



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

Amended Tentative Agenda of Meeting

December 14, 2011

9:00AM

TOPIC

PAGE(S)

Public Hearing

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Regulations for Possession and Repackaging of Drugs in Certain Mental Health Facilities

1-13

Call to Order: Gill Abernathy, Chairman

- Approval of Agenda

Approval of previous Board meeting minutes:

- September 20, 2011, Full Board Meeting 1-12
- September 27, 2011, Special Conference Committee and Informal Conference Committee 13-18
- October 6, 2011 Telephone Conference Call 19-21
- October 13, 2011, Telephone Conference Call 22-23
- October 19, 2011, Special Conference Committee and Informal Conference Committee 24-29
- November 22, 2011, Special Conference Committee and Informal Conference Committee 30-31
- November 29, 2011, Regulation Committee for Automated Counting Devices, Automated Dispensing Devices, and Definition of "Low Volume" Handout
- November 30, 2011, Panel of the Board, Formal Hearing Handout

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

DHP Director's Report: Diane Reynolds-Cane, M.D.

Regulations: Elaine Yeatts

- Update on Regulatory Action & Preliminary Legislative Report Handout
- Discuss Regulation Committee's recommendations to:
 - Adopt NOIRA regarding 18 VAC 110-20-355, automated counting devices 32-34
 - Remove definition of "low volume" from guidance document 110-9 35-36

- Discuss petition for rulemaking to reschedule tetrahydrocannabinol from Schedule I to Schedule II for medical use 37-52

Miscellaneous:

- Request to require mandatory CE on emergency and disaster preparedness 53-57
- Request to discuss concern regarding diversions of hydrocodone drug products 58-69
- Request to consider amending pharmacist to pharmacy technician ratio in 18VAC110-20-270 70-81
- Request to extend delegation of authority for disciplinary matters 82
- Consider amending guidance document 110-41 regarding changes a pharmacist may make to a prescription for a Schedule II controlled substance Handout
- Review agency's consideration of paperless licensing

Reports:

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

New Business

Consideration of consent order

Adjourn

***The Board will have a working lunch at approximately 12 noon, to include presentation of plaques to former Board members John O. Beckner, Leo H. Ross, and Gerard Dabney and gift to retiring staff member, Gloria Williams. Immediately following adjournment of the meeting, a panel will be convened for a formal hearing.**



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- Request to extend delegation of authority for disciplinary matters 76
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New Business**Consideration of consent orders (if any)****Adjourn**

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Proposed regulations – Public Hearing, December 14, 2011

BOARD OF PHARMACY

Repackaging in CSB's and BHA's

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
13. <u>Approval of a repackaging training program</u>	<u>\$50</u>

D. Annual renewal fees.

1. Pharmacist active license – due December 31	\$90
2. Pharmacist inactive license – due December 31	\$45
3. Pharmacy technician registration – due December 31	\$25
4. Pharmacy permit – due April 30	\$270
5. Physician permit to practice pharmacy – due February 28	\$270
6. Medical equipment supplier permit – due February 28	\$180
7. Humane society permit – due February 28	\$20
8. Nonresident pharmacy – due April 30	\$270
9. Controlled substances registrations – due February 28	\$90

10. Innovative program continued approval based on board order not to exceed \$200 per approval period.	
11. Approval of a pharmacy technician training program	\$75 every two years
12. <u>Approval of a repackaging training program</u>	<u>\$30 every two years</u>

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
11. <u>Approval of a repackaging training program</u>	<u>\$10</u>

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

h. Approval of a repackaging training program \$50

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 |

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.
2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:
 - a. A description of how each pharmacy will comply with all applicable federal and state law;
 - b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;
 - c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;
 - d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;
 - e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;
 - f. The policy and procedure for ensuring accuracy and accountability in the delivery process;
 - g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and
 - h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.
3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.
 - C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.
 2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:
 - a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;
 - b. Procedure for providing counseling;
 - c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;
 - d. The procedure for assuring confidentiality of patient information; and
 - e. The procedure for informing the patient and obtaining consent for using such a delivery process.
 3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.
- D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.
- E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

Part XVI

Controlled Substances Registration for Other Persons or Entities

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

Part XVI

Controlled Substances Registration for Other Persons or Entities

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected consistent with subsection B of this section.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved

by the board who is authorized to administer ~~or otherwise possess~~ the controlled substances ~~for that type entity~~.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.
2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.
3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.
4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.
2. In an emergency medical services agency, the operational medical director shall supervise.
3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who

have successfully completed a training program for repackaging of prescription drug orders in a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, and overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-725. Repackaging by a CSB or BHA.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB or BHA, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB or BHA using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB or BHA.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB or BHA.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB or BHA.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB or BHA for subsequent repackaging. If retained by the CSB or BHA, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB or BHA and shall include the following:

a. Date of destruction;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Drug name and strength;

e. Quantity of drug destroyed; and

f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB or BHA for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia, and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB, BHA, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval. A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a

self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB or BHA.

As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB or BHA may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging that complies with the requirements of 18VAC110-20-340 B and subsections G, H, and J of 18VAC110-20-725. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply and obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II-V controlled substances shall not be stocked. The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia, shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

(DRAFT/UNAPPROVED)

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

September 20, 2011
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Gill B. Abernathy, Chairman

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

MEMBER ABSENT: Brandon K. Yi

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General (business portion)
Rachel Baer, Assistant Attorney General (formal hearings)
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Eusebia Joyner, Disciplinary Program Specialist

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

INTRODUCTION OF NEW BOARD MEMBERS: Ms. Abernathy welcomed two new members to the Board of Pharmacy, R. Crady Adams and Empsy Munden.

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

APPROVAL OF MINUTES: The Board reviewed draft minutes for June 8, 2011 (Board Meeting); July 25, 2011 (Telephone Conference Call); August 16, 2011 (Panel Formal Hearing); and August 25, 2011 (Ad Hoc Committee, Continuous Quality Improvement). There was an amendment made to the June 8, 2011 full board meeting minutes to include on page 10 the allowable circumstances for compounding

17 alpha hydroxyprogesterone caproate.

Motion: **The Board voted unanimously to approve the minutes as amended. (motion by Kozera, second by Dabney)**

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

DHP DIRECTOR'S REPORT: Dr. Cane reported that the Department of Health Professions (DHP) was presented with the Council on Licensure, Enforcement and Regulation (CLEAR) Regulatory Excellence Award at the September 9, 2011 annual meeting that was held in Pittsburgh, for its development of the Sanctioning Reference Points (SRP) program. Dr. Elizabeth Carter (Director, Board of Health Professions) and Neil Carter (Visual Research) developed the SRP program which is the first tool of its kind to standardize sanctions.

Arne Owens reported on DEA's National Take-Back Day, the last one bringing in approximately five tons of unwanted drugs statewide. The next National Take-Back Day is scheduled for October 29, 2011, and DHP will take part in publicizing the event. Mr. Owens highlighted a booklet which had been distributed by Board staff to the Board, "A Roadmap for Local Communities in Virginia" to host a successful drug take-back program. The Office of the Attorney General published this booklet in order to assist local communities in organizing their own programs.

REGULATIONS: Ms. Yeatts provided a status update of the Board's current regulatory packages. The proposed regulations for administrative fees for duplicate licenses and verifications are at the Secretary's Office and the proposed regulation to eliminate the requirement for an alarm system for certain EMS agencies is at the Governor's Office.

- Emergency Regulations for CSBs, BHAs, and Crisis Stabilization Units

Additionally, Ms. Yeatts stated the emergency regulations for CSBs, BHAs, and crisis stabilization units will expire December 19, 2011. Ms. Yeatts explained that the Board could consider requesting a six-month extension of the emergency regulations, since the permanent replacement regulations will not become effective prior to December 19, 2011. This would extend the emergency regulations to June 18, 2012.

Motion: **The Board voted unanimously to request that the emergency regulations for CSBs, BHAs, and crisis stabilization units be extended for 6 months until June 18, 2012. (motion by Rhodes, second by Shinaberry)**

- Adoption of Proposed Regulations for On-Hold

Ms. Yeatts reported that a Notice of Intended Regulatory Action (NOIRA) was published for public comment on May 9, 2011, for

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Prescriptions

the proposed regulations concerning on-hold prescriptions. Responses were received until June 8, 2011. All responses received supported amending regulations. Additionally, she reported that a committee of the Board met on May 17, 2011 to draft proposed regulations on the subject. Ms. Yeatts requested that the Board review the received public comments and the draft proposed regulations as recommended by the committee and consider adopting proposed regulations either as recommended or with amendments.

Motion:

The Board voted unanimously to adopt the proposed regulations for on-hold prescriptions as recommended by the committee. (motion Rhodes, second by Dabney)

- Adoption of Emergency Regulations for Continuous Quality Improvement:

Ms. Yeatts reminded the Board that § 54.1-3434.03, recently enacted, requires the Board to promulgate emergency regulations for implementing continuous quality improvement programs (CQI) in all pharmacies. She also stated that a taskforce representing various areas of pharmacy practice met on May 18, 2011 and August 25, 2011 to draft proposed emergency regulations. At the August meeting, the committee requested staff to research whether current statutory language for peer review would offer pharmacists confidentiality protections; if not, what action could be taken to create such protections; and if the effective date of the rules could be delayed to provide an educational period for the licensees. Ms. Juran reported that Board counsel indicated current peer review language does not appear to provide civil protections and that an interested stakeholder could seek a legislative amendment, if desired. Mr. Casway then stated that the rules could not defer the effective date for implementing the requirements, but that it would be the Board's decision as to whether it would impose a sanction for a violation of non-compliance. It was recommended that pharmacies should have an opportunity to implement the CQI programs prior to being issued a sanction for non-compliance. It was stated that many pharmacies, including hospitals and retail chains, already have a CQI program in place or report to a patient safety organization (PSO). Additionally, James Pickral, representing the Virginia Pharmacist Association, indicated that many independent pharmacies also currently have either a CQI program or report to a PSO. After discussion, the Board agreed to direct inspectors during a routine inspection to cite non-compliance with these requirements as a comment only for six months from the date authorizing the publishing of the emergency regulations.

Motion:

The Board voted unanimously to direct inspectors during a routine pharmacy inspection to record on the inspection report non-compliance regarding § 54.-3434.03 and the CQI

emergency regulations as a comment only and to not impose a monetary penalty for non-compliance with these requirements for six months from the date authorizing the publishing of the emergency regulations. (motion Kozera, second by Allen).

Action Item:

The Board agreed to consider amending Guidance Document 110-9 at a future board meeting to include a possible monetary penalty for non-compliance of § 54.-3434.03 and the CQI emergency regulations when cited during an inspection after the first six-month period from the date authorizing the publishing of the emergency regulations.

The Board also discussed the term “dispensing error”. It was determined a dispensing error occurs after the final verification of the pharmacist, regardless of whether the drug has been delivered to the patient or not. The fact that a drug incorrectly prepared was verified to be accurate by the pharmacist and made ready for delivery to the patient is sufficient to constitute a dispensing error. Lastly, it was noted in the proposed definition of “dispensing error”, section 3, that “medication” and “wrong”, were not the correct terms to use. It was suggested that “drug” and “incorrect” be used instead.

Motion:

The Board voted unanimously to adopt the emergency regulations as required by § 54.-3434.03 regarding continuous quality improvement programs and as recommended by the taskforce, with amendments to the definition of “dispensing error”, section 3, using “drug” instead of “medication” and “incorrect” instead of “wrong”. (motion by Allen, second by Rhodes)

Motion:

To afford another opportunity to receive public comment, the Board voted unanimously to adopt a second Notice of Intended Regulatory Action (NOIRA) for the permanent replacement regulations regarding continuous quality improvement programs. (motion by Stelly, second by Adams)

- Consideration of Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reviewed with the Board three petitions for rulemaking regarding monthly audit requirements in Regulation 18 VAC 110-20-490. The petitioners indicated that current auditing requirements are overly burdensome, because improvements in technology since this regulation became effective could potentially automate or eliminate some of the manual processes currently required. Ms. Yeatts indicated twenty-one public comments were received, all supporting an amendment to the regulation. Ms. Yeatts stated that the Board must either approve the petitions for rulemaking and adopt a Notice of Intended Regulatory Action (NOIRA) or deny the petition and state the reason for denial.

Motion:

The Board voted unanimously to approve the petitions for rulemaking regarding automated dispensing devices, but to expand the petition to include all of Regulation 18VAC 110-20-490 and adopt a Notice of Intended Regulatory Action. (motion by Adams, second by Kozera)

- Review “Run Dry” Requirement for Automated Counting Devices:

Ms. Juran reported that Delegate Chris Jones had indicated in a recent conversation with her that the “run dry” requirement in Regulation 18VAC 110-20-355 may currently be overly burdensome. He explained to Ms. Juran that there is an increasing trend to use automated counting devices to more securely store certain slow-moving drugs which do not inherently empty from the bin every sixty days. Ms. Juran stated she reviewed the other states’ regulations for automated counting devices and none had a “run dry” requirement. Alan Friedman representing Kaiser Permanente addressed the Board with his concerns for the regulation. He explained that current counting devices rely on gravity to empty the device to ensure the “first drug in” is the “first drug out”, unlike the baker cells used in past when the “run dry” requirement was put in place. He believes the “run dry” requirement is no longer necessary and the Board should consider either eliminating the requirement or requiring an annual “run dry”.

Motion:

The Board voted unanimously to refer the review of the “run dry” requirement in Regulation 18VAC 110-20-355 to the regulation committee and for it to collect further information for consideration by the Board. (motion by Munden, second by Rhodes)

UPDATE ON ACTION
ITEMS:

- Statistics Regarding Delegated Authority:

Ms. Juran and Ms. Reiniers-Day discussed with the Board the use of the delegated authority to review cases that was approved during the June 8, 2011 board meeting. Ms. Reiniers-Day reported the past year’s history for the Board in that, for the time period September 1, 2010 to August 31, 2011, for patient care cases involving a medication error, ten pre-hearing consent orders were entered and fifty confidential consent agreements were entered. All ten pre-hearing consent orders involved a child’s medication error. Ms. Reiniers-Day further advised that since the June 8, 2011, board meeting, she and Ms. Juran discussed six cases, with two being handled as pre-hearing consent orders and four being handled as confidential consent agreements.

Action Item:

The Board requested that Board staff monitor the number of medication error cases involving pediatric patients received for

the next six months and provide the Board with this information.

MISCELLANEOUS:

- Request for Consideration of Amending Guidance Document 110-9, Major 24 regarding Definition of "Low Volume":

Ms. Juran reminded the Board that USP Chapter 797 allows sterile compounding of hazardous drugs in an area not physically separated from other preparation areas if the compounding of hazardous drugs is limited to a "low volume". To offer guidance to the inspectors, the Board had defined "low volume" at the June board meeting to mean no more than 15 compounded hazardous preparations per week or as defined by USP. Subsequent to the June board meeting the Board received a letter from Hank Rahe, Technical Director, Containment Technologies Group, Inc., requesting the Board amend the definition of "low volume" in Guidance Document 110-9, Major 24, to place the burden of proof on the manufacturer of the engineering control to state the low-volume benchmark based on independently produced data and studies. Mr. Rahe was present at the board meeting and offered comment that with the use of a Containment Aseptic Compounding Isolator (CACI) a much larger volume of hazardous drugs can be compounded safely compared to a Class II biological safety cabinet.

Motion:

The Board voted unanimously to refer the request for amending the definition of "low volume" in Guidance Document 110-9, Major 24, to the regulation committee for further review and for Board staff to obtain any additional information from industry experts for consideration by the committee and full Board. (motion by Shinaberry, second by Allen)

- Request for Guidance for Reconciliation of Perpetual Inventories:

Staff requested guidance from the Board concerning "reconciliation" during a perpetual inventory of Schedule II drugs as required in Regulation 18VAC 110-20-240. The Board discussed that the perpetual inventory record should accurately reflect the "physical count" of the Schedule II drug on-hand at the time of inventory. Additionally, the Board agreed that reconciliation involves a comparison of the "physical count" and the "theoretical count" and that a recording must be made explaining any difference between the two counts. The Board agreed to clarify these expectations in Guidance Documents 110-9 and 110-16.

Motion:

The Board voted unanimously to amend Guidance Document 110-9, Major Deficiency 15, and Guidance Document 110-16 to clarify that the perpetual inventory record must accurately

indicate the “physical count” of the Schedule II drug on-hand at the time of inventory and that the “reconciliation” required at least monthly means to record an explanation for any difference between the physical count and the theoretical count. (motion Kozera, second by Adams)

- Review Joint Commission’s Study Recommendations

Ms. Juran briefly shared with the Board the study reports that were presented to the Joint Commission on Health Care on September 19, 2011. The two studies resulted from the General Assembly referring the following bills to be studied: HB 1961, HB 1966, and SB 878. No action was taken by the Board at this time.

- Concerns Regarding 15-Minute Prescription Guarantee Dispensing Policies by Pharmacists and ISMP:

Ms. Juran reviewed with the Board a letter received from a pharmacist expressing concerns for his employer, Harris Teeter Pharmacy, intending to implement a “15-minute Prescription Guarantee” in August 2011, similar to the policy previously implemented by Rite Aid Pharmacy. The letter references another letter from the Institute for Safe Medication Practices (ISMP) sent to the National Association of Boards of Pharmacy (NABP) requesting NABP “explore and assist members in employing methods to eliminate inducements to consumers that insinuate or promise prescriptions will be dispensed within timeframes that may compromise patient safety.” This letter from ISMP was shared with the Board, along with NABP’s response to ISMP. In that response, NABP expressed a shared concern and requested ISMP share verifiable information to identify and substantiate concerns noted by ISMP. During the discussion of the letters, Board counsel advised that prohibiting a pharmacy from offering a 15-minute prescription guarantee might be construed by the U.S. Federal Trade Commission as a restraint of trade absent an express statutory provision authorizing the Board to restrict/prohibit this practice. The Board expressed concerns for the 15-minute prescription guarantee policy and that it would like to review any information provided by ISMP to NABP for future consideration of this matter.

Motion:

The Board voted unanimously to draft a letter to NABP expressing concern for the “15-minute prescription guarantee” policy and requesting that any information provided by ISMP be shared with the Board for future consideration of this matter. (motion Rhodes, second by Kozera)

- Schedule Dates for 2012 Full Board Meetings:

Ms. Juran stated that meeting dates for the full board meetings needed to be scheduled for the upcoming year. The dates agreed upon were March 13, 2012, June 12, 2012, September 19, 2012 and December 12, 2012.

REPORTS:

- Report from PMP:

Carolyn McCann, Deputy Director, Prescription Monitoring

Program (PMP), addressed the Board on upcoming changes that will be taking place. On October 19, 2011, the reporting system will shut down for a system upgrade and reopen on October 24, 2011 to accept new data. Ms. Yeatts reviewed a legislative proposal submitted by the PMP to Dr. Cane for consideration. Additionally, she stated on October 1, 2011 regulatory changes regarding reporting requirements will go into effect, and data will be rejected after January 1, 2012 if the new format is not utilized.

- Chairman's Report-
Announcement of
Committee Appointments:
- Report on Board of Health
Professions:

Ms. Abernathy reviewed with the Board the upcoming committee appointments for the 2011/2012 year.

Robbie Rhodes reported that the Regulatory Research Committee met on July 29, 2011 to receive public comment on the scope of practice of nurse practitioners. Comments that were received supported nurse practitioners being given autonomous prescription authority. On October 14, 2011, the committee will meet for a round table discussion regarding nurse practitioners' scope of practice and team delivery. The August 2, 2011 full board meeting was cancelled and the next meeting is scheduled for October 24th. There have also been several recent appointments made to the Board of Health Professions and these new appointees will be attending the October 24th meeting.

- Report on Licensure
Program

Mr. Johnson reported that the Board issued 1,230 licenses for the period of June 1, 2011 through August 31, 2011, including 397 pharmacists and 586 pharmacy technicians. Inspectors performed 293 facility inspections including 89 routine inspections of pharmacies: 18 resulted in no deficiency, 23 with deficiencies, and 48 with deficiencies and a consent order. No new applications for innovative (pilot) programs were received. There are currently three active pilot programs: Institutional Pharmacy Solutions, Tech Bar Code Scan (Omnicare), and Dulles Urgent Care Center – InstyMeds Automated Dispensing Systems.

- Report on Disciplinary
Program

Ms. Reiniers-Day reported that, as of September 19, 2011, there were 233 open cases docketed for the Board, as follows: entry-two; investigation-64; probable cause-90; administrative proceedings division-two; informal-15; formal-two; and pending closure-58.

Ms. Reiniers-Day also reviewed the Quarterly Performance Report for the fourth quarter (April 1, 2011 through June 30, 2011) regarding patient-care cases that indicate a clearance rate of 93%, pending caseload greater than 250 business days of 8% and 96% closure rate within 250 business days.

Action Item:

The Board requested that, for future meetings, Board staff

provide a trend report to review the tracking of cases, to include the number of cases opened and closed.

- Executive Director's Report

Ms. Juran reported that there will be a USP Live Webinar named "Compounding Total Parenteral Nutrition Preparations: A 2011 Investigation of Bacterial Outbreak" to discuss factors that resulted in the contamination of compounded TPNs that caused an outbreak of *serratia marcescens* earlier this year that killed nine people. Registration is full at this time, but that USP will re-air at a later date on their website for free. Ms. Juran also stated that she will be attending the NABP Executive Forum, September 21-22, 2011 in Chicago and that she will be leading the panel discussion on physician dispensing requirements. She will also attend the NABP/AACP-District 1 & 2 Meeting, October 20-22, 2011 in Boston, along with Ms. Allen, Mr. Adams, Ms. Munden, Ms. Shinaberry, and Mr. Leo Ross. Additionally, she was invited to participate this upcoming January on NABP's Task Force to review and recommend revisions to the Controlled Substances Act. She also reported that DEA had issued a notice of intent to temporarily schedule three synthetic cathinones under temporary scheduling provisions to avoid any hazards to public safety.

NEW BUSINESS:

There was no new business at this time.

**CONSIDERATION OF
CONSENT ORDERS:**

There were no consent orders for consideration.

**REQUESTS FOR
EXAMINATION
ACCOMMODATION:**

Motion for closed meeting:

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

**Motion to certify the
purpose of the closed
meeting:**

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

Dabney).

Motions:

The Board voted to approve the examination accommodation request from Abiy Tekle allowing him twice the normally allotted amount of time for completing the Virginia Federal and State Drug Law Examination and a private room with a proctor appropriately monitoring his testing experience. (motion by Kozera, second by Dabney; opposed by Adams and Stelly).

Mr. Casway departed the meeting at 2:00 p.m. and Rachel Baer, Assistant Attorney General, served as board counsel for the remainder of the board meeting.

FORMAL HEARINGS:

BRIAN P. MUSGROVE
Pharmacist Reinstatement
Applicant
License # 0202-009540

Mr. Musgrove appeared to discuss his application to reinstate his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the August 5, 2011, Notice.

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

Ms. Allen did not participate in this hearing.

Cecile Custer, DHP Senior Investigator, testified on behalf of the Commonwealth.

Brian P. Musgrove testified on his own behalf.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the board voted 8-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Brian P. Musgrove. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day and Rachel Baer attend the closed meeting.

Reconvene:

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

Decision:

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

the board and read by Ms. Baer.

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the board voted 8-0 that Mr. Musgrove's application to reinstate his license to practice as a pharmacist be approved contingent upon certain terms and conditions.

PHILIP D. RICHARD
Pharmacist Reinstatement
Applicant
License # 0202-004237

Mr. Richard appeared to discuss his application to reinstate his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the August 30, 2011, Notice.

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

Darren Buss, Pharmacy District Manager, Rite Aid Pharmacy and Nan Dunaway, DHP Pharmacy Inspector, testified on behalf of the Commonwealth.

Philip D. Richard testified on his own behalf.

Closed Meeting:

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

Reconvene:

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

Decision:

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

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the board voted 9-0 that Mr. Richard's application to reinstate his pharmacist license be denied and his license be continued on indefinite suspension for a period of not less than one year.

Adjourn:

With all business concluded, the meeting adjourned at 6:40 p.m.

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Gill Abernathy, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

DRAFT/UNAPPROVED

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Tuesday, September 27, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 11:30 a.m.

PRESIDING: Brandon K. Yi, Committee Chair

MEMBERS PRESENT: Gerard Dabney, Committee Member

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

WAL-MART PHARMACY
#10-1811
Permit No. 0201-003090

Dadrion A. Gaston, Director of Pharmacy Regulatory Affairs; Janelle St. Louis, Pharmacy Manager; and Michael Henson, Marketing Manager appeared on behalf of Wal-Mart Pharmacy to review allegations that Wal-Mart Pharmacy #10-1811 may have violated portions of the laws and regulations governing the conduct of pharmacy as stated in the August 19, 2011, Notice.

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Wal-Mart Pharmacy #10-1811. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee closed this case as no violation.

WAL-MART PHARMACY
#10-1523

Dadrion A. Gaston, Director of Pharmacy Regulatory Affairs; Janelle St. Louis, Pharmacy Manager; and Michael

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Permit No. 0201-002882

Henson, Marketing Manager appeared on behalf of Wal-Mart Pharmacy to review allegations that Wal-Mart Pharmacy #10-1523 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 19, 2011, Notice

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Wal-Mart Pharmacy #10-1523. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Wal-Mart Pharmacy #10-1523 subject to certain terms and conditions.

(This Consent Order shall be effective upon endorsement by Wal-Mart Pharmacy #10-1523 and the Board).

SAM'S PHARMACY #10-4788
Permit No. 0201-004247

Dadrion A. Gaston, Director of Pharmacy Regulatory Affairs; Kelly Bishop, Pharmacy Manager; Shantelle Brown; and Jay Picklesimer appeared on behalf of Sam's Pharmacy to review allegations that Sam's Pharmacy #10-4788 may have violated portions of the laws and regulations governing the conduct of pharmacy as stated in the August 19, 2011, Notice.

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Sam's Pharmacy #10-4788. Additionally, he moved that Cathy Reiniers-Day and

Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee closed this case as no violation.

ADJOURN:

With all business concluded, the meeting adjourned at 3:00 p.m.

Brandon K. Yi
Committee Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, September 27, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 3:00 p.m.

PRESIDING: Brandon K. Yi, Committee Chair

MEMBERS PRESENT: Gerard Dabney, Committee Member

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

JUSTIN D. TAYLOR
Pharmacy Technician
Applicant Justin D. Taylor and Monique Brenson, a friend, appeared to discuss Mr. Taylor's application for registration as a pharmacy technician and to review allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the August 19, 2011, Notice.

Closed Meeting: Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Justin D. 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. Dabney, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to approve Mr. Taylor's application to practice as a pharmacy technician.

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

LISA R. BRADY
Registration No. 0230-015089

Lisa R. Brady appeared to discuss allegations that she may have violated an Order of the Board of Pharmacy entered January 7, 2011 and portions of the laws and regulations governing the practice of pharmacy technicians as stated in the August 11, 2011, Notice.

Closed Meeting:

Upon a motion by Mr. Dabney, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Lisa R. Brady. 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. Dabney, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue an Order that Ms. Brady comply 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 Ms. Brady, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Brady within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such

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timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 5:35 p.m.

Brandon K. Yi
Committee Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, October 6, 2011

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

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

TIME & PURPOSE:

Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 9:30 a.m., on October 6, 2011, to consider the summary suspensions of the registrations of Katherine E. Howard, Fallone R. Brown and Amber D. Coleman to practice as pharmacy technicians in the Commonwealth of Virginia.

PRESIDING:

Gill B. Abernathy, Chair

MEMBERS PRESENT:

Crady Adams
Jody H. Allen
Gerard Dabney
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Brandon K. Yi

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General

POLL OF MEMBERS:

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

With nine (9) 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 this matter.

KATHERINE E. HOWARD
Registration No. 0230-017318

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

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

Upon a motion by Mr. Rhodes and duly seconded by Ms. Munden, the Board unanimously voted that, with the Notice of Hearing, a Consent Order be offered to Ms. Howard for the indefinite suspension of her registration for not less than two years.

FALLONE R. BROWN
Registration No. 0230-013791

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

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Fallone R. Brown poses a substantial danger to the public; and that the registration of Ms. Brown to practice as a pharmacy technician be summarily suspended; and that, with the Notice of Hearing, a Consent Order be offered to Ms. Brown for the indefinite suspension of her registration for not less than two years.

AMBER D. COLEMAN
Registration No. 0230-018717

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

Upon a motion by Mr. Yi and duly seconded by Mr. Rhodes, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Amber D. Coleman poses a substantial danger to the public; and therefore, said registration shall be summarily suspended; and that a Consent Order be offered to Ms. Coleman for the revocation of her registration.

ADJOURN:

With all business concluded, the conference call adjourned
at 10:30 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Gill B. Abernathy, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, October 13, 2011

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 3:00 p.m., on October 13, 2011, to consider the summary suspension of the registration of Regina L. Herndon to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams
Jody H. Allen
David C. Kozera
Ellen B. Shinaberry
Brandon K. Yi

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

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

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

REGINA L. HERNDON
Registration No. 0230-008148

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

Upon a motion by Mr. Adams and duly seconded by Ms. Allen, the Board unanimously voted that, with the evidence

presented, the practice as a pharmacy technician by Regina L. Herndon poses a substantial danger to the public; and therefore, that the registration of Ms. Herndon to practice as a pharmacy technician be summarily suspended; and that, with the Notice of Hearing, a Consent Order be offered to Ms. Herndon for the indefinite suspension of her registration for not less than two years.

ADJOURN:

With all business concluded, the conference call adjourned at 3:18 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Gill B. Abernathy, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, October 19, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, 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: David C. Kozera, Committee Chair

MEMBERS PRESENT: Jody H. Allen, Committee Member

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

BARBARA A. ALLEN
Registration No. 0230-017734
Barbara A. Allen appeared to discuss allegations that she may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the September 7, 2011, Notice.

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

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

Decision: Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Allen an Order that places her registration to practice as a pharmacy technician under certain terms and conditions.

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

Allen, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Allen 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.

MARK P. ETRE
Registration No. 0230-017331

Mark P. Etre appeared with Hunter W. Jamerson, his attorney; and Mouline Etre, his mother, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the September 7, 2011, Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Etre an Order that requires him to enter into the Health Practitioners' Monitoring Program.

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

STEPHEN C. ATWELL

Stephen C. Atwell appeared with Mary Ann Kirkpatrick,

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Pharmacy Intern Registration
No. 0203-013249

Dean, Student Affairs, Shenandoah University, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy interns as stated in the September 7, 2011, Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Atwell an Order that requires him to comply with his contract with the Health Practitioners' Monitoring Program.

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

BRIAN J. PUCKETT
License No. 0202-205287

Brian J. Puckett appeared with Sridhar Yaratha, his sponsor, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the September 7, 2011, Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a

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closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Brian J. Puckett. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Puckett an Order that requires him to comply with his contract with the Health Practitioners' Monitoring Program.

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

ADJOURN:

With all business concluded, the meeting adjourned at 4:30 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera
Committee Chair

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Wednesday, October 19, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 4:30 p.m.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: Jody H. Allen, Committee Member

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

SHENANDOAH VALLEY
COMPASSIONATE
PHARMACY
Permit No. 0201-003907

Mary Ann F. Kirkpatrick, Dean, Student Affairs, Shenandoah University, appeared on behalf of Shenandoah Valley Compassionate Pharmacy to review allegations that Shenandoah Valley Compassionate Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 7, 2011, Notice

Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Shenandoah Valley Compassionate Pharmacy. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

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

Decision: Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Shenandoah Valley Compassionate

Pharmacy subject to certain terms and conditions regarding inspection deficiencies.

(This Consent Order shall be effective upon endorsement by Shenandoah Valley Compassionate Pharmacy and the Board).

ADJOURN:

With all business concluded, the meeting adjourned at 7:30 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera
Committee Chair

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, November 22, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Brandon K. Yi, Committee Chair

MEMBERS PRESENT: Pratt P. Stelly, Committee Member

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

NEIL S. DHILLON
License No. 0202-209674

Neil S. Dhillon appeared with Meredith Dhillon, his wife, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the October 12, 2011, Notice.

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

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

Decision: Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee adopted the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Dhillon an Order with a reprimand due to failure to secure drugs.

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

ADJOURN:

With all business concluded, the meeting adjourned at 12:10 p.m.

Brandon K. Yi
Committee Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

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

November 29, 2011
Second Floor
Conference Center

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

- CALL TO ORDER:** The meeting was called to order at 1:15 PM.
- PRESIDING:** Ellen Shinaberry, Chairman
- MEMBERS PRESENT:** Gill Abernathy
David C. Kozera
Cradly Adams
Empsy Munden
Robert M. Rhodes
- MEMBER ABSENT:** Jody Allen
- STAFF PRESENT:** Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
- APPROVAL OF AGENDA:** With no changes made to the agenda, the agenda was approved as presented.
- PUBLIC COMMENTS:** Comments were received at the time the issue was taken up by the committee.
- "RUN DRY" REQUIREMENT FOR AUTOMATED COUNTING DEVICES:** The committee discussed information in the agenda packet and concerns regarding devices not currently being able to guarantee that the first tablets placed in the device will be the first tablets dispensed from the device. Therefore, the committee remained concerned that a recalled drug could potentially remain in the device longer than anticipated. Alan Friedman with Kaiser Permanente was present and offered public comment urging the committee to eliminate or extend the current run dry requirement.
- MOTION:** **The committee voted unanimously to recommend to the full board on December 14, 2011 that Regulation 18VAC110-20-355 be amended to eliminate the run dry requirement and include the following statement, "In the event of drug recall involving one of multiple lots placed in a cell in the last four months, all drug will be removed from the cell and not used for patient care." (motion by Abernathy, second by Adams.)**

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

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

MOTION:

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

AUTOMATED DISPENSING
DEVICES:

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

Ms. Yeatts departed at approximately 4:15pm.

ADJOURN:

With all business concluded, the meeting adjourned at 5:15PM.

Caroline D. Juran
Executive Director

Ellen Shinaberry, Chairman

Date

BOARD OF PHARMACY

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.
2. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.
3. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:
 - a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.
 - b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.
 - c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.
 - d. ~~The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.~~
 - e. ~~The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.~~
 - f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.
 - g. The PIC or his designee shall be exempt from the audit requirements in 3c of this subsection if reconciliation software which provides a statistical analysis over a period of time based on peer-to-peer comparisons of use for that unit or department to monitor overrides and open discrepancies is used to

identify suspicious activity which includes but is not limited to use beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed at least monthly. Reports identifying suspicious activity and a record of the focused audit shall be maintained.

4. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

5. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

- a. at least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;
- b. automatically identifies and isolates the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generates a report verifying the applicable settings;
- c. electronically tracks drug expiration dates and generates proactive reports allowing for the replacement of drugs prior to their expiration date; and,
- d. electronically detects the opening of the device, identifies the person accessing the device, automatically denies access to the device during malfunctions and mechanical errors, and generates reports of any malfunction and mechanical error.

6. The audit shall also check for compliance with written policy and procedures consistent with 54.1-3434.02 A for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

7. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

8. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

- a. Manual Schedule VI distribution records and reports indicating suspicious activity with focused audits may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required ~~signatures~~ initials may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section ~~if authorized by~~ consistent with DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
SUMMARY SUSPENSION MINUTES**

Wednesday, November 30, 2011
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A quorum of the Board of Pharmacy ("Board") was called to order at 9:30 a.m.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams
Gerard Dabney
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry

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

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

Closed Meeting: Ms. Shinaberry moved, and the Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Tammy H. Irby. Additionally, she moved that Caroline D. Juran, Cathy Reiniers-Day, Howard Casway, Eusebia L. Joyner, Wayne T. Halbleib and Mykl Egan attend the closed meeting.

TAMMY H. IRBY
Pharmacy Technician
Registration Number
0230-003661

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
FORMAL HEARING MINUTES

Wednesday, November 30, 2011
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:45 a.m.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams
Gerard Dabney (present for Ms. Lilliston's hearing)
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly (present for Ms. Hoerrner's hearing)

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

QUORUM: With seven (7) members participating and three (3) members unable to participate, it was established that a quorum of the Board of Pharmacy ("Board") was called to order.

TANYA P. LILLISTON
Pharmacist Reinstatement Applicant
License # 0202-010431

A formal hearing was held in the matter of Tanya P. Lilliston following the mandatory suspension of her pharmacist license by the Department of Health Professions on September 9, 2011.

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

Ms. Lilliston appeared with Jonathan M. Joseph, her attorney.

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the panel voted 7-0 that Ms. Lilliston's pharmacist license be reinstated with certain terms and conditions.

Gerald Dabney departed at 3:00 p.m. and Pratt P. Stelly arrived.

JENNIFER W. HOERRNER
Pharmacist Reinstatement Applicant
License # 0202-207347

A formal hearing was held in the matter of Jennifer W. Hoerrner following the mandatory suspension of her pharmacist license by the Department of Health Professions on August 19, 2011.

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

Kim Hood, DHP Investigative Assistant, testified on behalf of the Commonwealth.

Jennifer W. Hoerrner appeared with Christopher M. Malone, her attorney.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Ms. Stelly, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Jennifer W. Hoerrner. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the Board and read by Mr. Casway.

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE**

Tuesday, December 6, 2011
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, 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 Chair

MEMBERS PRESENT: Jody H. Allen, Committee Member

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

ROB B. ABDELNOUR
License No. 0202-209178

Rob B. Abdelnour appeared to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the November 15, 2011, Notice.

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

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

Decision: Upon a motion by Ms. Allen, and duly seconded by Mr. Yi, the Committee adopts the Findings of

“Run dry” requirement for Automated Counting Devices, 18VAC110-20-355

- Regulation Committee met November 29, 2011.
- Committee recommends to full board to consider adopting Notice of Intended Regulatory Action (NOIRA) to amend Regulation 18 VAC 110-20-355 regarding automated counting devices.
 - Specifically recommends striking language regarding “run dry” requirement and including the following language, “In the event of a drug recall involving one of multiple lots placed in a cell of an automated counting device in the last four months, all drug shall be removed from the cell and not used for patient care.”

Possible Board Options:

- Adopt NOIRA to amend 18VAC110-20-355 as recommended or with amendments, **OR**
- Take no action to amend 18VAC110-20-355

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

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

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

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

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

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

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

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

4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, the expiration date on the bin's label shall reflect the expiration date

assigned to the earlier lot, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.

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

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.
2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.
3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

Definition of “Low Volume” as used by USP Chapter 797

- Regulation Committee met November 29, 2011.
- Board counsel has advised that the Board cannot define the term within a guidance document.
- Committee recommends to not define the term “low volume” since USP has indicated its newly formed expert panel will revisit this issue.

Possible Board Options:

- Remove the definition of “low volume” from guidance document 110-9 as advised by counsel and take no further action as recommended by committee, **OR**
- Convene expert witnesses in an attempt to define “low volume” in regulation.

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	54.1-3410.2		3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better over 60 days late (6mo+60 days). Corrective action not taken within one month of certification report.	54.1-3410.2	Review 2 most recent reports	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2	Low volume defined as 15 or less hazardous drug CSP/week or as defined by USP. Review 2 months records.	2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs; or, no documentation of initial and semi-annual media-fill testing for persons performing high-risk level CSPs; or, documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test; or, high-risk drugs intended for use are improperly stored.	54.1-3410.2		5000 per incident within previous 30 days

Petition Regarding Tetrahydrocannabinol

- Received petition for rulemaking to reschedule tetrahydrocannabinol from Schedule I to Schedule II.

Possible Board Options:

- Approve petition for rulemaking and adopt Notice of Intended Regulatory Action (NOIRA) to place tetrahydrocannabinol into Schedule II, **OR**
- Deny petition for rulemaking and provide reason.

CONWAY
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NOV 08 2011

DHP

October 20, 2011

**Via Facsimile @ 1.804.527.4472
& Regular Mail.**

Commonwealth of Virginia
Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

RE: *Jeffrey W. Blessing*
Petition for Rule-making
CLF File No.: 11-127

Dear Sir/Madam:

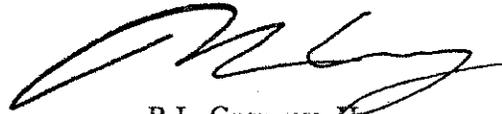
Please note our representation of Mr. Jeffrey W. Blessing in the above referenced matter.

Also, We enclose a Petition for Rule-making for filing and processing in the above referenced matter. We would appreciate it if you would copy us with any and all correspondence on the matter, including your final determination.

Thank you for your assistance with this matter.

Very truly yours,

CONWAY LAW FIRM, P.L.L.C.



B.L. Conway, II

BLC/bjc
Enclosures
xc: Mr. Jeffrey Blessing



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

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

Petition for Rule-making

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

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix.)
Blessing, Jeffrey W.

Street Address
102 Cassard Lane

Area Code and Telephone Number
(276) 594-6922

City
Gate City

State
VA

Zip Code
24251

Email Address (optional)

Fax (optional)

Respond to the following questions:

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

Va Code 54.1 - 3446 and 54.1 - 3448
(Sch. I) (Sch. II)

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

Reschedule Tetrahydro-cannibol Form From Schedule I to Schedule II based on new findings and national trend towards legalization for medical use. I suffer from Bi-Polar Disorder and Obsessive-Compulsive Disorder. Other Medications have proven unsuccessful due to side effects. Marijuana provides effective treatment for Bi-Polar and Obsessive Compulsive Disorder.

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

54.1 - 3443 Authority to reschedule drugs.

Signature:

Jeffrey W. Blessing

Date:

10/20/2011

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COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

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

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

October 25, 2011

Jeffrey W. Blessing
102 Cassard Lane
Gate City, VA 24251

Dear Mr. Blessing:

The Virginia Board of Pharmacy would like to thank you for submission of a petition for rule-making to amend regulations to reschedule Tetrahydro-cannibol from Schedule I to Schedule II. In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on November 21, 2011. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until December 11, 2011.

Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language. This matter will be on the Board's agenda for its meeting on December 14, 2011, and you will be informed of the Board's decision on your request after that meeting.

Again, the Board appreciates your interest in amending the regulations governing the practice of pharmacy.

Very truly yours,

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

cc: Elaine J. Yeatts
Agency Regulatory Coordinator

B. L. Conway, II
Conway Law Firm



Logged in: DHP

Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

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

Commenter: Stephen M. LaHaye, Pharm.D. - St. Francis Medical Center *

11/22/11

Rescheduling of Tetrahydro-cannibol from Schedule I to Schedule II for medical use

21160

I am opposed to the request for Rescheduling of Tetrahydro-cannibol from Schedule I to Schedule II for medical use. In the hospital setting, it would be impossible for pharmacists to verify the source of the product or determine an appropriate dosing regimen. The January 2011 DEA Position on Marijuana (http://www.justice.gov/dea/marijuana_position.pdf) states,

"THE DEA POSITION ON MARIJUANA

Until the Department of Justice and the FDA can determine legitimate medicinal uses and mechanisms to insure the safety and efficacy of the supply for legitimate patients, tetrahydro-cannibol should remain a Schedule I substance in Virginia. Thank you for the opportunity to comment.

Marijuana is properly categorized under Schedule I of the Controlled Substances Act (CSA), 21U.S.C. classification, including evidence that smoked marijuana has a high potential for abuse, has no accepted medicinal value in treatment in the United States, and evidence that there is a general lack of accepted safety for its use even under medical supervision."

Back to List Comments

* Nonregistered public user

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§ 54.1-3446. Schedule I.

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

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

Acetylmethadol;

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

Betacetylmethadol;

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetylbutyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxidine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacymorphan;

Morpheridine;

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

Phenadoxone;

Phenampromide;

Phenomorphane;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tilidine;

Trimeperidine.

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine;

Heroin;

Hydromorphanol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine;

Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

Alpha-ethyltryptamine (some trade or other names: Monase; a-ethyl-1H-indole-3-ethanamine; 3-2-aminobutyl] indole; a-ET; AET);

4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-4-bromo-2,5-dimethoxyphenyl]-1-aminoethane; alpha-desmethyl DOB; 2C-B; Nexus);

3,4-methylenedioxy amphetamine;

5-methoxy-3,4-methylenedioxy amphetamine;

3,4,5-trimethoxy amphetamine;

Alpha-methyltryptamine (other name: AMT);

Bufotenine;

Diethyltryptamine;

Dimethyltryptamine;

4-methyl-2,5-dimethoxyamphetamine;

2,5-dimethoxy-4-ethylamphetamine (DOET);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);

Ibogaine;

5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT);

Lysergic acid diethylamide;

Mescaline;

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo -b,d] pyran; Synhexyl);

Peyote;

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocyn;

Salvinorin A;

Tetrahydrocannabinols, except as present in marijuana and dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration;

Hashish oil (some trade or other names: hash oil; liquid marijuana; liquid hashish);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);

3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;

3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);

N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);

4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);

Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);

Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl) -pyrrolidine, PCPy, PHP);

Thiophene analog of phencyclidine (some other names: 1-1-(2-thienyl) -cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);

1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);

3,4-methylenedioxypropylvalerone (other name: MDPV);

4-methylmethcathinone (other names: mephedrone, 4-MMC).

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:

Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);

Mecloqualone;

Methaqualone.

5. 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 stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4, 5-dihydro-5-phenyl-2-oxazolamine);

N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);

Fenethylamine;

Ethylamphetamine;

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;

Methcathinone (some other names: 2-(methylamino)-propionophenone; alpha-(methylamino) propionophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432);

Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

N,N-dimethylamphetamine (other names: N,N-alpha-trimethyl-benzeneethanamine, N,N-alpha-trimethylphenethylamine).

6. Any material, compound, mixture or preparation containing any quantity of the following substances:

N-3-methyl-1-(2-phenethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl), its optical and geometric isomers, salts, and salts of isomers;

1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP), its optical isomers, salts and salts of isomers;

1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP), its optical isomers, salts and salts of isomers;

N-1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl] propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine), alpha-methylfentanyl);

N-1-(1-methyl-2-phenethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl), its optical isomers, salts and salts of isomers;

N-1-(1-methyl-2-(2-thienyl)ethyl)-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl), its optical isomers, salts and salts of isomers;

N-1-benzyl-4-piperidyl]-N-phenylpropanamide (other name: benzylfentanyl), its optical isomers, salts and salts of isomers;

N-1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl), its optical isomers, salts and salts of isomers;

N-3-methyl-1-(2-hydroxy-2-phenethyl)-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers;

N-(3-methyl-1-(2-thienyl)ethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl), its optical and geometric isomers, salts and salts of isomers;

N-1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (other name: thenylfentanyl), its optical isomers, salts and salts of isomers;

N-phenyl-N-1-(2-thienyl)ethyl-4-piperidyl]-propanamide (other name: thiofentanyl), its optical isomers, salts and salts of isomers;

N-(4-fluorophenyl)-N-1-(2-phenethyl)-4-piperidyl]-propanamide (other name: para-fluorofentanyl), its optical isomers, salts and salts of isomers.

(1972, c. 798, § 54-524.84:4; 1973, c. 479; 1976, c. 614; 1977, c. 302; 1979, cc. 387, 435; 1982, c. 505; 1984, cc. 186, 192; 1986, c. 463; 1988, c. 765; 1994, c. 763; 1996, c. 408; 1997, c. 594; 1999, c. 722; 2000, c. 348; 2005, c. 119; 2008, c. 59; 2011, cc. 384, 410.)

§ 18.2-251.1. Possession or distribution of marijuana for medical purposes permitted.

A. No person shall be prosecuted under § 18.2-250 or § 18.2-250.1 for the possession of marijuana or tetrahydrocannabinol when that possession occurs pursuant to a valid prescription issued by a medical doctor in the course of his professional practice for treatment of cancer or glaucoma.

B. No medical doctor shall be prosecuted under § 18.2-248 or § 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol for medical purposes when such action occurs in the course of his professional practice for treatment of cancer or glaucoma.

C. No pharmacist shall be prosecuted under §§ 18.2-248 to 18.2-248.1 for dispensing or distributing marijuana or tetrahydrocannabinol to any person who holds a valid prescription of a medical doctor for such substance issued in the course of such doctor's professional practice for treatment of cancer or glaucoma.

(1979, c. 435.)

Rules - 2011

[Federal Register Volume 76, Number 131 (Friday, July 8, 2011)]

[Proposed Rules]

[Pages 40552-40589]

From the Federal Register Online via the Government Printing Office [www.gpo.gov]

[FR Doc No: 2011-16994]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA-352N]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated June 21, 2011, the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. \1\ Because DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner (denying the petition), along with the supporting documentation that was attached to the letter.

\1\ Note that "marihuana" is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, "marijuana."

FOR FURTHER INFORMATION CONTACT:

Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

June 21, 2011.

Dear Mr. Kennedy:

On October 9, 2002, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, you petitioned DEA to have marijuana removed from schedule I of the CSA and rescheduled as cannabis in schedule III, IV or V.

You requested that DEA remove marijuana from schedule I based on your assertion that:

- (1) Cannabis has an accepted medical use in the United States;
- (2) Cannabis is safe for use under medical supervision;
- (3) Cannabis has an abuse potential lower than schedule I or II drugs; and
- (4) Cannabis has a dependence liability that is lower than schedule I or II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (DHHS). DHHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, DHHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that DHHS submitted to DEA is attached hereto.

Based on the DHHS evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail also is attached hereto. In short, marijuana continues to meet the criteria for schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The DHHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* According to established case law, marijuana has no "currently accepted medical use" because: The drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not

been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

You also argued that cannabis has a dependence liability that is lower than schedule I or II drugs. Findings as to the physical or psychological dependence of a drug are only one of eight factors to be considered. As discussed further in the attached documents, DHHS states that long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.

The statutory mandate of 21 U.S.C. 812(b) is dispositive. Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States" and "lack of accepted safety for use under medical supervision." 21 U.S.C. 812(b).

Accordingly, and as set forth in detail in the accompanying DHHS and DEA documents, there is no statutory basis under the CSA for DEA to grant your petition to initiate rulemaking proceedings to reschedule marijuana. Your petition is, therefore, hereby denied.

Sincerely,

Michele M. Leonhart,
Administrator.

Attachments:

Marijuana. Scheduling Review Document: Eight Factor Analysis

Basis for the recommendation for maintaining marijuana in schedule I of the Controlled Substances Act

Date: June 30, 2011

Michele M. Leonhart
Administrator

Department of Health and Human Services,
Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science
Washington, D.C. 20201.

December 6, 2006.

The Honorable Karen P. Tandy
Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C.
20537

Dear Ms. Tandy:

This is in response to your request of July 2004, and pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b), (c), and (f), the Department of Health and Human Services (DHHS) recommends that marijuana continue to be subject to control under Schedule I of the CSA.

Marijuana is currently controlled under Schedule I of the CSA. Marijuana continues to meet the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the attached analysis, marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of an accepted level of safety for use under medical supervision. Accordingly, HHS recommends that marijuana continue to be subject to control under Schedule I of the CSA. Enclosed is a document prepared by FDA's Controlled Substance Staff that is the basis for this recommendation.

Should you have any questions regarding this recommendation, please contact Corinne P. Moody, of the Controlled Substance Staff, Center for Drug Evaluation and Research. Ms. Moody can be reached at 301-827-1999.

Sincerely yours,

John O. Agwunobi,
Assistant Secretary for Health.

Enclosure:

Request for Mandatory Continuing Education

- Received request to require a one-time mandatory two-hour CE requirement of pharmacists, as permitted in §54.1-3314.1 J, in the specific subject area of emergency and disaster preparedness.

Possible Board Options:

- Approve publishing of requirement, no later than January 1, 2012, to mandate CE requirement in 2012 as requested or with amendments, **OR**
- Approve publishing of requirement as part of renewal notification letter in 2012 to mandate CE requirement in 2013 as requested or with amendments, **OR**
- Deny request of mandatory CE in emergency and disaster preparedness.

Emergency and Disaster Preparedness Training for Pharmacists

The earthquake and hurricane the week of August 23rd were stark reminders of how quickly disastrous events can unfold. While Virginia was largely spared severe damage from these natural events, the potential from both natural and man-made disasters is catastrophic. Our strategic location outside the nation's capitol, multiple military bases and key large cities increases the potential for Virginia becoming a target for terrorist activities, including biological warfare and chemical agents. Pharmacists can provide crucial support in response to natural or man-made disaster situations. Pharmacists in every practice setting need to be prepared to respond to emergencies, disasters and threats.

I propose that the Board of Pharmacy for the Commonwealth of Virginia mandate a one-time mandatory continuing education requirement of two credits to prepare pharmacists to meet these community needs in case of disaster. This education will provide a familiarity with our emergency plans and knowledge about where to find the answers to issues as they arise. It is not intended to be all-encompassing.

Section 54.1-3314.1 of the regulations of the Board of Pharmacy supports a requirement of up to two hours of continuing education in a specific subject area. The breadth and depth of an introductory instruction in preparedness would be best served by a two hour requirement.

In a disaster, prior familiarity with and knowledge of our twelve push-packs, deployment from the Strategic National Stockpiles to regional units, then to area Points of Distribution (PODs) and mini-PODS will better prepare pharmacists to dispense medication on the scale of 500 to 2,000 patients per hour, as designed. Mass dispensing in rapid response will define our ability to meet potential bioterrorism threats such as anthrax. The Virginia response plan mobilizing PODs estimates a need of 1,500 trained participant pharmacists, pharmacy students, and pharmacy technicians to successfully reach our citizens throughout the Commonwealth within the 48 to 72 hour response window of many biologic and chemical agents (per VaMRC plan documents). Pharmacy services play a crucial role in ongoing care at shelters in the aftermath of a disaster.

Retail pharmacies have reached out to the community and trained many pharmacists in immunization and basic cardiac life support. These skills may be crucial in a response effort; however, the many differences between mass immunization and one-on-one situations require prior familiarity with the concepts. In 2009, the Medical Reserve Corp of Virginia successfully tested the mass immunization design of pandemic influenza or small pox exposure using influenza vaccination in Henrico County as a model with pharmacists, pharmacy technicians and pharmacy students. This requirement will also heighten awareness of the Medical Reserve Corp, and their organizational role in emergency response from the community sectors and garner much needed manpower.

Attached is a list of emergency preparedness continuing education resources for pharmacists. Multiple options for pharmacists to obtain preparedness education at little cost via the web or via membership in a pharmacy association exist. The CDC Train website is a free service. The Virginia Pharmacists' Association offered a presentation by Mr. Charles Baker, pharmacy consultant for the Virginia Department of Health for emergency preparedness and response, at the July 2011 meeting. I have reached out to the Medical College of Virginia/

Virginia Commonwealth University for consideration of program development. They are exploring funding for this important project. Training to join the Virginia Medical Reserve Corp would be an additional personal choice.

We have only to look to the chaos of the New Orleans Astrodome after hurricane Katrina to extrapolate the value of pharmacy in emergency and disaster preparedness. By mandating a one-time requirement of two continuing education credits, pharmacists in the Commonwealth of Virginia will be better prepared to participate in disaster and emergency response. Thank you for your consideration.

Respectfully submitted,

Karen R Mulheron, RPh
Pharmacist, Inova Fair Oaks Hospital
3600 Joseph Siewick Drive
Fairfax, VA 22033
(703) 391-3641

:attachment

Pharmacy Continuing Education in Emergency Preparedness and Response

1. <http://ce.nurse.com/0513-0000-11-019-h01-p/botulinum-toxin/>
2. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2759
3. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2531
4. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2641
5. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2858
6. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2013
7. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2762
8. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2909
9. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2565
10. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2618
11. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2545
12. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2782
13. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=1962
14. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=1979
15. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2884
16. http://www2a.cdc.gov/TCEOnline/registration/detailpage.asp?res_id=2650
17. <http://www.michiganpharmacists.org/resources/emergency/>

This website provides nine credit hours for pharmacists. While the courses are not ACPE accredited, the BOP of Michigan states, "The Board has recognized that pharmacists are first responders in a crisis event, and that they tend to be placed in decision-making positions during these events." As such, Michigan certifies these courses for their pharmacists' CE.

18. <http://rxugace.com/programs/details/538>

This sight for the State of Georgia is the inspiration for this request. The CE's are scheduled to expire as of 12/31/11. At this time, there is no plan to extend the expiration. All pharmacists in Georgia are considered to have completed the instruction. It is included for reference; it provides a good oversight of the pharmacist's role in preparedness.

§ 54.1-3314.1. Continuing education requirements; exemptions; extensions; procedures; out-of-state licensees; nonpractice licenses.

A. Each pharmacist shall have obtained a minimum of 15 continuing education hours of pharmaceutical education through an approved continuing pharmaceutical education program during the year immediately preceding his license renewal date.

B. An approved continuing pharmaceutical education program shall be any program approved by the Board.

C. Pharmacists who have been initially licensed by the Board during the one year preceding the license renewal date shall not be required to comply with the requirement on the first license renewal date that would immediately follow.

D. The Board may grant an exemption from the continuing education requirement if the pharmacist presents evidence that failure to comply was due to circumstances beyond the control of the pharmacist.

E. Upon the written request of a pharmacist, the Board may grant an extension of one year in order for a pharmacist to fulfill the continuing education requirements for the period of time in question. Such extension shall not relieve the pharmacist of complying with the continuing education requirement for the current period.

F. The pharmacist shall attest to the fact that he has completed the continuing education requirements as specified by the Board.

G. The following shall apply to the requirements for continuing pharmaceutical education:

1. The provider of an approved continuing education program shall issue to each pharmacist who has successfully completed a program certification that the pharmacist has completed a specified number of hours.

2. The certificates so issued to the pharmacist shall be maintained by the pharmacist for a period of two years following the renewal of his license.

3. The pharmacist shall provide the Board, upon request, with certification of completion of continuing education programs in a manner to be determined by the Board.

H. Pharmacists who are also licensed in other states and who have obtained a minimum of fifteen hours of approved continuing education requirements of such other states need not obtain additional hours.

I. The Board shall provide for an inactive status for those pharmacists who do not wish to practice in Virginia. The Board shall require upon request for change from inactive to active status proof of continuing education hours as specified in regulations. No person shall practice in Virginia unless he holds a current active license.

J. As part of the annual 15-hour requirement, the Board may require up to two hours of continuing education in a specific subject area. If the Board designates a subject area for continuing education, it shall publish such requirement no later than January 1 of the calendar year for which the specific continuing education is required.

(1992, c. 868; 2008, c. 672.)

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Request to Discuss Concerns Regarding Hydrocodone Diversions

- Staff received a request from Crady Adams to include on the agenda a discussion regarding diversions of hydrocodone containing drug products. Goal of discussion is to determine if possible action is needed to address or prevent diversions of hydrocodone containing drug products.
- Information entitled, “Hydrocodone Background” supplied by Mr. Adams.

Additional Background Information Provided by Staff:

- Excerpt of NOIRA from 2007 which highlights Board’s consideration to possibly include hydrocodone products in the monthly perpetual inventory requirement.
- Excerpt from public comment received from National Association of Chain Drug Stores in response to NOIRA.
- Final regulation regarding monthly perpetual inventory did not include hydrocodone products.
- Excerpt from Vermont’s newsletter published June 2009.
- Excerpt from Vermont’s newsletter published September 2009.
- Excerpt from Virginia law and regulation regarding unprofessional conduct.

Possible Options:

- Recommend Regulation Committee discuss what possible actions the Board could take to address or prevent diversion of hydrocodone containing drug products, **OR**
- Take no action.

Hydrocodone Background

- 12-6-2011 Charlottesville (VA) Daily Progress: "Pain killers deaths triple in last decade." [likewise in VPHA Pharmacy News Flash and Wall Street Journal]
- 10-30-2011 ABCNews.go.com: "New York Senator Kemp Hannon on September 8, 2011 introduced a bill in the New York Legislature to move HC from DEA Schedule III to Schedule II after a June pharmacy robbery in Long Island, NY resulting in killing 4 people.
- 10-7-2011 U.S.Dept of Justice: "Seizure of HC increased from 4343 in 2000 to 102,281 in 2006, a twenty-five fold increase in only 6 years. Increase of 48% in the number of HC Rx written from 2000 to 2006. In 2005 HC exposures resulted in more deaths than any other narcotic analgesic.
- 9-2011 CMS-Center for Program Integrity: "Identifies HC along with other opioids as the most commonly abused prescription product."
- 9-18-2011 Los Angeles Times: "Public health experts calling addiction to prescription drugs an epidemic."
- 9-8-2011 Longislandexchange.com: "New York State Senator pushing to enforce stricter laws controlling HC."
- 8-24-2011 Huffington Post: "Deaths from prescription pain killers oxycontin and HC surpass deaths from skin cancer, HIV and alcoholic liver disease (British Medical Journal.
- 8-20-2011 Timesnews.net: "Feds resist control for HC, the nation's second most abused drug."
- 8-2011 PPPmagazine.com: San Diego California hospital developed audit process to help identify diversion.
- 7-16-2011 Fbi.gov: "Dublin, Ohio pharmacist sentenced for illegally distribution of HC."
- 7-11-2011 Pinedaleroundup.com: "Pinedale, Wyoming pharmacist arrested for illegally distributing HC to a minor."
- 6-22-2011 Nola.com: "New Orleans, Louisiana pharmacist indicted in Medicaid prescription scam involving painkillers oxycontin and HC."
- 6/2011 DEA-Office of Diversion Control: "Diversion (of drugs) by doctors and pharmacists and drug theft are major sources of diverted drugs."

4-14-2011 NACDS official statement: "commitment to partnering with law enforcement agencies to prevent and combat prescription drug diversion and misuse."

4-25-2011 Safemedicines.org "Cleveland, Ohio pharmacy technician charged with drug diversion of controlled drugs"

3-23-2011 Kboi2.com: "Lewiston, Idaho pharmacist sentenced to 5 years probation and revocation of license for diverting HC."

3-12-2011 Ktsm.com: "El Paso, Texas pharmacist accused of selling HC to customers for cash."

2-24-11 USAToday.com: "Florida police raid doctors and pharmacists in crack down on operation that illegally deals in pain pills."

2-7-2011 DailyFinance.com: "Drug store robberies target oxycontin and HC. Over 1800 pharmacy robberies in past 3 years."

1-13-2011 Pharmacytimes.com "In 2006 the Office of National Drug Control Policy reported that 34 rogue web sites dispensed over 100 million units of HC, the most widely abused prescription drug"

9-22-2010 Fda.gov: "Pennsylvania pharmacist charged with illegal distribution of controlled substances 577,000 tablets of controlled drugs with sales of over \$1 million."

5-4-2010 Washington State Board of Health disciplines pharmacy technician who diverted HC.

5-11-2010 PharmacyTimes.com: Article: Drug Diversion and Abuse: Diversion in the Pharmacy

4-12-2010 Dallasnews.com: "Parkland, Texas hospital pharmacist reports unexplained theft of over 100,000 doses of controlled drugs."

2-19-2010 USPharmacist.com: Case report: "Physician's office employee consuming excessive carisoprodol and HC involved in fatal traffic accident."

12-1-2009 U.S.Pharmacist Law C.E. "Prescription Drug Abuse: Strategies to Reduce Diversion. "Over 6,500 pharmacy thefts occur annually with at least one half attributed to employees."

9-11-2009 NACDS Pharmacy and Technology Conference/Boston: presentation from Michael Mone, RPH, JD VP, Anti-Diversion, Cardinal Health recommends "periodic

auditing of HC in pharmacies".

3-25-2009 Marketingcharts.com: "IMS reports that in 2008 HC/APAP was the most widely prescribed prescription over lisinpril and simvastatin."

8-20-2007 Associated Press: "In Appalachia retail sales of HC are highest in nation mainly in rural parts of West Virginia, Kentucky and Tennessee." A 2004 government study estimated between 2 million and 3 million doses of codeine, oxycodone and HC are stolen annually from pharmacies, distributors and drug manufacturers. This does not include estimates of diverted pharmaceuticals."

7-23-2007 Justice.gov/DEA: North Carolina pharmacist indicted for running an unlawful prescription dispensing operation.

2-1-2004 Pharmacytimes.com: "HC products continue to lead nation in prescription drug abuse. Street values can range from \$4 to \$8 per pill."

7-22-2003 Sherrif.org: Broward County, Florida: "Three pharmacists plead guilty to illegally selling pain killers.

4-2001 J Am Pharm Assn: Article- "Onset of Illegal Use of Drugs Among Pharmacists"

2/1992 APS Bulletin: "On April 8, 1992 Texas moved HC from DEA Schedule III to Schedule II."

1971 DEA: "Hydrocodone placed in Schedule II, Combinations in Schedule III"

(End)



Virginia
Regulatory
Town Hall

townhall.virginia.gov

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

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Periodic Review
Document preparation date	5/31/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

Purpose

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

Regulations of the Board of Pharmacy are complex and broad in scope and applicability to a variety of practice settings. Periodically, it is necessary to review and revise to clarify existing requirements, add new language to address problems that have arisen, delete outmoded regulation, or revise requirements to allow for newer technologies. In its promulgation of amended regulations as described in the substance section of this document, the Board will consider the need to incorporate interpretative language now found in several guidance documents and will also include some provisions that have been tested in pilot programs that are currently approved.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

- There needs to be clarification of the storage of will-call drugs; there is confusion as to whether they have to be in Rx department, which is alarmed after hours, or whether staff can reach over a counter and access them.
- The Board may also need to clarify whether medical devices can be displayed outside the Rx department or maintained similar to drug paraphernalia.

18VAC110-20-210. Disposal of drugs by pharmacies.

There are several issues relating to the disposal of drugs by pharmacies. There are very few, if any, appropriately licensed incinerators for drug disposal in Virginia, therefore it is difficult to use this methodology. Additionally, the laws of many state and federal agencies, e.g. DEA, Board of Pharmacy, EPA, etc., regarding the proper method for drug disposal appear to conflict with one another. The Board will examine the DEA rules, the NABP model rules and regulations from other states for suggested amendments.

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

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- The Board may require a perpetual inventory for Schedule II drugs and possibly hydrocodone products, to include a monthly count-back to reconcile count at least every 30 days.
 - The Board may need to clarify #3 on storage of records to allow for storing records within the building where drugs are located.
 - The Board may delete #4 as it is confusing and may be unnecessary.
 - It may add a requirement to maintain Schedule VI invoices and may add language in guidance document 110-35 to include allowance for retail pharmacies to use chart orders.

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

There should be clarification of how subsection C applies in institutions, primarily language about initialing the labels on IV's and maybe first doses, with no permanent record.

The Board will consider modification to the ratios of pharmacist to technician trainee and pharmacy technicians. If the ratio is eliminated, there would need to be other safety parameters established.

In subsection E, the Board may add a requirement to retain knowingly forged prescriptions (possibly after verifying with prescriber).

18VAC110-20-275. Delivery of dispensed prescriptions.

A rule is necessary to require that the contract and policy and procedure manual for alternate delivery sites be maintained at both pharmacy and the alternate site.

The regulation may be modified to add allowance for a pharmacy technician to serve as responsible party at an alternate delivery site to follow pilot program.

The provisions for alternate delivery sites, as approved by Board, will be examined to ensure patient safety and compliance are not being compromised for convenience. The language "if required by law" will be removed in subsections B and C

18VAC110-20-280. Transmission of a prescription order by facsimile machine.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



September 5, 2007

Elizabeth Scott Russell, RPh
Executive Director
Virginia Board of Pharmacy
Department of Health Professions
6603 W. Broad Street, 5th Floor
Richmond, VA 23230-1712
Via facsimile: 804-662-9313

RE: Notice of Intended Regulatory Action to amend 18 VAC 110-20-10 et seq.

Dear Ms. Russell:

On behalf of the approximately 1,022 chain pharmacies operating in 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") notice of intended regulatory action (NOIRA) to amend 18 VAC 110-20-10 et seq. Our comments to the various items being considered by the Board are as follows:

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

1. 18 VAC 110-20-110 – Pharmacy permits generally

- *"The Board will consider adding language from guidance document 110-40 regarding about how far in advance of the opening date may a new pharmacy permit be issued. An amendment is necessary to ensure that a permit can not be issued to operate a pharmacy from a private residence or dwelling."*

We are concerned that the three-week timeframe specified in guidance document 110-40 is insufficient and does not allow applicants to complete all of the activities necessary to open a new pharmacy before the scheduled opening date. For example, in order to obtain a DEA license, a pharmacy must first have a pharmacy permit number to submit to DEA. Additionally, a pharmacy permit number is required before a pharmacy can complete the enrollment process with third party payors. In most cases, three weeks is not enough time to complete this process with all payors (particularly with Medicaid and Medicare). This delay impacts the new pharmacy's ability to serve patients, and puts permit holders in the difficult position of being unable to fill prescriptions for the neediest of patients. We urge the Board to revise guidance document 110-40 and provide new pharmacies with a permit at least six weeks prior to opening, and also to allow for a similar timeframe when the Board addresses this issue in regulations. Alternatively, we ask the Board to consider granting a temporary permit based upon the submission of an application and blueprint. A temporary permit number would allow the pharmacy to complete all of the required processes before opening to the public. This would streamline and expedite permit processes for the benefit of patients.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

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7.18 VAC 110-20-240 – Manner of maintaining records, prescriptions, inventory records.

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- *“The Board may require a perpetual inventory for Schedule II drugs and possibly hydrocodone products, to include a monthly count-back to reconcile count at least every 30 days.”*

We assume that the Board’s reason for proposing a perpetual inventory requirement for Schedule II drugs and hydrocodone is to identify drug diversion. However, a perpetual inventory requirement is not the best means of accomplishing this goal. We believe that a more effective tool for identifying diversion, fraud and abuse is the Virginia Prescription Monitoring Program.

We are concerned that a perpetual inventory requirement would be very labor intensive and difficult to comply with considering the wide variety of hydrocodone products that exist and the number of prescriptions that are written for both schedule II drugs and hydrocodone (in particular. One NACDS member reports that hydrocodone is the most prescribed / filled drug in their pharmacies.) Additionally, we are concerned that such a mandate would ultimately create disruptions to pharmacy workflow and detract from patient care. We ask that the Board weigh these concerns in determining whether to move forward with a perpetual inventory proposal. However, if the Board decides that a perpetual inventory requirement is necessary in spite of our concerns, we ask that the proposal be limited to schedule II drugs only, and not be required for hydrocodone products. We would also ask that the perpetual inventory requirement be crafted to allow pharmacies flexibility to maintain records in a way that does not impede daily pharmacy operations or interfere with patient care.

- *“It may add a requirement to maintain Schedule VI invoices and may add language in guidance document 110-35 to include allowance for retail pharmacies to use chart orders.”*

To require that invoices be maintained for Schedule VI (non-controlled prescription drugs) would require tremendous storage space that pharmacies currently use for other purposes. Sales invoices are business records which are not always physically maintained in the pharmacy department. Therefore, we ask the Board not to mandate that pharmacies maintain copies of their Schedule VI invoices as part of their official pharmacy records. It is our understanding the Board’s intent with the proposed invoice requirement is to establish a mechanism to track illegal drug purchases due to alleged instances of pharmacies purchasing drugs from unlicensed sources. Rather than impose these onerous recordkeeping requirements on legitimately operating pharmacies, NACDS would like to work with the Board to craft regulations that would provide a workable solution this problem and provide the Board with a mechanism to identify and prevent such occurrences.

DEA Updates Form for Reporting Theft or Loss of Controlled Substances

Reprint from NABP e-News November 12, 2008

Drug Enforcement Administration (DEA) has an updated electronic version of DEA Form 106 for reporting the theft or loss of controlled substances through its online application system. Available for DEA registrants as of October 28, 2008, the updated electronic DEA Form 106 (found at <https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>) requires registrants to include the National Drug Code (NDC), which will help to accurately track controlled substances reported as stolen or lost. With the implementation of the NDC number, DEA will no longer require registrants to enter specific information pertaining to product lost or stolen. **The paper version of DEA Form 106 is obsolete as of October 28, 2008.**

Proposed Rules

The Board has filed the proposed changes to its administrative rules with the Interagency Committee on Administrative Rules. The most recent changes that are reflected on the Web site include definitions added to distinguish the types of long-term care (or home care) pharmacies, those serving only residents of an institution, or those serving both residents and former residents. See new Part 18 of the proposed rules.

Based on comments received and the Board's further evaluation, it decided to remove the requirement for inventorying all hydrocodone products. The Board realized the significant amount of work needed to accomplish this task as well as the importance of monitoring these products. The Board chose to make inventorying all hydrocodone products a recommendation versus a mandatory requirement. The Board strongly urges pharmacist managers to do a "trend analysis" (ie, a monthly review of purchases of hydrocodone products to determine if there is a change in the trend). If a change is noted, then perform a count. The Board feels that this will not only help avoid problems with diversion, but will alert pharmacist managers to potential problems sooner.

The Board plans to submit proposed statutory changes concerning substitution during the next legislative session to better address electronic prescriptions (Title 18 V.S.A. §4605 and 4606). See revised Section 19.9 (d) of the proposed rules.

Disciplinary Actions

The Office of Professional Regulation issues press releases of all disciplinary actions taken during the month. The full text of decisions can be accessed for reading or printing from the Office of Professional Regulation Web site. The direct link to the search page is www.vtprofessionals.org/opr1/searchdiscipline.htm. Disciplinary actions range from warnings, a finding of no

unprofessional conduct with an administrative penalty, to revocation. The Board took action against the following licensees since December 2008:

Pharmacist: **Jeffrey D. Huntress**, Pittsford, NY. Violation: Falsifying continuing education records. Sanction: Conditioned for two years, Administrative Penalty of \$250. The Board accepted a Stipulation and Consent Order effective on February 2, 2009.

Pharmacist: **Steven A. Hollister**, South Burlington, VT. Violation: Repeated inspection violations, etc, allowing technicians to work without registration. Sanction: Conditions were imposed, Administrative Penalty of \$1,000. The Board accepted a Stipulation and Consent Order effective on February 2, 2009.

Pharmacist: **Cynthia J. Koch**, Windsor, VT. Violation: Multiple dispensing related errors. Sanction: Reprimand, Conditioned, Administrative Penalty of \$500. The Board accepted a Stipulation and Consent Order effective on March 26, 2009.

Pharmacist: **Lawrence J. Mango**, Hoosick Falls, NY. Violation: Allowed pharmacy technician to work without registration. Sanctions: Reprimand and Administrative Penalty of \$1,000. The Board accepted a Stipulation and Consent Order effective on March 26, 2009.

Pharmacy: **Price Chopper Pharmacy #171**, Bennington, VT. Violation: Allowed pharmacy technician to work without registration. Sanctions: Reprimand and Administrative Penalty of \$1,000. The Board accepted a Stipulation and Consent Order effective on March 26, 2009.

Pharmacy: **Price Chopper Pharmacy #165**, Burlington, VT. Violation: Allowed pharmacy technician(s) to work without registration. Sanctions: Reprimand and Administrative Penalty of \$1,000. The Board accepted a Stipulation and Consent Order effective on April 28, 2009.

Pharmacy Technician: **Tara L. Dimick**, Hyde Park, VT. Violation: Drug diversion. The Board voted to summarily suspend technician's registration effective on April 29, 2009.

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The *Vermont Board of Pharmacy News* is published by the Vermont Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Vermont Board of Pharmacy

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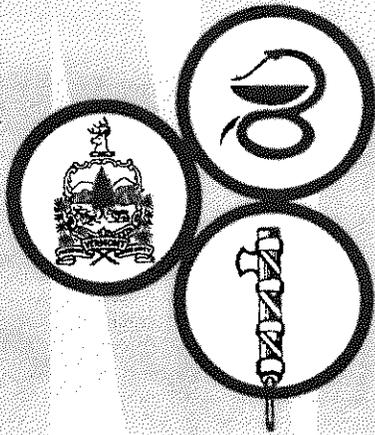
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September 2009



Vermont Board of Pharmacy

Vermont Secretary of State
Office of Professional Regulation
Board of Pharmacy
National Life Building, North, FL 2
Montpelier, VT 05620-3402
www.vtprofessionals.org

Published to promote voluntary compliance of pharmacy and drug law.

Board Members

The members of the Vermont Board of Pharmacy and their term expiration dates are as follows: **Steven M. Vincent, RPh**, chairman, Newport, VT (December 2013); **Julie A. Eaton, RPh**, vice chair, Rutland, VT (December 2013); **Ann Overton**, secretary, (public member), Essex Junction, VT (December 2010); **Jeffrey P. Firlilik, RPh**, Williston, VT (December 2009); **Larry L. Labor, RPh**, Morgan, VT (December 2010); **Earl W. Pease, PharmD**, Essex, VT (December 2012); and **Emma J. Pudvah**, (public member), Hardwick, VT (December 2012).

The Board members may be contacted by writing to the Vermont Secretary of State, Office of Professional Regulation, Board of Pharmacy, National Life Building, North, FL 2, Montpelier, VT 05620-3402. The phone number to the main office is 802/828-1505.

Staff: **Christopher D. Winters, Esq.**, director of the Office of Professional Regulation; **Larry S. Novins**, legal counsel; **Amy C. Carlson**, chief investigator; **Carla Preston**, unit administrator, phone: 802/828-2875, e-mail: cpreston@sec.state.vt.us; and **Kristy Kemp**, administrative assistant, phone: 802/828-2373, e-mail: kkemp@sec.state.vt.us.

Web site: www.vtprofessionals.org or www.sec.state.vt.us.

The Ryan Haight Online Pharmacy Consumer Protection Act

The Ryan Haight Online Pharmacy Consumer Protection Act amends the Federal Food, Drug, and Cosmetic Act to address illegal diversion of prescription drugs through the Internet. It was signed into law in October 2008, and became effective April 13, 2009. Ryan Haight was a 17-year-old boy who easily acquired prescription narcotics from an online Web site by simply filling out a questionnaire. A doctor who never saw Haight wrote the prescription and the drugs were mailed directly to his house. On February 12, 2001, Haight overdosed on the narcotic and died at the young age of 18. The Ryan Haight Online Pharmacy Consumer Protection Act addresses the problem of Internet prescription drug diversion in three ways.

First, it requires Internet pharmacy Web sites to display information identifying the business, pharmacist, and physician associated with the Web site.

Second, the act bars the selling or dispensing of a prescription drug via the Internet when the Web site has referred the customer to a doctor who then writes a prescription without ever seeing the patient.

Third, the act provides states with new enforcement authority modeled on the Federal Telemarketing Sales Act that will allow a state's attorney general to shut down a rogue site across the country rather than solely in that specific state.

Vermont Prescription Monitoring Program Update

The Vermont Department of Health, Division of Alcohol and Drug Abuse Programs' Web site for the Vermont Prescription Monitoring Pro-

gram is up and running. The Vermont Prescription Monitoring System (VPMS) became fully operational in April 2009. Pharmacies have been required to report all their Schedule II, III, and IV prescriptions dispensed to the VPMS database since January 2009. For detailed information on the program and also how to register so that you can access the system, go to the Vermont Department of Health's Web site, or for the direct link visit www.healthvermont.gov/adap/VPMS.aspx. The Board encourages pharmacists to register for access to the monitoring system and to help inform prescribers about the system. This program is an excellent tool to prevent prescription medication diversion and abuse. As a health care provider, it is important to be aware of the increasing problem with prescription drug abuse; preventing or stopping this abuse is an essential part of patient care. Pharmacists play a vital role in preventing prescription drug abuse. Physicians are the gatekeepers to access, but the pharmacist also plays an important role in ensuring that the medication is being used appropriately. The VPMS may provide essential information in order for the health care provider to determine if a medication is for a legitimate medical purpose. Pharmacists and prescribers who utilize the database and identify cases of drug abuse or misuse may share that information with other pharmacists and prescribers who are providing health care to the patient in question. If you have difficulties in registering, e-mail vpms@vdh.state.vt.us.

Proposed Rules

The Board has filed its Final Proposed Administrative Rules with the Secretary of State's Office and the Legislative Committee on Administrative Rules. The Board anticipates an October 1, 2009 effective date. There have been many changes to the rules since August 2003, when they were last updated; therefore, it is difficult to highlight the most significant changes. Please be sure to read the updated rules to ensure compliance. The statutes and rules include mandatory reporting requirements (Title 3 V.S.A. Ch 5 §128) and specific timelines for reporting theft or loss of controlled substances, changes in pharmacist managers, etc. The most recent version is posted on our Web site at www.vtprofessionals.org.

Inventory Reminder of Hydrocodone Products

As mentioned in the Board's last *Newsletter*, the mandate to inventory all hydrocodone products was removed from the proposed rules. The Board decided to make inventorying all hydrocodone products a recommendation and strongly urges pharmacist managers to do a "trend analysis," i.e., a monthly review of purchases of hydrocodone products to determine if there is a change in the trend. If a change is noted, then perform a count. The Board feels that this will not only help avoid problems with diversion, but will alert pharmacist managers to potential problems sooner. The Board will periodically include this reminder in its *Newsletter*. Your cooperation is greatly appreciated.



§ 54.1-3316. Refusal; revocation; suspension and denial.

The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;
2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;
3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;
4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;
5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;
6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;
7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;
8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;
9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;
10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;
11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;
12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;
13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or
14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

(1972, c. 798, § 54-524.22:1; 1976, c. 614; 1977, c. 86; 1982, c. 401; 1988, c. 765; 1992, c. 868; 1994, c. 296; 2007, c. 662.)

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.

Request to Amend Regulation Regarding Pharmacist to Pharmacy Technician Ratio

- Staff received a request from Dave Kozera to include item on agenda.

Background Information Provided by Staff:

- During 2007 periodic review of regulations, Board eliminated pharmacist to pharmacy technician ratio of 1:4, but subsequently realized that §54.1-3320 contained the same ratio. Therefore, Board corrected language in final regulation to conform to 1:4 ratio as required in statute.
- During 2010 General Assembly Session, §54.1-3320 was amended to state, “Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations. (Board did not introduce legislative proposal.)

Possible Options:

- Recommend Regulation Committee discuss if Board should amend pharmacist to pharmacy technician ratio listed in Regulation 18VAC110-20-240, **OR**
- Adopt NOIRA to eliminate or amend pharmacist to pharmacy technician ratio in Regulation 18VAC110-20-240, **OR**
- Take no action.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Periodic Review
Document preparation date	5/31/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

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

Regulations of the Board of Pharmacy are complex and broad in scope and applicability to a variety of practice settings. Periodically, it is necessary to review and revise to clarify existing requirements, add new language to address problems that have arisen, delete outmoded regulation, or revise requirements to allow for newer technologies. In its promulgation of amended regulations as described in the substance section of this document, the Board will consider the need to incorporate interpretative language now found in several guidance documents and will also include some provisions that have been tested in pilot programs that are currently approved.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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- There needs to be clarification of the storage of will-call drugs; there is confusion as to whether they have to be in Rx department, which is alarmed after hours, or whether staff can reach over a counter and access them.
- The Board may also need to clarify whether medical devices can be displayed outside the Rx department or maintained similar to drug paraphernalia.

18VAC110-20-210. Disposal of drugs by pharmacies.

There are several issues relating to the disposal of drugs by pharmacies. There are very few, if any, appropriately licensed incinerators for drug disposal in Virginia, therefore it is difficult to use this methodology. Additionally, the laws of many state and federal agencies, e.g. DEA, Board of Pharmacy, EPA, etc., regarding the proper method for drug disposal appear to conflict with one another. The Board will examine the DEA rules, the NABP model rules and regulations from other states for suggested amendments.

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

- The Board may require a perpetual inventory for Schedule II drugs and possibly hydrocodone products, to include a monthly count-back to reconcile count at least every 30 days.
- The Board may need to clarify #3 on storage of records to allow for storing records within the building where drugs are located.
- The Board may delete #4 as it is confusing and may be unnecessary.
- It may add a requirement to maintain Schedule VI invoices and may add language in guidance document 110-35 to include allowance for retail pharmacies to use chart orders.

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

There should be clarification of how subsection C applies in institutions, primarily language about initialing the labels on IV's and maybe first doses, with no permanent record. The Board will consider modification to the ratios of pharmacist to technician trainee and pharmacy technicians. If the ratio is eliminated, there would need to be other safety parameters established.

In subsection E, the Board may add a requirement to retain knowingly forged prescriptions (possibly after verifying with prescriber).

18VAC110-20-275. Delivery of dispensed prescriptions.

A rule is necessary to require that the contract and policy and procedure manual for alternate delivery sites be maintained at both pharmacy and the alternate site.

The regulation may be modified to add allowance for a pharmacy technician to serve as responsible party at an alternate delivery site to follow pilot program.

The provisions for alternate delivery sites, as approved by Board, will be examined to ensure patient safety and compliance are not being compromised for convenience. The language "if required by law" will be removed in subsections B and C

18VAC110-20-280. Transmission of a prescription order by facsimile machine.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



September 5, 2007

Elizabeth Scott Russell, RPh
Executive Director
Virginia Board of Pharmacy
Department of Health Professions
6603 W. Broad Street, 5th Floor
Richmond, VA 23230-1712
Via facsimile: 804-662-9313

RE: Notice of Intended Regulatory Action to amend 18 VAC 110-20-10 et seq.

Dear Ms. Russell:

On behalf of the approximately 1,022 chain pharmacies operating in 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") notice of intended regulatory action (NOIRA) to amend 18 VAC 110-20-10 et seq. Our comments to the various items being considered by the Board are as follows:

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

1. 18 VAC 110-20-110 – Pharmacy permits generally

- *"The Board will consider adding language from guidance document 110-40 regarding about how far in advance of the opening date may a new pharmacy permit be issued. An amendment is necessary to ensure that a permit can not be issued to operate a pharmacy from a private residence or dwelling."*

We are concerned that the three-week timeframe specified in guidance document 110-40 is insufficient and does not allow applicants to complete all of the activities necessary to open a new pharmacy before the scheduled opening date. For example, in order to obtain a DEA license, a pharmacy must first have a pharmacy permit number to submit to DEA. Additionally, a pharmacy permit number is required before a pharmacy can complete the enrollment process with third party payors. In most cases, three weeks is not enough time to complete this process with all payors (particularly with Medicaid and Medicare). This delay impacts the new pharmacy's ability to serve patients, and puts permit holders in the difficult position of being unable to fill prescriptions for the neediest of patients. We urge the Board to revise guidance document 110-40 and provide new pharmacies with a permit at least six weeks prior to opening, and also to allow for a similar timeframe when the Board addresses this issue in regulations. Alternatively, we ask the Board to consider granting a temporary permit based upon the submission of an application and blueprint. A temporary permit number would allow the pharmacy to complete all of the required processes before opening to the public. This would streamline and expedite permit processes for the benefit of patients.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

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8. 18 VAC 110-20-270 – Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

- *“The Board will consider modification to the ratios of pharmacist to technician trainee and pharmacy technicians. If the ratio is eliminated, there would need to be other safety parameters established.”*

NACDS supports the elimination of pharmacy technician and pharmacy technician trainee ratios. We believe that an individual pharmacist should be allowed to supervise as many pharmacy technicians and pharmacy technician trainees as he or she determines is appropriate for their individual practice setting. Other groups, including the National Association of Boards of Pharmacy (NABP), share this view. In the NABP Task Force on Pharmacy Manpower Shortage Committee Report for 1999-2000, the group recommended the elimination of pharmacy technician ratios altogether.

The existing ratio acts as a barrier to better patient care by preventing pharmacies from maximizing use of pharmacy technicians and pharmacy technician trainees to perform non-discretionary tasks. A study¹ conducted on activities performed in community pharmacies showed that 68% of a pharmacist's time is spent performing administrative, operational and non-judgmental functions that can be safely performed by pharmacy technicians. Conversely, the study indicated that pharmacists only spent about 30% of their time on judgmental tasks such as reviewing and interpreting prescriptions, assessing patients' drug therapy, resolving clinical conflicts, contacting physicians for prescription changes and clarification, and counseling patients. Therefore, a significant opportunity exists through eliminating pharmacist to technician ratios, for technicians to free-up pharmacists' time for patient care services. We applaud the Board for considering a regulation change that will allow pharmacists to focus on performing patient care activities.

We do not believe, however, that it is necessary for the Board to develop additional “safety” measures should the ratio be eliminated. Virginia's current laws and regulations already establish parameters to ensure that only appropriately trained pharmacy technicians can work in a pharmacy and clearly define the types of duties that technicians can perform. Additional “safety parameters” would be redundant, especially since there is no correlation between technician ratios and patient safety issues.

9. 18 VAC 110-20-320 – Refilling of Schedule III through VI prescriptions.

- *“Subsection D may be amended to allow for early refill due to good cause or absence (vacation). That subsection may also be amended to clarify that the*

¹ *“Pharmacy Activity Cost and Productivity Study / Arthur Andersen; National Association of Chain Drug Stores Education Foundation. -- Alexandria, VA: National Association of Chain Drug Stores, 1999.*

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VIRGINIA ACTS OF ASSEMBLY -- 2010 SESSION

CHAPTER 90

An Act to amend and reenact § 54.1-3320 of the Code of Virginia, relating to supervision of pharmacy technicians.

Approved March 9, 2010

[H 587]

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3320 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3320. Acts restricted to pharmacists.

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

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

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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.

13. Status of Pharmacy Technicians

State	Designation	Does State?			Technician Registration Fee	Registration Renewed Schedule
		License Technicians?	Register Technicians?	Certify Technicians?		
Alabama	Pharmacy Technician	No	Yes	No	\$60	Biennial H
Alaska	Pharmacy Technician	Yes	No	No	\$100 HH	Biennial
Arizona	Pharmacy Technician	Yes	No	No	B	Biennial
Arkansas	Pharmacy Technician	No	Yes	No	\$70	Biennial
California	Pharmacy Technician	Yes	Yes	No	\$50	Biennial
Colorado	Unlicensed Personnel, Unlicensed Assistant	No	No	No	N/A	N/A
Connecticut	Pharmacy Technician	No	Yes	No	\$50	Annual - 3/31
Delaware	Pharmacy Technician	No	No	No	None	N/A
District of Columbia	Ancillary Personnel	No J	No J	No J	—	—
Florida	Pharmacy Technician	No	Yes	No	\$100	Biennial
Georgia	Pharmacy Technician	No	No	No	—	—
Guam	Pharmacy Technician	No	Yes	No	J	J
Hawaii	Pharmacy Technician	No	No	No	N/A	N/A
Idaho	Pharmacy Technician	No	Yes M	Yes M	\$35	Annual
Illinois	Pharmacy Technician	No	Yes	No	\$40 initial; \$25 renewal	Annual
Indiana	Pharmacy Technician	No	No	Yes K	\$25	Biennial
Iowa	Pharmacy Technician	No	Yes	No H	\$55, \$22 trainee	Z
Kansas	Pharmacy Technician	No	Yes	No	\$25	Biennial
Kentucky	Pharmacy Technician	No	Yes	No	\$25	Annual
Louisiana	Pharmacy Technician	No	No	Yes	\$100	Annual
Maine	Pharmacy Technician	No	Yes	No	\$20	Annual
Maryland	Pharmacy Technician	No	Yes	No	\$45	Biennial G
Massachusetts	Pharmacy Technician	No	Yes	No	\$60	Biennial G
Michigan	Pharmacy Personnel	No	No	No	—	—
Minnesota	Pharmacy Technician	No	Yes	No	\$20	Annual
Mississippi	Pharmacy Technician L	No	Yes	No	\$25	Annual
Missouri	Pharmacy Technician	No	Yes	No	\$35 W	Annual
Montana	Pharmacy Technician	No	Yes	Yes AA	\$60 initial; \$50 renewal	Annual
Nebraska	Pharmacy Technician	No	Yes	No	\$25	Biennial RR
Nevada	Pharmaceutical Technician L	No	Yes	No	\$40	Biennial
New Hampshire	Pharmacy Technician	No	Yes	No	\$25	Annual - 4/01
New Jersey	Pharmacy Technician	No	Yes	No	N/A	N/A
New Mexico	Pharmacy Technician N	No	Yes	No	\$30	Biennial
New York	Unlicensed Person	No	No	No LL	N/A	N/A
North Carolina	Pharmacy Technician	No	Yes	No	\$30	Annual
North Dakota	Registered Pharmacy Technician	No	Yes	No	\$35	Annual
Ohio	Qualified Pharmacy Technician	No	No	No	N/A	N/A
Oklahoma	Pharmacy Technician	No	Yes O	No	\$40	GG
Oregon	Pharmacy Technician	Yes A	No	No	\$35	1 year - Sep
Pennsylvania	Pharmacy Technician	No	No	No	N/A	N/A
Puerto Rico	Pharmacy Technician	No	Yes	Yes	\$50	3 years
Rhode Island	Pharmacy Technician	Yes	—	No	\$40	Annual
South Carolina	Pharmacy Technician	No	Yes	Yes	\$40 initial; \$25 renewal	Annual
South Dakota	Pharmacy Technician	No	Yes	No	\$25	Annual
Tennessee	Pharmacy Technician	No	Yes	No	\$50 biennial	Cyclical
Texas	Pharmacy Technician	No	Yes	No	\$59 initial; \$56 renewal	Biennial
Utah	Pharmacy Technician	Yes	No	No	\$60	Biennial
Vermont	Pharmacy Technician	No	Yes	No	\$50	Biennial
Virginia	Pharmacy Technician	No	Yes	No	\$25	Annual
Washington	Pharmacy Technician	No	No	Yes	\$50 initial; \$40 renewal	Annual
West Virginia	Pharmacy Technician	No	Yes	No	\$25 X	Biennial
Wisconsin	Pharmacy Technician	No	No	No	—	—
Wyoming	Registered Pharmacy Technician K	Yes KK	Yes KK	No	\$50	Annual

* See "Footnotes (*)" on pages 38.

** Contact the state board of pharmacy office to obtain requirements.



13. Status of Pharmacy Technicians (cont.)

State	Technician Training Requirements	Technician CE Requirements	Technician Examination Requirement	Can Board Deny, Revoke Suspend, or Restrict Technician Registration?	Maximum Ratio of Technicians to Pharmacist in an:	
					Ambulatory Care Setting	Institutional Care Setting
Alabama	No	3 hrs/yr MM	—	Yes	3:1*	3:1*
Alaska	Yes S	10 hrs/2 yrs	No	Yes	None	None
Arizona	Yes	NN	Yes - PTCB	Yes	None	None
Arkansas	No	None	No	Yes	2:1	2:1
California	Yes CC	No	No CC	Yes	Varies*	2:1
Colorado	No	N/A	No	N/A	3:1	3:1
Connecticut	Yes S	No	No	Yes	2:1* or 3:1	3:1*
Delaware	Yes	N/A	No	N/A	None	None
District of Columbia	No J	—	—	—	—	—
Florida	Yes Q	20 hrs/2 years	No	Yes	3:1	3:1
Georgia	No	None	No	N/A	3:1*	3:1*
Guam	No J	None J	No	Yes	None J	None J
Hawaii	No	N/A	No	No	None	None
Idaho	Yes OO	Yes	Yes	Yes	6:1*	6:1*
Illinois	Yes PP	Yes	Yes QQ	Yes	None	None
Indiana	Yes	No	No U	Yes	4:1*	4:1*
Iowa	Yes H	No	No	Yes	None	None
Kansas	Yes	No	Yes	Yes	2:1 or 3:1*	2:1 or 3:1*
Kentucky	No	None	No	Yes	None	None
Louisiana	Yes	10 hrs	Yes	Yes	3:1*	3:1*
Maine	Yes	No	No	Yes	3:1*	3:1*
Maryland	Yes	Yes	Yes	Yes	None	None
Massachusetts	Yes	No BB	Yes	Yes	4:1*	4:1*
Michigan	No	—	—	—	None	None
Minnesota	No	No	No	Yes	2:1*	2:1*
Mississippi	No I	No	No	Yes	2:1	2:1
Missouri	No	None	No	Yes	None*	None*
Montana	Yes** T	Yes SS	Yes AA	Yes	3:1*	3:1*
Nebraska	Yes** I	No	No	Yes	2:1	2:1
Nevada	Yes	Yes Y	No	Yes	3:1*	3:1
New Hampshire	No	None	No	Yes	None	None
New Jersey	No	No	—	Yes	Varies	Varies
New Mexico	Yes**	None	Yes AA	Yes	4:1	4:1
New York	No	No	No	No	2:1	2:1
North Carolina	Yes	None	No	Yes	2:1*	2:1*
North Dakota	Yes R	Yes 10 hrs/1 yr	No FF	Yes	3:1	4:1
Ohio	Yes	No	Yes	No	None	None
Oklahoma	Yes	None	No	Yes JJ	2:1	2:1
Oregon	Yes	Yes P	Yes P	Yes	None	None
Pennsylvania	No	None	No	N/A	None	None
Puerto Rico	Yes F	20 hrs/3 yrs	Yes	Yes	5:1	5:1
Rhode Island	Yes	None	—	Yes	None	None
South Carolina	Yes DD	10 hrs/yr EE	Yes DD	Yes	3:1*	Varies*
South Dakota	Yes S	None	No	Yes	2:1*	2:1*
Tennessee	No	None	No	Yes	2:1*	2:1*
Texas	Yes C	D	Yes	Yes	2:1*	None
Utah	Yes	20 hrs/2 yrs	Yes E	Yes	3:1	3:1
Vermont	No	No	No	Yes	None	None
Virginia	Yes V	5 hrs/yr	Yes V	Yes	4:1	4:1
Washington	Yes	None	Yes AA	Yes	3:1*	3:1*
West Virginia	Yes I	None	Yes	Yes	4:1	4:1
Wisconsin	No	—	—	—	4:1	4:1
Wyoming	Yes	6 hrs	Yes AA	Yes	3:1	3:1

* See "Footnotes (*)" on pages 38.

** Contact the state board of pharmacy office to obtain requirements.

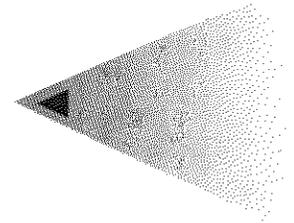
78
72

13. Status of Pharmacy Technicians (cont.)

Survey of Pharmacy Law

LEGEND

- | | |
|---|--|
| <p>A — All new pharmacy technicians have one year after initial licensure to obtain certification.</p> <p>B — Technician trainee – \$36 Certified technician – \$72</p> <p>C — A person may be a technician trainee for no more than two years while seeking certification through PTCB. Contact the Board for specific on-site training requirements.</p> <p>D — Same as PTCB requirements.</p> <p>E — PTCB examination or the ExCPT and Utah law examination.</p> <p>F — 1,000 hours of internship under direct supervision of a registered pharmacist and passing an examination prepared by the Board are required for certification. Designated pharmacy technician intern for 3 years maximum.</p> <p>G — Biennial at birthday.</p> <p>H — Technicians must be under the immediate and personal supervision of the pharmacist. Technician training must be documented and maintained. National certification by nationally accredited certifying body effective July 1, 2010.</p> <p>I — Training requirements developed by training pharmacies and approved by the Board.</p> <p>J — The Board is proposing/developing regulations.</p> <p>K — Designated as a “technician-in-training” prior to meeting requirements for licensure. (IN – Technician-in-training permit is good for one year from date of issuance and must be upgraded to certified pharmacy technician by submitting proof of completion of approved training.)</p> <p>L — The term “Support Personnel” is also used.</p> <p>M — May register as “technician-in-training” for one year until they obtain certification. This registration is renewable once for one year.</p> <p>N — A “Pharmacy Technician” is a subset of “Supportive Personnel.”</p> <p>O — Technicians are not considered “registered” but are issued a “permit.”</p> <p>P — Required for certified pharmacy technicians but not pharmacy technicians.</p> <p>Q — Pharmacy technicians may register in Florida if they receive 1,500 hours of work experience, completed a training program, or if they are certified by the national board.</p> <p>R — Technicians must complete American Society of Health-System Pharmacists-accredited program or an equivalent program.</p> <p>S — On-the-job training by PIC appropriate to technician’s duties.</p> <p>T — Technician utilization plan filed with Board or didactic course.</p> <p>U — Passage of the PTCB examination is one way to become certified as a technician in this state. Must also file application for licensure.</p> | <p>V — To be eligible for registration a pharmacy technician must either hold current PTCB certification or must have passed a training program and examination approved by the Board.</p> <p>W — Plus a fingerprint fee paid to a contracted agency.</p> <p>X — \$25 initial; \$30 renewal/2 years.</p> <p>Y — However, technicians must complete six hours of in-service training per year and one hour of jurisprudence as do pharmacists (NV – see page 31).</p> <p>Z — Biennial by birth month; trainee registration 1 year, not reusable.</p> <p>AA — PTCB or ExCPT certification required.</p> <p>BB — However, “certified pharmacy technicians” must maintain certification.</p> <p>CC — Educational training and/or PTCB examination are ways to qualify for technician registration.</p> <p>DD — To be certified as a pharmacy technician an individual must have worked for 1,000 hours under the supervision of a licensed pharmacist as a technician and must have completed a Board of Pharmacy-approved technician course as provided for in subsection (D); a high school diploma or equivalent; and passed the National Pharmacy Technician Certification Examination or a Board of Pharmacy-approved examination and has maintained current certification; and fulfilled CE requirements as provided for in Section 40-43-130(G).</p> <p>EE — As a condition of registration renewal, a registered pharmacy technician shall complete 10 hours of ACPE- or CME I-approved CE each year. A minimum of four hours of the total hours must be obtained through attendance at lectures, seminars, or workshops.</p> <p>FF — Requires PTCB examination for reciprocity.</p> <p>GG — Annual (by birth month).</p> <p>HH — Plus one-time application fee of \$50.</p> <p>II — Odd numbered years.</p> <p>JJ — Revoked 36 pharmacy technician permits including one probation.</p> <p>KK — “Technicians-in-Training” are registered until they meet the requirements for licensure. The technician-in-training permit is valid for no more than two years from date of issue.</p> <p>LL — Legislation has been introduced to certify technicians.</p> <p>MM — One hour must be live CE.</p> <p>NN — Twenty hours of which two hours must be pharmacy law ACPE or Board-approved providers.</p> <p>OO — See IDAPA 27.01.01. 251(C).</p> <p>PP — Refer to 225 ILCS 85/17.1</p> <p>QQ — Beginning on January 1, 2010, within two years of becoming employed as a registered technician, must become</p> |
|---|--|



LicensingLaw

Legend continued on page 38

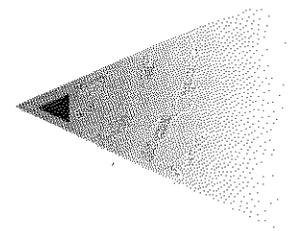
LEGEND — cont.

- certified by successfully passing PTCB or other Board-approved examination. Does not apply to pharmacy technicians hired prior to January 1, 2008. Refer to 225 ILCS 85/9. CE is required for certification.
- RR — Biennial January 1 of odd years.
- SS — Must be PTCB-approved or ICPT-approved.

- LA — If pharmacy technician candidate is present, then maximum ratio for technicians is 2:1. If not, then maximum ratio for technicians is 3:1.
- MA — 3:1 provided one intern and one certified technician. 4:1 provided at least two certified technicians or one certified technician and one intern.
- ME — 4:1 with an advanced pharmacy technician.
- MN — Specific functions are exempted from the 2:1 ratio as follows: for intravenous admixture preparation, unit-dose dispensing, prepackaging, and bulk compounding, ratio is 3:1. One additional technician per pharmacy if that technician is PTCB certified.
- MO — Technician must be under the direct supervision and responsibility of a pharmacist.
- MT — Ratio is 3:1. Licensee may ask Board for variance based on established criteria or greater upon Board approval.
- NC — Ratio may be increased above 2:1 if additional technicians are certified and the Board approves the increase in advance.
- NV — Technician to pharmacist ratio is now 3:1; however, initial prescription data input can now only be done by a registered pharmaceutical technician or a pharmacist. A clerk may enter demographic and insurance data only on new prescriptions
- SC — The PIC shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; at least two of these three technicians must be state certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state certified. Pharmacy

Footnotes*

- AL — 3:1 if one technician is PTCB-certified. All technicians must be at least 17.
- CA — In community pharmacy, the ratio is 1:1 for the first pharmacist on duty, then 2:1 for each additional pharmacist on duty. 2:1 if pharmacy services patients of skilled nursing facilities or hospices. A pharmacist may also supervise one pharmacy technician trainee gaining required practical experience.
- CT — Refer to Section 20-576-36 of the Regulations of Connecticut State Agencies. In summary, ratio not to exceed 2:1 when both technicians are registered. Ratio of 3:1 permitted when there are two registered technicians and one certified technician. However, a pharmacist is permitted to refuse the 3:1 ratio for the 2:1 ratio. In an institutional outpatient pharmacy, ratio is 2:1. The pharmacist manager may petition the Commission to increase ratio to 3:1 in a licensed or institutional outpatient pharmacy. Inpatient pharmacy ratio is 3:1 generally, but pharmacy can petition for ratio of up to 5:1; satellite pharmacy 3:1, but can petition for up to 5:1.
- GA — One of the three pharmacy technicians must be certified. Board may consider and approve an application to increase the ratio in a hospital pharmacy.
- ID — Ratio includes technicians, technicians-in-training, and student pharmacists. No longer allowed cashiers/clerks in pharmacy.
- IN — Technicians must be under the immediate and personal supervision of the pharmacist.
- KS — The ratio may be 3:1 if at least two of the pharmacy technicians have a current certification issued by PTCB or a current certification issued by any other pharmacy technician certification organization approved by the Board.



LicensingLaw

Footnotes continued on page 39

NABPLAW Online Search Terms

Status of Pharmacy Technicians (type as indicated below)

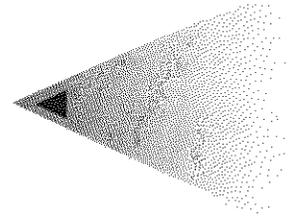
- ◆ technician & requirements
- ◆ support & personnel & requirements
- ◆ technician & training
- ◆ technician & registration

Note: "ancillary personnel"; "support personnel"; and "non-licensed personnel" can be substituted for "technician."

Survey *of* Pharmacy Law

Footnotes (*) – cont.

- technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30(14).
- SD — Exception to the ratio may be allowed if the specific requirements listed in administrative rule are met. See ARSD 20:51:29:19.02 and 20:51:29:19.03.
- TN — 3:1 if technician is certified.
- TX — 3:1 if at least one of the technicians is not a pharmacy technician trainee.
- WA — A pharmacy may use more technicians than the prescribed 3:1 upon approval of the Board.



Licensing law

Virginia Board of Pharmacy

Delegation of Authority for Disciplinary Matters

The Board of Pharmacy delegates to the executive director the authority to offer a prehearing consent order (PHCO) in the following circumstances:

1. Action taken by another state board of pharmacy – PHCO would require compliance with other state's action.
2. Single dispensing error with no patient harm involving an individual who is a minor or medically compromised, or a drug with a narrow therapeutic index – PHCO would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.
3. Inspection report as part of an investigation which resulted in the citing of deficiencies, as identified in Guidance Document 110-9, for which the guidance document recommends a monetary penalty – PHCO would impose the recommended monetary penalty as indicated in Guidance Document 110-9.

The Board of Pharmacy delegates to the executive director the authority to offer a confidential consent agreement (CCA) in the following circumstances:

1. Single dispensing error with no patient harm, except as noted in #2 above – CCA would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.

The Board of Pharmacy delegates to the executive director the authority to close cases that have insufficient evidence of a violation of law or regulation.

Virginia Board of Pharmacy

Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance

On November 19, 2007, the DEA published in the Federal Register the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that “the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally.” This, however, is in opposition to DEA’s previous policy which permitted the pharmacist to make limited changes to a prescription written for a Schedule II controlled substance after oral consultation with the prescriber. DEA plans to resolve this confusion through future rulemaking and instructs pharmacists to adhere to state regulations or policy regarding changes that a pharmacist may make to a schedule II prescription. Therefore, through policy, the Board will allow a pharmacist to make limited changes to a schedule II prescription as stated below.

When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or ~~change~~ correct the patient’s address upon verification, correct the patient’s name upon verification, or add the prescriber’s DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the ~~patient’s name,~~ controlled substance prescribed (except for generic substitution permitted by law) or the prescriber’s signature.



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

695

www.dea.gov

AUG 24 2011

Mr. Carmen Catizone, M.S., R.Ph., D.Ph.
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, Illinois 60056

Dear Dr. Catizone:

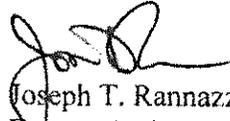
This correspondence is in response to your letter dated July 26, 2011, to the Drug Enforcement Administration (DEA) seeking clarification on DEA's policy regarding information a pharmacist may provide when it is missing from a prescription for a schedule II controlled substance. Thank you for contacting DEA on this issue.

DEA is aware that pharmacists are sometimes presented with prescriptions for schedule II controlled substances that are missing information required for a valid prescription under state or federal law. In accordance with DEA regulations, pharmacists have a corresponding responsibility with practitioners for the proper prescribing and dispensing of controlled substances and must ensure that prescriptions for controlled substances conform in all essential respects to the law and regulations. 21 C.F.R. §§ 1306.04(a) and 1306.05(f). In particular, DEA regulations require that all prescriptions for controlled substances be dated as of, and signed on, the day when issued and bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. 21 C.F.R. § 1306.05(a). Whether it is appropriate for a pharmacist to make changes to the prescription, such as adding the practitioner's DEA number to the prescription or correcting the patient's name or address, varies case-by-case based on the facts present. Consequently, DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.

To this end, pharmacists and other practitioners must be mindful of what dispensing-related activities violate the Controlled Substance Act (CSA). For instance, it is unlawful to knowingly or intentionally furnish false or fraudulent material information in, or omit any material information from any application, report, record, or other document required to be made, kept, or filed under the CSA; to dispense a controlled substance in violation of 21 U.S.C. 829, which includes requirements for a schedule II controlled substance prescription; or to knowingly or intentionally use in the course of dispensing of a controlled substance a registration number that is fictitious, revoked, suspended, expired, or issued to another person. See e.g., 21 U.S.C. §§ 842(a)(1), (2), and (5), and 843(a)(2), (3), and (4)(A).

I would like to thank you again for your willingness to work with DEA and I look forward to our continued cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joseph T. Rannazzisi', written in a cursive style.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

**Virginia Board of Pharmacy
December 14, 2011
Inspection Report**

Licenses Issued for Period of September 1 – November 30, 2011

<u>License Type</u>	<u>Count</u>
Pharmacy	
Controlled Substances Registration	16
CE Courses	0
Medical Equipment Supplier	19
Non-resident Pharmacy	19
Non-resident Wholesale Distributor	17
Non-restricted Manufacturer	0
Pharmacist	130
Pharmacist-Volunteer Registration	2
Pharmacy	18
Pharmacy Intern	305
Pharmacy Technician	377
Pharmacy Technician Training Program	1
Physician Selling Controlled Substances	23
Pilot Programs	0
Restricted Manufacturer	3
Warehouser	3
Wholesale Distributor	0
Total	933

Inspections Completed for Period of September 1 – November 30, 2011

<u>License Type</u>	<u>Count</u>
Controlled Substances Registration	43
Medical Equipment Supplier	33
Non-Restricted Manufacturer	1
Physician Selling Drugs Location	6
Restricted Manufacturer	5
Warehouse	2
Wholesale Distributor	1
Pharmacy	175

	<u>Count</u>
Change of Location	6
New	17
Reinspection	1
Remodel	17
Routine	134

	<u>Count</u>	
No Deficiency	32	24%
Deficiency	35	26%
Deficiency & IPHCO	67	50%

Total Facility Inspections Completed **266**

**Virginia Board of Pharmacy
December 14, 2011
Inspection Report**

Inspection Deficiencies

Deficiency	Count	Description
Major 15	23	Perpetual inventory not being maintained as required; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required
Major 9a	26	Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.
Major 14	9	No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V
Major 20	8	Pharmacist not checking and documenting repackaging, compounding, or bulk packaging
Major 3	7	Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months
Major 13	5	No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V
Major 26	5	Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test
Major 8	3	Refrigerator/freezer temperature out of range greater than +/- 4 degrees

Deficiency	Count	Description
Minor 8	16	Emergency access alarm code/key not maintained in compliance
Minor 19	14	Not properly documenting partial filling
Minor 14	14	Records of receipt (invoices) not on site or retrievable
Minor 13	12	Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate
Minor 38	12	ADD loading, records, and monitoring/reconciliation not in compliance
Minor 5	7	No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees
Minor 24	9	Labels do not include all required information
Minor 27	8	Repackaging records and labeling not kept as required or in compliance
Minor 9	8	Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)
Minor 39	7	EMS procedures or records not in compliance