug abuse. Virginia, along with six other states, was recently awarded the grant and discussions have begun for identifying ways to reduce prescription drug abuse. Dr. Cane also commented on the successful turnout for the New Board Member Orientation that was held at the Department of Health Professions on Friday, September 28, 2012. She stated that the orientation appeared very informative to the new and existing Board members. It included a panel presentation which discussed the effectiveness of the boards and the responsibilities that the members are to assume.

REPORT ON ENFORCEMENT  
ACTIVITIES:

Faye Lemon, Director of the Enforcement Division at DHP, provided an overview of the activities occurring within the division. Ms. Lemon introduced Pamela Twombly as one of the new Deputy Directors for Enforcement, Wanda Jackson, Case Intake Manager who oversees pharmacy cases, and Vicki Garrison, Pharmacy Inspector, who recently served as acting Deputy Director for Enforcement and assisted in supervising the inspection program. Ms. Lemon explained that the Enforcement Division has authority in statute to inspect and investigate. Their department conducts facility-related inspections for the Boards of Pharmacy, Veterinarian Medicine, and Funeral. In addition to inspections, investigations are conducted by the Enforcement Division based on complaints received by the agency. These cases are submitted to each individual board once the investigation is complete, to determine if a violation has taken place. Ms. Lemon reported that the amount of pharmacy cases increased from 317 in 2011 to 573 in 2012. She speculated that the increase may be a result of the pharmacy inspection process which was fully implemented in July 2011. She further stated that she is recruiting for the vacant pharmacy inspector position in northern Virginia. When asked about the type of training the inspectors/investigators receive, Ms. Lemon stated that it takes at least 18 months to completely train the individual. Internal training is provided in addition to training from outside entities such as the Council on Licensure, Enforcement and Regulation (CLEAR).

NABP-REPORT ON THE  
IMPLEMENTATION OF THE  
PARE EXAMINATION:

Elizabeth Scott (Scotti) Russell, NABP Government Affairs Manager, presented to the Board an outline regarding the implementation of the PARE Examination (Pharmacist Assessment for Remediation Evaluation). Ms Russell explained that this exam could be utilized by the boards of pharmacy to evaluate competency of pharmacists wishing to reinstate a license following a suspension or revocation. The Board could also use the exam, if warranted, to evaluate competency of a pharmacist with a lapsed license who has not practiced for a significant number of years.

The PARE exam is computer-based, consisting of 210 questions with a maximum testing time of 4.5 hours. The cost of the exam is \$250.00 that would be paid by the licensee directly to NABP. The content areas of the exam are focused 50% in medication safety and practice of pharmacy, 25% in professional ethics and pharmacy judgment and 25% on clinical

pharmacy practice. Details regarding the registration process were provided by Ms. Russell. The testing site would be determined by the board. She indicated that the PARE exam has not been administered to date, but that several boards of pharmacy have expressed interest to require the examination in the near future.

CHAIRMAN'S REPORT:

Mr. Kozera provided a report of the NABP Interactive Member Forum that he attended on September 19<sup>th</sup> and September 20<sup>th</sup>. The meeting provided an opportunity for the various states to share issues of concern and best practices occurring within their states. Some of the discussed topics included pharmacy technician educational requirements; licensure prerequisites such as criminal background checks; strategies for addressing drug shortages; and, current and future uses of the prescription monitoring programs.

REPORT ON LICENSURE PROGRAM:

Mr. Johnson reported that the Board issued 1,383 licenses and registrations for the period of June 1, 2012 through August 31, 2012, including 400 pharmacists, 156 pharmacy interns, and 645 pharmacy technicians. Inspectors conducted 328 facility inspections including 110 routine inspections of pharmacies; 33 resulted in no deficiency, 17 with deficiencies, and 60 with deficiencies and a consent order. There are currently five active innovative (pilot) programs, one pilot program pending approval, and three applications for pilot programs to be scheduled for reviewed by an informal conference committee.

REPORT ON DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of December 12, 2011; March 12, 2012; June 8, 2012, and September 28, 2012. For the final date, open cases are 62 at the investigation stage; 46 at the probable cause stage; 25 at the administrative proceedings division stage; 12 at the informal stage; two at the formal stage; and 88 at the pending closure stage.

Due to a position vacancy in the Administrative Proceedings Division, there is a backlog of cases which may result in the percentage of patient care cases closed within the required 250 business days to decrease for the next few reports. Recruitment for the position is underway and staff reassignments have been implemented to address the backlog.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran reported that she received approval to travel to the NABP/AACP District 1 & 2 meeting that will be held in Skytop, Pennsylvania on October 14<sup>th</sup> through 16<sup>th</sup>. Other board members who had expressed interest in attending were identified as Ms. Shinaberry, Mr. Adams, Ms. Warriner, Mr. Rhodes, and Ms. Allen. Additionally, Ms. Juran stated that she will attend the Tri-Regulator meeting to be held in Washington DC October 17<sup>th</sup> and 18<sup>th</sup>. This will be the first-ever meeting of National Association of Boards of Pharmacy, Federation of State Medical Boards, and the National Council of State Boards of Nursing. Even though it is recognized that while each association is different, there is a common regard for protecting the public through state licensure activities. By collaborating, there are potential benefits to be

gained in order to better protect the public health, safety and welfare. It will also recognize the value of involving a broader constituency as issues emerge and encourage other health care regulatory representatives to participate in relevant and pertinent issues. Ms. Juran also stated that the October newsletter was just recently disseminated. She highlighted that the July newsletter had an article referencing "red flags" that a pharmacist should consider when evaluating a suspicious prescription. On October 20<sup>th</sup>, Ms. Juran will be presenting at the Virginia Society of Health Systems Pharmacists Fall Seminar in Norfolk. Effective as of September 28, 2012, Pallavi Lee resigned as the pharmacy inspector for the Northern Virginia Region. The Enforcement Division has begun recruitment for this position. Ralph Orr, Program Manager for the PMP (Prescription Monitoring Program), is now the chairman for the PMP steering committee. In addition, the PMP Interconnect has currently 26 states that have committed with the NABP. Ten of those states are currently actively sharing data. New Mexico is the most current state to go live with the program but is only sharing data with Arizona at this time. They are to expand to other states later this month. Kentucky is hopefully in the process of becoming active in the near future. Ms. Juran also reported on the White House Subcommittee of Forensic Science meeting that she recently attended on behalf of the Virginia Forensic Science Board. The Office of the President is interested in establishing national standards in some fashion and invited certain states to attend the recent meeting to discuss how the states vary with respect to oversight for forensic science.

REPORT ON HEALTH  
PRACTITIONER  
MONITORING PROGRAM  
(HPMP):

Dr. Penelope Ziegler, Medical Director, VCU-Health Practitioner Monitoring Program (HPMP) and Peggy Wood, Program Manager, Health Practitioner Monitoring Program (HPMP), gave an overview of the program to the Board. Dr. Ziegler stated that the Board of Pharmacy was the third largest Board with participants. The most common diagnosis for the practitioners in the program is substance abuse which is at 90%. Data collected indicate that the physicians' substance of choice to abuse is alcohol, while nurses and pharmacists primarily abuse prescription drugs. Other diagnoses within the HPMP are psychiatric disorders and physical conditions. The HPMP evaluates the practitioner by assessing their condition and creates a treatment plan based off their diagnosis. The Virginia HPMP was established in 1997 by the General Assembly and was formerly known as the Health Practitioners Intervention Program (HPIP). The name of the program was changed in 2009 to the Health Practitioners Monitoring Program (HPMP). It is operated by Virginia Commonwealth University (VCU), Department of Psychology under memorandum of agreement with the Department of Health Professions. The program consists of staff and a medical director from VCU. HPMP monitors the treatment of the impaired licensee to determine if and when a recovered licensee may resume practice in the applicable profession and under what restrictions. Failure to comply with the monitoring may be cause for dismissal from the program. Dr. Ziegler explained that health care practitioners can be referred to the HPMP program by a board order, DHP staff (investigator), colleagues, peer assistance programs, physicians or therapists. The Board of

Pharmacy has the third largest group of participants, after the Boards of Nursing and Medicine. There are 36 pharmacy licensees in the program as of August 31, 2012. Admissions to the HPMP program since 2003 for the Board of Pharmacy have been a total of 160 practitioners. Dr. Zeigler stated that the pharmacists have a 60% positive outcome with completion of the program, while pharmacy technicians' success rate is less than 20%.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an update of ongoing regulatory processes. She stated that the emergency regulations related to implementation of continuous quality improvement (CQI) programs became effective October 1, 2012 and will be in place until September 30, 2013. A notice of intended regulatory action (NOIRA) for the replacement regulations for CQI has recently been published. Public comment on the NOIRA will be accepted from October 8, 2012 until November 7, 2012. Ms. Juran reminded the Board of its previous decision in 2011 to not impose a monetary penalty for noncompliance on this issue within the first 6 months of the emergency regulations becoming effective. As of April 1, 2013, a monetary penalty could be imposed if the Board establishes such monetary penalty at its next meeting.

Ms. Yeatts also reported that the proposed regulations for automated dispensing devices are currently at the Secretary's office. The regulatory amendments that address on-hold prescriptions are currently at the Governor's office, and the public comment period for the NOIRA regarding the number of continuous hours worked by pharmacists closes October 8, 2012.

- Adoption of proposed regulations for changes to run dry requirement for automated counting devices:

The Board discussed draft proposed regulatory amendments to Regulation 18VAC110-20-355, prepared by staff, for run-dry requirements for automated counting devices. Soumi Saha, Government Relations and Regulatory Affairs Coordinator for Kaiser Permanente addressed the Board concerning how the run-dry requirements affect their pharmacies. Ms. Saha explained that the drugs that were being dispensed by the automated counting devices were fast-moving and did not stay in the cells for extended periods of time. Mr. Kozera suggested that in section C5b of the draft proposed regulation that the phrase "with a record made of the run dry date," be added following the phrase "The bin has been "run dry".

MOTION:

**The Board voted 9-1 to adopt the proposed regulatory amendments of Regulation 18VAC110-20-355 regarding the run dry requirement for automated counting devices as amended by Mr. Kozera.  
(motion by Stelly, second by Allen)**

After further discussion, it was determined that the approved regulatory amendment to Regulation 18VAC110-20-355 did not adequately address the need to remove recalled drug product if the automated counting

device stored slow-moving drugs.

**MOTION:**

**The Board voted unanimously to reconsider and amend the prior motion regarding run-dry requirements for automated counting devices.**

**(motion by Allen, second by Adams)**

A recommendation was made to add language to section C5 "or if a recalled drug is known to remain in the bin" following the phrase "...in the last three months".

**MOTION:**

**The Board voted unanimously to adopt the proposed regulatory language, as amended in sections C5b and C5, of Regulation 18VAC110-20-355 regarding run dry requirements for automated counting devices.**

**(motion by Allen, second by Adams)**

**ADOPTION OF GUIDANCE DOCUMENT DISPENSING AUTHORIZED GENERICS:**

Ms. Juran indicated that staff has received calls from pharmacists requesting guidance as to whether a pharmacist may dispense an authorized generic for a prescription written for a Schedule II branded drug product or if a new prescription written for the authorized generic would be necessary. Because authorized generics are identical to the branded drug and are not recognized as a therapeutically equivalent drug product in FDA's Orange Book and Virginia's laws regarding substitution appear to only address substitution with a therapeutically equivalent drug product as identified in the Orange Book, it is unclear what actions the pharmacist must take. A draft guidance document prepared by staff was presented for the Board's consideration. The Board expressed concerns for how the patient would know that an authorized generic had been dispensed since the labeling requirement for the phrase "generic for" as listed in Regulation 18VAC110-20-330 would not apply.

**ACTION ITEM:**

**The Board requested staff to survey the other state boards of pharmacy to determine how they are addressing the issue of dispensing authorized generics and to report back at the December full board meeting for further consideration.**

**REQUEST TO OFFER COMMENT TO BOARD OF HEALTH PROFESSIONS REGARDING PHARMACIST SCOPE OF PRACTICE REVIEW:**

Dr. Elizabeth Carter, Executive Director for the Board of Health Professions, requested comments from the Board regarding the recent pharmacist scope of practice review. Dr. Carter stated that public comment was obtained from July 2012 to August 2012 for suggestions on how broadening a pharmacist's scope of practice can help improve patient care. She requested from the Board feedback regarding the possible expansion of a pharmacist's scope of practice. Tim Musselman, Executive Director for the Virginia Pharmacists Association, stated that they were drafting legislative language for the upcoming General Assembly Session to expand allowances for collaborative practice agreements to include a provision for pharmacists to initiate drug therapy. The physician would set perimeters for the pharmacist and any implementation of drug therapy would be post-diagnosis. The Board did not express any significant concerns for the possible expansion to

pharmacist's scope of practice as discussed.

Additionally, Dr. Carter distributed the survey conducted for pharmacy technicians. She requested that the Board submit any comments to Ms. Juran no later than October 12, 2012.

AMEND GUIDANCE  
DOCUMENT 110-36  
REGARDING USP  
STANDARDS:

Following the June board meeting, staff identified a conflict between the recordkeeping requirements in USP and Guidance Document 110-36. Additionally, the inspectors had expressed concerns for allowing certain records to be maintained off-site since it could impact the timely completion of the inspection report. The allowance to maintain certain records electronically appeared sufficient for addressing any storage concerns for records. The Board reviewed the draft amendments to Guidance Document 110-36, prepared by staff, regarding USP standards.

MOTION:

**The Board voted unanimously to approve the amendments, as presented, to Guidance Document 110-36 regarding USP standards.. (motion by Warriner, second by Allen)**

CONSIDERATION OF  
REQUEST FOR A MEMBER  
TO PARTICIPATE  
TELEPHONICALLY AT  
CERTAIN BOARD  
MEETINGS:

Staff had been approached by a member for guidance regarding whether a board member could participate via telephone at board meetings if inclement weather prevented travel. Counsel reviewed the statutory allowances with the Board and advised that the board should determine if it is comfortable with members participating via telephone in compliance with the law. Mr. Casway explained that as an appointed member it is advisable that members make every effort to attend in person barring emergency circumstances or sickness. The Board was supportive of allowing a member to participate via telephone under emergency circumstances only in compliance with 2.2-3708.1.

GUIDANCE FROM COUNSEL  
REGARDING LEADERSHIP  
ROLES IN PROFESSIONAL  
ASSOCIATION AND  
APPEARANCES OF  
POSSIBLE CONFLICTS OF  
INTEREST:

Mr. Casway discussed the possible appearance of conflict of interest when a Board member is serving in leadership roles in professional associations. Mr. Casway stated that the member needs to determine if he can serve on the Board and the association without any inappropriate conflicts, and he may want to reconsider before agreeing to become a member of any legislative or regulatory committee of a professional association. Mr. Casway also reviewed with the Board prohibitions to discuss Board issues outside of properly noticed meetings.

REVIEW OF DRAFT BYLAWS  
OF NABP DISTRICT 2:

Ms. Juran presented the Board with the draft bylaws for NAPB District 2 and asked the members to review the information and submit feedback. Also, Ms. Juran stated that if any member wishes to be on the Board of Directors for the NABP District 2 to let her know. All comments needs to be submitted by October 12, 2012.

SCHEDULING OF 2013  
DATES FOR FULL BOARD  
MEETINGS:

The Board reviewed suggested dates for the upcoming 2013 full board meetings. The tentative dates selected were March 12, 2012, June 18, 2013, September 10, 2013 and December 12, 2013. Mr. Kozera also announced the appointed members to the standing committees for the year 2013.

CONSIDERATION OF  
CONSENT ORDERS:

**MOTION FOR 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 a Consent Order. Additionally, it was moved that Caroline Juran, 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 deliberation. (motion by Allen, second by Warriner)

**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 Allen, second by Warriner)

**MOTION:**

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of James T. Marrow, Pharmacist. (motion by Warriner, second by Stelly)

**ADJOURN:**

With all business concluded, the meeting adjourned at 4:10pm.

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David C. Kozera, Board Chairman

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, October 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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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:

Ellen B. Shinaberry, Committee Member

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director

DAVID J. FRANZA  
Registration No. 0230 010812

David J. Franza did not appear, however, the committee chose to proceed in his absence as the notice was mailed to Mr. Franza's legal address of record. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 26, 2012, Notice.

Shevaun Roukous, DHP Adjudication Specialist, was present as staff for this conference.

Closed Meeting:

Upon a motion by Ms. Shinaberry, 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 David J. Franza. 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. Shinaberry, 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 revoke his pharmacy technician registration due to drug diversion.

BESSIE N. KOLB  
Registration No. 0230 004757

Bessie N. Kolb appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 26, 2012, Notice.

Ms. Roukous was present as staff for this conference.

Closed Meeting:

Upon a motion by Ms. Shinaberry, 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 Bessie N. Kolb. 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. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Kolb a Consent Order for the indefinite suspension of her pharmacy technician registration for a period not less than one year due to drug diversion.

MOSLEM ESKANDARI  
License No. 0202 011379

Moslem Eskandari appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 26, 2012, Notice.

Mykl Egan, DHP Adjudication Specialist, was present as staff for this conference.

Closed Meeting:

Upon a motion by Ms. Shinaberry, 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 Moslem Eskandari. 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. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Eskandari an Order imposing a reprimand and placing his pharmacist license under certain terms and conditions.

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

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ADJOURN:

With all business concluded, the meeting  
adjourned at 3:05 p.m.

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David C. Kozera  
Committee 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

Tuesday, November 6, 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 9:30 a.m.

PRESIDING:

Jody H. Allen, Committee Chair

MEMBERS PRESENT:

Pratt P. Stelly, Committee Member

STAFF PRESENT:

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

PATRICIA S. MUNDY  
License No. 0202 006657

Patricia S. Mundy appeared with Hunter W. Jamerson, her attorney, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 15, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Patricia S. Mundy. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee closed this case as undetermined.

JESSICA L. MALIN  
Registration No. 0230 004410

Jessica L. Malin did not appear at the informal conference. The committee chose to proceed in her absence as the notice was mailed to Ms. Malin's legal address of record. The committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 15, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jessica L. Malin. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Malin a Consent Order for the indefinite suspension of her pharmacy technician registration for a period of not less than two years.

LAWRENCE D. BARLOW  
License No. 0202-005311

Lawrence D. Barlow appeared with Pamela Baker, a pharmacy technician and his attorneys, Franklin A. Swartz and Jeffrey Swartz, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 7, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose

of deliberation to reach a decision in the matter of Lawrence D. Barlow. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Barlow an Order with a reprimand and terms and conditions.

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

STEPHEN A. BROWN  
Registration No. 0230 010910

Stephen A. Brown did not appear at the informal conference. The committee chose to proceed in his absence as the notice was mailed to Mr. Brown's legal address of record. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 17, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of

Stephen A. Brown. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Brown an Order to impose a monetary penalty and require him to obtain ten (10) additional hours of continuing pharmacy education.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Brown, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Brown 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 5:30 p.m.

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Jody H. Allen  
Committee Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

---

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Tuesday, November 6, 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 5:30 p.m.

PRESIDING:

Jody H. Allen, Committee Chair

MEMBERS PRESENT:

Pratt P. Stelly, Committee Member

STAFF PRESENT:

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

FREE CLINIC OF FRANKLIN  
COUNTY  
Permit No. 0201-003124

Lois McDonald, Executive Director, and Duane C. Lenart, Pharmacist-in-Charge, appeared on behalf of Free Clinic of Franklin County, to review allegations that Free Clinic of Franklin County may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 26, 2012, Notice.

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee closed this case as no violations and requested that Ms. Reiniers-Day send a letter to the Free Clinic of Franklin County that approves the waiver request for 18 VAC 110-20-190 (C) retroactive to June 30, 2010.

ADJOURN:

With all business concluded, the meeting adjourned at 6:00 p.m.

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Jody H. Allen  
Committee Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

---

Date

(DRAFT/NOT APPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF TELEPHONE CONFERENCE CALL

Tuesday, November 20, 2012

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

TIME & PURPOSE:

Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 10:00 a.m., on November 20, 2012, to consider the summary suspension of the registrations of Teresa C. Hayes, Ryan W. Wright and Jennifer M. Craighead to practice as pharmacy technicians in the Commonwealth of Virginia.

PRESIDING:

David C. Kozera, Chair

MEMBERS PRESENT:

R. Crady Adams  
Dinny Li  
Empsy Munden  
Ellen B. Shinaberry  
Rebecca Thornbury

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director  
Caroline D. Juran, Executive Director  
Howard Casway, Senior Assistant Attorney General  
Mykl Egan, DHP Adjudication Specialist  
Shevaun Roukous, DHP Adjudication Specialist  
Corie E. Tillman Wolf, Assistant Attorney General  
Wayne T. Halbleib, Senior Assistant Attorney General

PUBLIC PRESENT:

Leslie Williams, Corporate Wellness Health Protection

POLL OF MEMBERS:

The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

TERESA C. HAYES  
Registration No. 0230-019617

Corie E. Tillman Wolf presented a summary of the evidence in this case.

Upon a motion by Mr. Adams and duly seconded by Ms. Shinaberry, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Teresa C. Hayes poses a substantial danger to the public; and therefore, the registration of Ms Hayes shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered for the indefinite suspension of her registration in lieu of a formal hearing.

RYAN W. WRIGHT  
Registration No. 0230-007018

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Mr. Adams and duly seconded by Ms. Munden, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Ryan W. Wright poses a substantial danger to the public; and therefore, the registration of Mr. Wright shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered for the indefinite suspension of his registration for not less than two (2) years in lieu of a formal hearing.

JENNIFER M. CRAIGHEAD  
Registration No. 0230-010622

Mr. Halbleib presented a summary of the evidence in this case.

Upon a motion by Ms. Shinaberry and duly seconded by Ms. Li, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Jennifer M. Craighead poses a substantial danger to the public; and therefore, the registration of Ms. Craighead shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered for the indefinite suspension of his registration for not less than two (2) years in lieu of a formal hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 11:04 a.m.

\_\_\_\_\_  
David C. Kozera, Chair

\_\_\_\_\_  
Cathy M. Reiniers-Day  
Deputy Executive Director

\_\_\_\_\_  
Date

19

**Agenda Item: Adoption of Proposed Regulations**

**Replacement of Emergency Regulations for Continuous Quality Improvement Programs**

**Included in your agenda package are:**

A copy of Emergency Regulations in effect from 10/1/12 to 9/30/13

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

A copy of comment on the NOIRA

**Staff note:**

There was a comment period on the NOIRA from 10/8/12 to 11/7/12

**Board action:**

Consideration of the comment on NOIRA and emergency regulations

Adoption of proposed amendments to replace emergency regulations

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;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

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

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

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

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

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

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

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

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

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign

Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

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

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

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

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

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

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

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

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

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

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

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

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

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

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

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

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

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

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

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

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

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

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use

properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

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

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

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).
2. "Room temperature" means the temperature prevailing in a working area.
3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.
4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).
5. "Excessive heat" means any temperature above 40°C (104°F).
6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

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

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

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

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

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

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

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

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

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

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

1. Notification requirements:

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

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

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

2. Documentation and record requirements; remedial action:

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

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 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.

Date / Time filed with the Register of Regulations	VA.R. Document Number: R ____ - ____
	Virginia Register Publication Information Date:

## Transmittal Sheet: Notice of Intended Regulatory Action

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

Promulgating Board: Board of Pharmacy

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

Chapters Affected:

18 vac 110 - 20: Virginia Board of Pharmacy Regulations

Action Title: Continuous quality improvement programs

Agency Summary: The purpose of the proposed action is summarized as follows:  
  
As mandated by Chapter 124 of the 2011 General Assembly, the Board has specified the elements of a continuous quality improvement program in a pharmacy in Emergency Regulations. The Board is seeking comment on its Intended Regulatory Action to replace the emergency regulations with permanent regulations. The regulation may be viewed at: [www.townhall.virginia.gov](http://www.townhall.virginia.gov).

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

Federal:

Is a public hearing planned for the proposed stage? Yes

Public comments may be submitted until 5:00 p.m. on November 7, 2012

Agency Contact: Caroline Juran, RPh  
Executive Director  
(804)367-4416  
(804)527-4472  
caroline.juran@dhp.virginia.gov

Contact Address: Department of Health Professions  
9960 Mayland Drive  
Suite 300  
Richmond, VA23233-1463

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

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November 7, 2012

Ms. Elaine Yeatts  
Department of Health Professions  
9960 Mayland Drive, Suite 300  
Richmond, VA 23233

*Via email*

Dear Ms. Yeatts:

On behalf of 198 member companies operating in the state of Virginia, the National Association of Chain Drug Stores (NACDS) thanks the Virginia Board of Pharmacy (“the Board”) for considering our comments on the Notice of Intended Regulatory Action (NOIRA) and emergency regulation to institute a Continuous Quality Improvement (CQI) program for all pharmacies.

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In Virginia, there are about 1,251 pharmacies, of which 1,102 are chain pharmacies. Those chain companies employ approximately 97,123 Virginia residents, including 4,651 pharmacists, and pay about \$692 million in state taxes annually. As a group, Virginia chain and independent pharmacies employ approximately 97,924 full- and part-time workers including about 4,925 pharmacists, paying almost \$696 million in state taxes annually.

**Consistency with Other State CQI Programs**

Chain pharmacy is committed to patient safety and continuously improving the quality of the pharmacy services we provide. However, we do believe that any CQI program should mirror those programs that are currently being used by other states. As chain pharmacies operate in multiple states, compliance with numerous states’ CQI programs is more feasible when similar programs are used across multiple states. Variations among state programs make compliance challenging and may have a financial impact for chain pharmacies operating in multiple states where there is a need to adopt multiple state programs.

In addition, due to the programming differences in CQI programs, all pharmacies may not be able to accommodate the changes needed to accurately report to the CQI program by the April 1, 2013 effective date. Some pharmacies will have to undergo extensive programming changes as some pharmacies are already using other CQI programs as required by other states and will need to adjust to meet the requirements that are specified

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www.nacds.org

in the proposed rules. Therefore, we ask the Board to extend the compliance date beyond March 31 to allow pharmacies adequate time to make the needed changes in order to comply effectively with the proposed requirements.

### **Need for Legal Protections for Pharmacies**

More than ten years ago, the Institute of Medicine (IOM) focused national attention on the need to reduce preventable medical errors through quality improvement programs. The IOM has recognized that for any quality improvement program to be successful, health care providers who evaluate errors must feel safe to do their assessment. This requires creation of a confidential, non-punitive environment with all of the needed legal protections. These legal protections must assure that the documents, records, proceedings, information and participants in the programs remain confidential, and are protected from any means of legal discovery or use as evidence in civil lawsuits or administrative proceeding. Errors are mistakes, not intentional acts, and should be treated with a non-punitive approach that uses the lessons learned from the error to prevent future errors. Successful patient safety programs depend on encouraging health care providers to voluntarily discuss and learn from their mistakes. Establishing adequate legal protections for the documents, records, proceedings and participants in pharmacy CQI programs are needed as a prerequisite before requiring these beneficial programs so that health care providers feel safe to speak candidly while participating in these programs.

### **Need for Peer Review**

As written, the rule does not afford pharmacists the same spectrum of protections that are given to other healthcare providers in the Section 54.1-2516 of the Annotated Code of Virginia. By comparison, the rule does not establish the same level of peer review protections for the proposed pharmacy CQI programs as the statute ensures for other healthcare providers who are protected from discovery if discussed in a licensing board proceeding. Therefore, we ask that pharmacy personnel be provided the same protections that are given to other healthcare professionals. As explained above, these protections are *imperative* for any pharmacy CQI program to effectively serve its purpose.

### **Suggested Language Changes to Proposed Rule**

In addition to the abovementioned concerns NACDS and its members would like to suggest the following changes to the proposed language:

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

Dispensing Error: We believe that any errors that have been identified and corrected prior to leaving the pharmacy should not be considered a dispensing error and should not be included as a part of the proposed definition. Therefore, we suggest that the proposed definition be revised as follows:

*One or more of the following discovered after the final verification by the pharmacist and receipt by the patient or patients caregiver.*

#### **18VAC110-20-418. Continuous Quality Improvement programs**

Subsection (B)(2)(b) of the proposed language requires the pharmacist-in-charge or a designee to perform a systematic, ongoing analysis as defined in the definitions section of the proposed rule and requires the analysis to be performed within 30 days of identifying the error. However, the definitions section of the proposed rule does not define systematic ongoing analysis nor does it provide a citation of where this may already be defined in other state regulation. Therefore, we ask the state to specifically define this term as intended in the definitions section for ease of reference.

Subsection (B)(2)(e) requires pharmacies to maintain a separate record that is available for inspection to ensure compliance. We believe that because the proposed rule will require a systematic ongoing analysis on individual errors within 30 days, an aggregate record that is suitable for inspection should be created every 90 days as these errors are already being reported on the monthly basis. Not only will this eliminate the burden on pharmacies but it will also align the CQI program with the requirements of other state programs that are already in use.

Lastly, Section A and subsection (B)(2)(e)(4) require pharmacies to record a zero report when no dispensing errors have occurred within the past 30 days. NACDS and its members oppose any requirements for pharmacies to have to record or submit zero reports to a CQI or Patient Safety Organization system when no errors have actually occurred. In addition, we oppose any rules that would impose penalties on pharmacies for not reporting to the system when there are no errors to report. While we understand and fully support the purpose of the CQI system, we believe that it is burdensome, time consuming and unnecessary for pharmacies to use this system to report when no incidents or patient injury has occurred. We aren't aware of any other state that requires zero reporting. Therefore, we ask that this language be removed from the proposed rules.

NACDS and its members appreciate the opportunity to submit comments on the proposed rules and we look forward to working with the Board on these important issues. We applaud the Board's efforts to ensure patient safety and we fully support efforts that are aimed to continuously improve the quality of care patients receive.

Please do not hesitate to contact me if you have any questions or concerns about our comments.

Sincerely,



Jill K. McCormack, Regional Director  
State Government Affairs  
[jmccormack@nacds.org](mailto:jmccormack@nacds.org)  
(717) 592-8977

**Agenda Item: Adoption of Proposed Regulations for Working Conditions for Pharmacists**

**Included in your agenda package are:**

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

A copy of the Agency Background Document

A copy of comments on the NOIRA

**Staff note:**

There was a comment period on the NOIRA from 9/10/12 to 10/10/12

**Board action:**

Consideration of the comment on NOIRA

Action on proposed amendments

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## Notices of Intended Regulatory Action

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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 address a petition for rulemaking requesting amendments to specify a limitation of excessive hours of work without any breaks for pharmacists. The regulation is necessary to prevent, to the extent possible, prescription errors due to fatigue and lack of concentration by pharmacists in the important task of assuring the accuracy and integrity of controlled substances. The action is the result of a petition for rulemaking by a pharmacist and was strongly supported in comment on the petition.

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

Statutory Authority: § 54.1-2400 and Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54 of the Code of Virginia.

Public Comment Deadline: October 10, 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.

VA.R. Doc. No. R12-19 (Project 3337); Filed August 8, 2012, 4:36 p.m.

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### TITLE 22. SOCIAL SERVICES

#### STATE BOARD OF SOCIAL SERVICES

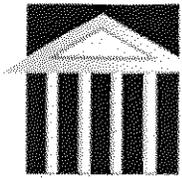
##### Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Social Services has WITHDRAWN the Notice of Intended Regulatory Action to repeal **22VAC15-30, Standards for Licensed Child Day Centers** and promulgate **22VAC15-31, Standards for Licensed Child Day Centers**, which was published in 25:26 VA.R. 4468 August 31, 2009. Enactments 75 through 78 of the 2012 Acts of Assembly abolished the Child Day-Care Council and transferred its powers and duties to the State Board of Social Services effective July 1, 2012. This regulatory action will be promulgated by the State Board of Social Services under a new Notice of Intended Regulatory Action.

Agency Contact: Debra O'Neill, Children's Program Licensing Consultant, Department of Social Services, Division of Licensing Programs, 801 East Main Street,

Richmond, VA 23219, telephone (804) 726-7648, FAX (804) 726-7132, TTY (800) 828-1120, or email [debra.oneill@dss.virginia.gov](mailto:debra.oneill@dss.virginia.gov).

VA.R. Doc. No. R09-2086; Filed August 20, 2009, 9:51 a.m.



Virginia  
Regulatory  
Town Hall

[townhall.virginia.gov](http://townhall.virginia.gov)

## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18VAC110-20
<b>Regulation title</b>	Regulations Governing the Practice of Pharmacy
<b>Action title</b>	Safe working conditions
<b>Date this document prepared</b>	June 19, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

The purpose of the planned regulatory action is to address a petition for rulemaking requesting amendments that will specify a limitation of excessive hours of work without any breaks for pharmacists. Regulation is necessary to prevent, to the extent possible, prescription errors due to fatigue and lack of concentration by pharmacists in the important task of assuring the accuracy and integrity of controlled substances. The action is the result of a petition for rulemaking by a pharmacist and was strongly supported in comment on the petition.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

**§ 54.1-2400 -General powers and duties of health regulatory boards**

*The general powers and duties of health regulatory boards shall be:*

...

6. *To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

The specific statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including regulations pertaining to the safety and integrity of drugs is found in § 54.1-3307 of the Code of Virginia.

**§ 54.1-3307. Specific powers and duties of Board.**

*The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:*

- 1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.*
- 2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.*
- 3. Controls and safeguards against diversion of drugs or devices.*
- 4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.*
- 5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.*
- 6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.*
- 7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.*

8. *Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.*

9. *Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.*

## Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

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While the Board is not aware of studies documenting the error rate for pharmacists working extensive hours continuously, every pharmacist who spoke to the Board and members of the Board are aware that fatigue and lack of concentration can and do lead to errors in filling, reviewing for drug interactions and dispensing prescription drugs. For other professions who rely on mental acuity, such as airline pilots, there is a limitation on continuous hours of work. Therefore, the Board believes it is essential for public health and safety that some reasonable limitation be instituted on continuous hours of work without any breaks for pharmacists in Virginia.

The primary issue that must be resolved in the development of regulations is the extent to which an exception to the 12-hour rule will be allowed. All agreed that there must be an exception for an emergency situation in order to keep a pharmacist on duty, but some want a pharmacist to be able to opt out of the 12-hour rule. Whether that would defeat the purpose of the regulatory restriction is an issue for further discussion by the Board.

## Substance

*Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

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The Board has not determined the specific language to be proposed, but the Regulation Committee recommended a limitation of 12 hours for a pharmacist to be on duty dispensing prescriptions and a requirement that there be a 30 minute uninterrupted break for at least 6 hours of work plus an additional 15 minute break thereafter. There may be a limitation of 12 hours within a 24-hour period or no more than 60 hours over a five-day work period. The Board would include an exception for emergencies (i.e.; when a replacement pharmacist does not report for work) or for imminent patient need (i.e.; when the pharmacist must complete an urgent prescription).

There are similar provisions in neighboring states, and the Board has requested information be obtained about requirements in all states. In North Carolina, a permit holder cannot require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than 6 continuous hours per work day must be allowed during that time period to take a 30-minute meal break and one additional 15-minute break.

In West Virginia, no pharmacist can work more than 12 hours within a 24-hour period without at least 8 hours off duty within the 24 hours, except in a case of emergency when a pharmacist calls off work. The pharmacist on duty may work more than 12 hours in order to keep the pharmacy open. The pharmacists must document and make available to the Board the date and the amount of time worked beyond the 12 hour limit along with the reason for the extended work hours. Other states with similar regulations include: AL, FL, MN, MA, MO, NJ, OK, TN; and Texas has similar requirements in a policy statement.

The Pharmacy Alliance, a national organization of pharmacists dedicated to better working conditions, strongly supports the limitation on work hours and mandatory breaks as one of a number of issues that it believes constitute workplace safety violations. The Board has taken the comments and requests of the Alliance under advisement but did not expand the specific focus of the petition to include other workplace issues.

### Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

Since there are no specific requirements in regulation for safe working conditions for pharmacists, the only alternative is the promulgation of an amendment through the regulatory process.

### Public participation

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail to Elaine Yeatts at 9960 Mayland Drive, Henrico, VA 23233; by fax to (804) 527-4434 or by email to [elaine.yeatts@dhp.virginia.gov](mailto:elaine.yeatts@dhp.virginia.gov).

Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi>). Both oral and written comments may be submitted at that time.

The Board will utilize the participatory approach as members of the Regulation Committee has reviewed the petition for rulemaking and heard significant comment from the public about working conditions in pharmacies. Public participation was encouraged and evident in discussions of the issues during the Committee and Board meetings at which this item was on the agenda. Public comment was encouraged as the Board considers necessary and appropriate changes to the regulation.

### Family impact

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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There is no impact of the proposed regulatory action on the institution of the family.

# Comments on Working Conditions NOIRA Va. Regulatory Townhall

9/16/12 10:40 am

**Commenter:** David J Halla Owner Grays Pharmacy \*

## **response to long working hours**

Long hours have been a way of life for the past 40 years. There was a period of time where Pharmacies (both chains and independents) made enough gross margin to support a staff large enough to handle the work load adequately. I have owned Grays for the past 24 years. During that time "I had a dream" that someday I would be in a position to have a full time Pharmacist and take a little pressure off of me. Then the insurance companies and Government took control, not the Boards of Pharmacy, and reduced the gross margin to a point that relief is not on it's way(if I'm experiencing this, so aren't the chains).

So here we go again. More rules and regulations on how we are to take care of patients because some still have not got the message. We're having to do more with less in order to survive!

If the Boards of Pharmacy want to survive as an vital part of the practice of Pharmacy then take control and make it a little easier on us rather than more difficult thru more regulations. Suggestioin: Board members should only be Pharmacists that are in the trenches each day-we know what's going on and know how to fix most things!

9/17/12 9:01 am

**Commenter:** Bronwyn M Burnham \*

## **working conditions for pharmacists**

I support this proposed change to the Regulations Governing the Practice of Pharmacy in Virginia to establish a limitation on the number of hours a pharmacist can work continuously to 12, and a requirement for breaks during a 12 hour shift. As a retail pharmacist, I work long days ,standing on my feet, without a break. The retail environment allows the ptaient access to the pharmacist 12 to 14 hours a day which does not allow too many opportunities to take an appropriate break. This proposal would allow a pharmacist to reduce fatigue and improve concentration while improving overall work performance.

10/6/12 12:54 pm

**Commenter:** F W RICHARDS, JR \*

## **WORKING CONDITIONS FOR PHARMACISTS**

I DO NOT WANT THE BOARD OF PHARMACY SETTING THE NUMBER OF HOURS A PHARMACIST MAY WORK OR THE NUMBER OF BREAKS REQUIRED. I DO WANT THE BOARD TO STATE THE NUMBER OF TECHNICIANS ONE PHARMACIST MAY SUPERVISE BECAUSE I THINK BIG BUSINESS WILL TRY TO SQUEEZE BLOOD OUT OF A TURNIP IF POSSIBLE. I BELIEVE THOSE LIMITS HAVE ALREADY BEEN SET. AS AN INDEPENDENT PHARMACY OWNER, I WEAR MANY HATS DURING THE DAY AND DO NOT NEED MORE RULES AND REGULATIONS TO COMPLICATE MY ALREADY OVER-REGULATED PRACTICE. LEAVE IT UP TO THE INDIVIDUAL TO DECIDE WHAT HE/SHE CAN SAFELY FILL DURING THE DAY. THERE SHOULD BE A MEANS AVAILABLE FOR AN EMPLOYEE PHARMACIST OR TECHNICIAN TO CONTACT THE BOARD ANONYMOUSLY IF WORKING CONDITIONS ARE ABUSIVE, DANGEROUS, OR RECKLESS AND COULD CONTRIBUTE TO MISTAKES OR HARM TO PATIENTS. THE BOARD COULD THEN INSPECT THE SITUATION AND TAKE APPROPRIATE ACTION BASED ON EXISTING REGULATIONS.

10/7/12 8:54 am

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**Commenter:** Myra Clements, retired RPh \*

### **Break time for pharmacists**

When I was working, mostly I worked in a specialty pharmacy where I was the only pharmacist assigned to the pharmacy for the 8.5hrs that it was open. I did not take a break either as a 15 minute break or a lunch break due to orders that would come if I was gone. My tech could fill orders but I had to check them so being away for more than 5 minutes or so was difficult for me. I ate lunch in the pharmacy at my desk which was away from the sterile production, but on a very busy day it would have been nice to have a break just to rest. I never had that chance for approximately 18 years in which I worked in this pharmacy. To get paid for the time that I worked through lunch, I had to submit a form each week stating that I had not had a break during the day. I was paid for the time that I did not take a lunch break only if I submitted the form mentioned previously. Pharmacists need a break. If the time for their break time is posted, the public would get used to the off time and not come during that short time span. In the hospital setting, several rotating pharmacists who had been trained in the speciality areas could cover for a meal break. Standing on your feet for 8 hours or more daily is hard on the body as well as mentally challenging. I would like to see a provision made where pharmacists would be granted time off for a lunch or dinner break.

10/9/12 10:48 am

**Commenter:** Ken Lenviel, CVS/Pharmacy \*

### **Pharmacist Lunch break and Shift Limits**

I am a retail pharmacist for a chain pharmacy in Virginia. I am on my feet for 13 hours a shift and really have a difficult time getting a lunch break with the ever increasing volume our stores are seeing. It would be nice to have a requirement that chain pharmacies set a designated 30 minute break so that we can get our eyes away from the computer for a few minutes.

I also support the limit to a 12 hour workday, as 13 hours is exhaustive to be standing on my feet. We also have a responsibility to accurately dispense medications to patients and I definitely see fatigue playing a role in dispensing errors at pharmacies around the state. This change would improve the work environment for pharmacists by allowing us to be more alert and focused.

10/9/12 10:47 pm

**Commenter:** H. Otto Wachsmann, Jr. Stony Creek Pharmacy \*

### **Pharmacy Work Conditions**

As someone who has worked in community pharmacy for approximately 20 of my 26 years as a licensed pharmacist, I regret that I seem to be witnessing the de-professionalization of pharmacy. There was once a time when the pharmacist in charge was afforded the privilege of doing just that, being in charge of the pharmacy department. I recall there were certain other regulations in place to prevent non-pharmacist management from making that determination. Sadly to say we have become a profession of employee pharmacists.

That being said, I believe it inappropriate for the BOP to regulate mandatory breaks in a one size, fits all kind of way for all pharmacies. In my pharmacy, we are only open for nine hours at a time. We are not a high volume pharmacy filling 400 prescriptions a day. We run at a fairly even pace most days and actually less busy than in years past as mandatory mail order or mailorder pharmacies that "steal" our patients and preferred Part D plans are eroding our business. We try very hard to meet the needs of our existing patients in a timely fashion as it's our greatest strength as the next nearest pharmacy is over twenty miles away. Quite honestly, if I am forced to step away from the counter for thirty minutes for a mandatory lunch break, I am more concerned I will be likely to allow an error to pass as I attempt to catch up on the prescriptions brought in by patients on their lunch breaks which have been dumped out by the doctor's office for their lunch break. You can't predict pharmacy, patients don't make appointments. When I think we're not going to be busy, we are and visa versa.

Otto Wachsmann

I believe what will have a bigger impact on reducing errors in my relatively low volume pharmacy is for the BOP to look into fixing the "noise" generated by false PBM DUR messages that are sent. Optima Health for example, sends DUR messages for things like Max Day of 3 per day when you are billing for 30 tabs as a 30 day supply. It is extremely frustrating to receive (and pay for the privilege of receiving) e-scripts at my pharmacy meant for Stoney Creek Pharmacy in Nellysford by UVA residents who do not provide their NPI number and give the UVA outpatient pharmacy as their office telephone. You look them up in the NPI directory and get the phone number for the School's administrative person who registered their NPI number. There is no way to contact the prescriber. Manufacturer coupon cards and third party cards with incomplete and wrong information with unreadable 4 point font numbers on them create a lot of wasted effort and frustration. If the BOP could create some regulations to eliminate or reduce these unnecessary distractions that kill workflow, we will have a lot more time to talk with our patients, check for errors and allow us all a better quality in the workplace. Community pharmacy is far too focused on trivial things right now that don't do anything that adds to patient care as much as making sure they meet the things that an insurance audit is likely to charge them back for such as calculating 18 drops per ml in an ophthalmic preparation instead of 21.5 drops per ml. Please help us by allowing us to focus back on pharmacy by correcting the things generated by outside forces which are bad for pharmacy. We have worked hard to be professionals. Please allow us to determine the best way for us to practice in our particular environment. If a licensee believes it is unsafe, allow them to make a complaint with the BOP and have it handled on a case by case basis.

10/9/12 11:29 pm

**Commenter:** Amber Darr, Leesburg Pharmacy \*

#### **Working Conditions for Pharmacists**

I agree with the proposed regulation of limiting work shifts for pharmacists. In addition, I agree to the mandatory requirement that employers provide pharmacists a 30 minute break for a 6 hour work period with an additional 15 minute break if needed during a longer shift. It is about time that the pharmacy profession joins the rest of the working population by giving pharmacists the break they need to stay fresh and minimize errors. It has been far too long that employers have been allowed to force pharmacists to work long hours without a scheduled break. It would be a complete disservice to all pharmacists as well as the patients they serve if this does not pass.

Thank you,

Amber Y. Darr, PharmD

10/10/12 6:54 am

**Commenter:** Lori Burgess, PharmD Marion Family Pharmacy \*

#### **Lunch break**

As a retail pharmacist for 10 years, I would cherish a 30 minute lunch break. Fortunately, I have a great work environment, but some of my colleagues work in stressful situations and need a break! I am 100% for this. And also for the limiting the work day to 12 hours. Thanks!

10/10/12 7:32 am

**Commenter:** John P. Crowder \*

#### **Hours worked, regulations:**

Having worked for various chains, Peoples Drug/CVS, Drug Fair/Rite Aid, Kmart, most of those job descriptions called for generally working 12 hour shifts. This in turn allowed the pharmacist in many cases to work 3 days one week and 4 days the following week, a very desirable situation for many people. It also allowed the chain to staff stores with fewer people by working 3 people with extra shifts they were able to staff 2 stores, rather than 1&1/2, also saving payroll dollars on benefits. About 11 years ago I decided to open my

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own independently owned drug store. I scheduled my hours to be open 10 hours a day monday thru friday and 5 hours a day on Saturdays and closed on Sundays. I felt this hourly arrangement was about the maximum that I could personally could work "behind the counter", rather than a moral/ religious issue. I worked in this fashion for 18 months before I was financially able to employ relief pharmacists to lighten the work burden. I want to emphasize that there are many issues that involve workplace stress and accuracy beyond the actual hours on the clock. One of the larger issues is ancillary staffing(technicians/clerks), their quality, skill sets, productivity and their relationship with the pharmacy and pharmacist. The new licensure requirements have had only a modest improvement, primarily because often these newly licensed employees now have considerable leverage over the pharmacist with regard to the nature of their work responsibilities. Secondly is work load and distractions intrinsic to the actual work environment. We have for years increased access to the pharmacist by both phone, computer(e-mail, ques), and diminishing physical barriers. While this has been successful in raising the profile of the practicing pharmacist, the work load (ie prescriptions filled per hour)has skyrocketed, at the same time that reimbursement has plummeted. Ideas of differing revenue streams, such as vaccinations, MTM, and counseling offer hope of a changing nature of practice, the reality is that with the diminished ability of the public to pay for services through private and public insurance there is little hope that these secondary revenue streams will maintain their current profitability. Additional to the basic process of filling prescriptions is the new emphasis for detail, documentation and judgement that now accompanies the filling process. This documentation and judgement requirements decreases the value of pharmacy technicians, as there are no courses to prepare technicians for this duty. At times I feel as if the Board is in a race with other Boards to see who can out-regulate each other, and at the same time allowing PBM's and Mega-chains to de-facto set all the rules(PLEASE DON'T). I requested to transfer a prescription recently from CVS and I noticed that there was no doctor listed on the prescription bottle. When I called and asked for the information and transfer, I was told that "when the robot fills the prescription sometimes that information is cut off"!!!! Lets not lose sight of the first responsibility, accurately filling prescriptions. Additional issue; can the Board of Pharmacy and the Board of Medicine get together and define parameters for pain management. How about- if a pain management practitioner is prescribing large doses of controlled substances require the patient to undergo periodic blood level studies, to diminish the ability to "sell on the street" their prescriptions.

Thank you for your consideration

John P. Crowder III



**Submitted via E-Mail**

October 10, 2012

Ms. Elaine Yeatts  
Virginia Board of Pharmacy  
9960 Mayland Drive  
Henrico, VA 23233

**RE: Virginia Notice of Intended Regulatory Action: Pharmacists Work Hours**

Dear Ms. Yeatts:

On behalf of our 19 member companies operating in the state of Virginia, we appreciate the opportunity to comment on the Notice of Intended Regulatory Action to promulgate draft regulations governing pharmacists work hours and break requirements.

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In Virginia, there are about 1,251 pharmacies, of which 1,102 are chain pharmacies. Those chain companies employ approximately 97,123 Virginia residents, including 4,651 pharmacists, and pay about \$692 million in state taxes annually. As a group, Virginia chain and independent pharmacies employ approximately 97,924 full- and part-time workers including about 4,925 pharmacists, paying almost \$696 million in state taxes annually.

Chain pharmacy is committed to providing quality care to patients, and to promoting a safe work environment in the pharmacy to accomplish this aim. We share the Board of Pharmacy’s commitment to promoting patient safety. In today’s reformed health care system, pharmacists face increasing pressure to deliver high quality health care services to a greater number of patients. In light of the increased demands on pharmacists’ time, we encourage the Board to focus on rules that will enable pharmacies and pharmacist to utilize innovative practices to meet growing patient demand, rather than rules that would impose arbitrary requirements on pharmacist work hours.

As the state works to draft regulations that would govern pharmacists work hours, we urge the Board to take into consideration that every pharmacy environment is unique with many interdependent factors such as teamwork, technology, practice environment and relationships with local physicians and other practitioners. Pharmacy management needs to have the flexibility to evaluate the needs of each pharmacy and determine the optimal number of pharmacists, pharmacy technicians, and other support staff needed in a particular pharmacy to efficiently fill prescriptions. Mandating how many hours a

pharmacist may work or mandating a certain time or length for breaks may not work in all environments and may not be desirable for the pharmacist. Therefore, we ask that the proposed regulations are drafted as permissive to allow pharmacists the option to set his and her schedule within the scope of the work day so that it is not disruptive to patient care.

Community pharmacies are the face of neighborhood healthcare. The innovative programs of chain pharmacies deliver unsurpassed value - improving health and wellness and reducing healthcare costs. We see pharmacists as valuable healthcare professionals that provide more services than dispensing prescriptions. Through face-to-face counseling, the pharmacist-patient relationship helps people take medications correctly. This improved medication adherence means a higher quality of life, and the prevention of costly treatments. On a daily basis, community pharmacists provide other innovative and preventive services such as vaccinations, health education, screenings and disease management which are reliable and readily accessible to all patients. The role of pharmacists in providing these services has become more important in reducing health care costs. Therefore, we believe that flexibility in work schedules is essential in order to ensure patient access to all the services that community pharmacists provide.

Thank you for the opportunity to comment on this very important issue. We look forward to continuing to work with you as you draft the proposed regulations.

Please don't hesitate to contact me directly to further information or assistance on this or any other issue involving chain pharmacy.

Sincerely,



Jill McCormack, Regional Director  
State Government Affairs  
717-525-8962  
jmccormack@nacds.org

 **KAISER PERMANENTE**<sup>®</sup>  
2101 East Jefferson Street  
Department of Pharmacy Services, 3-West  
Rockville, MD 20852

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October 10, 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 limit the maximum number of hours a pharmacist may work continuously without a scheduled break.

Kaiser Permanente is mindful of the issue at hand and understands the concerns of the Board of Pharmacy and the rationale behind the NOIRA. Namely, lengthy work hours with no scheduled breaks for pharmacists may contribute to fatigue and a lapse in concentration which may lead to medication errors resulting in harm to the constituents of the Commonwealth. Kaiser Permanente also understands the need to establish a balance due to the desire on the part of employers to create an efficient and cost-conscious business model.

Patient safety is of utmost concern to Kaiser Permanente and we have implemented several considerations to create an appropriate work environment for our pharmacists to decrease exhaustion, increase attentiveness, and ultimately decrease the probability of medication errors. Specifically, Kaiser Permanente has implemented the following scheduling parameters for our pharmacists:

- Pharmacists are typically scheduled for 8.5 hour shifts;
- Pharmacists may not be scheduled for a shift that exceeds 10.5 hours;
- Pharmacists receive a 15 minute paid break for every four hours they are scheduled to work;
- Pharmacists receive a 30 minute unpaid lunch break for shifts greater than six hours; and
- Pharmacists are allowed at least 10 hours of off-time between consecutive shifts.

Kaiser Permanente is committed to ensuring the well-being of our pharmacists while protecting the safety of our patients, and has arrived at this best practice model through the input of our labor union which is comprised of pharmacist representatives. The Labor Management Partnership successfully represents the interests of physicians, pharmacists, managers, and front-line employees. By making our patients the focus of decisions, we strive to create the best work environment and deliver the best quality care and service. It is important to note, however, that the above parameters are intended to be flexible in case of emergency in order to remain

operational and continue to serve our patients. Deviating from these parameters is the exception to the standard of practice at Kaiser Permanente.

In addition to the parameters on maximum length of shifts and breaks, pharmacists are provided with ergonomic equipment to help decrease fatigue such as special flooring and foot rests. Pharmacists are also encouraged to routinely rotate workstations within the pharmacy to decrease tiredness and redundancy in their work.

Kaiser Permanente appreciates the willingness of the Virginia Board of Pharmacy to address concerns raised by pharmacists that may lead to harmful outcomes for the constituents of the Commonwealth. As the practice of pharmacy continues to grow and become more strenuous, it is important to keep the welfare of our pharmacists in mind to ultimately decrease the probability of medication errors, while balancing the business needs of pharmacy organizations.

Thank you again for the opportunity to offer remarks on the maximum number of hours a pharmacist may work continuously without a scheduled break. Should you have any questions, please do not hesitate to contact me.

Sincerely,



Soumi Saha, PharmD, JD  
Government Relations and Regulatory Affairs Coordinator  
Office – 301-816-5885  
soumi.s.saha@kp.org

cc: Caroline D. Juran, Executive Director, Virginia Board of Pharmacy  
Kristin Bear, Senior Legal Counsel, Kaiser Permanente  
Alan Friedman, Regulatory, Quality and Professional Affairs Manager, Kaiser Permanente  
Laurie Kuiper, Senior Director Government Relations, Kaiser Permanente  
Robert Axelrod, Senior Legislative Manager, Kaiser Permanente



# VIRGINIA PHARMACISTS ASSOCIATION

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October 10, 2012

Caroline D. Juran  
Executive Director  
Virginia Board of Pharmacy  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico Virginia 23233-1463

Comments on NOIRA: "Addressing hours of continuous work by pharmacists"

Dear Ms. Juran,

The Virginia Pharmacists Association urges the Board of Pharmacy to consider all cases where patient safety was put in jeopardy due to pharmacists placed into situations where they are overworked and under staffed. Prescription volumes continue to rise and the demand placed on many pharmacists to fill a prescription in a limited, defined period of time is becoming the norm. Overwhelming situations like this can be difficult enough during ideal working conditions. Unfortunately, pharmacists can face non-ideal working conditions where 12-14 hour days are commonplace with no ability to even take a short break.

However, we also urge the Board to use caution in considering regulations mandating hour limits or breaks that do not provide the flexibility needed in many pharmacy work environments. Pharmacists may opt to stay past the end of their shift to help ease the transition to the incoming pharmacist, especially during times when the workload is very high. If that pharmacist approaches their hour limit, one would have to step away and would not be able to assist the incoming pharmacist. Depending on how the regulations are written, that pharmacist could be exposed to disciplinary action or lawsuits if an error would occur during the time spent past the prescribed limit, regardless of who actually was responsible for the error.

Patient safety could in fact be compromised by mandated regulations that are too broad and do not allow for flexibility across all practice settings. It may potentiate errors when pharmacists stop their work mid-task to enforce a mandatory break or hour limit. We urge the Board to consider all options to ensure that pharmacists feel that they are practicing in the safest work environment possible, while also addressing any concerns of the impact that a broad mandate could have on the practice of pharmacy in all work environments.

Sincerely,



Timothy S. Musselman, Pharm.D.  
Executive Director  
Virginia Pharmacists Association

October 10, 2012

Caroline Juran, R.Ph.  
Executive Director  
Virginia Board of Pharmacy  
Department of Health Professions  
9960 Mayland Drive, Suite 300  
Richmond, VA 23233

**Re: NOIRA – Addressing Hours of Continuous Work by Pharmacists  
EPIC Pharmacies Public Comment**

Dear Ms. Juran:

As you know, our firm is counsel for EPIC Pharmacies. EPIC represents a network of independent pharmacies across the Commonwealth. I am writing, on behalf of EPIC, to express concerns regarding the above-captioned NOIRA and to offer several points for the Board of Pharmacy to consider.

First, EPIC is concerned that there is not sufficient evidence of the need for the proposed action. There are not demonstrated specific instances of public harm in Virginia resulting from lack of such regulation. EPIC is also concerned that the petitioners' goals will not be accomplished through the proposed action: prescription errors due to fatigue cannot be avoided by adoption of the one-size-fits-all work limitations.

Individual pharmacists vary widely in their ability to handle workload volume, continuous working hours, and total shift length. Likewise, individual pharmacies vary widely in their prescription volume and staffing levels. Every pharmacist in Virginia bears an individual responsibility to assess his or her own capacity and workplace environment and to appropriately address fatigue. Likewise, every pharmacy in Virginia bears an individual responsibility to assess its staffing and work shift schedules in order to ensure a safe and focused workforce. Fatigue, however, does not universally set in after twelve hours of total work or six hours of uninterrupted work – it is determined by a pharmacist's capacity to focus as well as a function of how much sleep a pharmacist received the night before. Because of the wide variations between individual pharmacists and pharmacies, there is no foundation for establishing universal standards to define the onset of fatigue.

Unfortunately, the proposed action may actually harm patients, pharmacists, and pharmacies. Patients benefit from continuity of care – forcing breaks or a shift change could result in a different pharmacist dispensing a prescription than the pharmacist that received a prescriber's instructions. Important information may be lost during mandated staffing changeovers, thus creating a real risk of public harm.

The proposed action may also have negative unintended consequences for pharmacists and pharmacies. Pharmacists often schedule their shifts to accommodate family and professional obligations. A pharmacist who wanted to work fourteen hours in order to build in vacation time later in the week would

be precluded from doing so under the proposed action, regardless of his capacity to do so with full control of his faculties.

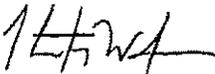
Additionally, pharmacies, in particular independent community pharmacies, would suffer disproportionately under the proposed action. Many EPIC pharmacies are owner-operated. If a pharmacist is limited to certain hours of continuous work, and he is the only pharmacist available, then the pharmacy's hours are limited *de facto* by regulatory action. In many of the communities served by EPIC pharmacies, this means that when the pharmacist has reached his regulated hourly limits then patients are foreclosed from any local dispensing option until that pharmacist is eligible to work again or to return from a mandated break.

EPIC also has concerns regarding the legality of the proposed action. It is not clear that the Board of Pharmacy has the statutory authority to regulate a pharmacist's hours of service. Further, the proposed action also gives rise to concerns about infringement upon Virginia's pro-commerce tenets. Virginia has a long-standing public policy to allow the marketplace to self-govern on issues that are fundamentally business decisions. EPIC believes that individual pharmacies are best positioned to establish work shift schedules which simultaneously protect the pharmacy's patients and ensure efficient pharmacy operations.

The Board of Pharmacy has traditionally drawn a clear line between its duty to ensure the safe practice of pharmacy and its desire for the private sector to retain decision-making over legitimate business decisions. Keeping with those traditional roles, EPIC respectfully requests that the Board of Pharmacy decline to promulgate regulations in response to the petition for rulemaking. Promulgating regulations of this type could cause unintended harm to patients, pharmacists, and pharmacies, while failing to address the petitioners' concerns.

Thank you very much for the opportunity to offer public comment on this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,



Hunter W. Jamerson

cc: Elaine Yeatts, Department of Health Professions  
Tommy Thompson, R.Ph.  
Robert Borgatti, Jr., R.Ph.

**Yeatts, Elaine J. (DHP)**

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**From:** Juran, Caroline (DHP)  
**Sent:** Wednesday, August 22, 2012 10:52 AM  
**To:** Parrish, Roland (VDH)  
**Cc:** Trump, David (VDH); Forlano, Laurie (VDH); Dempsey, Maureen (VDH); Levine, Marissa (VDH); Mauskapf, Robert (VDH); Baker, Charles (VDH); Yeatts, Elaine J. (DHP)  
**Subject:** RE: NOIRA-continuous hours of work by pharmacists

Craig,

Thank you for your comments for the Board to consider. A date for a public hearing will not be set until after the Board receives approval to publish proposed regulations. At this point, the Board is only at the stage of accepting public comment on the NOIRA and that public comment period ends on October 10, 2012.

Please let me know if you have any additional questions.

Caroline

Caroline D. Juran  
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**From:** Parrish, Roland (VDH)  
**Sent:** Wednesday, August 22, 2012 9:55 AM  
**To:** Juran, Caroline (DHP)  
**Cc:** Trump, David (VDH); Forlano, Laurie (VDH); Dempsey, Maureen (VDH); Levine, Marissa (VDH); Mauskapf, Robert (VDH); Baker, Charles (VDH)  
**Subject:** NOIRA-continuous hours of work by pharmacists

Caroline,

I wish to comment on the recent NOIRA regarding a request to amend the regulations so as to limit the number of continuous hours that a pharmacist can work without a break. As a pharmacist I support the premise that beyond some number of hours of continuous work that almost all pharmacists will experience sufficient mental and physical fatigue so as to make them more prone to make a dispensing error than they would if they were working a standard eight hour shift. I do not know nor do I have data to support as to what that number of hours should be.

In my capacity as the Director of the Division of Pharmacy Services for the Virginia Department of Health I do wish to comment on the potential impact of this regulatory action on the agency's ability to respond to public health emergencies. Again this is not in opposition to this regulatory action but a suggestion that language maybe needed that will allow for pharmacists and pharmacy technicians working under the direction of or on behalf of the Virginia Department of Health in a public health emergency be exempted from any continuous hours of work restrictions. The current VDH Emergency Operations Plan does not mandate the length of time that pharmacists or pharmacy technicians can work but plans typically refer to two twelve hours shifts per 24 hour response cycle. I am concerned that depending on Medical Reserve Corp response to a given public health emergency that pharmacists, pharmacy technicians and key pharmacy supervisory staff working for and on behalf of VDH in order to respond to a public health emergency would need to work longer hours than might be permitted under proposed amendments to existing regulations.

At this time has a date been set for the hearing on this regulatory amendment?

Thanks,

Craig

R. Craig Parrish  
Director, VDH, Division of Pharmacy Services  
Richmond, VA 23219  
(804) 786-4326

## Authorized Generics

### Background:

- 14 states responded to recent staff survey
- 7 states allow substitution with an authorized generic
- 7 states do not allow substitution and require new prescription for authorized generic

### In packet:

- 2009 newsletter article from Kentucky Board of Pharmacy
- Excerpt from 2012 Approved Drug Products with Therapeutic Equivalence Evaluations, 32<sup>nd</sup> Edition

Continued from page 1

2. training of all persons likely to perform tests; and
3. written plan defining what to do in event of an exposure.

To obtain information and a Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form, CMS-116, visit the following Web site: [www.cms.hhs.gov/CLIA/06\\_How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories.asp](http://www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.asp).

You may also contact the Cabinet for Health, Office of Inspector, at 275 E Main Street 5EA, Frankfort, KY 40621, or by phone at 502/564-7963 (for pharmacies A-J, the contact person is Connie Barker, ext 3280; for pharmacies K-Z, the contact person is Jason Bishop, ext 3298).

### **Authorized Generics and Substitution Laws**

*Submitted by John Slone, PharmD Candidate, University of Kentucky College of Pharmacy*

In recent years, drug manufacturers have been introducing a class of products to the market known as "authorized generics"; these products represent previously "brand name" medications from the original brand manufacturer that have been repackaged and sold under a generic label. These products are often released to coincide with the release of the first abbreviated new drug application-labeled generic product. These authorized generics have recently been the subject of confusion among pharmacists with regard to Kentucky's generic substitution laws and the requirement that substituted drugs must be published as therapeutically equivalent.

Part of the confusion lies in the fact that distributors or computer systems have no uniform method for indicating that a product is an authorized generic version of a brand name medication; sometimes the products are labeled as "AB rated" by the distributor or computer system, even though no such entry will exist when a pharmacist searches the Food and Drug Administration's (FDA) "Orange Book" by active ingredient. However, in the preface to the current edition of the "Orange Book," FDA has the following statement: "Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder's drug product even if the application holder's drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder." (29<sup>th</sup> edition, page vii.) Essentially, this means that regardless of what code a drug product is given, authorized generics may still be substituted for that manu-

facturer's original product, despite any rating on the manufacturer's original drug product. Example: if a patient is started on a drug in which the product is controlled-release and generic equivalent products would normally be rated "B," you may still consider an authorized generic to be therapeutically equivalent and substitutable.

So what does this mean to a pharmacist in Kentucky? In general, this means authorized generics are therapeutically equivalent by FDA standards, but there is no easy way to search for such products in the "Orange Book," as the search tool does not include these types of products. However, as FDA considers authorized generics to be repackaged versions of new drug application-approved drugs, the package for the drug product must still indicate the original manufacturers' name. This name should match the company listed in the "Orange Book" as the manufacturer of the reference listed drug. To find the manufacturer, one may visit the electronic "Orange Book" at [www.accessdata.fda.gov/scripts/cder/ob/default.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) and search by proprietary name or active ingredient; in the search results, look for the line where the RLD field is labeled "Yes."

Please note that even though FDA publishes a list of authorized generic products ([www.fda.gov/AboutFDA/CentersOffices/CDER/ucm126391.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm126391.htm)), it is only updated quarterly and companies only report authorized generics marketed on a yearly basis. If you have questions regarding an authorized generic, you should contact FDA or the Board of Pharmacy.

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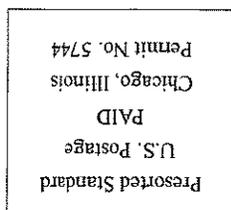
Page 4 – September 2009

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Michael A. Burlison, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor  
& Executive Editor

Larissa Doucette - Communications Manager



KENTUCKY BOARD OF PHARMACY  
National Association of Boards of Pharmacy Foundation, Inc  
1600 Feehanville Drive  
Mount Prospect, IL 60056

FS



# APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS

32<sup>nd</sup> EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER  
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF PHARMACEUTICAL SCIENCE  
OFFICE OF GENERIC DRUGS

2012

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dosage form, route of administration and are identical in strength or concentration (e.g., chlordiazepoxide hydrochloride, 5mg capsules). Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling.

**Pharmaceutical Alternatives.** Drug products are considered pharmaceutical alternatives if they contain the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms or strengths (e.g., tetracycline hydrochloride, 250mg capsules vs. tetracycline phosphate complex, 250mg capsules; quinidine sulfate, 200mg tablets vs. quinidine sulfate, 200mg capsules). Data are generally not available for FDA to make the determination of tablet to capsule bioequivalence. Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate-release or standard-release formulations of the same active ingredient.

**Therapeutic Equivalents.** Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

FDA classifies as therapeutically equivalent those products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable *in vitro* standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations. *The concept of therapeutic equivalence, as used to develop the List, applies only to drug products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., propoxyphene hydrochloride vs. pentazocine hydrochloride for the treatment of pain).* Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder's drug product even if the application holder's drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder. Therapeutic equivalence determinations are not made for unapproved, off-label indications.

FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and minor aspects of labeling (e.g., the presence of specific pharmacokinetic information) and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.

**Bioavailability.** This term means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes

## Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000

**Guidance Document: 110-9**

<b>Major Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Penalty</b>
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180		250
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200		250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240		250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250



Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, <del>compounding</del> , or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
<i>20a. Pharmacist not checking and documenting non-sterile compounding</i>	<i>54.1-3410.2, 18VAC110-20-355</i>		500
<i>20b. Pharmacist not checking and documenting sterile compounding</i>	<i>54.1-3410.2, 18VAC110-20-355</i>		5000
21. No clean room	54.1-3410.2		5000 10000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 <del>over 60 days late (6mo → 60 days)</del> <i>not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.</i>	54.1-3410.2		3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better <del>over 60 days late (6mo → 60 days)</del> <del>Corrective action not taken within one month of certification report</del> <i>not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.</i>	54.1-3410.2	Review 2 most recent reports	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs or high risk CSPs assigned inappropriate beyond use date (BUD); or, no documentation of initial and semi-annual (6 months +14 days) media-fill testing for persons performing high-risk level CSPs; or, documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test; or, high-risk drugs intended for use are improperly stored;</p>	<p>54.1-3410.2</p>		<p>5000 per incident within previous 30 days up to 3 incidents; schedule for IFC for &gt; 3 incidents</p>
<p>25a. No documentation of initial and semi-annual (6 months +14 days) media-fill testing for persons performing high-risk level CSPs</p>	<p>54.1-3410.2</p>		<p>5000 per incident within previous 30 days up to 3 incidents; schedule for IFC for &gt; 3 incidents</p>
<p>25b. High-risk drugs intended for use are improperly stored</p>	<p>54.1-3410.2</p>		<p>5000 per incident within previous 30 days up to 3 incidents; schedule for IFC for &gt; 3 incidents</p>
<p>25c. Documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test;</p>	<p>54.1-3410.2</p>		<p>5000 per incident within previous 30 days up to 3 incidents; schedule for IFC for &gt; 3 incidents</p>

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>26. Annual (12 months + 30 days) training documentation involving media-fill tests for low and medium-risk levels not maintained for &gt; 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs &gt; 45 days after receipt of a failed media-fill test  <i>No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level CSPs</i></p>	<p>54.1-3410.2</p>		<p>500</p>
<p>26a. <i>No documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs &gt; 45 days after receipt of a failed media-fill test</i></p>	<p>54.1-3410.2</p>		<p>500</p>
<p>27. Compounding using ingredients in violation</p>	<p>54.1-3410.2</p>		<p>1000</p>
<p>28. Compounding copies of commercially available products</p>	<p>54.1-3410.2</p>	<p>per Rx dispensed up to maximum of 100 RX or \$5000</p>	<p>50</p>
<p>29. Unlawful compounding for further distribution by other entities</p>	<p>54.1-3410.2</p>		<p>500</p>
<p>30. Security of after-hours stock not in compliance</p>	<p>18VAC110-20-450</p>		<p>500</p>
<p>31. For LTC, ADD being accessed for orders prior to pharmacist review and release</p>	<p>18VAC110-20-555</p>		<p>250</p>
<p>32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling</p>	<p>54.1-3410.2</p>		<p>2000</p>
<p>33. <i>Low or medium-risk CSPs assigned inappropriate beyond use date (BUD)</i></p>	<p>54.1-3410.2</p>		<p>1000</p>

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**Minor Deficiencies**

If three (3) or more minor deficiencies are cited, a \$250 monetary penalty shall be imposed. Another \$100 monetary penalty will be added for each additional minor deficiency over the initial three.

Minor Deficiency	Law/Regulation Cite	Conditions
<b>General Requirements:</b>		
1. Repealed 6/2011		
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold



Guidance Document: 110-9

Minor Deficiency	Law/Regulation Cite	Conditions
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
11. Storage of will-call not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404, 54.1-3434 and 18VAC110-20-240	
14. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. Minor 17 combined with Minor 16 – 6/2011		
18. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling	54.1-3412, 18VAC110-20-255, 18VAC110-20-310, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	

Guidance Document: 110-9

Minor Deficiency	Law/Regulation Cite	Conditions
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
25. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
<b>Repackaging, specialty dispensing, compounding:</b>		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained; <del>compounded products not properly labeled or assigned appropriate expiration date</del>	54.1-3410.2	
<i>30a. Compounded products not properly labeled</i>		
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	54.1-3410.2	30%-threshold
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	30%-threshold

Minor Deficiency	Law/Regulation Cite	Conditions
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	
<b>Hospital specific or long-term care specific:</b>		
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
35. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
36. After hours access or records not in compliance	18VAC110-20-450	10% threshold
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
38. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
39. EMS procedures or records not in compliance	18VAC110-20-500	10% threshold
40. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
41. Maintaining floor stock in L/TCF not authorized	18VAC110-20-520 and 18VAC110-20-560	