COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor **(804) 367-4456 (Tel)**
Richmond, Virginia 23230 **(804) 527-4472(Fax)**

Tentative Agenda of Meeting

December 16, 2009

9:00AM

TOPIC	PAGE(S)
Call to Order: Jennifer Edwards, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-35
◦ September 2, 2009, Board meeting	
◦ September 22, 2009, special conference committee	
◦ October 20, 2009, special conference committee	
◦ November 10, 2009, telephone conference call	
◦ November 10, 2009, special conference committee	
◦ December 1, 2009, telephone conference call	
Public Hearing: Proposed regulations on drug donation program	36-44

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

Regulations: Elaine Yeatts	
• Update on regulation processes	45
• Adopt proposed regulations on nurses not signing ADD deliveries or give to the regulation committee to draft	46-50
• Review public comment and adopt response to public comment and final regulations on unprofessional conduct	
Legislation:	
• update on prospective 2010 legislation-Scotti Russell, Elaine Yeatts	51-56
Reports:	
• Report on Board of Health Professions-Jennifer H. Edwards	
New Business	

Consideration of consent orders

Adjourn

***The Board will have a working lunch at approximately 12 noon. Formal panel hearings will convene at the conclusion of the Board meeting.**

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 2, 2009
Second Floor
Board Room 2

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

CALL TO ORDER:	The meeting was called to order at 9:03AM.
PRESIDING:	Jennifer H. Edwards, Chair
MEMBERS PRESENT:	Gill B. Abernathy John O. Beckner Willie Brown Gerard Dabney David C. Kozera Leo H. Ross Michael E. Stredler Brandon K. Yi, Vice Chair
MEMBERS NOT PRESENT:	Bobby Ison
STAFF PRESENT:	Caroline D. Juran, Deputy Executive Director Howard M. Casway, Senior Assistant Attorney General Elaine Yeatts, Senior Policy Analyst Sandra Whitley Ryals, Director, DHP Sammy Johnson, Deputy Director of Enforcement Sharon Davenport, Administrative Assistant
QUORUM:	With nine members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was distributed prior to the beginning of the meeting.
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 ON UNPROFESSIONAL CONDUCT:	The Board held a public hearing on proposed regulations to establish regulations on unprofessional conduct. There was no comment offered on the proposed regulations during the hearing.
DHP DIRECTOR'S REPORT	Ms. Ryals discussed the Revenue and Expenditure Analysis in handout A. She explained that the Board has a revenue surplus which exceeds the 10% allowance and therefore, suggested that the Board adopt a one-time reduction for renewal fees due on or before December 31, 2009, February 28, 2010 and April 30, 2010. She stated that a permanent reduction is not recommended as the

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Board's expenditures are projected to exceed revenue in 2011. Ms. Edwards asked if the analysis included the agency's increased costs associated with information technology services and Ms. Ryals acknowledged that the analysis did include this information.

Additionally, Ms. Ryals reviewed the patient care disciplinary case processing times found in handout A and stated that the agency has met and exceeded the goals set for clearance rate, age of pending caseload and time to disposition. During the fourth quarter of fiscal year 2009, the agency's clearance rate was 114%, age of pending caseload was 9.5%, and time to disposition was 92%. She then reviewed statistics specific to the Board and stated that during the fourth quarter of fiscal year 2009, the clearance rate was 71%, age of pending caseload was 9%, and time to disposition or the percent of patient care cases closed in 250 business days was 100%. She applauded the Board's achievements remarking that huge progress had been made. She, also, emphasized the importance of continuing to strive for a 100% clearance rate to prevent a future backlog of cases. Ms. Ryals, also, applauded the Board's efforts in recently reviewing the inspection process and stated that an efficient and meaningful inspection program would be key to continuing forward progress.

LEGISLATION UPDATE:

Ms. Yeatts stated that the agency has submitted a legislative package to the executive branch to review. The Board has one legislative proposal which is the annual scheduling bill that the Board reviewed and approved in June which conforms Virginia schedules of controlled substances to federal regulations. Additionally, she stated that a second agency legislative proposal regarding the use of agency subordinates in informal conferences may impact on the Board.

REGULATION UPDATE:

Ms. Yeatts provided an update on current regulation processes which included a statement that the final amendments to regulations from the periodic review became effective September 2, 2009.

ADOPTION OF FINAL REGULATIONS ON EXPIRATION/RENEWAL DATES:

Ms. Yeatts explained that the Board needed to adopt final regulations to replace emergency regulations that had changed the expiration dates for facilities in order to stagger the Board's workload in renewing its licenses. The public comment period on proposed regulations ended on 8/7/2009 with no public comment filed.

Motion:

The Board voted unanimously to adopt the proposed amendments to expiration dates for facilities without any change as final regulations. (motion by Kozera, second by Beckner)

FAST TRACK REGULATIONS FOR CHANGES TO STAT BOXES:

Ms. Juran reminded the Board of the request at the June 2009 meeting of the Virginia Health Care Association (VHCA) for changes in the regulation related to stat-drug boxes in long term care facilities. Specifically, VHCA was requesting Schedule II oral drugs be allowed in the boxes to cover initiation of pain treatment while waiting for orders to be filled by the provider pharmacy. The Board Chairman had appointed an ad hoc committee at that meeting to work with representatives of LTCF pharmacy to develop a recommendation for changes prior to this Board meeting, but the ad hoc committee was unable to meet. Board staff did work with key parties to develop draft language to present to the full Board. Ms. Juran reviewed this draft language with the Board. The draft language allows for no more than 20 oral solid dosage units of each schedule in Schedules II-V per box with a conversion allowance for liquids. Additionally, the Board reviewed public comment from Jack Gross, General Manager of PharMerica-Virginia Beach, who did not oppose the draft changes prepared by staff and VHCA, but suggested an alternative plan which included combining the drugs in Schedules II-V from the emergency drug kit and the stat-drug box into one kit. The Board, also, heard comment from Wendy Walter, Fairmont Crossing, Amherst, VA, Hill Hopper, General Manager of NeighborCare Richmond, and Joseph Ward, MD regarding the two proposed changes for stat-drug boxes and the immediate need to have Schedule II pain medications readily available in the stat-drug box to meet nursing home patients' needs. After some discussion, the Board determined that while Mr. Gross' suggestion had merit it would require a change to both 18VAC110-20-540 and 18VAC110-20-550 and should possibly be considered during the next regulatory review process. The Board determined that there would likely not be any opposition to this change and thus could be adopted using the fast-track process.

Motion:

The Board voted unanimously to adopt, as a fast-track regulation, the draft amendments to 18 VAC 110-20-550 prepared by staff. (Attachment A) (motion by Stredler, second by Brown)

ADOPTION OF REDUCTION IN RENEWAL FEES FOR 2009/2010:

To address revenue surplus issue discussed earlier in the meeting, Ms. Yeatts presented draft amendments to three sets of Board regulations that would provide for a one-time fee reduction for the next renewal cycle for all licensees. Additionally, Ms. Yeatts explained that fee reduction is an exempt action under the Administrative Process Act.

Motion:

The Board voted unanimously to adopt the reduction in renewal fees for 2009/2010 as presented. (Attachment B) (motion by Kozera, second by Stredler)

CORRECTION OF CITE IN REGULATION 18VAC110-20-106

Ms. Yeatts explained that an error was made during the recent periodic regulatory review process. The cite reference to 18VAC110-20-90 in Regulation 18VAC110-20-106 was stricken, however, the intention was to reference both 18VAC110-20-90 and 18VAC110-20-100. Ms. Yeatts stated that the correction would be exempt from the Administrative Process Act.

Motion:

The Board voted unanimously to adopt the exempt regulation change to add the reference to subsection B of 18VAC110-20-90 back into Regulation 18VAC110-20-106 as presented in handout D of the agenda package. (motion by Abernathy, second by Beckner)

UPDATE ON ACTION ITEMS:
REPORT OF AD HOC COMMITTEE ON INSPECTION PROCESSESS:

Ms. Juran provided the Board with an informal recommendation of the ad hoc committee, appointed by the Board at its last meeting and which met on July 17, 2009 and August 26, 2009 to develop a recommendation for streamlining the inspection program and developing standard sanctions for expedited consent orders. The plan is that these expedited consent orders based on approved standard penalties would be offered by the pharmacy inspectors at the conclusion of the inspection. After reviewing numerous deficiencies to determine appropriate disciplinary action, the committee recommended that individual deficiencies believed to be more egregious or "major" should be assigned a monetary penalty which would be imposed on the pharmacy permit when found in violation, unless the pharmacy requested an informal conference to review the possible violation. Additionally, the committee recommended that other deficiencies believed to be less egregious or "minor" should be listed together and that a $250 monetary penalty would be imposed against the pharmacy permit when any three deficiencies from this list was cited. For each additional deficiency over three from this list, another $100 monetary penalty per deficiency would be imposed. Any pharmacy that does not consent to the standard penalty would be scheduled for in information conference, most likely before an agency subordinate.

The Board reviewed and discussed the committee's recommendations related to major and minor deficiencies. The Board made several changes to the list. Mr. Yi stated that he supported the concept of imposing monetary penalties against a pharmacy permit, but expressed concern regarding the public information which could result. He stated that a pharmacy owner may not be able to control the individual actions of the employed pharmacists and feared the public information associated with the violations may be unfair to the pharmacy owner.

Lastly, Sammy Johnson, Deputy Director of Enforcement stated

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that a new pharmacy inspection report would be created to reflect the identified deficiencies and would be posted online for public view when ready.

Motion:

The Board voted 8-1, with Mr. Yi voting no, to adopt the process for pharmacy inspectors to offer a pharmacy an expedited consent order to which the pharmacy may choose to immediately pay the standard monetary penalties associated with the deficiencies as presented by the committee and amended by the Board, and to make these standard monetary penalties a Board guidance document. (motion by Beckner, second by Kozera) (Attachment C)

Action item:

Ms. Abernathy requested staff to provide a progress report following 6 months from implementation. Ms. Ryals stated that she would suggest a progress report be given by staff at each Board meeting.

MISCELLANEOUS: SPECIAL-USE PERMITS FOR PSDS WANTING TO SELL 2-3 TOPICAL PRODUCTS, I.E., LATISSE, 4% HYDRO-QUINONE, AND TRETINOIN CREAM; WAIVERS:

Ms. Juran stated that staff has received written requests from two different physicians requesting waivers from specific regulations regarding practitioners of the healing arts to sell controlled substances. One physician wishes to only dispense Latisse. The second physician wishes to dispense Latisse and perhaps other topical cosmetic products such as hydroquinone. Ms. Juran explained that other physicians have telephoned the Board office in the past requesting waivers for dispensing tretinoin creams. Physicians have specifically requested a waiver of the alarm system or outside monitoring of the alarm and the restricted access provision to the drug stock. Ms. Juran commented that the Board could waive the requirements, for good cause shown, through the issuance of a limited-use license as stated in 18VAC110-20-30 when the scope, degree or type of services provided to the patient is of a limited nature. After some discussion, the Board determined that good cause had not been shown and therefore, denied the request for the aforementioned waivers.

Motion:

The Board voted unanimously to deny the request for waivers of restricted access and alarm requirements by the two physicians. (motion by Beckner, second by Ross)

BOARD INTERPRETATION OF NEW LANGUAGE IN 18VAC110-20-270:

Ms. Juran explained that staff had received a number of comments after the publication of final regulations from pharmacists who were very concerned with the elimination of ratios from the regulations and who felt that corporate decisions would be made on staffing and that employee pharmacists would have no say as to how many persons they may safely supervise. Additionally, while ratios were removed from regulation, staff realized that statute still includes a maximum ratio of 1:4, pharmacist to pharmacy technicians. Additionally, Ms. Juran stated that since the new

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regulation does not directly address ratios, but the statute does, there is some confusion as to the Board's expectation. Most recently, staff received a phone call from a chain pharmacy that wants to establish a primary training pharmacy with 1 pharmacist supervising 4 pharmacy technicians and 4 pharmacy technician trainees at one time. The pharmacist questioned staff whether this would meet compliance. Because of these recent issues, Ms. Juran stated that staff was requesting that the Board interpret the new regulation in the context of the statute to determine how many pharmacy technicians and pharmacy interns a pharmacist may safely supervise at one time.

Mr. Casway advised the Board that, in his reading of §54.1-3320, no pharmacist shall supervise more than four persons performing pharmacy technician duties at one time, regardless of whether this person performing pharmacy technician duties is a registered pharmacy technician, technician in training or pharmacy intern. Additionally, he stated that he believed if the pharmacy intern was gaining hours of practical experience and therefore, performing duties restricted to a pharmacist, then the pharmacy intern would not be considered part of the 1:4 pharmacist to pharmacy technician ratio. Ms. Juran then reminded the Board that guidance document 110-33 addresses the use of a pharmacy intern as a pharmacy technician, when the pharmacy intern would be considered part of the ratio, and that the ratio of pharmacy intern to pharmacist shall be 1:1. Lastly, Mr. Casway advised the Board that the new regulation appears to be in direct conflict with statute and suggested adopting an exempt amendment to the regulations to address the conflict.

Motion:

The Board voted unanimously that the restriction in §54.1-3320 of one pharmacist supervising no more than four pharmacy technicians is interpreted to mean that a pharmacist shall not supervise more than four persons performing pharmacy technician duties at one time, regardless of whether this person performing pharmacy technician duties is a registered pharmacy technician, technician in training or pharmacy intern; that pharmacy interns gaining hours of practical experience and therefore, performing duties restricted to pharmacists, under direct monitoring by the pharmacist, shall not be considered part of the 1:4 pharmacist to pharmacy technician ratio; and the Board to adopt an exempt change to 18 VAC 110-20-270 to resolve the conflict with statute and clarify this issue. (motion Beckner, second by Stredler) (Attachment D)

SET MEETING SCHEDULE FOR 2010: ***see footnote for change to schedule**

The Board selected its 2010 meeting dates as follows:
March 10, 2010
June 2, 2010

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September 1, 2010
November 30, 2010

REPORT ON BOARD OF HEALTH PROFESSIONS, JENNIFER EDWARDS:

Ms. Edwards stated that the Regulatory Research Committee continues to study the possible need to regulate genetic counselors and has determined that persons performing kinesiotherapy do not meet the qualifications for a profession to be regulated by this agency. Additionally, Ms. Edwards stated that she may soon be resigning from the Board of Health Professions due to conflicts with personal commitments.

NEW BUSINESS:

Ms. Abernathy stated that she is concerned with the lack of oversight for medication errors and requested that the Board take up this cause again now that federal regulations on the subject are in place. Additionally, she questioned whether the Board should establish a committee to review possible areas of pharmacy that may need regulating and for which no regulations currently exist. After a brief discussion, it was determined that a committee is not currently needed, but that these areas could possibly be identified during the next periodic regulatory review process.

ADJOURN:

With all business concluded, the meeting adjourned at 12:45 PM

Caroline D. Juran
Deputy Executive Director

Jennifer H. Edwards, Board Chair

Date

<u>*Note:</u> subsequent to the meeting, based on conference room and staff availability, three of the meeting dates had to be changed. The new schedule is as follows:

March 9, 2010-DHP-Conference Center, Board Room 4
June 2, 2010-DHP-Conference Center, Board Room 2
September 8, 2010-DHP-Conference Center, Board Room 2
December 15, 2010-DHP-Conference Center, Board Room 2

PRELIMINARY

Project 2134 – Fast-track

BOARD OF PHARMACY

Stat-drug box in nursing homes

18VAC110-20-550. Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

   a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

   b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

   c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, time and name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

   a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

   ~~b. The stat-drug box shall contain no Schedule II drugs.~~

   ~~c.~~ The stat-drug box shall contain no more than ~~one~~ 20 solid dosage units per schedule of Schedule ~~III~~ II through V ~~drug~~ drugs ~~in each therapeutic class and no more than five doses of each~~ except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

Project 2110 – final exempt

BOARD OF PHARMACY

Fee reduction

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

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

D. Annual renewal fees.

1. Pharmacist active license	$90
2. Pharmacist inactive license	$45
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Physician permit to practice pharmacy	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90
10. Innovative program continued approval based on board order not to exceed $200 per approval period.	

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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 or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

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

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

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

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

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license – December 31, 2009	$50
2. Pharmacist inactive license – December 31, 2009	$25
3. Pharmacy technician registration – December 31, 2009	$15
4. Pharmacy permit – April 30, 2010	$210
5. Physician permit to practice pharmacy – February 28, 2010	$210
6. Medical equipment supplier permit – February 28, 2010	$140
7. Humane society permit – February 28, 2010	$20
8. Nonresident pharmacy – April 30, 2010	$210
9. Controlled substances registrations – February 28, 2010	$50

18VAC110-30-15. Fees.

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

B. Fee for initial license for a practitioner of the healing arts to sell controlled substances.

1. The application fee for initial licensure shall be $240.

2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

C. Renewal of license for a practitioner of the healing arts to sell controlled substances.

1. The annual fee for renewal of an active license shall be $90. For the annual renewal due on ~~before~~ December 31, ~~2006~~ 2009, the fee shall be $50.

2. The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee.

3. The fee for reinstatement of a license expired for more than one year shall be $210.

D. The fee for reinspection of any facility shall be $150.

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

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.

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

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

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

E. Reinstatement fees.

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

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

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

a. Nonrestricted manufacturer permit	$240
b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240

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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~~ February 28, 2010, the following fees shall be imposed for a license or permit:

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

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Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians performing duties on an expired license/registration (within 1 year)	18VAC110-20-80 and 18VAC110-20-105	per individual	100
5. Pharmacy technicians or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application	application fee 250
8. Refrigerator/freezer temperature out of range or not monitored	18VAC110-20-150		100
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500

Major Deficiency	Law/Reg Cite	Conditions	$
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
13. No biennial inventory, or over 30 days late	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained or monitored as required	18VAC110-20-240	will not be cited until 9/1/2010	250
16. Theft/loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240 and 18VAC110-20-250		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-425 and 18VAC110-20-420	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. Non-sterile compounding not in compliance with USP 795	54.1-3410.2		250
22. Sterile compounding not in compliance with USP 797	54.1-3410.2		1000
23. Compounding using ingredients in violation	54.1-3410.2		1000

Major Deficiency	Law/Reg Cite	Conditions	$
24. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
25. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
26. Security of after-hours stock not in compliance	18VAC110-20-450		500
27. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250

Minor Deficiencies

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

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation

Minor Deficiency	Law/Regulation Cite	Conditions
6. Current dispensing reference not maintained	18VAC110-20-170	
7. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
8. Expired drugs in working stock or dispensed drugs being returned to stock not in compliance	18VAC110-20-200 18VAC110-20-355	10% threshold
9. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
10. Storage of will-call not in compliance	18VAC110-20-200	
11. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
12. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404 and 18VAC110-20-240	
13. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
14. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
15. Prescriptions do not include required information	54.1-3408.01 and 54.1-3410	10% threshold
16. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3

Minor Deficiency	Law/Regulation Cite	Conditions
18. Not properly documenting partial filling	18VAC110-20-320	
19. Offer to counsel not made as required	54.1-3319	per Rx
20. Prospective drug review not performed as required	54.1-3319	
21. Engaging in alternate delivery not in compliance	18VAC110-20-275	
22. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
23. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	
24. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
25. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	
Repackaging, specialty dispensing, compounding:		
26. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	
27. Unit dose procedures or records not in compliance	18VAC110-20-420	
28. Robotic pharmacy systems not in compliance	18VAC110-20-425	

Minor Deficiency	Law/Regulation Cite	Conditions
29. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
Hospital specific or long-term care specific:		
30. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
31. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
After hours access or records not in compliance	18VAC110-20-450	
32. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	
33. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-550	
34. EMS procedures or records not in compliance	18VAC110-20-500	
35. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-560	
36. Maintaining floor stock in LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	

Project 2116 – Final exempt

BOARD OF PHARMACY

Correction of cite

18VAC110-20-106. Requirements for continued competency.

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Original certificates showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such original certificates to the board upon request in a manner to be determined by the board.

Part VII
Prescription Order and Dispensing Standards

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.

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

Tuesday, September 22, 2009
Commonwealth Conference Center
Second Floor
Board Room 2

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:	Brandon K. Yi, Committee Chairman
MEMBERS PRESENT:	John Beckner, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
RIMA SHURBAJI License Number 0202-206984	Rima Shurbaji appeared with her attornies, Michael Goodman and Christy Vanderline, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 28, 2009, Notice.
Closed Meeting:	Upon a motion by Mr. Beckner, 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, ("Code"), for the purpose of deliberation to reach a decision in the matter of Rima Shurbaji. 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. Beckner, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Ms. Shurbaji and have her complete the continuing pharmacy education program "Medication Error CE & Training Series-Quality Related Event 8 Hour Course",

ACPE #0707-9999-09-999-H05-P. Said hours shall be in addition to the 15 hours required for the renewal of her license.

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

SHALEETA CURTIS-RADFORD
Registration No. 0230-013362

Shaleeta Curtis-Radford appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the August 27, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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, for the purpose of deliberation to reach a decision in the matter of Shaleeta Curtis-Radford. 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. Beckner, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to order Ms. Curtis-Bradford to successfully complete two (2) additional continuing pharmacy education hours, in the subject of medication errors.

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

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.

TODD A. SMITH
License Number 0202-207008

Todd A. Smith appeared to discuss the allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 27, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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, for the purpose of deliberation to reach a decision in the matter of Todd A. Smith. 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. Beckner, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted that Mr. Smith be reprimanded and that he be assessed a $2500 monetary penalty. Further, pursuant to § 54.1-2400(15) of the Code, Mr. Smith shall submit to a physical and mental evaluation.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Smith, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Smith within such time. However, the requirement that Mr. Smith submit to a physical and mental evaluation can not be appealed. 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 3:00 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Brandon K. Yi, Chairman

Date

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

Tuesday, October 20, 2009
Commonwealth Conference Center
Second Floor
Training Room 2

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 11:00 a.m.

PRESIDING: David Kozera, Committee Chair

MEMBERS PRESENT: John Beckner, Committee Member

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

MARINA QUINTANILLA
Registration No. 0230-011506

Ms. Quintanilla did not appear at the informal conference. The Committee chose to proceed in her absence as the Notice was mailed to Ms. Quintanilla's legal address of record, both regular and certified mail. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 28, 2009, Notice.

Closed Meeting: Upon a motion by Mr. Beckner, 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 Marina Quintanilla. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Quintanilla a Consent Order for the revocation of her pharmacy technician registration. Additionally, they requested that a Notice for a formal hearing be mailed to Ms. Quintanilla with the consent order.

ADJOURN: With all business concluded, the meeting adjourned at 12:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

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

Tuesday, November 10, 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 8:30 a.m., on November 10, 2009, to consider the summary suspension of the registration of Stephanie Campbell to practice as a pharmacy technician and Robert McKenney to practice as a pharmacist in the Commonwealth of Virginia .

PRESIDING: Jennifer Edwards, Chair

MEMBERS PRESENT:
Gill Abernathy
John Beckner
Willie Brown
Jennifer H. Edwards
Bobby Ison
Dave Kozera
Leo H. Ross
Michael E. Stredler
Brandon Yi

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth Scott Russell, Executive Director
Eusebia Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
James Schliessmann, Assistant Attorney General
Wayne Halbleib, 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 nine members participating and one member unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

STEPHANIE CAMPBELL
Registration No. 0230-06300

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

Decision:

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

ROBERT MCKENNEY
License No. 0202-010727

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

Decision:

Upon a motion by Mr. Yi, duly seconded by Mr. Stredler, the Board unanimously voted that with the evidence presented, the practice as a pharmacist by Mr. McKenney poses a substantial danger to the public; and therefore, that the license of Mr. McKenney to practice pharmacy be summarily suspended; and that a Consent Order be offered to Mr. McKenney for the indefinite suspension for not less than one year of his license in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:15 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Jennifer Edwards, Chair

Date

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

Tuesday, November 10, 2009
Commonwealth Conference Center
Second Floor
Training Room 2

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 10:00 a.m.

PRESIDING: Dave Kozera, Committee Chair

MEMBERS PRESENT: John Beckner, Committee Member

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

KELLY TAYLOR, III
Pharmacist Applicant

Kelly Taylor appeared to discuss his application for licensure as a pharmacist and allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 2, 2009, Notice.

Closed Meeting: Upon a motion by Mr. Beckner, 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 Kelly Taylor. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to approve Mr. Taylor's application for a pharmacist license contingent upon his complying 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. Taylor, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Taylor 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.

ANDREW NORRIS
License No. 0202-006294

Andrew Norris appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 15, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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 Andrew Norris. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to serve an Order to reprimand Mr. Norris, impose a monetary penalty and require him to complete 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. Norris, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Norris 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.

DOROTHY ELLINGTON
Registration No. 0230-012221

Dorothy Ellington did not appear at the informal conference. The committee chose to proceed in her absence as the Notice was mailed to Ms. Ellington's legal address of record. The committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 15, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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 Dorothy Ellington. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Ellington a Consent Order for the revocation of her pharmacy technician registration. Additionally, they requested that a Notice for a formal hearing be mailed to Ms. Quintanilla with the Consent Order.

MICHELLE ROMATOWSKI
Registration No. 0230-010789

Michelle Romatowski did not appear at the informal conference. The committee chose to proceed in her absence as the Notice was mailed to Ms. Romatowski's legal address of record. The committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 15, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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 Michelle Romatowski. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Romatowski a Consent Order for the revocation of her pharmacy technician registration. Additionally, they requested that a Notice for a formal hearing be mailed to Ms. Romatowski with the Consent Order.

NICHOLAS ARDUIN
License No. 0202-206213

Nicholas Arduin appeared with Johnathon Venzie, his attorney, to discuss the allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 15, 2009, Notice.

Closed Meeting: Upon a motion by Mr. Beckner, 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 Nicholas Arduin. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order requiring Mr. Arduin to comply with his contract with the Health Practitioner's Monitoring Program.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Arduin, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Arduin 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 MITCHELL
License No. 0202-006713

James Mitchell appeared with Stephen Forbes, his attorney, to discuss the allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 4, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, 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 James Mitchell. 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. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Mr. Mitchell and impose a monetary penalty.

ADJOURN:

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

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

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

Tuesday, December 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 8:40 a.m., on December 1, 2009, to consider the summary suspension of the registration of Nancy P. Copeland to practice as a pharmacy technician in the Commonwealth of Virginia .

PRESIDING: Brandon K. Yi, Vice-Chair

MEMBERS PRESENT:
Gill Abernathy
John Beckner
Bobby Ison
Dave Kozera
Michael Stredler

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Wayne Halbleib, 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 this matter.

NANCY P. COPELAND
Registration No. 0230-010030

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

Decision:

Upon a motion by Mr. Beckner, duly seconded by Mr. Kozera, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Nancy P. Copeland poses a substantial danger to the public; and therefore, that the registration of Ms. Copeland to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Copeland for the revocation 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

Eusebia L. Joyner
Disciplinary Program Specialist

Brandon K. Yi, Vice-Chair

Date

Public Hearing

Drug Donation Program

In agenda package:

- **Copy of proposed regulations**

Board action:

- **None required at this meeting**

3b

Project 1606 - Proposed

BOARD OF PHARMACY
Drug donation program

Part I
General Provisions

18VAC110-20-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

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

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

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

"DEA" means the United States Drug Enforcement Administration.

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

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted from a practitioner authorized to prescribe directly to a pharmacy without interception or intervention from a third party, or from one pharmacy to another pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or

harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-20-400. Returning of drugs and devices.

~~A.~~ Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of § 54.1-3411.1 of the Code of Virginia.

Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

~~B. Any pharmacy accepting drugs returned from nursing homes for the purpose of redispensing to the indigent free of charge shall maintain a copy of a written agreement with the nursing home in accordance with § 54.1-3411.1 B of the Code of Virginia and a current policy and procedure manual describing the following:~~

~~1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;~~

~~2. Procedure for determining the suitability and integrity of drugs for redispensing to include assurance that the drugs have been stored according to official compendial standards; and~~

~~3. Procedure for assigning a beyond-use date on redispensed drugs.~~

18VAC110-20-740. Drug donation sites.

Any pharmacy with a current active pharmacy permit may apply on a form provided by the board for registration as a drug donation site. A registered drug donation site may receive eligible donated drugs, transfer such donated drugs to another registered drug donation site, or redispense the donated drugs in accordance with § 54.1-3411.1 of the Code of Virginia to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Drugs collected under the drug donation program may not be dispensed to any other patient, sold, or otherwise distributed except as authorized in 18VAC110-20-770 or 18VAC110-20-790.

18VAC110-20-750. Eligible drugs.

A. Drugs may be accepted by a registered drug donation site only if the following criteria are met:

1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium Class A or B container requirements, or better, as set forth in § 54.1-3411.1 A 2 of the Code of Virginia;

2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and

3. The drugs have not been adulterated or misbranded.

B. The following drugs shall not be accepted by a drug donation site:

1. Schedule II-V controlled substances or any other drug if such return is inconsistent with federal law;

2. Drugs determined to be hazardous for donation based on (i) the pharmacist's professional judgment, experience or knowledge, or (ii) available reference materials;

3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and

4. Drugs that have been previously compounded.

18VAC110-20-760. Procedures for collecting eligible donated drugs.

A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy of the donor form to the person donating the drug at the time of the donation and shall maintain the original

donor form. A donor form is not required for drugs donated by a patient residing in a long-term care facility or other facility where drugs are administered to that patient if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed;

2. A statement that the donor intends to voluntarily donate the prescription drug for redispensing;

3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements;

4. Contact information for the patient or patient's agent;

5. The date of donation;

6. A listing of the donated drugs to include name, strength, and quantity;

7. A statement that private health information will be protected;

8. The signature of the patient or patient's agent; and

9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.

D. Donated prescription drugs shall be stored within the prescription department, separate from other drug inventory.

E. Prior to transferring any donated drugs or redispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable.

F. A drug donation site may not charge a fee for collecting donated drugs.

18VAC110-20-770. Procedure for transferring donated prescription drugs.

A. A drug donation site may transfer eligible donated prescription drugs to another drug donation site for the purpose of redispensing.

B. The transferring drug donation site shall provide a transfer record to the receiving drug donation site that includes the following:

1. The names and addresses of the transferring site and the receiving site;

2. The name, strength, and quantity of each donated drug being transferred; and

3. The date of transfer.

C. The original transfer record shall be maintained by the transferring drug donation site.

D. A copy of the transfer record shall be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and it shall be maintained by the receiving drug donation site.

18VAC110-20-780. Procedure for dispensing donated prescription drugs.

A. A drug donation site redispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.

B. The pharmacy redispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug

redispensed, consistent with the provisions of subdivision 10 of § 54.1-3301 of the Code of Virginia.

C. Recipients of a redispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for the purpose of redispensing pursuant to § 54.1-3411.1 of the Code of Virginia. The drug donation site shall maintain this form.

D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.

18VAC110-20-790. Procedures for disposing of donated prescription drugs.

A. A drug donation site in possession of donated prescription drugs ineligible for redispensing shall dispose of such drugs in compliance with 18VAC110-20-210.

B. A drug donation site shall maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.

18VAC110-20-800. Records.

A. All records required for drug donation programs shall be maintained chronologically for two years.

B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records.

C. Storage of records.

1. Transfer, dispensing, and disposal records may be stored in an electronic database or record.

2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image that provides an exact, clearly legible image of the document.

3. Records may be stored in secured storage, either on or offsite.

D. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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. 4/09).

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

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

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

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

Application for a Controlled Substances Registration Certificate (rev. 4/09).

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. 3/09).

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

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 Pharmacy Technician (eff. 3/09).

Registration for a Pharmacy to be a Collection Site for Donated Drugs (eff. 4/09).

Regulatory Actions – Board of Pharmacy
December, 2009

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Signing of automated dispensing devices in hospitals Stage: NOIRA - *Register Date: 10/26/09* *Comment closed 11/26/09* *Regulatory Committee to review comment & draft proposed language*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Standards of conduct Stage: Proposed - *Register Date: 8/31/09* *Comment closed 10/30/09* *Board to adopt Final Regulations and response to comment at meeting on 12/16/09*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Drug donation program Stage: Proposed - *Register Date: 11/23/09* *Comment closes 1/22/10* *Public Hearing – Board meeting 12/16/09*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Stat-drug boxes in long-term care facilities Stage: Fast-Track - *Register Date: 11/23/09* *Effective 1/7/10*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Changes in renewal dates for pharmacies and permitted facilities Stage: Final - *Register Date: 11/23/09* *Effective 12/23/09*

Adoption of Final Regulations

Standards of Conduct – Unprofessional Conduct

In agenda package:

- **Comment on proposed regulations**
- **Proposed regulations**

Board action:

- **Consider and respond to comment**
- **Adopt final regulations as proposed or with amendments**

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 30, 2009

Elizabeth Scott Russell, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
via email: scotti.russell@dhp.virginia.gov

Dear Ms. Russell:

Re: Proposed Amendments to 18 VAC 110-20-25

On behalf of the approximately 990 chain pharmacies operating in the state of Virginia, the National Association of Chain Drug Stores (NACDS) thanks you for the opportunity to submit comments on the Virginia Board of Pharmacy's ("Board") proposed amendments to18 VAC 110-20-25 pertaining to unprofessional conduct for pharmacists. While we generally support the Board's proposed rules for unprofessional conduct, we are concerned with the inclusion of language under 18 VAC 110-20-25 (7) that would require a pharmacist respond "appropriately" to a known dispensing error. For the reasons discussed below, we respectfully urge the Board to delete this particular provision from the proposed rule language prior to adoption.

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P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

18 VAC 110-20-25 (7) would specifically establish that "[f]ailing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient" would constitute unprofessional conduct under the regulation. Accordingly, any pharmacist found to be in violation of this provision would be subject to disciplinary action by the Board in accordance with Va. Code Ann. § 54.1-3316 (2). NACDS has the following concerns with this standard:

- ***This would create a punitive approach for dispensing errors which runs contrary to the overall aim of improving patient safety.*** Mandating *any* response to a dispensing error runs contrary to the overall goal of improved patient safety, especially when failure to meet the standard will result in disciplinary action. According to the Institute of Medicine (IOM) Report *To Err is Human: Building a Safer Health System* (December 1999), for any quality improvement program to be successful, health care providers who evaluate errors must feel safe to do their assessment in a non-punitive environment. Successful patient safety programs depend on encouraging health care providers to voluntarily discuss and learn from their mistakes. The language under 18 VAC 110-20-25 (7) would have a negative effect on patient safety activities.
- ***An "appropriate" response is a subjective standard.*** It is unclear what specifically constitutes an "appropriate" response under the proposed rule. We assume that the Board drafted the proposed rule in a manner so as not to prescribe a specific course of action following a dispensing error and to instead allow individuals to determine the

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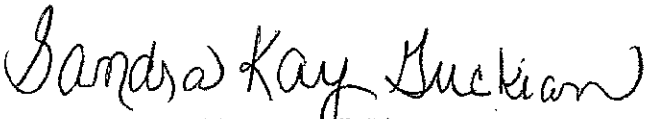
proper response depending on the particular situation. While we agree that flexibility in this area is crucial to the success of any pharmacy patient safety program, we are concerned that this vague mandate could compel pharmacists to somehow respond to even the most minor errors (such as those which were caught before they left the pharmacy and would therefore have no impact on patient safety) for fear of being subject to disciplinary action.

Chain pharmacy is committed to patient safety and to continuously improving the quality of the pharmacy services we provide. Many of our members have already voluntarily implemented patient safety initiatives to meet this aim. Because we are concerned that the proposed language under 18 VAC 110-20-25 (7) may hinder these efforts, NACDS asks that board to delete this language from the proposed rule:

> The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:
>
> ...
>
> ~~7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;~~

NACDS thanks the Board for considering our comments on this matter. Please do not hesitate to contact us if we can provide further assistance. I can be reached by phone at 703-837-4195 or via e-mail at sguckian@nacds.org.

Sincerely,



Sandra Kay Guckian, M.S., R.Ph.
Vice President and Deputy Director, State Government Affairs

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;

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.

2010 Legislation – Pharmacy

Rescheduling bill

In agenda package:

- **Copy of legislation approved for introduction**

Board action:

- **None required at this meeting**

Department of Health Professions
2010 Session of the General Assembly

Draft Legislation

A bill to amend §§ 54.1-3448 and 54.1-3454 of the *Code of Virginia* to add tapentadol to Schedule II and lacosamide to Schedule V in conformity with recent federal scheduling changes.

Be in enacted by the General Assembly:

1. That §§ 54.1-3448 and 54.1-3454 of the *Code of Virginia* are amended and reenacted as follows:

§ 54.1-3448. Schedule II.

The controlled substances listed in this section are included in Schedule II:

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;

Opium extracts;

Opium fluid extracts;

Powdered opium;

Granulated opium;

Tincture of opium;

Codeine;

Dihydroetorphine;

Ethylmorphine;

Etorphine hydrochloride;

Hydrocodone;

Hydromorphone;

Metopon;

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Oripavine (3-O-demethylthebaine or 6,7,8,14-tetradehydro-4, 5-alpha-epoxy-6-methoxy-17-methylmorphinan-3-ol);

Morphine;

Oxycodone;

Oxymorphone;

Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine; cocaine or any salt or isomer thereof.

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

Levo-alphacetylmethadol (levo-alpha-acetylmethadol)

(levomethadyl acetate) (LAAM);

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone - Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

Moramide - Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylicacid;

Pethidine (other name: meperidine);

Pethidine - Intermediate - A, 4-cyano-1-methyl-4-phenylpiperidine;

Pethidine - Intermediate - B, ethyl-4-phenylpiperidine-4-carboxylate;

Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Remifentanil;

Sufentanil;

Tapentadol.

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

Amphetamine, its salts, optical isomers, and salts of its optical isomers;

Phenmetrazine and its salts;

Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;

Methylphenidate;

Lisdexamfetamine, its salts, isomers, and salts of its isomers.

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

Amobarbital;

Glutethimide;

Secobarbital;

Pentobarbital;

Phencyclidine.

5. The following hallucinogenic substance:

Nabilone.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are immediate precursors to amphetamine and methamphetamine or phencyclidine:

Phenylacetone;

1-phenylcyclohexylamine;

1-piperidinocyclohexanecarbonitrile (other name: PCC).

§ 54.1-3454. Schedule V.

The controlled substances listed in this section are included in Schedule V:

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Pyrovalerone.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];

Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].