



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

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

September 2, 2009

9:00AM

<u>TOPIC</u>	<u>PAGE(S)</u>
Call to Order: Jennifer Edwards, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-18
• June 10, 2009, Board meeting	
• June 10, 2009, Panel hearings	
• July 1, 2009, Telephone conference call	
• July 15, 2009, Ad hoc committee on inspection processes	
• July 22, 2009, Special conference committee	
Public Hearing: Proposed regulations on unprofessional conduct	19-20
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 Report: Sandra Whitley Ryals, Director	
• Discussion of Revenue and Expenditure Analysis	handout
Legislation:	
• Update-Scotti Russell, Elaine Yeatts	
Regulations: Elaine Yeatts	
• Update on regulation processes	21
• Adoption of final regulations on expiration dates	22-31
• Fast track regulations for changes to stat boxes	handout
Update on Action Items: Scotti Russell	
• Report of ad hoc committee on inspection processes	32 and handout
Miscellaneous:	
• Special-use permits for PSDs wanting to sell 2-3 topical products, i.e. Latisse, 4% hydroquinone, and tretinoin cream-waivers	33-34
• Board interpretation of new language in 18 VAC 110-20-270	35
• Set meeting schedule for 2010	

Reports:

- Report on Board of Health Professions-Jennifer H. Edwards

New Business

Consideration of consent orders (if any)

Adjourn

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

(DRAFT/UNAPPROVED)

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

June 10, 2009
Second Floor
Conference Room 2

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

CALL TO ORDER: The meeting was called to order at 9:20AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Willie Brown
Gerard Dabney
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Sandra Whitley Ryals, Director, DHP
Betty Revere, Administrative Assistant

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

APPROVAL OF AGENDA: An amended agenda was distributed prior to the beginning of the meeting. With one addition, discussion of the inspection "ticketing" program, the amended agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes included in the agenda package. With no changes to the minutes, the minutes were approved as presented.

PUBLIC HEARING ON PROPOSED REGULATIONS FOR CHANGING EXPIRATION DATES: The Board held a public hearing on proposed regulations to replace emergency regulations related to change in expiration dates for facilities. There was no comment offered on the proposed regulations during the hearing.

PUBLIC COMMENTS: Beverley Soble, Virginia Health Care Foundation and Wendy Walter, Fairmont Crossing, Amherst, VA requested that the Board consider changing its regulations to allow Schedule II controlled substances to be maintained in the stat boxes for long term care

facilities. Ms. Soble stated that nursing homes frequently receive orders for patients on nights and weekends when it is not possible to receive timely medications from pharmacies. Under the best circumstances, i.e. midweek and daytime, there is typically at least a six to eight hour delay in getting an ordered medication. She stated that there are other standards under CMS and VDH that are violated if patients are not receiving pain medication in a timely manner. She also stated that she has taken steps to explore all viable options; including obtaining discharge medications when patients are sent from the hospital to the nursing home, and the use of the automated dispensing devices (ADD), but these did not appear viable. Ms. Abernathy questioned why the ADD option was not feasible, and Ms. Walter explained that expense was the primary reason with the current reimbursement structure, but also, even if a home could afford one ADD, there is no one place to put it to be geographically accessible because of the distance from the device to other nursing units. Ms. Soble also stated that they had determined that MD, NC, and WV all allowed Schedule II drugs for first doses, but all did so under different processes.

As a result of the comments, the Chairman appointed a committee of the Board to include Mr. Beckner, Mr. Ross, and Mr. Yi to meet with representatives for nursing homes and long term care pharmacies to develop a recommendation for this issue. Ms. Russell stated that DEA would need to be consulted to ensure that any recommendation would not violate DEA regulations.

DHP DIRECTOR'S REPORT

Ms. Ryals briefly reported that the Health Care Workforce Center was progressing well in its mission. She reminded the Board that as of July 1, 2009, the name Health Practitioners' Intervention Program (HPIP) will change to Health Practitioners' Monitoring Program (HPMP) to reflect the monitoring rather than treatment nature of the program. She acknowledged Ms. Russell for her participation on the internal committee that developed recommendations for changes to the program to more closely align the program with the mission of DHP and effect cost savings, and her continued participation on the external committee with VCU to implement needed changes and efficiencies. Ms. Ryals also mentioned that the Department continued to do well with all three performance measures, and that she would have more details at a future meeting.

Ms. Ryals discussed the security breach of the Prescription Monitoring Program. She outlined all steps that had been taken by the Department from the moment the breach was discovered to the present, to include the dates and content of the various notifications. She stated that the matter is still under investigation, that it is a criminal matter, and that for this reason certain details

cannot be given at this time. She stated that the responsible party, if found, will be held accountable. In response to questions about future steps, Ms. Ryals stated that vulnerability assessments are being done on all systems, and that everything has been or is being reconfigured to assure security to the maximum extent possible.

Ms. Ryals stated that Q & A related to the breach, as well as advice for persons questioning possible identity theft, is available on the main page of the DHP website, and this information is frequently updated.

When asked about funding of the notifications and recovery effort, Ms. Ryals stated that expenses related directly to the PMP, such as notifications, are coming from the PMP budget. For other general expenses, such as increases in IT security, the expense will be spread across all boards, as is currently the process for handling other general expenses of the Department.

Ms. Ryals addressed the revenue and expenditure analysis letter in the agenda package. This analysis is required to be done at least once each biennium by Virginia law. The Board, at the current time, is in the position of having a surplus, but Ms. Ryals is not recommending that the Board reduce fees as it is anticipated that expenditures may be increasing primarily due to significant increases in IT costs. Ms. Ryals suggested that the Board wait until the September board meeting to take any action on the Department's recommendations. By this next meeting, actual year-end data will be available, and the Department hopes that it will have IT cost projections from VITA.

ELECTION OF OFFICERS

Mr. Kozera called for nominations for the office of Chairman. Mr. Ross nominated Jennifer Edwards. With no additional nominations, the Board voted unanimously to close nominations (motion by Brown, second by Beckner). On a voice vote, the Board elected Ms. Edwards as Chairman for the term July 1, 2009 through June 30, 2010. Mr. Kozera called for nominations for the office of Vice Chairman. Mr. Ross nominated Brandon Yi. With no additional nominations, the Board voted unanimously to close nominations (motion by Beckner, second by Edwards). On a voice vote, the Board elected Mr. Yi as Vice Chairman for the term July 1, 2009 through June 30, 2010.

LEGISLATION UPDATE:

Ms. Russell stated that the Board has one legislative proposal to review and approve, which is the annual scheduling bill included in the agenda package. This year, DEA has scheduled two new drugs that need to be added to the Virginia schedules, tapentadol to Schedule II and lacosamide to Schedule V.

Motion:

The Board voted unanimously to approve the legislative proposal for scheduling tapentadol and lacosamide as presented. (motion by Beckner, second by Stredler)

The Board reviewed a legislative proposal initiated by the Office of Community Integration for People with Disabilities to amend the Drug Control Act to allow an unlicensed person to administer any normally self-administered drugs to a patient in a private residence. Current law restricts this to oral or topical drugs. The Board expressed no concerns about this legislation and took no action.

REGULATION UPDATE:

Ms. Russell provided an update on current regulation processes to include that the final amendments to regulations from the periodic review are under review in the Governor's office. The proposed regulations on standards of conduct are also at the Governor's office.

**PROPOSED REGULATIONS,
DRUG DONATION
PROGRAMS:**

The Board reviewed proposed regulations for drug donation programs to replace the emergency regulations currently in place until April 9, 2010. The proposed regulations are identical to the emergency regulations.

Motion:

The Board voted unanimously to adopt proposed regulations for drug donation programs as presented in the agenda package. (motion by Ross, second by Edwards)

**PETITION FOR
RULEMAKING:**

The Board reviewed a petition for rulemaking from Eric Hampton requesting the Board to amend regulations to delete the requirement for a nurse's signature for delivery of drugs to an automated dispensing device in a hospital. The petition was published on April 13, 2009. The comment period ended on May 13, 2009. The Board received a number of comments on Townhall, all supportive of the petition, the majority from staff at Martha Jefferson Hospital.

Motion:

The Board voted unanimously to initiate the rulemaking process on the petition, and to publish a NOIRA. (motion by Ison, second by Yi)

**UPDATE ON MEDICAL
EQUIPMENT SUPPLIERS
AND VERBAL ORDERS:**

Ms. Russell reminded the Board that, at the last board meeting, there had been a discussion as to whether a medical equipment supplier could lawfully accept a verbal order or had to have a written order. A prescriber had complained to staff that a medical equipment supplier was forcing him to provide a written order if he tried to call in a prescription. The Board had requested that staff further research this issue before the June meeting to determine whether a guidance document was needed. Staff determined that

most medical equipment suppliers were accepting verbal orders in some cases for the purpose of not delaying care, but then were obtaining a written order as a standard practice since most all insurance plans require a written order for reimbursement of claims. Based on this information, Ms. Russell stated that she did not believe a guidance document was needed.

DELEGATION OF
APPROVAL OF REQUESTS
FOR A TESTING
ACCOMMODATION
PURSUANT TO THE ADA:

The Board reviewed a bylaw addition that would delegate to the Executive Director, the approval of additional testing time upon a request with the appropriate supporting documentation for an accommodation under the Americans with Disabilities Act (ADA). Requests for accommodations other than additional time will still be presented to the Board for review and decision.

Motion:

The Board voted unanimously to adopt the bylaws change presented in the agenda, delegating to the Executive Director, the review and approval of additional testing time as an ADA testing accommodation. (motion by Stredler, second by Ross)

AMENDMENT OF
GUIDANCE DOCUMENT
110-24:

The Board reviewed amendments to Guidance Document 110-24 to establish standards for the competency examination for applicants for licensure by endorsement who were initially examined prior to a nationally accepted examination. The first "national exam" was offered by NABP in 1975, but it was not until June 1, 1979 that all states were expected to use the NABP examination. Prior to this date, persons may very likely have taken and passed a state approved competency examination. The amendments to the guidance document provide that documentation of passing such examination is satisfactory evidence of meeting the same standard of competence required for licensure by examination in Virginia at that time. After June 1, 1979, an applicant must have passed the NABP examination.

Motion:

The Board voted unanimously to adopt the amendments to Guidance Document 110-24 as presented in the agenda. (motion by Beckner, second by Dabney)

DISCUSSION OF THE
INSPECTION PROCEDURES:

Ms. Russell stated that staff was continuing to work on electronic inspection forms, and the new procedures for leaving a pre-hearing consent order at the conclusion of the inspection by which a pharmacy could elect to pay monetary penalties for certain inspection violations. Mr. Ison expressed some concern that all deficiencies may not be appropriate for this type of process. Ms. Russell suggested that a committee meet prior to the next Board meeting to complete the work done by the previous committee and make a recommendation to the full board in September.

Mr. Kozera appointed Mr. Ison, Mr. Stredler, Ms. Edwards, and

5

himself to this committee. Ms. Russell stated that she would contact each member and find a mutually agreeable date for this meeting.

REPORT OF BOARD OF
HEALTH PROFESSIONS,
JENNIFER EDWARDS:

Ms. Edwards stated that BHP has been studying the need for licensing of certain emerging professions, specifically orthotists, prosthetists, medical interpreters, polysomnographers, surgical assistants and surgical technologists. She stated that BHP is contacting other agencies to determine who should regulate medical interpreters, and BHP plans to move ahead with looking into the potential for licensing surgical assistants and technologists. The following is an excerpt from the May 12, 2009 BHP minutes:

Orthotists and Prosthetists – The Committee recommended that the professions not be regulated and the motion of the Committee was seconded by Ms. Hughes and carried unanimously.

Medical Interpreters – The Committee requested that staff contact the Department of Health and the Department of Medical Assistance Services to seek their input regarding the state's oversight of the profession.

Polysomnographers – The Committee requested that Mr. Crow present his presentation to the Respiratory Therapy Advisory Committee for their review and recommendation back to the Board.

Surgical Assistants and Surgical Technologists – The Committee requested a public hearing for additional public comment prior to rendering a recommendation to the full Board.

REPORT OF DISCIPLINARY
CASELOAD

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of June 9, 2009: there were 79 cases at the enforcement level, 31 cases at the probable cause level, 5 cases at the informal conference level, 1 case at the formal hearing level and 12 cases at the APD level. Further, she stated that the Board had a total of nine Priority A cases; eight at the enforcement level, and one at the formal hearing level. Since the last board meeting on March 10, 2009, 75 cases have been closed.

REQUEST FOR TESTING
ACCOMMODATION:

Ms. Russell stated that the Board had received a request for a testing accommodation other than additional time, pursuant to a disability, that the Board needed to review.

Motion:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711 (A) (7) of the Code of Virginia for the purpose of consultation with legal counsel and briefings by staff members pertaining to probable litigation. Additionally,

6

it was moved that Scotti Russell, Cathy Reiniers-Day, Caroline Juran, and Howard Casway attend the closed meeting because their presence was deemed necessary. (motion by Stredler, second by Ross)

Motion:

The Board voted unanimously to certify, to the best of its ability, 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 just concluded. (motion by Stredler, second by Ross)

Motion:

The Board voted unanimously to grant the request by Jaxon L. Zimmerman for double time to take the pharmacy technician examination, but denied Mr. Zimmerman's request for a reader based on the fact that the ability to read is an integral part of the duties of a pharmacy technician, and the reading of the examination is the only means for the Board to assess an applicant's ability to read and comprehend written material. (motion by Stredler, second by Brown)

ADJOURN:

With all business concluded, the meeting adjourned at 12:48 PM

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date

**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

Wednesday, June 10, 2009
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 12:49 p.m.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: John O. Beckner
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

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

DENNIS W. EPPERSON
Registration # 0230-006809

A formal hearing was held in the matter of Dennis W. Epperson following the summary suspension of his pharmacy technician registration on May 14, 2009, and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Mr. Epperson was not present at the hearing. The Panel proceeded in Mr. Epperson's absence as the Notice of Formal Hearing dated May 14, 2009, was mailed to Mr. Epperson's legal address of record, both regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Mr. Epperson and the hearing proceeded in his absence.

William Clay Garrett, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.



Melissa Marshall, Pharmacy Operations Manager, Carilion Roanoke Memorial Hospital Pharmacy, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Stredler and duly seconded by Mr. Ross, the Panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of Dennis W. Epperson. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Elizabeth Revere, 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.

Decision:

Upon a motion by Mr. Stredler and duly seconded by Mr. Beckner, the Panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett and amended by the Panel and read by Mr. Casway.

Upon a motion by Mr. Beckner and duly seconded by Ms. Edwards, the Panel voted 6-0 that Mr. Epperson's registration be revoked.

ADJOURN:

With all business concluded, the meeting adjourned at 1:20 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

9

**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, July 1, 2009

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, 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 was held at 8:35 a.m., on July 1, 2009, to consider the summary suspension of the registration of Nycindia N. Bell, to practice as a pharmacy technician.

PRESIDING:

Brandon K. Yi, Vice Chairman

MEMBERS PRESENT:

Gill Abernathy
John Beckner
Bobby Ison
David C. Kozera
Michael E. Stredler

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director
Howard Casway, Senior Assistant Attorney General
William Clay Garrett, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS:

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

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

NYCINDIA N. BELL
Registration Number 0230-006902

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



Decision: Upon a motion by Mr. Kozera, and duly seconded by Mr. Beckner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Nycindia N. Bell poses a substantial danger to the public; and therefore, that the registration of Nycindia N. Bell, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Bell for the indefinite suspension of her registration in lieu of a hearing.

ADJOURN: With all business concluded, the conference call adjourned at 8:50 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Brandon Yi, Vice Chairman

Date

**VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON INSPECTION PROCESS**

July 15, 2009
Commonwealth Conference Center
Board Room 4

Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy was called to order for the purpose of discussing improvements to the inspection process.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: Jennifer H. Edwards
Michael E. Stredler
Bobby Ison

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Sammy Johnson, Deputy Director of Enforcement

DISCUSSION: The committee discussed the Board's initiative, as established at the March 2007 Board Retreat, to begin imposing monetary penalties through the inspector issuing a modified consent order at the point of inspection, when the on-site inspection discloses certain violations of law or regulation. The committee began identifying violations which could feasibly be handled by this process and suggested monetary penalties were discussed. The committee determined that an additional meeting would be necessary to complete its goal, which is to present to the full Board their suggestions for violations and corresponding monetary penalties at the September 2, 2009, Board meeting.

ADJOURN: The meeting adjourned at 2:30 p.m.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Chair

Date

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

Wednesday, July 22, 2009
Commonwealth Conference Center
Second Floor
Board Room 3

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

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: David C. Kozera, Committee Chairman

MEMBERS PRESENT: Brandon K. Yi

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

RONALD M. DOUGLAS
License Number 0202-009714
Ronald M. Douglas appeared to discuss his petition for reinstatement of his pharmacist license as stated in the June 9, 2009, Notice.

Closed Meeting: Upon a motion by Mr. Yi and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A.(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Ronald M. Douglas. 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.

Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to approve Mr. Douglas' application to reinstate his pharmacist license with terms and conditions.

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

Douglas, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Douglas 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.

RONALD M. DOUGLAS, M.D.
Applicant for a License to Sell
Controlled Substances by a
Practitioner of the Healing Arts

Ronald M. Douglas, M.D., appeared to discuss his application for licensure to sell controlled substances by a practitioner of the healing arts and allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 9, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code, for the purpose of deliberation to reach a decision in the matter of Ronald M. Douglas. 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. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to approve Dr. Douglas' application for licensure to sell controlled substances by a practitioner of the healing arts.

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

JAMES Q. UNDERWOOD, III
License Number 0202-006303

James Q. Underwood, III, appeared to discuss his petition for reinstatement of his pharmacist license as stated in the May 4, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code, for the purpose of deliberation to reach a decision in the matter of James Q. Underwood, III. 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. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to deny Mr. Underwood's petition for reinstatement of his pharmacist license.

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

GINO J. BORTOLUZZI
License Number 0202007760

Gino J. Bortoluzzi appeared with Ken Simpson, the pharmacy technician at his store, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 30, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code,

for the purpose of deliberation to reach a decision in the matter of Gino J. Bortoluzzi. 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. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Mr. Bortoluzzi, assess a \$50,000 monetary penalty and stay a portion of that penalty upon Mr. Bortoluzzi passing the Virginia Drug Law Examination, as well as his having to obtain additional continuing pharmacy education hours.

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

RALPH U. MADU
License Number 0202013071

Ralph U. Madu appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 30, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code, for the purpose of deliberation to reach a decision in the matter of Ralph U. Madu. 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. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Mr. Madu and have him obtain additional continuing pharmacy education hours.

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

ADJOURN:

With all business concluded, the meeting adjourned at 5:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

Project 1341 - Proposed

BOARD OF PHARMACY

Standards of conduct

18VAC110-20-25. Unprofessional conduct.

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

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

2. Willfully or negligently breaching the confidentiality of a patient, unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family, or other conduct that results or could result in personal gain at the expense of the patient;

19

6. Failing to maintain adequate safeguards against diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered, and that such registration is current; or

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing.

20

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

Staff Note: Status of regulations for the Board as of mailing of agenda

Action: None – provided for information only

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Signing of automated dispensing devices in hospitals</p> <p><u>Stage:</u> NOIRA - At Secretary's Office</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Changes in renewal dates for pharmacies and permitted facilities</p> <p><u>Stage:</u> Proposed - Register Date: 6/8/09 Comment closed: 8/7/09 Adoption of Final Regulations: 9/2/09 Expiration of Emergency Regulations: 9/22/09</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Standards of conduct</p> <p><u>Stage:</u> Proposed - Register Date: 8/31/09 Comment closes: 10/30/09</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Drug donation program</p> <p><u>Stage:</u> Proposed - DPB Review in progress</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Periodic review</p> <p><u>Stage:</u> Final - Register Date: 8/3/09 Effective date: 9/2/09</p>

21

Project 1311 - Final

BOARD OF PHARMACY

Changes in renewal dates for pharmacies and permitted facilities

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Permitted physician licensed to dispense drugs	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. Nonresident pharmacy	\$270
9. Controlled substances registrations	\$90
10. Robotic pharmacy system approval	\$150
11. Innovative program approval.	\$250

If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.

12. Approval of a pharmacy technician training program	\$150
13. Approval of a continuing education program	\$100

D. Annual renewal fees.

1. Pharmacist active license – <u>due December 31</u>	\$90
2. Pharmacist inactive license – <u>due December 31</u>	\$45
3. Pharmacy technician registration – <u>due December 31</u>	\$25

4. Pharmacy permit – <u>due April 30</u>	\$270
5. Physician permit to practice pharmacy – <u>due February 28</u>	\$270
6. Medical equipment supplier permit – <u>due February 28</u>	\$180
7. Humane society permit – <u>due February 28</u>	\$20
8. Nonresident pharmacy – <u>due April 30</u>	\$270
9. Controlled substances registrations – <u>due February 28</u>	\$90
10. Innovative program continued approval based on board order not to exceed \$200 per approval period.	
11. Approval of a pharmacy technician training program	\$75 every two years

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

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

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

1. Pharmacist license	\$210
2. Pharmacist license after revocation or suspension	\$500
3. Pharmacy technician registration	\$35
4. Pharmacy technician registration after revocation or suspension	\$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	\$240
b. Physician permit to practice pharmacy	\$240
c. Medical equipment supplier permit	\$210
d. Humane society permit	\$30
e. Nonresident pharmacy	\$115
f. Controlled substances registration	\$180
g. Approval of a pharmacy technician training program	\$75
G. Application for change or inspection fees for facilities or other entities.	
1. Change of pharmacist-in-charge	\$50
2. Change of ownership for any facility	\$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	\$150
5. Board-required inspection for a robotic pharmacy system	\$150
6. Board-required inspection of an innovative program location	\$150
7. Change of pharmacist responsible for an approved innovative program	\$25
H. Miscellaneous fees.	
1. Duplicate wall certificate	\$25
2. Returned check	\$35

FORMS (18VAC110-20)

Application for Registration as a Pharmacy Intern (rev. 8/07).

Affidavit of Practical Experience, Pharmacy Intern (rev. 8/07).

Application for Licensure as a Pharmacist by Examination (rev. 8/07).

Instructions for Reinstating or Reactivating a Pharmacist License (rev. 11/07).

Application to Reinstate or Reactivate a Pharmacist License (rev. 11/07).

Application for Approval of a Continuing Education Program (rev. 8/07).

Application for Approval of ACPE Pharmacy School Course(s) for Continuing Education Credit (rev. ~~8/07~~ 4/09).

Application for License to Dispense Drugs (permitted physician) (rev. 8/07).

Application for a Pharmacy Permit (rev. ~~8/07~~ 3/09).

Application for a Nonresident Pharmacy Registration (rev. 7/08).

Application for a Permit as a Medical Equipment Supplier (rev. ~~8/07~~ 3/09).

Application for a Controlled Substances Registration Certificate (rev. 8/07).

Application for a Permit as a Humane Society (rev. ~~8/07~~ 3/09).

Application for Registration as a Pharmacy Intern for Graduates of a Foreign College of Pharmacy (rev. 8/07).

Closing of a Pharmacy (rev. 8/07).

Application for Approval of a Robotic Pharmacy System (rev. 8/07).

Inspection Required for Approval of a Robotic Pharmacy System (rev. 8/07).

Application for Approval of an Innovative (Pilot) Program (rev. 8/07).

Pharmacy Technician Registration Instructions and Application (rev. ~~7/08~~ 3/09).

Instructions for Reinstating a Pharmacy Technician Registration (rev. 11/07).

25

Application to Reinstate a Pharmacy Technician Registration (rev. 11/07).

Application for Approval of a Pharmacy Technician Training Program (rev. 8/07).

Application for Registration for Volunteer Practice (rev. 8/07).

Sponsor Certification for Volunteer Registration (rev. 8/07).

Preceptor Verification Form (rev. 8/07).

Application for Reinstatement of Registration as a Pharmacy Intern (eff. 9/07).

Affidavit for Limited-Use Pharmacy Technician (rev. 8/07).

Limited-Use Pharmacy Technician Registration Instructions and Application (rev. 7/08).

Application for Registration as a Limited-Use Pharmacy Technician (eff. 7/08).

18VAC110-50-20. Fees.

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

B. Initial application fees.

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

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

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

26

6. Controlled substances registration \$90

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

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

E. Reinstatement fees.

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

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

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

F. Application for change or inspection fees.

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

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

~~H. For the annual renewal due on or before December 31, 2006, the following fees~~

~~shall be imposed for a license or permit:~~

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

FORMS (18VAC110-50)

Application for a Permit as a Restricted Manufacturer (rev. ~~8/07~~ 3/09).

Application for a Permit as a Nonrestricted Manufacturer (rev. ~~8/07~~ 3/09).

Application for a Permit as a Warehouser (rev. ~~8/07~~ 3/09).

Application for a License as a Wholesale Distributor (rev. ~~8/07~~ 3/09).

28

Application for a Nonresident Wholesale Distributor Registration (rev. ~~8/07~~ 9/08).

Application for a License as a Wholesale Distributor -- Limited Use for Distribution of
Medical Gases Only (rev. ~~8/07~~ 3/09).

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

_____ (Signature of certifying official)

Name and title of certifying official: Elizabeth Scott Russell, Executive Director

Name of agency: Board of Pharmacy, Department of Health Professions

Date: _____



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Request to Extend Life of Emergency Regulation up to Six Months

According to § 2.2-4011.D of the Code of Virginia (effective 7/1/07): **In the event that an agency concludes that despite its best efforts, a replacement regulation [for an emergency regulation] cannot be adopted before expiration of the 12-month period..., it may seek the prior written approval of the Governor to extend the duration of the emergency regulation for a period of not more than six additional months.**

Any such request must be submitted to the Governor at least 30 days prior to the scheduled expiration of the emergency regulation and shall include a description of the agency's efforts to adopt a replacement regulation together with the reasons that a replacement regulation cannot be adopted before the expiration of the emergency regulation. Upon approval of the Governor, the duration of the emergency regulation shall be extended for a period of no more than six months. Such approval shall be in the sole discretion of the Governor and shall not be subject to judicial review. Agencies shall notify the Registrar of Regulations of the new expiration date of the emergency regulation as soon as practicable.

Agency name	Board of Pharmacy, Department of Health Professions
Regulation Title/ VAC Citation	18VAC110-20 Regulations Governing the Practice of Pharmacy 18VAC110-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen
Action title	Change in renewal dates
Stage	Proposed (comment ends 8/7/09)
Town Hall action/stage #	2675 / 4950
Date emergency reg expires	9/22/09
Requested new expiration date	3/21/10

Rationale

*Please describe the **agency's** best efforts to promulgate a permanent regulation before the expiration of the emergency regulation and provide the reason(s) why the effective period of this emergency regulation should be extended up to 18 months.*

Chapter 330 of the 2008 Acts of the Assembly authorized the Board of Pharmacy to adopt emergency regulations to implement changes in renewal dates for licensed or permitted pharmacy facilities. The emergency regulations and Notice of Intended Regulatory Action were adopted on June 4, 2008, submitted for executive branch review on June 6, 2008, and approved by the Governor for publication on September 23, 2008. They were submitted to the Registrar and became effective on the same day.

Following the comment period on the NOIRA which ended on October 22, 2008, the Board adopted proposed regulations at its next scheduled meeting, which was December 10, 2008. The proposed package was posted on Townhall on December 18, 2008; approval from the Governor for publication was posted on May 11, 2009. The regulation was submitted to the Register of Regulations that day with publication on June 8, 2009. Comment on the proposed regulation ends August 7, 2009. The Board intends to adopt final regulations at its meetings scheduled for September 2, 2009, but that will not allow sufficient time for approval and publication of a final regulation before expiration on September 22, 2009. The Board has acted as expeditiously as possible at each stage of the regulatory process.

Different renewal dates for pharmacy facilities have been in effect for the last two renewal cycles. To revert to a December 31st renewal for all facilities and pharmacies would be chaotic and costly for the board and its licensees. Pharmacies have already renewed for 2009 in April and other facilities renewed in February. The Board requests a six-month extension to allow for continuation of the current renewal schedule.

Submitted by

Name: Elaine J. Yeatts Title: Agency Regulatory Coordinator

Signature: _____ Date: _____

Send this form directly to Gena Boyle in the Governor's Policy Office and send copies of this form to your Cabinet Secretary and Melanie West of DPB.

Approved by

Governor's Office

Name: _____ Title: _____

Signature: _____ Date: _____

Ad Hoc committee on inspection processes:

Background: The ad hoc committee, appointed by the Board at its last meeting, chaired by Dave Kozera, members Mickey Stredler, Bobby Ison, and Jennifer Edwards met twice, July 17 and August 26 to develop a recommendation for streamlining the inspection program and developing standard sanctions for expedited consent orders that would be offered by the pharmacy inspectors at the conclusion of the inspection. The problem being addressed is the inefficiency and ineffectiveness of the current inspection process and subsequent attempts to adjudicate these cases. As discussed

The sanction document will be a handout at the meeting as the committee will hold its last meeting subsequent to this agenda going out.

Action: To adopt as a guidance document standard sanctions as recommended by the committee and as may be amended by the Board.

Russell, Scotti

From: Juran, Caroline
Sent: Monday, August 10, 2009 10:01 AM
To: Russell, Scotti
Subject: FW: License for dispensing topical products

FYI- She contacted me, again. Told her that I thought it would be on Sept's agenda and I would follow-up with her after the meeting.

From: Nicole Hayre [mailto:drhayre@yahoo.com]
Sent: Monday, August 10, 2009 9:50 AM
To: Juran, Caroline
Subject: Fw: License for dispensing topical products

Dear Ms Juran,

This is the email we discussed. I greatly appreciate your time on this matter.

Sincerely,

Nicole Hayre, MD, FAAD
 Cosmetic Dermatology Center

8405 Greensboro Dr., STE 110
 McLean, VA 22102
 (703)827-8600

--- On Wed, 7/22/09, drhayre@yahoo.com <drhayre@yahoo.com> wrote:

From: drhayre@yahoo.com <drhayre@yahoo.com>
 Subject: License for dispensing topical products
 To: scotti.russell@dhp.virginia.gov
 Date: Wednesday, July 22, 2009, 10:19 AM

Dear Ms Russell,

I appreciate your time yesterday discussing my dilemma regarding prescription product disbursement in my office. In summary, I believe the current rules in place in Virginia make sense for most prescriptions, but a category of products has evolved over the recent years for which I believe it may be wise for the Board of Pharmacy to consider as candidates for a new type of disbursement license, or an exception to the current rule. These products are generally topical cosmetic products with excellent safety profiles, such as Hydroquinones and Latisse. I am sure since the launch of Latisse that the board has been inundated with calls regarding licensing to carry this and other cosmetic topical products. I am also sure that most of the practices that would like to carry these products do not have facilities which would pass your strict requirements. Certainly, there have been many requests for exceptions.

What I am proposing, is that the Board of Pharmacy please consider these cosmetic topical products for a type of license which would limit dispensing at the licensed site to these products. I propose that requirements would require simply that the products be kept in a locked cabinet or closet which is under the physician's supervision. Unfortunately, an extra alarm is cost prohibitive for carrying just a couple of topical products.

I believe that the proposed changes would benefit not only law-abiding physicians such as myself, who want to provide safe products and convenience to their patients, but also the Board of Pharmacy, as it will help to handle and streamline this issue which has recently developed.

I appreciate your time and consideration in this matter,
Nicole Hayre, MD, FAAD

Issue: Under the new regulation, are technician trainees counted in the 1:4 ratio?

Background: The Board has received a number of comments after the publication of final regulations, from pharmacists who are very concerned with the elimination of ratios from the regulations, who feel that corporate decisions will be made on staffing and that employee pharmacists will have no say as to how many persons they can safely supervise regardless of what the regulations state. We discovered during the rulemaking process that although the ratios had been removed from the regulation, the statute still includes a maximum ratio of 1:4 pharmacist to pharmacy technicians. Since the publication of final regulations, we have had phone calls from at least one chain that wants to establish a primary training pharmacy with 1 pharmacist to 4 pharmacy technicians to 4 pharmacy technician trainees at a time.

Action: Interpret whether the new regulation means that a pharmacy can have unlimited pharmacy interns and technician trainees in the context of the statute.

Laws and regulations:

from § 54.1-3320...

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more than four pharmacy technicians at one time.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

...

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

...

18VAC110-20-10. Definitions.

...

"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.

...

18VAC110-20-270. 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 directly monitoring the activities of a person enrolled in an approved pharmacy technician training program who is performing the tasks restricted to a pharmacy technician prior to registration in accordance with § 54.1-3321 D of the Code of Virginia shall not monitor more than two such trainees at the same time, and at no time shall a pharmacist supervise more than four persons performing technician functions to include technicians and trainees. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time.

...