



# COMMONWEALTH OF VIRGINIA

## Meeting of the Board of Pharmacy

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

(804) 367-4456 (Tel)  
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### Tentative Agenda of Meeting

June 12, 2012

9:00AM

#### TOPIC

#### PAGE(S)

**Call to Order:** Gill Abernathy, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda
- Approval of previous Board meeting minutes:
  - March 13, 2012, Full Board Meeting 1-13
  - April 12, 2012, Telephone Conference Call 14-15
  - April 30, 2012, Special Conference Committee and Informal Conference Committee 16-19
  - May 2, 2012, Panel Formal Hearing 20-21
  - May 2, 2012, Regulation Committee – Pharmacy Working Conditions 22-24
  - May 15, 2012, Special Conference Committee and Informal Conference Committee 25-26

**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:** Diane Reynolds-Cane, M.D.

**Regulatory Actions:** Elaine Yeatts

- Regulatory Update 27
- Regulation Committee Report:
  - recommendation regarding petition for rulemaking on working conditions for pharmacists 28-40
  - recommendation regarding request from *The Pharmacy Alliance* on pharmacy working conditions 41-55

**Miscellaneous:** Caroline D. Juran

- Request from Crady Adams to discuss length of time associated with and access to final orders 56

- Request from staff for guidance regarding:
  - nine-month allowance in Regulations 18VAC110-20-101 D and 18VAC110-20-111 C 57-58
  - when more than one pharmacist involved in the dispensing process 59-62
- Define “annual” and “semiannual” in Guidance Document 110-36, clarify record retention requirement, and establish threshold for compliance in guidance document 110-9 63-67

**Reports:**

- Report on Workforce Survey – Elizabeth Carter
- 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

**Election of Officers – Chairman and Vice-Chairman**

**New Business**

- Evaluation and Revision of Sanction Reference Points System – Neal Kauder 68

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

**Adjourn**

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

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY  
DRAFT/ MINUTES OF BOARD MEETING**

March 13, 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 9:15 AM.

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

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

**MEMBERS ABSENT:** Brandon K. Yi

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Arne Owens, Chief Deputy Director, DHP  
Elaine J. Yeatts, Senior Policy Analyst, DHP  
Heather Hurley, Administrative Assistant  
Rachel Baer, Assistant Attorney General- arrived approximately 1:30pm

**STAFF ABSENT:** Howard M. Casway, Senior Assistant Attorney General

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

**APPROVAL OF AGENDA:** Staff requested that the agenda be amended to include a presentation of information for a possible summary suspension and that it be heard just prior to adjournment. The agenda was approved as amended.

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for December 14, 2011 (Public Hearing); December 14, 2011 (Full Board Meeting); December 14, 2011 (Panel of the Board, Formal Hearing); January 10, 2012 (Special Conference Committee and Informal Conference Committee); February 14, 2012 (Special Conference Committee and Informal Conference Committee); February 16, 2012 (Regulation Committee for Pharmacist to Pharmacy Technician Ratio); February 16, 2012 (Informal Conference Committee, Pilot Program); and March 6, 2012 (Special Conference Committee and Informal Conference Committee).

**MOTION:**

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

**PUBLIC COMMENTS:**

There were no public comments offered at this time.

**DHP DIRECTOR'S REPORT:**

Arne Owens, Chief Deputy Director for the Department of Health Professions (DHP), presented the Director's report on behalf of Dianne Reynolds-Cane, M.D., Director of DHP. Mr. Owens reported that all of the bills that were submitted by DHP passed through both houses of the General Assembly.

Mr. Owens also commented that the next DEA-sponsored "Drug Take Back Day" is scheduled to take place on April 28, 2012 and that DHP will assist in promoting the event.

Mr. Owens reported there is a new agency travel policy which is more tightly controlled. A new form for requesting travel authorization has been implemented and all out-of-state travel must be submitted to the Secretary's Office for approval.

Concerning budget issues, Mr. Owens discussed the ongoing case process improvement efforts to reduce costs and improve efficiencies. Many efforts have been implemented and improvements have resulted. Ms. Juran has been assigned the action lead for the case processing effort to consider expanding the offering of pre-hearing consent orders which could reduce costs for both licensees and the agency. It is hoped that more efficiency efforts will be implemented in the next month or two.

**LEGISLATION UPDATE:**

Ms. Yeatts referenced the legislative report included in the agenda packet and provided a summary of legislation from the 2012 General Assembly Session which may be of possible interest to the Board. She reported that HB 265 passed regarding the Board of Health Professions meeting annually instead of quarterly. She clarified that HB 266 does not impact a pharmacist's ability to administer immunizations. She stated that HB 346 passed allowing nurse practitioners to practice as part of a patient care team. HB347 passed resulting in several changes to the Prescription Monitoring Program which includes a requirement of the dispenser to report the method of payment for the prescription. HB 508 amends provisions regarding the criminalization of synthetic cannabinoids. HB 733 addresses a pharmacist's authority to compound a drug under certain circumstances. HB 1140 passed which places carisoprodol into Schedule IV which is consistent with federal rules. HB 1161 requires the Virginia Department of State Police to enter into a memorandum of understanding to establish participation in a real-time electronic recordkeeping and monitoring system for the sale of ephedrine or related compounds. The bill is effective January 1, 2013. SB 592 proposed placing tramadol into Schedule IV. It passed in the Senate, but died in the House. This bill carried an automatic fiscal impact due to possible cost increases for the correctional system.

**REGULATIONS:**

Ms. Yeatts provided an update of the Board's current regulatory actions. The emergency regulations and Notice of Intended Regulatory Action

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(NOIRA) concerning continuous quality improvement programs (CQI) remain in the Governor's Office. The regulations were required to be effective December 20, 2011. The proposed regulations concerning the modifications of requirements for automated dispensing devices may be adopted by the Board later during this meeting. The public comment period concerning the NOIRA for changes to the run-dry requirement for automated counting devices will close April 25, 2012. The final regulations for repackaging in community service boards and behavioral health authorities may be adopted by the Board later during this meeting. The proposed regulations regarding administrative fees for duplicate licenses and verifications remain in the Secretary's Office, as well as the proposed regulations for on-hold prescriptions.

ADOPTION OF FINAL  
REGULATIONS FOR  
REPACKAGING IN  
COMMUNITY SERVICE  
BOARDS AND BEHAVIORAL  
HEALTH AUTHORITIES:

Ms. Yeatts reminded the Board that §54.1-3420.2 requires the Board to promulgate regulations related to an allowance for repackaging drugs in community service boards and behavioral health authorities. Additionally, she reported that the emergency regulations will expire June 18, 2012 and therefore, the Board should adopt final regulations at this meeting. One public comment offered during the recent public comment period was reviewed. To clarify any confusion that may exist regarding the board's requirement, it was stated that §54.1-3420.2 C authorizes the repackaging of a drug in a CSB or BHA for the purpose of assisting a client with self-administration and that the law addresses repackaging of a drug, not administration of a drug. Additionally, Ms. Yeatts indicated that the statement "consistent with subsection B of this section" as found in subdivision C4 of the proposed final regulations needed to be deleted since it had been previously deleted in an exempt regulatory action.

MOTION:

**The Board voted unanimously to remove the statement "consistent with subsection B" in subdivision C4 of the proposed final regulations for repackaging in CSB's and BHA's and adopt the proposed final regulations as amended. (motion by Kozera, second by Allen)**

ADOPTION OF PROPOSED  
REGULATIONS FOR  
AUTOMATED DEVICES FOR  
DISPENSING AND  
ADMINISTERING OF DRUGS:

In response to receiving suggested minor edits from Ms. Abernathy in advance of the meeting, Ms. Yeatts provided the Board with a handout for its consideration that staff created which captured suggested changes in bold font. Additionally, Ms. Yeatts indicated that the word "indicating" found in 8a of the handout was a typographical error and should be stricken. The one comment received during the recent public comment period was reviewed, and Ms. Yeatts stated that the Board should adopt proposed regulatory changes to 18VAC110-20-490 during this meeting.

MOTION:

**The Board voted unanimously to remove the word "indicating" found in 8a of the handout and adopt the proposed regulatory changes to 18VAC110-20-490 regarding automated devices for dispensing and administering as presented in the handout and amended. (motion by Allen, second by Shinaberry)**

PETITION FOR  
RULEMAKING

Ms. Yeatts presented to the Board a petition for rulemaking submitted by Louis Kaufman, representative of Robert's Home Medical, which requested that medical equipment suppliers (MES) be allowed to transfer prescriptions from one MES to another. Mr. Kaufman had been informed previously by Board staff that Board regulations do not directly address the ability of an MES to transfer prescriptions to another MES. Mr. Kaufman indicated that for many years as a practice standard medical equipment suppliers have been transferring prescriptions to other medical equipment suppliers in order to meet the patient's needs. He stated that patients frequently require equipment delivery to multiple locations, e.g., patient discharged from hospital in Charlottesville traveling home to Harrisonburg would require a delivery from a MES in Charlottesville for travel home and then subsequent delivery from a MES in Harrisonburg once residing at home. Preventing an MES from transferring prescriptions could negatively impact patient care and place excessive burdens on the patient. Additionally, he reported that the competitive bidding process implemented by CMS appeared to support an MES transferring a prescription to another MES.

Because Board counsel was unable to attend the meeting due to illness, Ms. Juran indicated that the Board could possibly adopt a guidance document to allow a MES to transfer prescriptions to another MES; however, staff would need to confirm this understanding with Board counsel prior to implementing. If counsel did not agree that the Board could adopt guidance, then the Board could adopt a Notice of Intended Regulatory Action to allow in regulation an MES to transfer prescriptions.

**MOTION:**

**The Board voted unanimously to take one of the following actions: adopt a guidance document, if advised by Board counsel, which would authorize a medical equipment supplier to transfer prescriptions to another medical equipment supplier; the document would be drafted by Board staff and approved by the Board Chairman; or, adopt a Notice of Intended Regulatory Action to allow in regulation an MES to transfer prescriptions, if Board counsel advises that the Board may not authorize such in a guidance document. (motion by Kozera, second by Shinaberry)**

**UPDATE ON ACTION ITEMS:**

**REQUEST TO ELIMINATE  
PHARMACY TECHNICIAN  
TO PHARMACIST RATIO IN  
18VAC110-20-270B**

Jody Allen, Regulation Committee Chairman, reminded the Board that it had received a request during the December 14, 2011 full board meeting to eliminate the current 4:1 pharmacy technician to pharmacist ratio as found in Regulation 18VAC110-20-270. The matter was referred to the Regulation Committee and a committee meeting was subsequently held on February 16, 2012. She reported that the Regulation Committee voted unanimously to recommend the following to the full Board: that it not amend Regulation 18VAC110-20-270 B to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time; that the ratio remain the same until further information is received from the upcoming Board of Health Profession's scope of practice review; and, that staff continue to gather

information from other states on their efforts to evaluate ratios. In addition to the full Board's ability to approve or deny the request to eliminate the ratio, Ms. Allen commented that the Board could also consider postponing the decision until the Regulation Committee has had an opportunity to review the report from the upcoming Board of Health Professions' pharmacy scope of practice review.

**MOTION:**

The Board voted to deny the request to amend Regulation 18VAC110-20-270 B to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time. (motion by Stelly, second by Adams; four in favor, five opposed; motion did not carry)

**MOTION:**

On a second motion, the Board voted to postpone the decision to deny or approve the request to amend Regulation 18VAC110-20-270 B to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time until the Regulation Committee has had an opportunity to review the report from the upcoming Board of Health Professions' pharmacy scope of practice review and report its recommendation back to the full Board. (motion by Kozera, second by Adams; six in favor, three opposed)

**ACTION ITEM:**

Ms. Stelly requested that staff assist the Regulation Committee in its future discussion of ratio by obtaining information on disciplinary action regarding drug diversions during the last year in states that do not have a pharmacy technician to pharmacist ratio.

**MISCELLANEOUS:**

**REVIEW FOR COMPLIANCE  
WALGREENS' MECHANISMS  
FOR TRANSFERRING  
PRESCRIPTIONS:**

Ms. Juran explained that effective January 1, 2012 Walgreens is no longer participating in Express Scripts and therefore, there was an unusually high demand from patients around that time to transfer prescriptions from Walgreens to pharmacies participating with their insurance company. Walgreens implanted two mechanisms to expedite the transfer process and decrease staff interruptions which could lead to errors. Board staff began receiving calls from pharmacists wanting to know if the TransferSafe and the TransferRx mechanisms used by Walgreens to transfer certain prescriptions were compliant with State laws. After obtaining additional information from Rusty Maney from Walgreens, Ms. Juran reviewed the mechanisms with Board counsel. It was determined in this preliminary review that the mechanisms used to transfer Schedule VI drugs did appear to comply with State laws. Board counsel advised Ms. Juran to have the full Board formally review the mechanisms at its next full Board meeting. Rusty Maney and Al Carter from Walgreens were present at the full Board meeting and answered the Board members' questions regarding the two mechanisms. Mr. Carter stated that the TransferSafe mechanism had been turned off during the last week to further enhance security measures to ensure that pharmacists could only access information while working on-duty at a pharmacy. Mr. Carter indicated that enhancements to the TransferSafe mechanism will not change the process as previously implemented, but will only improve

the security technology. Additionally, Mr. Carter stated that the TransferSafe mechanism is used only to transfer prescriptions of Schedule VI drugs; the TransferRx mechanism is used to transfer prescriptions of drugs in Schedule III – VI. To comply with federal requirements, Mr. Carter stated that the TransferRx mechanism is used to transfer prescriptions for drugs in Schedules III-V only after verbal communication with a pharmacist. When using TransferRx to transfer prescriptions for drugs in Schedules VI, Mr. Carter stated the transfer information is communicated via fax in accordance with 18VAC110-20-360.

**MOTION:**

**The Board voted unanimously that, in concept, the TransferSafe and TransferRx mechanisms as described by Walgreens appears to meet compliance with Regulation 18VAC110-20-360; TransferSafe may be used to transfer prescriptions for drugs in Schedule VI; and TransferRx may be used to transfer prescriptions for drugs in Schedules III-VI, if compliant with federal rules. (motion by Munden, second by Adams)**

**PRESENTATION BY  
WALGREENS FOR  
APPROVAL, IN CONCEPT, OF  
NEW STORE LAYOUT:**

Al Carter and Rusty Maney, from Walgreens presented a video to the Board showing a new store layout that Walgreens has constructed in other states. Walgreens believes the new layout will allow the pharmacist to be more accessible and have more time to counsel the customers, or assist with any questions that they might have. All phone calls are received by a central fulfillment center located in Florida, thereby decreasing staff distractions. Mr. Carter reported that pharmacists spend approximately 30% of their day fielding telephone calls. The data entry of most prescriptions is also handled remotely by the central fulfillment center in compliance with Regulation 18VAC110-20-276. The store layout physically separates the pharmacist from the area where the drugs are located; however, the pharmacist must enter that area to obtain the Schedule II drugs for the pharmacy technicians. Security cameras are located in the drug storage area and the pharmacist views monitors to supervise the pharmacy technician activity. Walgreens believes the security cameras are deterring drug diversions. Additionally, the pharmacist performs the verification of the accuracy of the dispensed drug by viewing photo images of the vial and the drug within the vial which are captured by the pharmacy technician during the dispensing process. Also, as a quality assurance, the dispensed quantity is weighed by the pharmacy technician to ensure accuracy of the dispensed quantity. The weight is viewed by the pharmacist during the verification process. In response to Board member questions, Mr. Carter indicated the following: only one prescription can be dispensed at a time; each dispensed drug is placed in a separate bag; the pharmacist's computer screen has a privacy filter on it to eliminate customer viewing; counseling has increased from 12% to 40% in stores with the new layout; the first store with this layout opened approximately one year ago; administration of immunizations and patient counseling will occur in the separate room located near the pharmacist's computer terminal; no drugs or paraphernalia will be stored in the separate room as this room is not part of the licensed prescription department; drugs to be administered in the separate room will have already been dispensed to the specific

patient; no drug diversions have occurred as of yet in the stores with the new layout; Indiana, Illinois, New York, and the District of Columbia have approved the new store layout and currently have stores with the new layout located in the area; no state as of yet has denied the approval of the new store layout; and Mr. Carter intends to seek approval from all state Boards of Pharmacy.

**MOTION:**

**The Board voted unanimously that, in concept, the new store layout as described by Walgreens appears to meet compliance with Regulations 18VAC110-20-150, 18VAC110-20-180, and 18VAC110-20-190 regarding physical and security standards, and the use of cameras and monitors for pharmacists on-duty to supervise pharmacy technicians and verify the accuracy of dispensed drugs appears to comply with 18VAC110-20-270. (motion by Munden, second by Stelly)**

**REQUEST FROM *THE PHARMACY ALLIANCE* TO DISCUSS IMPLEMENTING MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"**

Priscilla Gale addressed the Board on behalf of *The Pharmacy Alliance* with concerns of working conditions in the pharmacy which may contribute to prescription errors. Ms. Gale explained that it was not right to hold the pharmacists accountable for errors and not the facility permit holders. Her concerns were related to long work hours, lack of meal times or breaks, not enough staff, loud music being played in the store and corporate policies that were distracting and increase errors. There was also discussion of corporate standards in which prescriptions were guaranteed within a certain length of time. To assist the Board in its discussion, Ms. Juran commented that several of the nine issues referenced in the email from The Pharmacy Alliance on page 85 of the agenda packet had recently been discussed or addressed by this Board. Specifically, #1, the prohibition of guaranteeing a dispensed prescription to be ready in a specific period of time had been discussed at a recent full Board meeting and Board counsel had advised that prohibiting this business practice could be construed as a possible violation of the Federal Trade Commission; #2 and #3 regarding restrictions on the number of hours a pharmacist may continuously work and mandatory meal breaks will be discussed at the June board meeting at the conclusion of the public comment period for a recently received petition for rulemaking; #7 and #8 regarding the reporting of medication errors has recently been addressed in statute and the development of the CQI regulations currently awaiting the Governor's signature; and #9 regarding a prohibition in influencing a pharmacist's decision regarding the practice of pharmacy is already addressed in Regulation 18VAC110-20-110B. Therefore, Ms. Juran recommended that the Board may want to focus its discussion on the other items listed.

**ACTION ITEM:**

**Ms. Shinaberry recommended, and the full Board supported, that the following issues be referred to the Regulation Committee for further consideration: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization**

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administrations; requirement that other timed metrics regarding the phone, drive-thru, or cash register may only be imposed on pharmacy technicians and not pharmacists; and, prohibition of any non-pharmacist employ of the permit holder influencing the professional decision of the pharmacist. Staff was directed to research these subjects and provide information to the Regulation Committee to aid its discussion.

**ACTION ITEM:**

Because Board counsel was unable to attend the meeting, Mr. Adams agreed to table until the June Board meeting his request on the agenda to discuss the length of time associated with and access to final orders.

**REPORTS:**

**BOARD OF HEALTH  
PROFESSIONS:**

Robbie Rhodes, member of the Board of Health Professions, reported to the Board of Pharmacy the latest information concerning the Board of Health Professions. The Regulatory Research Committee and the full Board met on February 14, 2012. The Board of Health Professions voted that licensure is appropriate for Medical Laboratory Scientists and Medical Laboratory Technicians. Also, the committee's study of the Nurse Practitioner's scope of practice is currently being revised to reflect the significant changes resulting from HB 346. The committee is also moving forward with the Pharmacy review and will be researching team delivery within the context of how "patient care team" is defined in HB 346. Staff will give an update of the progress of the Pharmacy review at the May committee meeting. Lactation consultants may be submitting an application to the Board of Health Professions for review to determine if the profession needs to be regulated. The Virginia Perfusion Society requested that a study be initiated to regulate Perfusionists and the Board voted to table consideration of the request until the level of urgency can be ascertained by staff, given the Board's current workload. Delegate Dr. Christopher Stolle is expected to request the Department to conduct a study of options for accepting military training and experience as satisfying requirements for licensure, certification or registration as a health care provider. Mr. Rhodes also stated that the next full Board meeting of the Board of Health Professions is scheduled for May 8, 2012.

**LICENSURE PROGRAM:**

Mr. Johnson reported that the Board issued 939 licenses and registrations for the period of December 1, 2011 through February 29, 2012, including 132 pharmacists, 111 pharmacy interns, and 488 pharmacy technicians. In January 2012, the Board began receiving applications for pharmacy technician registration exclusively online eliminating the need for paper applications. Inspectors performed 281 facility inspections including 116 routine inspections of pharmacies: 31 resulted in no deficiency, 31 with deficiencies, and 54 with deficiencies and a consent order. There are currently two active innovative (pilot) programs. One additional pilot program is being reviewed for renewal and two new pilot programs were approved.

**DISCIPLINARY PROGRAM:**

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between September 19, 2011,

December 12, 2011, and March 12, 2012. Current open cases are 45 at the investigation stage; 73 at the probable cause stage; 11 at the administrative proceedings division stage; 8 at the informal stage; 3 at the formal stage; and 92 at the pending closure stage.

**EXECUTIVE DIRECTOR'S  
REPORT:**

Ms. Juran reported to the Board that she had contacted the Virginia Department of Health in order to increase awareness of the Medical Reserve Corp. An article is to be published regarding this issue in the May newsletter.

Ms. Juran gave an update on the percentages for completing the online workforce survey for the quarter of October through December 2011. The stats are as follows: Pharmacy Technicians are at 92.03% while Pharmacists are at 91.45%. Dr. Elizabeth Carter believes her staff should be able to provide a summary of the workforce surveys at the June full Board meeting.

Ralph Orr has requested that the Board be informed that the grace period for the recent regulatory changes has expired. Currently, all pharmacies must be reporting their dispensing data to the PMP within seven days of dispensing using the ASAP 4.1 version. Mr. Orr has been promoting these changes over the past year, but the Board of Pharmacy will be placing a reminder of this change in the July newsletter. Additionally, Virginia is now participating in the PMP interoperability with Ohio, Indiana, Connecticut and Michigan.

Ms. Juran stated she will be attending the NABP Annual Meeting this year, being held in Philadelphia May 19<sup>th</sup> through May 22<sup>nd</sup>. Former board member Leo Ross, will be attending the meeting, and she hopes current members of the Board will be able to attend as well.

Ms. Juran reported that interviews for the Board's Compliance Officer position were held this past week. There were seven strong candidates interviewed and a hiring offer will be extended in the very near future. Additionally, Heather Wright, assumed in January the position of Administrative Assistant III for Licensing. The position was previously held by Gloria Williams prior to her December retirement. Ms. Wright previously worked in the Board of Nursing.

Scott Arnott, Pharmacy Inspector for the northern Virginia region, has announced he is retiring as of July 2, 2012. Mr. Arnott has been an inspector with DHP for ten years, and has brought a wealth of knowledge to the agency. He previously worked for thirty years as Assistant Director and later Director of Pharmacy Services at Virginia Hospital Center in Arlington. Mr. Arnott has been an asset to the Board of Pharmacy as well as the agency, and he will be greatly missed. The Enforcement Division will likely begin recruiting efforts in the near future.

**NEW BUSINESS:**

There was no new business.

Ms. Rachel Baer, Assistant Attorney General, arrived at approximately 1:30 p.m.

**SUMMARY SUSPENSION:**

SHANNON C. WHITE  
Pharmacy Technician  
Registration Number:  
0230-017782

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

**MOTION FOR CLOSED MEETING:**

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Caroline D. Juran, Cathy Reiniers-Day, and Eusebia Joyner attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Kozera, second by Adams)

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

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

**MOTION:**

The Board voted unanimously in favor of the motion that, according to the evidence presented, the continued practice by Shannon C. White as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Shannon C. White to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. White for the suspension of her registration for not less than two years in lieu of a hearing. (motion by Adams, second by Kozera)

**ADJOURN:**

With all business concluded, the board meeting adjourned at 1:45pm.

\_\_\_\_\_  
Gill Abernathy, Board Chairman

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**VIRGINIA BOARD OF PHARMACY  
FORMAL HEARING MINUTES**

Tuesday, March 13, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 2

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

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

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**CALL TO ORDER:**

A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:10 p.m.

**PRESIDING:**

Gill B. Abernathy

**MEMBERS PRESENT:**

Crady Adams  
Jody H. Allen  
David C. Kozera  
Dinny Li  
Empsy Munden  
Robert M. Rhodes  
Ellen Shinaberry  
Pratt P. Stelly

**STAFF PRESENT:**

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

**QUORUM:**

With nine members of the Board present, a panel was established.

**KWADWO A. BEKOE**  
Pharmacist Reinstatement Applicant  
License # 0202-208457

Mr. Bekoe appeared to discuss his petition to reinstate his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the January 31, 2012, Notice.

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

Patricia Sheehan, DHP Senior Investigator, testified on behalf of the Commonwealth.

Kwadwo A. Bekoe was represented by Hunter W. Jemerson, Esquire, and testified on his own behalf.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Adams, the board voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Kwadwo A. Bekoe. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Rachel Baer attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Allen and duly seconded by Ms. Stelly, the board voted 9-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Wolf, amended by the board and read by Ms. Baer.

Upon a motion by Ms. Allen and duly seconded by Mr. Rhodes, the board voted 9-0 that the Board grant the application of Kwadwo Bekoe for reinstatement of his pharmacist license.

Ms. Shinaberry, Ms. Allen, Mr. Rhodes and Mr. Adams departed at 3:30 p.m.

JAMES Q. UNDERWOOD  
Pharmacist Reinstatement Applicant  
License # 0202-006303

Mr. Underwood appeared to discuss his application for reinstatement of his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the October 19, 2011, Notice.

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

Vicky Fox, DHP Senior Investigator, testified on behalf of the Commonwealth.

James Q. Underwood testified on his own behalf.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Adams, the board voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of James Q. Underwood. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day and Rachel Baer attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Munden and duly seconded by Mr. Kozera, the board voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the board and read by Ms. Baer.

Upon a motion by Ms. Munden and duly seconded by Ms. Stelly, the board voted 5-0 that the Board deny the application of James Q. Underwood for reinstatement of his pharmacist license and that his license be continued on indefinite suspension for not less than two years.

Adjourn:

With all business concluded, the meeting adjourned at 6:20 p.m.

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Gill B. Abernathy, Chairman

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Date

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Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, April 12, 2012

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

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

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 9:40 a.m., on April 12, 2012, to consider the summary suspension of the registration of Gina D. Kasper to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams  
David C. Kozera  
Dinny Li  
Robert M. Rhodes  
Pratt P. Stelly  
Brandon K. Yi

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director  
Eusebia L. Joyner, Disciplinary Program Specialist  
Mykl Egan, DHP Adjudication Specialist  
Corie E. Tillman Wolf, Assistant Attorney General

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 seven (7) members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

GINA D. KASPER  
Registration No. 0230-007682

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

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Upon a motion by Mr. Adams and duly seconded by Ms. Stelly, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Gina D. Kasper poses a substantial danger to the public; and therefore, the registration of Ms Kasper be summarily suspended.

Upon a motion by Ms. Stelly and duly seconded by Mr. Rhodes, the Board unanimously voted that, with a Notice of Hearing, a Consent Order be offered to Ms. Kasper for the revocation of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:54 a.m.

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Eusebia L. Joyner  
Disciplinary Program Specialist

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Gill B. Abernathy, Chair

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Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Monday, April 30, 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 9:00 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

JASON A. STROSNIDER  
Pharmacist  
Reinstatement Applicant  
License No. 0202-010456

Closed Meeting: Jason A. Strosnider appeared to discuss his petition for reinstatement of his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 17, 2012, Notice.

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

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

Decision: Upon a motion by Ms. Stelly, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reinstate

Mr. Strosnider's license to practice as a pharmacist with 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. Strosnider, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Strosnider 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.

LAURA J. GRAY  
Pharmacy Technician  
Reinstatement Applicant  
Registration No. 0230-002211

Laura J. Gray appeared to discuss her petition for reinstatement of her pharmacy technician registration and to review allegations that she may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the April 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 Laura J. Gray. 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 adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reinstate Ms. Gray's registration to practice as a pharmacy technician.

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

KATHERINE L. STAKE  
Registration No. 0230-012852

Katherine L. Stake appeared with David Stake, her father, to discuss allegations that she may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the February 8, 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 Katherine L. Stake. 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 adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Ms. Stake.

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

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is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 2:35 p.m.

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Jody H. Allen, 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 A PANEL OF THE BOARD

Wednesday, May 2, 2012  
Commonwealth Conference Center  
Second Floor  
Board Room 2

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

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

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CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:00 a.m.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams  
Jody Allen  
David C. Kozera  
Dinny Li  
Empsy Munden  
Pratt P. Stelly  
Brandon K. Yi

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

QUORUM: With eight (8) members of the Board present, a panel was established.

GINA D. KASPER  
Registration # 0230-007682

A formal hearing was held in the matter of Gina D. Kasper following the summary suspension of her pharmacy technician registration on April 12, 2012, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

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

Helene J. Kelly, DHP Senior Investigator; Krishna Gondi, Pharmacist-in-Charge, CVS/pharmacy #1565; and Lucila

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Jenkins, CVS Loss Prevention Manager, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Yi, the panel voted 8-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Gina D. Kasper. Additionally, he moved that Cathy Reiniers-Day, Eusebia Joyner, Caroline Juran, and Howard Casway attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Mr. Kozera and duly seconded by Mr. Adams, the panel voted 8-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Wolf and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Kozera and duly seconded by Ms. Stelly, the panel voted 8-0 that Ms. Kasper's registration to practice as a pharmacy technician be revoked.

Adjourn:

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

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Gill B. Abernathy, Chair

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Date

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF REGULATION COMMITTEE REGARDING PHARMACY WORKING  
CONDITIONS**

May 2, 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 1:05PM.

**PRESIDING:** Jody H. Allen, Committee Chairman

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

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Howard M. Casway, Senior Assistant Attorney General  
Elaine J. Yeatts, Senior Policy Analyst, DHP

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

The Regulation Committee met to discuss the specific mandates requested by The Pharmacy Alliance and referred to committee for further consideration during the March 13, 2012 full board meeting. Those mandates were: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization administration; requirement that other timed metrics regarding the phone, drive-thru, or cash register may only be imposed on pharmacy technicians and not pharmacists; and prohibition of any non-pharmacy employ of the permit holder influencing the professional decision of the pharmacist. Additionally, the Committee discussed a recent petition for rulemaking received on February 22, 2012 regarding working conditions. Specifically it requested regulations similar to West Virginia and North Carolina which require breaks for pharmacists working more than 6 continuous hours and a prohibition against pharmacists working more than 12 continuous hours per day.

**PETITION FOR  
RULEMAKING REGARDING  
PHARMACY WORKING  
CONDITIONS - REQUIRED  
BREAKS AND NUMBER OF  
CONTINUOUS HOURS  
PHARMACIST MAY WORK:**

The Committee first discussed the petition for rulemaking. The public comment period had closed on April 15, 2012. Ms. Yeatts provided a summary of the approximate twenty public comments received. All, but one were completely supportive of the petition.

**MOTION:**

The Committee voted unanimously to recommend to the full Board in June to accept the petition for rulemaking and publish a NOIRA to address pharmacy working conditions such as a requirement that no pharmacist may work more than 12 continuous hours in any 24-hour period or more than 60 hours in any 5-day period and an allowance for pharmacists working more than 6 continuous hours to take a 30-minute uninterrupted break and one additional uninterrupted 15-minute break, with emergency provisions for addressing immediate needs of patients.

REQUEST FROM *THE PHARMACY ALLIANCE* TO IMPLEMENT MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"

The Committee then discussed the specific mandate requests received from *The Pharmacy Alliance* and referred to committee for further consideration. Public comment was received from Mr. Bob Garland, pharmacist, who believes Regulation 18VAC110-20-110 addresses the concerns raised by The Pharmacy Alliance. The regulation states that the pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy and that any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit. He stated that the corporations may not clearly understand this regulation. Comment was also received by Ms. Kristen Barratt, pharmacist, who supported the concern for a drive-thru operating when there is only one pharmacist on-duty and no pharmacy technicians. Pursuant to §54.1-100, Board counsel indicated that the promulgation of regulation may require proof that an unregulated practice can harm or endanger the health, safety or welfare of the public; without such proof, the Board may be overreaching in its authority. Through lengthy discussions, concerns were expressed by various members for the current business practices, along with concerns for the Board's ability to lawfully regulate the practices.

**MOTION:**

The Committee voted unanimously to recommend the following to the full Board in June: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and pharmacists to provide evidence to the Board that the identified practices referred to the Committee can or have created patient harm; and, publish an article in an upcoming Board e-newsletter expressing concern for contemporary practices and restating the relevant sections §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary

**action against the pharmacy permit.**

ADJOURN: With all business concluded, the meeting adjourned at 4:40PM.

\_\_\_\_\_  
Jody H. Allen, Committee Chairman

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

DRAFT

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, May 15, 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: Brandon K. Yi, Committee Chair

MEMBERS PRESENT: David C. Kozera, Committee Member

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

JODI V. ETTARE  
Pharmacist License No. 0202-205862

Jodi V. Ettare appeared with Kenneth D. McArthur and J. Buckley Warden, her attorneys, to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 4, 2012, Notice.

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

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

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

voted to issue Ms. Ettare a reprimand and impose a monetary penalty of Two Thousand Dollars (\$2,000).

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Ettare, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Ettare 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 1:00 p.m.

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Brandon K. Yi, Chair

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Cathy M. Reiniers-Day  
Deputy Executive Director

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Date

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

Staff Note: Attached is a chart with the status of regulations for the Board as of May 25, 2012

Action: None – provided for information only

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Continuous quality improvement programs</p> <p><u>Stage:</u> Emergency/NOIRA - At Governor's Office for 163 days; regulations were to be effective by 12/20/11</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Modifications to requirements for automated dispensing devices</p> <p><u>Stage:</u> NOIRA - Register Date: 11/21/11 Board adopted proposed regulation 3/13/12; At DPB</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Change to run-dry requirement for automated counting devices</p> <p><u>Stage:</u> NOIRA - Register Date: 3/26/12 Comment closed April 25, 2012</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Administrative fees for duplicate licenses and verification</p> <p><u>Stage:</u> Proposed - At Secretary's Office for 295 days</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Amendments to address on-hold prescriptions</p> <p><u>Stage:</u> Proposed - At Governor's Office for 7 days</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Repackaging in CSB's and BHA's</p> <p><u>Stage:</u> Final - At Governor's Office for 18 days; <b>Emergency regulations expired 6/18/12</b></p>

**Agenda Item: Response to Petition for Rulemaking**

**Included in your agenda package are:**

A copy of the petition received from Kristen Barratt, R.Ph.

A copy of the initial Notice in *Register of Regulations*

A copy of comment on the petition

**Staff note:**

There was a comment period on the petition from March 12, 2012 to April 15, 2012

**Board action:**

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

**OR**

The Board may accept the petitioner's request for amendments to regulations and initiate rulemaking by adoption of a Notice of Intended Regulatory Action. This was the recommendation of the Regulation Committee.



# COMMONWEALTH OF VIRGINIA

## Board of Pharmacy

9960 Mayland Drive, Suite 300  
 (804) 367-4456 (Tel)  
 Henrico, Virginia 23233-1463  
 (804) 527-4472 (Fax)

### Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle Initial, Suffix.)  
 Barratt, Kristen L., R.Ph.

Street Address  
 793 Luchase Road

Area Code and Telephone Number  
 540-635-1915

City  
 Linden

State  
 VA

Zip Code  
 22642

Email Address (optional)  
 bargeratt@comcast.net

Fax (optional)  
 540-636-3291

### Respond to the following questions:

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

Section 18 VAC-110-20 Part IV. Pharmacies: develop a new regulation "Professional Work Environment"

Received

FEB 14 2012

Board Of Pharmacy

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

To model safe pharmacist working conditions in Virginia after those of surrounding states:

**West Virginia:**

**14.8. Professional Work Environment**

14.8.1. No pharmacist may work more than twelve (12) hours within a twenty-four (24) hour period without at least eight (8) hours off duty in that 24 hours, except in a case of emergency when a pharmacist calls off work, the pharmacist on duty may work more than twelve (12) hours in order to keep the pharmacy open. The pharmacists would have to document and date the amount of time worked beyond the twelve (12) hour limit along with the reason for the extended hours of work and make it available to the Board.

**North Carolina:**

**21 NCAC 46 .2512 PHARMACIST WORK CONDITIONS**

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

Currently there are many retail pharmacies in Virginia who schedule only one pharmacist on duty for 14 hours per day, and do not provide for any meal breaks away from the pharmacy. This working environment is unprofessional and unsafe and could endanger the health, safety or welfare of the public. This potential for harm is recognizable.

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

**TITLE 54.1 PROFESSIONS AND OCCUPATIONS**

**CHAPTER 1. GENERAL PROVISIONS**

**§ 54.1-100. REGULATIONS OF PROFESSIONS AND OCCUPATIONS.**

THE RIGHT OF EVERY PERSON TO ENGAGE IN ANY LAWFUL PROFESSION, TRADE OR OCCUPATION OF HIS CHOICE IS CLEARLY PROTECTED BY BOTH THE CONSTITUTION OF THE UNITED STATES AND THE CONSTITUTION OF THE COMMONWEALTH OF VIRGINIA. THE COMMONWEALTH CANNOT ABRIDGE SUCH RIGHTS EXCEPT AS A REASONABLE EXERCISE OF ITS POLICE POWERS WHEN IT IS CLEARLY FOUND THAT SUCH ABRIDGMENT IS NECESSARY FOR THE PRESERVATION OF THE HEALTH, SAFETY AND WELFARE OF THE PUBLIC.

NO REGULATION SHALL BE IMPOSED UPON ANY PROFESSION OR OCCUPATION EXCEPT FOR THE EXCLUSIVE PURPOSE OF PROTECTING THE PUBLIC INTEREST WHEN:

1. THE UNREGULATED PRACTICE OF THE PROFESSION OR OCCUPATION CAN HARM OR ENDANGER THE HEALTH, SAFETY OR WELFARE OF THE PUBLIC, AND THE POTENTIAL FOR HARM IS RECOGNIZABLE AND NOT REMOTE OR DEPENDENT UPON TENUOUS ARGUMENT;

SIGNATURE:

*Kristen Bargeratt, PA*

DATE:

2-15-12

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## Petition for Rulemaking – Request for Comment

Promulgating Board:	Board of Pharmacy	
Regulatory Coordinator:	Caroline Juran, RPh (804)367-4416 caroline.juran@dhp.virginia.gov	
Agency Contact:	Elaine J. Yeatts Agency Regulatory Coordinator (804)367-4688  elaine.yeatts@dhp.virginia.gov	
Contact Address:	Department of Health Professions 9960 Mayland Drive, Suite 300 Richmond, VA 23233	
Chapter Affected:		
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations	
Statutory Authority:	State: Chapters 33 and 34 of Title 54.1	
Date Petition Received	02/22/2012	
Petitioner	Kristen Barratt, R.Ph.	

### Petitioner's Request

To adopt regulations similar to those in NC and WV that establish a limitation on the number of hours a pharmacist can work continuously and a requirement for breaks during a shift.

### Agency Plan

Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at [www.townhall.virginia.gov](http://www.townhall.virginia.gov). Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting on June 12, 2012, and the petitioner will be informed of the Board's decision after that meeting.

Publication Date	03/26/2012 <i>(comment period will also begin on this date)</i>
Comment End Date	04/15/2012



Logged In: DHP

Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

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

All good comments for this forum [Show Only Flagged](#)[Back to List of Comments](#)

Commenter: Kristen Barratt \*

3/27/12 11:12 am

**working conditions for pharmacists**

Hundreds of retail pharmacists in Virginia are required to work more than 12 continuous hours (often up to 14 hours) per day and a large percentage of them are not allowed to leave the pharmacy for at least a 30 minute meal break. The State Boards of Pharmacy in both West Virginia and North Carolina have regulations that limit shifts to 12 continuous hours and NC also requires that a pharmacist be allowed to take a 30 minute meal break after working more than 6 continuous hours. These regulations have been adopted in WV and NC to protect the health, safety and welfare of the public and the health and welfare of their pharmacists. I am aware of no other retail profession where an employer can require an employee to work 14 hours consecutive hours per day, without a break. 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.

Commenter: James Rhodes, Pharmacist \*

3/29/12 8:01 am

**working conditions for pharmacists**

Pharmacists need a break when required to work 12, 13 & 14 hour shifts to rest and eat a meal without interruption. Often these long shifts require an hour to an hour and one-half travel to and from the store if covering a vacation or sickness extending the day to 16-17 hrs. This is dangerous for patients receiving medication as a tired pharmacist could possibly make a mistake that is harmful to the patient. Pharmacy is a profession that requires a great deal of mental alertness and long hours with no break diminish this capability. Please consider regulations that improve this situation.

Commenter: Denise Matheny, Pharmacist \*

4/1/12 9:02 pm

**working conditions for pharmacists**

I have worked in retail pharmacy for over 13 years. Pharmacy is a very demanding and lucrative profession. It requires compassion, knowledge, patience, and physical and mental alertness. A lot of these qualities come from within the individual, but others are provided from our unique working environment. We take an oath to care for and protect our patients. Prescription errors are a rare occurrence, but any process involving people is not immune from the possibility of human

error. We must be committed to continually improve quality measures to help ensure that prescriptions are dispensed safely and accurately. I support the proposed changes to improve working conditions for pharmacists.

**Commenter:** Stephen M. LaHaye, PharmD, BCPS \*

4/3/12 7:49 am

### **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 pharmacist in the hospital setting, a 30 minute meal break is required for any employee working more than 6 continuous hours. I fail to see why my retail counterparts are not covered by the same benefits we enjoy in health-systems.

**Commenter:** Cynthia Lester \*

4/5/12 8:14 am

### **Working Conditions For Pharmacist**

I have practiced pharmacy in the state of Virginia for 21 year. I have worked retail, hospital, and independant pharmacy. In my hospital & independant practice, I was given a break for lunch which was 30 minutes. This break was rather I worked an 8 hour shift or a 12 hour shift. I have floated for a chain before and a 12 hour day was frequently 15 to 16 hours due to a commute but in those cases I was fortunate to work for a company which did recognize our need for a time to relax, refresh & recharge ourselves both physically and metally. It is a long day to stand for 12 hours. If we are lucky, there is a semi-private place where we can stash a sandwlich a steal a bite or two on the run. Or if there is an overlap of pharmacists or two on duty, they take turns letting the other get a break. Our technicians have been known to get a 15 min break and a 30 min lunch. While the propsed petion will definitely benefit the pharmacists of the state of Virginia, I do think the people we will help the most are our patients. They have put their faith, trust, health and safety in our hands. As the most respected profession, we need to continue to be able to deliver the best care to them. It is my believe that a refreshed, alert, and rested pharmacist can deliver better health care to our patients. Errors, while infrequent, do occur and are more likely to occur when we are overworked, understaffed, and just plain exhausted mentally and physically. I support this petition and respectfully ask for your deepest consideration.

**Commenter:** Health Care Professional \*

4/5/12 12:54 pm

### **In support of a break**

I am a health care professional, not a pharmacist. While, 12 hours shift are the norm in many health care areas, the person who is working a 12 hour shift or even an 8 hour shift should not be expected to do so without a break. Everyone, no matter how educated and professional they are need a break. Errors are much more likely to happen if someone is tired, rushed or inattentive. We cannot prevent every error that happens in health care but we can prevent some by taking common sense actions. Giving a break is just common sense. Allowing the workload to be appropriate for the staffing for any given shift, be it inpatient or out patient setting is also common sense. Some tasks carry such a risk, that actions should be taken to make sure the person is focused on that one task and is not being asked to multi-task. Despite people thinking that they can multi-task, the human brain can really only handle one task at a time and handle it well. Medication errors while rare can kill or seriously injure a patient. Hopefully, this Board recognizes the need to protect the public. (But sadly, my experiences with the DHP show that they lack

common sense, judgment and integrity, just my opinoin based on my experiences. )

Thank you for this forum.

**Commenter:** Timothy Ellmers, PharmD (RMH Healthcare) \*

4/5/12 7:57 pm

### **Work Conditions for Pharmacists**

I am a clinical pharmacist at a local regional hospital in Harrisonburg, VA. I have not spent much time in the retail side of pharmacy so I will not be able to make comments in that regard. I would like to speak on behalf of all hospital pharmacists. I can not stress the importance of **PATIENT SAFETY!** I try to take a step back on all my decisions and think, will the patient be harmed? We do not intend to harm our patients, but we are all human and can make serious mistakes if we are tired without a standard break or long hours. However, when pharmacist are overworked and unable to take a break due to volume issues, mistakes can be made. We belong to a profession that requires perfection and continued alertness so that we can make sure all our T's are crossed and I's are dotted before sending that medication out to the patient.

#### ***Don't the patients expect that from us?***

When you look at what we as professionals do, **we are the phyicians double check.** When entering an order, I have to make sure I do not make a mistake PLUS make sure the physician is not making a mistake. That is a HUGE responsibility that we have to take on each and every day. I have worked long shifts and by 10 to 12 hours of working, my thinking process has slowed and I may miss something important that could affect the safety of the patient that I wouldn't have if I had rested.

The board has an obligation to help protect the safety of the patients we serve. I hope that you can all come to an agreement in regards to regulating the number of continous hours and break requirements a pharmacist can work during a shift. I am glad that the board is taking the time to review this issue as I believe this issue has not gotten the attention it deserves.

**Commenter:** Angela Ciolfi, health care consumer and parent \*

4/5/12 8:23 pm

### **Support reasonable limits on working hours for pharmacists**

As a patient, and now as a mother, I want to be confident that the person filling prescriptions is alert, attentive, and capable of catching mistakes, whether made by the pharmacy or the prescribing health care provider. I support common sense limits on working hours and standards for taking breaks during long shifts such as those adopted by our neighbors, MD and WV. For the health and safety of all Virginians who use their services, please take this opportunity to review and revise your regulations governing working hours for pharomicists.

**Commenter:** Erin Durst Pharm D. \*

4/6/12 9:28 am

### **Working Conditions for Phamacists**

In my short time as a Pharmacist I have worked in WV and VA as a retail Pharmacist. I have worked 14 hour shifts at a chain pharmacy and 9 hour shifts at an independent pharmacy. I cannot express how completely exhausting it is both mentally and physically to stand for 14hours without getting a lunch break. When working at the independent I have always received a lunch break and I feel this improves my accuracy. Getting time to put your brain in neutral gives you the break you need in a profession where perfection is the standard. Working such long hours without a lunch is extremely dangerous for patient safety. In a profession where there is no room for error, it should be without question that we should receive a lunch break. I appreciate that discussion has been opened to help shed light on this issue.

**Commenter:** Jennifer Haddock \*

4/7/12 2:27 pm

**Working Conditions for Pharmacists**

**Commenter:** Jennifer Haddock \*

4/7/12 2:57 pm

**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 hours, and a requirement for breaks during a 12 hour shift. In an intensely stressful environment where the smallest mistake can create the worst kind of outcome, it is imperative that this change be implemented. Please protect not only your pharmacists but your citizens as well!

**Commenter:** Debra Curtis \*

4/7/12 4:28 pm

**Va law for pharmacist hours/break requirements**

I feel that nobody should be required to work a 12 hour shift without getting proper breaks to eat or just to take a pause from what they are doing. If you are not giving breaks from your job you are more likely to make mistakes. That is with any job. Breaks are needed!! And making a pharmacist work 12 hours straight is not necessary in my opinion.

**Commenter:** M. Howard \*

4/8/12 8:36 am

**Overworked pharmacists**

Pharmacists are extremely important partners in the good health of Americans. Being a pharmacist requires attention to details, verifying dosages, handling of extremely potent medications, and working with patients on a one to one basis. They need to be on top of their game at all times. In order to carry out this important healthcare work, pharmacists need to care for themselves. It's imperative that our retailers employing pharmacists and making pharmacy services available to their customers be required to provide ample meal times and work days of reasonable length for our pharmacists. Errors made by exhausted pharmacists could be disastrous for patients. Give pharmacists a break.

**Commenter:** Christopher Riegert \*

4/8/12 8:27 pm

**working conditions for pharmacists**

It always surprises me that it is necessary to legislate breaks in schedules to facilitate safer working conditions for health professionals. I am assuming this is about safer working conditions and not just eating habits of pharmacists. I fully support safer working conditions, which as we all know, translates to less mistakes and thus better care for our patients. I'm also a realist in the sense that if some of the pharmacists are required to take a break, then the work will be that much more/harder when they return since extra personnel will not be provided to fill in while they are on this supposed break. I think more appropriate legislation would be to require more help based on acuity of care and number of prescriptions being filled.

**Commenter:** Consumer \*

4/9/12 8:12 am

**Reasonable breaks for pharmacists.**

I went to Walmart over the weekend to pick up a prescription. Clearly posted is a sign that states if there is only one pharmacist on duty the pharmacy will be closed for 1/2 hour at lunch time. Clearly Walmart understands the importance of giving a worker a lunch break. Allowing a pharmacist to take a real break for a half hour will help them to function better and make fewer errors. Hopefully, the DPH will be as enlightened as the evil giant Walmart. Thanks.

**Commenter:** Stephen Squires \*

4/9/12 7:14 pm

**Working Conditions for Retail Pharmacists**

I support mandatory breaks for retail pharmacists working 12 hour shifts, and the elimination of 14 hour shifts. I have worked 14 hour shifts in the past, and after hour eleven it became very difficult to focus. What other health care provider works 12 hours...even 8...without a lunch or bathroom break. Pharmacy should be mentally, not physically demanding. Pharmacists are well compensated, however that does not make them superhuman and able to go without meals or bathroom breaks. The bottom line is that the patients health is at stake. It is time for change..

**Commenter:** Bhavani Sudhagani,pharmacist \*

4/9/12 11:09 pm

**working conditions for pharmacists**

I strongly support the petition against long work hours for pharmacists without a meal break. I work for a large retail which gives us a break even when we work 8 hour shifts, I cannot imagine working straight 12 hours without a break. I really feel sorry for my friends who have to work for such a long shifts without a break. As retail pharmacists standing all the day on feet try to help constantly each patient who visit pharmacies with prescriptions and in the OTC isles helping them find right medications which makes us physically exhausted after certain number of hours. By profession itself a pharmacist needs to be mentally alert to dispense right medications and brain needs energy to stay alert which is not possible without a meal. I would like to strongly say that pharmacists, as a human being, just because he/she is being paid cannot be expected to work like machines which do not need a meal break. This kind of work environment is not only detrimental to the pharmacists' health in long run but also directly affecting the safety of patients getting medications from a less productive pharmacist who would otherwise be with a little 30 minutes meal break. So, please help patients and pharmacists to be in safe pharmacy environment.

**Commenter:** Timothy C Funk \*

4/11/12 1:39 pm

**hours**

I have several concerns about this possible change

1. You will still have to fill the same number of rx's a day you will just have less time to do it , Everyone seems to worry about mistakes, filling more rxs per hour seems to me to make that more likely not less
2. Cutting back hours will result in less hours pharmacy's will be open and reduce demand for pharmacists in a already tight market

3. Do not relish the idea that the State can limit my right to work.

4. I do support lunch break idea

**Commenter:** Elizabeth Early \*

4/13/12 2:48 pm

### **Work Conditions for Pharmacists**

Although the safety issues associated with long and consecutive hours has been documented by other healthcare industries, there seems to be little research related to the pharmacy industry. However, I believe that it is important that we listen to our colleges in WV and NC and evaluate our work conditions...not only for the safety concerns for our patients, but for our own health.

I have been involved in a number of patient safety reviews in my career, and a common response to the cause of the error has been worker fatigue or mental lapse of judgement. It has been shown that jobs that require multitasking and prioritization are more susceptible to fatigue. As a pharmacist, we must manage prescription queue, the telephone, the MD line, the fax, the e-prescriptions, the drop-off window, the drive-up window, the counseling window, the operations or work-arounds of the technology, the technician staff, immunizations, fill 300+ prescriptions a day and get all of this done in 15 minutes or less per prescription. In a hospital setting; we have to manage medication reconciliation issues, complex drug regimens, IV compatibilities, distribution functions, clinical monitoring, drugs that increase fall risks, meds that impact renal function, discharge counseling and issues that impact readmissions, as well as order verification and clarification. The demands are high, as well as the expectation for near perfect processing. Long shifts, various shifts and multiple days on duty impact our ability to perform at a near perfect level.

As the industry has focused on pharmacist's satisfaction, 12 hour shifts with multiple consecutive days have become the norm. However, these shifts increase the opportunity for fatigue and adverse effects on worker health. Working more than 40 hours per week or more than hours per day has shown to impact:

- Neck and musculoskeletal discomfort
- Increased risk for hypertension
- Increased incidence of cardiovascular disease
- Higher risk for diabetes
- Increased risk for pre-term birth
- More work place accidents

How many pharmacists do you know that suffer from a chronic disease or physical discomfort that could be related to their work shifts? In addition, it has been proven that the older we get, the more fatigue impacts our performance. As we all get older and are more susceptible to chronic diseases, we must do all we can to protect our own health...for ourselves, our families and our patients.

We owe it to ourselves and our patients to do better...I agree that we must improve pharmacist work conditions. I applaud the Virginia Board of Pharmacy for addressing this concern.

**Commenter:** Rebecca Williams \*

4/14/12 4:01 pm

### **Working Conditions for Pharmacists**

I have worked in retail pharmacy over the past 5 years and have worked multiple shifts over 12 hours. Pharmacy is a profession, like many others in the medical field, that requires intense concentration and multi-tasking on a daily basis. I feel it is risky to have pharmacists perform this sort of work over such long periods of time, especially without a break. In many retail locations, we as pharmacists are torn between not only verifying prescriptions and counseling patients, but also answering the phones, supervising technicians, administering immunizations,

etc. Pharmacists are stretched thin in many situations and having to maintain this for shifts greater than 12 hours without a break is potentially dangerous. Our profession demands perfection. Our patients deserve to always have quality medical care. We owe it to our patients to be able to perform at our best, but fatigue and lack of concentration undoubtedly happen over the course of such long shifts. Our colleagues in West Virginia and North Carolina have taken action to ensure the safety of their citizens and well-being of their pharmacists. I urge the Virginia BOP to do the same.

\* Nonregistered public user

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

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**From:** Board of Pharmacy  
**Sent:** Friday, April 13, 2012 8:29 AM  
**To:** Juran, Caroline (DHP); Yeatts, Elaine J. (DHP)  
**Subject:** FW: From Robert Gibson  
**Attachments:** From Robert Gibson

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**From:** [rgzburg@comcast.net](mailto:rgzburg@comcast.net) [mailto:[rgzburg@comcast.net](mailto:rgzburg@comcast.net)]  
**Sent:** Thursday, April 12, 2012 3:04 PM  
**To:** Board of Pharmacy  
**Subject:** From Robert Gibson

Virginia Commonwealth Board of Pharmacy  
Richmond, VA

To whom it may concern:

My name is Robert Gibson and I have been practicing retail pharmacy in Virginia for the past twenty years. It has been brought to my attention that this summer the board may take action/revise the code to either allow mandatory breaks away from the pharmacy or have a maximum numbers of hours that a pharmacist can work during a shift. I sincerely hope that action is taken. Over the past twenty years I have worked in several retail pharmacies that have filled over 3000 prescriptions per week. Many days we did not have time to eat lunch or even take a five-minute break to collect our thoughts. I find it ironic that over the years we have passed many pharmacy laws to help protect the health of the public but have missed one of the most simple causes of errors in the pharmacy, mental and physical fatigue. I have a neighbor who is a retired airline pilot and we have talked many times about the strict standards of the FAA to minimize pilot fatigue. When I told him of the long hours we work and the amount of prescriptions we fill he was shocked to hear there were no laws. In his exact words, "I'm surprised! A pharmacist can make fatal mistakes just like I could flying".

I ask that you take this matter very seriously and try to come up with a solution but please make sure that if you do pass action that you word the code so that it is specific. Maybe have the code state a break away from the pharmacy or a pharmacist must have certain number of hours off from the end of a shift. Something worded in a way so there cannot be any loopholes. I personally would strongly urge a required number of hours off between shifts. I have worked with many pharmacists that sometimes work 5 and 6 days straight and work twelve-hour shifts. While they think they are not mentally fatigued I am afraid that the general public maybe at risk.

Whatever action is taken please make sure that there cannot be room for interpretation that would water down the intended effect of the code. That would be an injustice to the public and only lip service to us.

Best regards,

Robert Gibson  
Harrisonburg, VA  
0202010386

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

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**From:** William Anderson 6424 [william.anderson@giantmartins.com]  
**Sent:** Friday, April 13, 2012 1:22 PM  
**To:** Board of Pharmacy  
**Subject:** Patient safety

I understand from heresay that the board is looking into the current working conditions as it pertains to patient safety. This is long overdue. I'm sure I do not need to waste your time sharing our day to day experience. I hope you will look at consecutive hours worked, mandated breaks for meals etc outside of the pharmacy, pharmacist to tech ratio, and the operating of a pharmacy completely alone. As you are well aware our profession accepts nothing below 100 % accuracy with any error having potentially life threatning results. We are looking to you to mandate conditions that will allow us to meet this percent..  
Thanks for you time..

Bill Anderson, Pharmacist  
Pharmacy Manager @ 6424  
Martins Pharmacy  
2035 East Market Ste 115  
Harrisonburg, Va 22801  
Phone: 540-442-7380  
Fax: 540-442-8089  
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## Request from *The Pharmacy Alliance* on pharmacy working conditions

- Regulation Committee's report and recommendation – Jody H. Allen, Committee Chairman

### Possible board action:

- Motion to adopt a Notice of Intended Regulatory Action to initiate rulemaking to address specific concerns for pharmacy work conditions

OR

- Motion to accept one or more of the committee's recommendations. The committee's recommendations are to: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and pharmacists to provide evidence to the Board that the identified practices referred to the Committee can or have created patient harm; and, publish an article in an upcoming Board e-newsletter expressing concern for contemporary practices and restating the relevant sections §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

OR

- Take no action.

Juran, Caroline (DHP)

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**From:** Priscilla Gale [p.gale@cox.net]  
**Sent:** Friday, March 16, 2012 10:14 AM  
**To:** Juran, Caroline (DHP)  
**Cc:** steve@steveariens.com; jpgakis@hotmail.com  
**Subject:** Information you requested  
**Attachments:** VABOP032012 (1).rtf; march 15 doc vabop.odt

(contained 2 attachments)

Attachment #1 from Priscilla Gale, 3/16/12

Thank you Virginia Board of Pharmacy for allowing me to speak on behalf of the Pharmacy Alliance today. We feel this is an important first step you took to protect the patients here in Virginia, and appreciate the time you have allotted us today.

The Pharmacy Alliance is a growing national group of Pharmacists who have in common, a mission to improve patient safety by reducing prescription errors. It is reported that 1.5 million people are harmed every year by medication errors *every year*, despite increasing educational demands on pharmacists. All of us here today understand errors are increasing at an alarming rate.

How did we get here?, you may ask. Every state has increased the level of education of all our pharmacy staff, including pharmacists. Education failed! Impossible, right? How could an educated staff make so many errors? Again, the question, how did we get here?

Well, a bit of regulatory history may clarify that answer. You see, when the Board of Pharmacy Practices and Acts were written at the turn of the century, the vast majority of the Pharmacists in Charge and the permit holders were one and the same. Simply stated, that means the pharmacies providing medications were INDEPENDENTS. If something went terribly wrong, both the PIC and the permit holder were forced to address the issue. Today, that is not the case. We, dispensing pharmacists, work for chains or large corporations. Further confounding our safety dilemma and medical errors situation, is the conflict of interest of allowing chain executives serve on the Board of Pharmacy.

Most chain representatives and safety organizations such as ISPM (Institute for Safe Medication Practices) have answers to the increased rate of errors. They maintain that errors occur when the pharmacy is slow, and well-staffed, and are due to technical issues such as trailing zeros, look-alike sound -alike medications, and prescriber handwriting issues. They maintain other prescription errors are due to pharmacist negligence or un-professionalism. Really? Slack time and trailing zeros.....who buys this? Only the interests selling it, that's who. Every pharmacist knows better!

We at The Pharmacy Alliance are serving at the battle lines. We know a different cause for increasing errors. We see clearly that eroding conditions in our work environment have been at the root of patient safety concerns. Workplace standards have deteriorated over the last 5 to 10 plus years and have now reached the tipping point. We have a no spin explanations for the increased rates in errors; I will briefly outline them in a list form.

But before this list, I stress above all, that our pharmacists feel that errors caused by physical fatigue due to more prescriptions per hour, no breaks, long schedules, long commutes, rotating schedules, exceed all other causes. We collectively definitively know that genesis of these problems are the mandatory 12 -14 hr shifts ( not counting that you must be there 15 minutes before the shift and you cannot close until all patients have been served). Mind you, this occurs without any scheduled meal or rest room breaks and having to work multiple such days in a row. And a reminder to all ... A Chain's Forty hours today means scheduled 55 hours one week and scheduled 25 the next. Such schedules preclude a Pharmacist from getting more than five to six

hours sleep between shifts, not taking account for NOVA traffic and excessive commutes. It doesn't take much intelligence to come to the conclusion that a fatigued Pharmacist can be a dangerous Pharmacist, in regard to medication errors. If any of you have any questions about how fatigue can affect accuracy of a person performing repetitive jobs, then you probably slept through last week, which was National Quality of Sleep week. Please look up sleep studies in VDOT or FAA. 7 days on – 7 days off – 12 hr shifts. Should they be outlawed/prohibited due to safety issues?

Now, the brief list of workplace safety violations I promised you that is perpetrated by our management and permitted by this board and out of the control of pharmacists and pharmacists in charge. It includes, but is not limited to: PHARMACIST SCHEDULING, PHYSICAL STANDARDS OF THE PHARMACY, AUTHORITY OVER PHARMACY PERSONNEL, NON-PHARMACY MANAGEMENT POLICIES APPLIED TO PHARMACISTS, AND MANDATED POLICIES DICTATING PHARMACISTS PROFESSIONAL DISCRETION

1: PHARMACIST SCHEDULING- includes 12-14 hour shifts, rest breaks, meal breaks, back to back shifts, commutes for floaters, 15 minute wait times, flu shot quotas.

2: PHYSICAL STANDARDS OF THE PHARMACY- is it ever safe to operate a drive through pharmacy? HIPAA?? How are the new prototypes of the pharmacy doing, the ones you see in Harris Teeter and Target without boundaries. How are these pharmacies without walls performing performing with standards of errors, HIPPA violations, counseling patients, etc.? Are the pharmacists distracted by non-pharmacy interruptions, or is the MUZAC too loud? Can they repeat drug orders while a customer is waiting to ask them where the floral department is located? Can you supervise your technicians over the freezer alarm buzzer?

3. AUTHORITY OVER PHARMACY PERSONNEL- Have you supervised a tech that had an ankle bracelet? I am not speaking of a fashion accessory here. Raises, promotions, rates of pay, schedules, integrity of the personell and terminations are all front end management issues. We just get stuck with their decisions.

4. STORE PERSONNEL POLICIES FOR NON PHARMACISTS MANDATED ON PHARMACIST- Such as answer call on ring three, policies ordering pharmacists to physically leave the pharmacy department to help a non-pharmacy customer find toothpicks or any other item, making eye contact with every customer, etc.

5. MANDATES ON PROFESSIONAL DISCRETION calling prescribers to specify tablet or capsule etc

Please accept this as a partial list of ways of which our corporate leaders are creating medication errors and accepting the cost of settling as the “cost of doing business”. It's a steal for the chains, and tragedy for our patients and dedicated pharmacists.

Finally, I have made copies of a recent survey conducted by The Oregon BOP for you today. Something to keep in mind, is that Oregon is one of the few boards that to the best of our knowledge, does not have chain exec representation on it. In summary, nearly 75% of the chain Pharmacists felt that their work environment did not promote patient safety, whereas 75% of the independent Pharmacists felt that their work environment did. It's all about responsibility.

In conclusion: We from the Pharmacy Alliance are here today because Pharmacists are making more and more medication errors that get to patients. We feel that it is not in our society's best interest for this to continue unchecked. Patients are being harmed, lives are being destroyed. Both the lives of victim patients and victim pharmacists. Sure, chains get fined here and there, but it's a slap of the wrist, not the ruin of life and careers the public and pharmacists endure after a medication error tragedy.

Today, you cannot pick up a newspaper or turn on the television without another report of pharmacy medication errors. It's a fact, the regulators are failing us. Pharmacists are practicing under unsafe conditions. It is time permit holder accept a higher degree of accountability when things go wrong in the Rx dept. Since the PIC has no control over the Rx dept policy and procedures, physical barriers between the patients, staffing and other issues that can affect patient safety, then the corporation, AKA the permit holder, must be held to a higher degree of responsibility and liability. Fines need to be levied in more direct proportion to the permit holder's assets and ability to pay. For example, if a Pharmacist is fined the equivalent of a day's pay, then the permit holder should be fined the equivalent of one day's profit. We are here today, with every paper and newspaper reporting errors and diversions. We need to change direction and change fast.

Thank you again for the time you have allowed me today to represent the findings of the Pharmacy Alliance. I hope now we all know how we got here. Follow our lead to get us out. We have a problem. The Pharmacy Alliance has answers! The Alliance will help. Just ask!

Attachment #2 from Priscilla Gale, 3/16/12

Priscilla Gale  
Virginia Contact  
The Pharmacy Alliance  
6023 Avenue S, Box #134  
Galveston, TX 77551

March 15, 2012

Dear Ms. Juran,

It was again a pleasure to speak to you and the board on behalf of The Pharmacy Alliance. The studies you requested from me are at the conclusion of this letter. To reiterate my presentation from Tuesday, The Pharmacy Alliance is calling for more corporate responsibility from the Chains and the large corporations that have unsafe policies and procedures.

I am confident that you are serious about keeping Virginia safe from medication errors. Because of the time you allowed me to speak, you are now aware of a serious a problem that exists in not only in Virginia, but nationally. Again, pharmacists everywhere and we at the Alliance believe that chains and corporations alike must be held responsible for medication errors that are due to policies, procedures, workplace conditions, and staffing issues that are **well known** to be a hazard to the public's health and safety.

Finally, the time has come for change. That is because sadly, the pharmacy owners are creating well publicized drug errors.

Again, chains and corporations must be held as accountable as an independent PIC/permit holder is. Times change, laws change. We in Virginia are not a group of independent pharmacies in control of our operations. We are dedicated pharmacists not in control of the systems that cause errors.

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Also, I need to mention manpower. There is no more a pharmacist shortage in your state. Conversely, here in VA there are many underemployed or unemployed pharmacists. Finding licensed and qualified pharmacy professionals is no longer an excuse for lack of qualified workers.

Again, the traditional medical culture of individual responsibility and blame no longer can be applied to pharmacy errors, as the workplace systems are set can be inherently dangerous.

Poorly/untrained teenagers and twenty-something cannot possibly replace experienced pharmacists. They cannot serve you a beer in a hot dog hut and have no business in the pharmacy department preparing dangerous medications.

You asked me for specific studies that examine pharmacist and workplace pressures that cause pharmacists to make medication errors, and underlying system failures. I spoke at great length of them Tuesday, and I am happy to substantiate pharmacists' experiences and concerns of TPA with studies. Additionally, I am sure you could ask the chains for more in depth studies. In the past, the large chains and corporations have used legal tactics to keep important studies from the public and governing entities by citing liability concerns and adverse effects on their image/reputation. Some Pharmacy Boards prohibit not sharing this information, and perhaps, because of your chain ties the corporations will feel they could make an exception for you! Or, you could always force the issue.

Some studies I have included for your consideration come from attorneys representing patients. I would like to point out to you that you represent patients as well. I have also included sleep deprivation studies in other fields such as aviation and transportation. I trust you will embrace these studies, unlike the North Carolina Board! After all, why you would allow a judge to decide what to do five years from now when you have an immediate problem to solve?

All of these studies reflect our inherent human frailty in attempting to do work, at a zero-error level, while pushing or exceeding a person's basic physical/mental limits. It should not matter if the study looks at a Pharmacist, truck driver, airline pilot or nurse in their work setting. All that should matter is that an employee is putting other people's health and well-being at risk, when trying to work past their personal safe limits. Being a licensed Pharmacist does not exempt us from these human limits. We need to have rest breaks, meal breaks, use the restroom, and be allowed to hydrate ourselves when working. We are human after all.

With all the components involved in today's pharmacy work environment and systems and timing metrics measured in SECONDS, we can no longer accept sole legal responsibility for errors like that of independent pharmacies. We are not independent of the chains and corporations. Again, some include for corporate policies that should not apply to pharmacists mandated on Pharmacists, a poor Rx dept. layout, under qualified staffing, poor integration of the various components can be the genesis of many med errors. Customer service policies mandated on pharmacists such as eye contact with all customers, answering the telephone in 20 seconds, filling a prescription in 15 minutes or less are unsafe to the dispensing process. Adding a stressed/fatigued pharmacy staff and it is impossible/irrational to segregate med errors as an individual Pharmacist's issue and ignore all the other contributing factors.

We believe that all BOP's are going to have to eventually face these complex issues and how they are ultimately affecting patient safety. Errors, oversights, and negligence **perpetrated by the chains** and **lack of regulation** are frequently on the front page and news program.

<http://abcnews.go.com/Business/story?id=6552337&page=1>

Ms. Juran, We are at a fork in the road here. You may choose the path many other BOPs are already on. That would lead to VA's BOP to start taking a harder stance on medication errors and in effect

blame the victim pharmacist rather than the perpetrator of the crime. The other fork is the path that accepts the fact that work place issues and patient safety issues are one and the same.

I hope you choose the correct path. The Pharmacy Alliance is determined to make this a very public national issue; it is hard for anyone to be against a public safety issue. The VA BOP has the chance to be an industry leader and take a proactive approach to this growing problem. We have noticed that the media is paying more attention to medication errors and reporting on them. We believe that it is just a matter of time before more non-pharmacy consumer focused groups align with us, calling for lessening medication errors in pharmacies. We look forward to working with the VA BOP to advance pharmacy safety issues and improve patient safety.

Thank you again for the time and sincere interest of the activities of the Pharmacy Alliance and your fierce interest in patient safety. You may contact us for any reason at any time. We can help. Just ask.

Sincerely,

Priscilla Gale, RPh, MBA  
Virginia Contact for The Pharmacy Alliance

Below are the studies you requested:

Pharmacist specific studies

<http://consumer.healthday.com/encyclopedia/article.asp?AID=646512>

<http://www.collegecentral.com/Article.cfm?CatID=car&ArticleID=139>

Above is from a Leesburg, Virginia tragedy, a high school student, pharmacist, and all beloved ones of a deceased young patient.

<http://www.pharmacyerrorlawfirm.com/>

[http://www.pharmacistactivist.com/2008/february\\_2008.shtml](http://www.pharmacistactivist.com/2008/february_2008.shtml)

<http://www.rpharms.com/current-campaigns-pdfs/workplacepressures.pdf>

[http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Policy&d\\_id=51&i=April+2011&i\\_id=724&a\\_id=17036](http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Policy&d_id=51&i=April+2011&i_id=724&a_id=17036)

<http://pharmsafety.org/extras.cfm>

[http://www.jointcommission.org/sea\\_issue\\_48/](http://www.jointcommission.org/sea_issue_48/)

[http://www.uspharmacist.com/continuing\\_education/ceviewtest/lesonid/105916/](http://www.uspharmacist.com/continuing_education/ceviewtest/lesonid/105916/)

<http://www.medicalnewstoday.com/releases/191236.php>

<http://www.wsna.org/Topics/Fatigue/documents/Fatigue-White-Paper.pdf>

<http://www.ncbi.nlm.nih.gov/books/NBK2656/>

<http://content.healthaffairs.org/content/21/5/182.full>

<http://www.cdc.gov/niosh/docs/99-101/>

<http://www.ismp.org/Newsletters/acutecare/articles/20050602.asp>

[http://www.nytimes.com/2011/08/07/magazine/the-phantom-menace-of-sleep-deprived-doctors.html?\\_r=1&pagewanted=all](http://www.nytimes.com/2011/08/07/magazine/the-phantom-menace-of-sleep-deprived-doctors.html?_r=1&pagewanted=all)

[http://www.shpa.org.au/lib/pdf/whatsnew/vic\\_workforce\\_Part3.pdf](http://www.shpa.org.au/lib/pdf/whatsnew/vic_workforce_Part3.pdf)

<http://www.medicalnewstoday.com/releases/227673.php>

<http://www.ahrq.gov/clinic/ptsafety/chap46a.htm>

<http://www.hse.gov.uk/humanfactors/topics/fatigue.htm>

[http://www.faa.gov/news/press\\_releases/news\\_story.cfm?newsId=11839](http://www.faa.gov/news/press_releases/news_story.cfm?newsId=11839)

Juran, Caroline (DHP)

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**From:** BGarlandJr@aol.com  
**Sent:** Wednesday, May 09, 2012 4:02 PM  
**To:** Juran, Caroline (DHP)  
**Subject:** May 2, 2012 Regulation Committee Meeting on Pharmacy Working Conditions  
**Attachments:** Presentation to Regulation Committee 5-2-12.pdf

Dear Caroline,

It was a pleasure to meet you in person and, again, thanks so much for the opportunity to speak at the recent meeting of the Regulation Committee on Pharmacy Working Conditions. I have attached the general text of my comments to the Committee.

I was encouraged that many, if not most, members of the committee appeared to be in agreement that the issues presented by *The Pharmacy Alliance* were valid concerns which have the potential to jeopardize the health and safety of the public. As I previously said, I have no connection to *The Pharmacy Alliance* and, to the best of my knowledge, I do not know any of its organizers. I was there to speak for myself based on my own experience.

While I was a little disappointed that the committee did not adopt specific recommendations to the Board that would address each concern, I do think that a guidance document or newsletter article on 18VAC110-20-110, B would help. It is very clear to me that this regulation places the Pharmacist-in-Charge or Pharmacist-on-Duty in full and complete control of the practice of pharmacy within the practice location. However, I do not think that is clear to many corporations.

As part of that guidance document, in addition to quoting the above regulation, I believe it would be correct to say:

- Only the PIC is "in full and actual charge of the pharmacy" (54.1-3401 and 54.1-3434). The term "in charge" means "having control over or responsibility for".
- Only the PIC or POD "shall control all aspects of the practice of pharmacy". (18VAC110-20-110, B)
- Only the PIC or POD can supervise pharmacy interns and technicians (54.1-3320, #7). It seems to me this obviously excludes store managers, district managers, and even (RPh) pharmacy supervisors (since they are neither the PIC or POD) from telling a technician what to do.
- Only the PIC or POD can determine the maximum number of technicians to be supervised (54.1-3320, D and 18VAC110-20-270, B).
- By implication in 18VAC110-20-110, B, only the PIC or POD can determine the minimum number of technicians required during the course of a given day.

I think you agree that it would be virtually impossible to gather safety data which would "prove" the wisdom of the various proposals from *The Pharmacy Alliance* just as it would be difficult to "prove" the wisdom of most Board Regulations. Our collective common sense tells us that these regulations do serve to protect the "public's health and safety". Perhaps a better name for this Committee would be "The Patient Health and Safety Committee".

In summary, I strongly believe that current regulations cover all of the concerns presented by *The Pharmacy Alliance*. The problem is that most pharmacists are either unaware of the applicable regulations or fear corporate retaliation. It is up to the Board of Pharmacy to make this clear to all. To that end, please forward this email to the full Board and any others of your choosing.

Sincerely,



Bob Garland, Jr., Pharmacist  
105 Woodhurst Ct.  
Charlottesville, VA 22901-2235  
[bgarlandjr@aol.com](mailto:bgarlandjr@aol.com)  
(434) 293-2045 (H)

Attachment to email from Mr. Garland:

**Presentation to Regulation Committee – Pharmacy Working Conditions**

Ladies and gentlemen, I appreciate the opportunity to speak to you today.

My name is Bob Garland, Jr. & I am a pharmacist with 44 years of experience. During that time, I have worked in independent, hospital, and chain pharmacy. I am here to offer comments on the proposed petition for rulemaking regarding pharmacist working conditions.

The Pharmacy & Drug Control Act mentions the word "safety" 46 times, most often in the phrase "public health and safety". It is clear from this act, as well as the Board of Pharmacy Regulations, that the Board exists to protect the public health and safety. In my opinion, all of these proposals are consistent with that goal and current regulations. The fact that a number of pharmacists feel that these proposals are necessary indicates that, in many instances, the current regulations are being violated and clarification is needed.

In the Pharmacy Act under Definitions, the:

**" Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease,** whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section

The Board of Pharmacy Regulations under 18VAC110-20-110 Pharmacy Permits says:  
B. **The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.**

I would like to address those requests individually.

**PROHIBITION OF ANY GUARANTEE OR ADVERTISEMENT THAT PROMOTES HOW FAST PRESCRIPTIONS WILL BE DISPENSED:**

I am sure we can all agree that every pharmacist has his or her own safe dispensing rate that can only be determined by the individual and no one else. What we can't agree on is what that rate is for each pharmacist and how it may vary by day or by hour. For me, most days I get the bear, but some days the bear gets me. This proposal would make it clear that guarantees or advertisements that promote speed at the expense of safety are not allowed.

**REQUIREMENT THAT DRIVE-THRU WINDOWS BE CLOSED WHEN THERE IS NO PHARMACY TECHNICIAN SUPPORT IN THE PRESCRIPTION DEPARTMENT:**

While I agree with the intent of this, I would go one step further and suggest that drive-thru windows should be closed at the discretion of the pharmacist when adequate pharmacy technician support is not available. Again, per regulation, "the pharmacist on duty shall control all aspects of the practice of pharmacy."

**PROHIBITION AGAINST MANDATORY CORPORATE PRODUCTION METRICS OR QUOTAS REGARDING PRESCRIPTION DISPENSING OR IMMUNIZATIONS:**

A mandatory quota implies that, if it is not obtained, there will be negative consequences. I have no problem with goals, but a mandatory quota has the potential to interfere with the safe practice of Pharmacy.

**REQUIREMENT THAT OTHER TIMED METRICS REGARDING THE PHONE, DRIVE-THRU, OR CASH REGISTER MAY ONLY BE IMPOSED ON PHARMACY TECHNICIANS AND NOT PHARMACISTS:**

This is one proposal that I do not agree with, but not for the reason you may think. I presume that what is being proposed refers to "Corporate timed metrics". Per existing statutes and regulations, only the Pharmacist-in-Charge can supervise pharmacy technicians, so I would not be in favor of allowing a corporation to impose timed-metrics pharmacy technicians and certainly not on pharmacists.

**PROHIBITION OF ANY NON-PHARMACIST EMPLOYEE OF THE PERMIT HOLDER INFLUENCING THE PROFESSIONAL DECISION OF THE PHARMACIST:**

This is already clearly prohibited by the Board of Pharmacy Regulations under 18VAC110-20-110 that I referenced earlier. Perhaps it needs to be clarified to include examples such as store managers, district managers, and even pharmacy supervisors, etc.

In summary, I think the practice of pharmacy has reached or possibly passed a crucial point in its history where there is a danger of the profession losing control to non-pharmacists and compromising patient safety. I would strongly recommend that this Committee and the full Board address the concerns expressed in this petition for rulemaking and return the practice of pharmacy to pharmacists as per the obvious intent of all statutes and regulations.

Thank you.

## **Request to Discuss Length of Time Associated with and Access to Final Orders**

- Request from Crady Adams to discuss the length of time a final order resulting from a disciplinary matter remains on a licensee's record and on the Board's website for viewing.

### **Background:**

Currently, public record requirements in the Freedom of Information Act and requirements regarding the finality of orders in the Administrative Process Act require orders to be maintained and accessible to the public for 85 years. Additionally, agency policy requires all boards to post orders on the agency's website once the orders become final.

**Request from staff for guidance regarding nine-month allowance in Regulations 18VAC110-20-101 D and 18VAC110-20-111 C**

**Background:** Staff is seeking an interpretation of the nine-month allowance in Regulations 18VAC110-20-101 D and 18VAC110-20-111 C. Is the intention of the regulation to allow an individual to perform tasks restricted to pharmacy technicians for no more than nine continuous months? Concern exists for individuals such as college students who may only perform duties during summer months or school breaks. If the nine month allowance begins each time the student enrolls or re-enrolls into a training program so to perform the duties of a pharmacy technician, then the individual could work intermittently for years without being required to obtain registration as a pharmacy technician.

**Action:**

- Motion to adopt a guidance document which captures interpretation of nine-month allowance to perform tasks restricted to a pharmacy technician.

## **18VAC110-20-10**

"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.

### **18VAC110-20-101. Application for registration as a pharmacy technician.**

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of an approved training program, and
2. A passing score on a board-approved examination.

C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.

D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.

### **18VAC110-20-111. Pharmacy technicians.**

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.

## **Request from staff for guidance when more than one pharmacist involved in the dispensing process**

**Background:** Regulation 18VAC110-20-270 C states, “After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction.” Staff is concerned about the requirement for one pharmacist to verify the accuracy in all respects and assume responsibility for the entire transaction when contemporary practices frequently involve more than one pharmacist in the dispensing process for a single prescription, i.e., one pharmacist may verify the accuracy of the data entry of the information and a second pharmacist may verify the accuracy of the dispensed drug. Additionally, Regulation 18VAC110-20-276 regarding central or remote processing requires the identification of individual pharmacists involved in individual dispensing functions and appears to conflict with the requirement of holding one pharmacist responsible for the entire transaction as indicated in 18VAC110-20-270 C. Furthermore, staff is aware that the dividing of individual dispensing functions is not limited to central or remote processing, but may occur in a single pharmacy, and there is concern that the recordkeeping requirements associated with this process may be unclear.

### **Possible Board Action:**

- Motion to adopt a NOIRA to amend pharmacist verification requirements in Regulation 18VAC110-20-270 and/or a guidance document which harmonizes the pharmacist verification requirements in Regulations 18VAC110-20-270 C and 18VAC110-20-276 and incorporates recordkeeping requirements in Regulation 18VAC110-20-255, when applicable.

**18VAC110-20-255. Other dispensing records.**

Pursuant to §54.1-3412 of the Code of Virginia, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

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

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

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

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation

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

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

**18VAC110-20-276. Central or remote processing.**

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

**Define “annual” and “semiannual” in Guidance Document 110-36, clarify record retention requirement, and establish threshold for compliance in guidance document 110-9**

**Background:** To assist pharmacists and pharmacy inspectors in understanding the Board’s expectations in complying with USP Chapters 795 and 797, the Board will consider defining the terms “annually” and “semiannually” within Guidance Document 110-36 while revising outdated information. Additionally, to assist in determining compliance, the Board will consider the appropriateness of adding a proposed 60-day threshold in Major Deficiencies 25 and 26 within Guidance Document 110-9.

**Action:**

- Motion to adopt proposed changes (or as amended) in one or both guidance documents 110-36 and 110-9.

**OR**

- Take no action.

**GUIDANCE DOCUMENT 110-36**  
**COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING**

~~§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF, the USP Pharmacists' Pharmacopeia (available beginning Summer 2005), and USP DI Volume III. Some individual chapters, such as 797, may be purchased individually. More information may be found at [www.usp.org](http://www.usp.org) under "Products". In accordance with 18VAC110-20-170, the Board requires any a pharmacy engaging in compounding activities to maintain a current reference containing the USP standards relating to compounding, preferably the USP Pharmacists' Pharmacopeia as it contains the specific information relating to pharmacy compounding to include common compounding monographs, standards on containers (Chapters 661 and 671), and several advisory chapters on packaging, compounding and pharmacy calculations, to include Chapters 1136, 1146, 1178, 1150, 1075, and 1160. to maintain references consistent with the pharmacy's scope of practice and with the public safety.~~

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 or 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained for 2 years from the date performed. Such records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

~~USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The board recognizes that some pharmacies are not currently compliant with the new physical requirements of Chapter 797 and is also cognizant of the time and costs associated with making the necessary capital improvements to facilities in order to comply with these new requirements. Therefore, the Board will allow pharmacies some time to make these improvements. However, the Board does expect at least compliance with the "old" standard of performing sterile compounding in at least a Class 100 (ISO 5) environment. The Board also expects pharmacies to be in compliance with policies and procedures, training and evaluation of personnel and the other requirements of Chapter 797 at the time of inspection.~~

*June 8, 2004*  
*Revised June 7, 2005*  
*Revised: June 5, 2006*  
*Revised: June 4, 2008*  
*Revised: June 12, 2012*

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**Board of Pharmacy  
Guidance Document 110-36**

~~Normally when an inspector cites a deficiency during an inspection, the pharmacy has 14 days to correct that deficiency and provide a response to the board as to the corrective action taken. If a pharmacy engaging in sterile compounding is cited for non compliance with the new physical standards of USP Chapter 797, the board will allow the pharmacy 90 days to submit a plan of action to correct the deficiency within 2 years of the date of inspection. However, the Board's expectation is that all pharmacies engaged in sterile compounding be in compliance no later than June 30, 2008.~~

~~Because of the changes to USP 797 that were published December 2007 and became effective June 1, 2008, the Board will allow a one-time extension until October 31, 2008 for pharmacies to comply with the physical standards provisions. After this date, the Board will begin enforcing the physical standards provisions, and non-compliance may result in a monetary penalty of not more than \$5000 per violation. Each sterile preparation that is compounded under conditions not in conformity with §54.1-3410.2, and by reference USP 797, may constitute a single violation.~~



*June 8, 2004  
Revised June 7, 2005  
Revised: June 5, 2006  
Revised: June 4, 2008  
Revised: June 12, 2012*

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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, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	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 over 60 days late (6mo+60 days). Corrective action not taken within one month of certification report.	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
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs; or, no documentation of initial and semi-annual (6 months + 60 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.	54.1-3410.2		5000 per incident within previous 30 days

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
26. Annual (12 months + 60 days) Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or \$5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000

# Board of Pharmacy - Sanctioning Reference Points WORKSHEET

Case Type (score only one)	Points	Score
Inability to safely practice .....	50	_____
Professional Practice Issues .....	35	_____
Prescription Error .....	10	_____

score only one

### Offense Factors (score all that apply)

Priority A or B .....	70	_____
Financial/Material gain .....	50	_____
Act of commission .....	50	_____
Respondent impaired during incident .....	50	_____
Patient injured .....	10	_____

score all that apply

### Prior History (score all that apply)

Any past substance abuse or treatment .....	30	_____
One or more prior Board violations .....	10	_____
Any prior similar Board violations .....	10	_____

score all that apply

**Total Respondent Score**

## THRESHOLDS

Knowledge Based .....	0-30
Reprimand/Monetary .....	31-120
Monitoring/Treatment/Refer to Formal .....	121 or more

Respondent Name: \_\_\_\_\_

Date: \_\_\_\_\_

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