



# COMMONWEALTH OF VIRGINIA

## Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor  
Henrico, Virginia 23233

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

### Tentative Agenda of Meeting

*June 2, 2010*

**9:00AM**

<u>TOPIC</u>	<u>PAGE(S)</u>
<b>Call to Order:</b> Jennifer Edwards, Chairman	
• Welcome and Introductions	
• Introduction of Dianne Reynolds-Cane, M.D., DHP Director and Arne Owens, DHP Senior Deputy Director	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-36
• March 9, 2010, Full Board meeting	
• March 9, 2010, Panel of the Board	
• March 24, 2010, Special Conference Committee	
• April 14, 2010, Panel of the Board	
• April 27, 2010, Special Conference Committee	
• May 6, 2010, Telephone Conference Call	
• May 17, 2010, Ad Hoc Inspection Committee	handout
• May 20, 2010, Telephone Conference Call	handout
• May 25, 2010 Special Conference Committee	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 Report:** Dianne L. Reynolds-Cane, M.D.

**Election of Officers, Chairman and Vice Chairman**

**Recognition of Board members whose terms are expiring**

- Leo Ross, 2<sup>nd</sup> term
- Willie Brown, 2<sup>nd</sup> term
- Bobby Ison, 2<sup>nd</sup> term
- Jennifer Edwards, 1<sup>st</sup> term
- Michael Stredler, 1<sup>st</sup> term

**Regulations:** Elaine Yeatts

- Update on regulation processes

- Adoption of exempt regulation 38-43
  - maintaining CE records to conform to statute
  - elimination in 18 VAC 110-20-690 C of incorrect cite
- Adoption of fast-track regulation to establish a nominal fee for duplicate license and written license verification 44-50
- Petition for rulemaking-add tramadol to Schedule IV 51-55
- Petition for rulemaking received-will publish, no action at this time 56-57

**Legislation:**

- 2011 Legislative Proposals-Russell
  - compounding 58-60
  - multiple prescriptions per blank 61
  - possibly a scheduling bill n/a
- Interpretation of HB964, Acts of Assembly Chapter 193-Kozera 62-63

**Miscellaneous:**

- Sanction Reference Evaluation, Neil Kauder 64-78
- Update on inspection program-Caroline Juran and Sammy Johnson handout
  - Thermometer, storage temperature issue-change to guidance document
  - USP-797
  - Pilot inspection update, going "live"
  - Changes to HIPDB/NPDB reporting, and how it may affect docketing of the inspection cases
- Further discussion of inspection program
  - PIC requirements-Ison
  - Request for use of CCA similar process for inspection deficiency monetary penalties-Bobby Ison and Howard Casway
  - General discussion
- Licensure process with respect to pharmacy residents-Ison
- Pharmacy "coupons" and impact on patient safety-Jennifer Edwards 79-80

**Reports:**

- Report on Board of Health Professions-Jennifer Edwards
- Executive Director's Report-Scotti Russell
  - NABP meeting report
  - Upcoming DEA meeting June 17-18

**New Business****Consideration of consent orders (if any)****Formal Hearing: Jermaine Moon, 1PM****Adjourn**

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

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

March 9, 2010  
Second Floor  
Board Room 4

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

---

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

**PRESIDING:** Jennifer H. Edwards, Chairman

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

**STAFF PRESENT:** Elizabeth Scott Russell, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
Caroline D. Juran, Deputy Executive Director  
Howard M. Casway, Senior Assistant Attorney General  
Elaine J. Yeatts, Senior Regulatory Analyst, DHP  
Sharon Davenport, Administrative Assistant  
Eusebia Joyner, Discipline Program Specialist

**QUORUM:** With 10 members present, a quorum was established.

**APPROVAL OF AGENDA:** There were three modifications to the agenda. Sandra Whitley Ryals, Director, DHP, was not able to be present to give the DHP report due to a family emergency. A handout was provided to the Board with information on the second quarter 2010 performance measures. Mr. Ison requested that an additional item be added to the agenda for discussion as to how the Board can assist PICs with compliance. Additionally, Ms. Reiniers-Day stated that a possible summary suspension would be presented. With these three changes, the agenda was approved as presented.

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for December 16, 2009; January 26, 2010; February 23, 2010; February 22, 2010; and February 24, 2010.

1

**Motion:**

**The Board voted unanimously to approve the minutes as presented with one minor change to the minutes of January 26, 2010, changing the name of the second to a motion from Mr. Yi to Mr. Kozera. (motion by Dabney, second by Brown)**

**PUBLIC COMMENTS:**

There were no public comments offered at this time.

**LEGISLATION UPDATE:**

Ms. Yeatts provided a summary of legislation from the 2010 General Assembly session that might be of possible interest to the Board.

**REGULATIONS:**

Ms. Yeatts provided an update on existing regulatory processes.

- Adoption of final regulations on drug donation programs:

Ms. Yeatts stated that the Board had received no comments during the comment period on the proposed regulations. She stated that there were no changes in final regulations from existing emergency regulations. The Board discussed whether the requirement for a signed donor form by nursing home patients was acting as a deterrent to pharmacies other than the provider pharmacy from registering as a donation site for a long term care facility. Staff provided information that the current regulations were formulated by an ad hoc committee that included long term care pharmacy representation, and that there were no issues with the donor form. Ms. Russell stated that the Board currently had two pharmacies registered as donation sites. Ms. Russell gave the opinion that the real barrier to pharmacies wanting to participate in these programs is that there is a financial disincentive to doing so. It is an additional burden in terms of workload, storage space for these drugs, and recordkeeping systems for no income. Ms. Abernathy expressed concern that, for the reasons just mentioned, the Board should make the process as simple as possible and not require anything non-essential such as possibly the donor form from nursing home patients. Ms. Yeatts again reiterated that the original committee drafting the regulations considered that the donor form requirement was necessary in this example because a pharmacy other than the provider pharmacy did not have the patient records and dispensing records that the provider pharmacy would have. She also reminded the Board that any substantive change now would require resubmitting the regulations again for public comment and further delaying the implementation of permanent regulations. As it is, the emergency regulations expire April 9, 2010 and a six-month extension is being requested to have permanent regulations in place. Any further delay in this process will mean a gap in which the emergency regulations expire, and any programs that may be ongoing will need to cease until permanent regulations become effective.

2

**Motion:** **The Board voted unanimously to adopt as final regulations the proposed regulations as published. (motion by Yi, second by Kozera)**

**Motion:** **The Board voted unanimously to have staff communicate with associations representing nursing homes to determine if there are barriers in Board regulations that are preventing more participation in drug donation programs. (motion by Abernathy, second by Ross)**

- Adoption of a fast-track regulation on removing the requirement for delivery signature by a nurse for drugs placed in ADDs in hospitals:

The Board reviewed draft regulations eliminating the requirement for a nurse to sign for delivery of drugs placed into an automated dispensing device (ADD) in a hospital. This proposal was a response to a petition for rulemaking, for which the Board received a number of responses in support of eliminating the requirement primarily for the reasons that it took the nurse away from more important patient care duties without providing any additional accountability for the process since it was not required that the nurse witness the drugs being stocked in the ADD. The Board received no additional comments during the NOIRA process, and it is not anticipated that there is any opposition to this action.

**Motion:** **The Board voted unanimously to adopt proposed regulation as presented to eliminate the requirement for a nurse's signature on the delivery record of drugs stocked in an ADD in a hospital. (motion by Ison, second by Beckner) Attachment 1.**

- Adoption of emergency regulations to implement HB150, effective date March 4, 2010.

House Bill 150 of the 2010 General Assembly provided authority for the Community Services Boards (CSBs) who hold controlled substances registrations as alternate delivery sites, to retain medications for certain patients with consent, and assist those patients with repackaging for self-administration. The bill also provides for crisis stabilization units in CSBs to have certain Schedule VI drugs stocked for administration by a nurse pursuant to an order of a prescriber, but in the absence of a prescriber. The bill contained an emergency enactment clause as well as a requirement for the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill. The regulations include provisions related to the retention and repackaging of medications by the CSBs, the training for any unlicensed persons assisting with repackaging at the CSBs, and storage and record requirements for the crisis stabilization units.

An ad hoc committee consisting of Board members and representatives of the CSBs met on February 23, 2010 and developed draft regulations for consideration by the Board. The Board reviewed the draft regulations and made some minor technical revisions. Prevention and reporting of errors was added

to the list of items to be included in an approved training program.

**Motion:**

**The Board voted unanimously to adopt emergency regulations to implement HB150, as recommended by the ad hoc committee and amended by the Board. (motion by Stredler, second by Brown) Attachment 2.**

**UPDATE ON THE NEW  
INSPECTION PROCESS:**

Caroline Juran provided the Board with a summary of all communication efforts that staff had made to provide notification to pharmacies and pharmacists of the new inspection procedures, including a newsletter article, email blast notification to all email addresses, and formal written notification to all pharmacies being inspected in the next six months of the new process and ways to prepare. In addition, she stated that forms, guidance documents, and FAQs are available on the web site explaining the new process and describing self-inspection suggestions for preparing to pass an inspection. Sammy Johnson, Deputy Director, DHP Enforcement Division, described the piloting of the new process; provided a partial sample of the inspection report being used; a sample of the summary of inspection listing whether deficiencies were found and if so, which ones; a sample of a inspection pre-hearing consent order which would be left by the inspector if warranted, and a listing of the types of deficiencies seen to date on the pilot inspections, and whether a penalty would have been imposed. Mr. Johnson stated that once we began "live" inspections using the new process in community pharmacies, the next step would be to further develop the hospital piece, particularly the requirements for USP 797. It was agreed that a committee of the Board, Mr. Ison, Ms. Abernathy, and Ms. Edwards will meet with staff to develop inspection criteria for sterile compounding compliance to be brought back to the Board at the June meeting if timelines do not change.

Board members expressed concerns about the availability of these actions on the web. Ms. Russell explained that any notice or order, of which the document imposing the monetary penalty is a consent order, is a public document and is available through license lookup. Mr. Ison expressed concern that these actions are attached to a pharmacy license and stay with that license available to the public forever. Ms. Russell stated that she is planning to look into whether these actions had to go on the Board's 90-day action list on the website, and whether there was a way to prevent this, although the documents would still be attached to the license and available to the public through license lookup or by request. She stated that she believes the 90-day action list on the website is automatically populated by the disciplinary database and there may not be an easy way to prevent these cases from being added. Mr. Ison asked

4

Mr. Casway to provide advice at the next Board meeting about whether a confidential consent agreement (CCA) would be an appropriate method for handling inspection deficiencies. Mr. Casway stated that he did not believe these would meet the criteria for use of a CCA. Mr. Ison asked if Mr. Casway could provide advice by the June Board meeting as to whether legislation could be developed to prevent Board actions related to inspection deficiencies from being public documents, possibly expanding the use of the CCA for this purpose. Mr. Casway stated that he could review the CCA statute, but did not expect his advice to change. Ms. Russell stated that the Board could look into a legislative proposal to further expand the use of the CCA, but did not know whether such a proposal would have support from the administration or be allowed to go forward as a Board initiative. After discussion, it was agreed that for the first six months of live inspections, the inspector would attempt to call the pharmacy alerting the PIC than an inspection would be performed at some point during the next two weeks.

**PIC TRAINING:**

Mr. Ison stated that he would like for the Board to offer some type of training for persons who become PIC to assist them in being able to pass a Board inspection. He added that some type of test may be appropriate. There was some discussion that a test would probably result in persons not agreeing to become a PIC, which would result in a shortage. Mr. Ison requested that a subcommittee be formed to look into appropriate training. Ms. Juran explained that all new PICs are provided with a guidance document outlining their responsibilities, and that staff will also forward a copy of the new inspection process document and how they should prepare for an inspection. Mr. Ison stated that while that was good, he did not believe that was enough and again asked the chairman to appoint a subcommittee. Ms. Edwards appointed a subcommittee of Mr. Ison, Mr. Ross, and Mr. Kozera to look into this.

**BOARD OF HEALTH  
PROFESSIONS:**

Ms. Edwards stated that the BHP had not met since the previous Board of Pharmacy meeting and as such had no new report.

**SUMMARY SUSPENSION:**

**Motion for  
closed meeting:**

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Scotti Russell, Cathy Reiniers-Day, Eusebia Joyner, Howard Casway, Corie Tillman Wolf and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Abernathy, second by Yi)

LAURA D. GOOLSBY  
Pharmacy Technician  
Registration Number:  
0230-008314

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

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

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

**Motion:**

The Board voted unanimously in favor of the motion that, according to the evidence presented, the continued practice by Laura Goolsby as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Laura Goolsby to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. Goolsby for the revocation of her registration in lieu of a hearing. (motion by Kozera; second by Beckner)

**CONFLICT OF INTEREST TRAINING:**

The conflict of interest training program provided through the Commonwealth of Virginia's Knowledge Center was accessed and provided to the Board members as a group. All training modules were completed by the Board members. All Board members except Mr. Stredler participated in the training. Mr. Stredler completed the training online in December 2009 and provided his certificate of completion.

**ADJOURN:**

With all business concluded, the meeting was adjourned at 1:30PM.

---

Elizabeth Scott Russell  
Executive Director

---

Jennifer Edwards, Chairman

---

Date

6

**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 §§54.3401 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. ~~At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.~~
3. ~~At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.~~
4. ~~3. 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.~~
5. ~~4. 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.
  - 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.

~~6.~~ 5. 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.

~~7.~~ 6. 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.

~~8.~~ 7. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

~~9.~~ 8. 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.

~~10.~~ 9. 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 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 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 10 a and b of this section if authorized by 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.

8

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

D. Annual renewal fees.

1. Pharmacist active license	\$90
2. Pharmacist inactive license	\$45
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Physician permit to practice pharmacy	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. Nonresident pharmacy	\$270
9. Controlled substances registrations	\$90
10. Innovative program continued approval based on board order not to exceed \$200 per approval period.	
11. Approval of a pharmacy technician training program	\$75 every two years
<u>12. 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. <u>Approval of a repackaging training program</u>	<u>\$50</u>

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

10

- |  |       |
|--|-------|
| 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 A dispensed prescription drug order for Schedule VI controlled substances prescriptions 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

11

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 which cannot be easily moved and which 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 or other person as authorized in 18VAC110-20-700 C.

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 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.

### **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, alternative 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 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, or to 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, or to 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

14

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. 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 that is designed for a person to be able to repack 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 which 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 repack.

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. A CSB or BHA using such other persons 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 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.

15

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, and in the following repackaging tasks:

- a. Selection of an appropriate container;
- b. Proper preparation of a container in accordance with instructions for administration;
- c. Selection of the drug;
- d. Counting of the drug;
- e. Repackaging of the drug within the selected container;
- f. Maintenance of records;
- g. Proper storage of drugs;
- h. Translation of medical abbreviations;
- i. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;
- j. Reporting and recording the client's failure to take medication;
- k. Identification, separation and removal of expired or discontinued drugs; and
- l. 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 and 18 VAC 110-20-725.
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 or BHA or by the board.
4. The program shall maintain records of training completion by persons authorized to repackage in accordance with §54.1-3420.2. 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 18 VAC 110-20-725, 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 18 VAC 110-20-340 B and 18 VAC 110-20-725, subsections G, H, and J. A primary provider pharmacy may also provide this service in compliance with the provisions of 18 VAC 110-20-535.

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

A. In accordance with § 54.1-3423, 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, 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  
MINUTES OF A PANEL OF THE BOARD**

Tuesday, March 9, 2010  
Second Floor  
Board Room 4

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

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

**CALL TO ORDER:** A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:50 p.m.

**PRESIDING:** Jennifer H. Edwards, Chair

**MEMBERS PRESENT:** Gill B. Abernathy  
Gerard Dabney  
Bobby Ison  
Leo H. Ross

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

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

**MICHELLE S. ROMATOWSKI**  
Registration # 0230-010789

Ms. Romatowski did not appear at the formal hearing. The panel chose to proceed in her absence as the Notice was mailed to Ms. Romatowski's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as stated in the January 28, 2010 Notice.

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

Scott A. Arnott, DHP Senior Investigator, and Heleen Anderson-Grant, HPMP Case Manager, testified on behalf of the Commonwealth.

20

---

Closed Meeting: Upon a motion by Ms. Abernathy, and duly seconded by Mr. Ross, the Panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Michelle S. Romatowski. Additionally, she moved that Scotti Russell and Howard Casway attend the closed meeting.

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

Decision: Upon a motion by Ms. Abernathy, and duly seconded by Mr. Dabney, the Panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Tillman Wolf and amended by the Panel and read by Mr. Casway.

Upon a motion by Mr. Ross, and duly seconded by Mr. Dabney, the Panel voted 5-0 that Ms. Romatowski's right to renew her pharmacy technician registration be revoked.

Adjourn: With all business concluded, the meeting adjourned at 2:30 p.m.

---

Cathy M. Reiniers-Day  
Deputy Executive Director

---

Jennifer Edwards, Chair

---

Date



DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, March 24, 2010  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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 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: Leo H. Ross, Committee Member

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

KAMRAN AGHA-AMIRI License # 0202-012082  
Kamran Agha-Amiri appeared with James E. Moore, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the December 29, 2009 Notice.

Closed Meeting: Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A.(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Kamran Agha-Amiri. 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. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Mr. Agha-Amiri and impose a monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Agha-Amiri, unless a written request is made to the

23

Board requesting a formal hearing on the allegations made against him is received from Mr. Agha-Amiri within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

JAMES V. ETTARE, II  
License No. 0202-206317

James Ettare appeared with Jodi Ettare, his wife and co-owner of Valley Compounding Pharmacy, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 25, 2010 Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Mr. Ettare and impose a monetary penalty.

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

JODI V. ETTARE  
License No. 0202-205862

Jodi Ettare appeared with James Ettare, her husband and co-owner of Valley Compounding Pharmacy, to discuss allegations that she may have violated certain laws and



regulations governing the practice of pharmacy as stated in the January 25, 2010 Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Ms. Ettare, impose a monetary penalty and to have an unannounced inspection of Valley Compounding Pharmacy with her as the pharmacist in charge and co-owner, being responsible for the cost.

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

MARY M. ALDRICH  
Registration No. 0230-008778

Mary Aldrich appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the February 11, 2010 Notice.

Closed Meeting:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Mary Aldrich. 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. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to impose no sanction with respect to Ms. Aldrich.

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

DONALD M. JOHNSON  
License No. 0202-004628

Donald Johnson appeared with Sarah J. Ownby, Pharmacy Technician; Beverly Morgan, CVS Pharmacy District Manager; and Donna Johnson, his wife, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 11, 2010 Notice.

Closed Meeting:

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

26

Decision: Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to have Mr. Johnson obtain additional continuing pharmacy education hours.

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

SARAH J. OWNBY  
Registration No. 0230-002571

Sarah Ownby appeared with Donald M. Johnson, Pharmacist; and Beverly Morgan, CVS Pharmacy District Manager; to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the February 11, 2010 Notice.

Closed Meeting: Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Sarah Ownby. 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. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to have Ms. Ownby obtain additional continuing pharmacy education hours.

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

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

OLGA L. ZYTGER  
License No. 0202-207370

Olga Zytcer appeared with Ari Zytcer, her husband. Additionally, Shan Wu, her attorney, participated by telephone to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 3, 2010 Notice.

Closed Meeting:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Olga Zytcer. 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. Ross, and duly seconded by Mr. Yi, the Committee closed this case as undetermined.

ADJOURN

With all business concluded, the meeting adjourned at 7:00 p.m.

---

Cathy M. Reiniers-Day  
Deputy Executive Director

---

Brandon K. Yi, Chair

---

Date

28

(DRAFT/UNAPPROVED 04/14/2010)

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF A PANEL OF THE BOARD**

Wednesday, April 14, 2010  
Second Floor  
Board Room 1

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 9:40 a.m.

PRESIDING: Jennifer H. Edwards, Chair

MEMBERS PRESENT: John O. Beckner  
Gerard Dabney  
Bobby Ison  
Leo H. Ross  
Michael E. Stredler

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

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

MISTIE L. BETZING  
Registration # 0230-004321

A formal hearing was held in the matter of Mistie L. Betzing following the summary suspension of her pharmacy technician registration on February 23, 2010, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Betzing was not present at the hearing. The Panel proceeded in Ms. Betzing's absence as the Notice of Formal Hearing dated March 3, 2010, was mailed to Ms. Betzing's legal address of record, both regular and certified mail. Ms. Edwards ruled that adequate notice was provided to Ms. Betzing and the hearing proceeded in her absence.

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

29

---

Nan Dunaway, DHP Pharmacy Inspector, and Donald Durkee, Sentara Leigh Hospital-Norfolk, Pharmacy Manager, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Beckner and duly seconded by Mr. Stredler, the Panel voted 6-0, 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 Mistie L. Betzing. Additionally, he moved that Cathy Reiniers-Day, Eusebia Joyner, and Howard Casway attend the closed meeting.

Reconvene:

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

Decision:

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

Upon a motion by Mr. Ross and duly seconded by Stredler, the Panel voted 6-0 that Ms. Betzing's registration be revoked.

ADJOURN:

With all business concluded, the meeting adjourned at 11:15 a.m.

---

Cathy M. Reiniers-Day  
Deputy Executive Director

---

Jennifer H. Edwards, Chair

---

Date

30

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY  
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, April 27, 2010  
Commonwealth Conference Center  
Second Floor  
Board Room 1

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 Special Conference Committee of the Board of Pharmacy was called to order at 9:15 a.m.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT: John O. Beckner, Committee Member

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

RICHARD B. LAKES  
Pharmacist Reinstatement  
Applicant  
License # 0202-004156

Richard B. Lakes appeared to discuss his petition for reinstatement of his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 26, 2010 Notice.

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

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

Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reinstate Mr. Lakes pharmacist license.

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

CHARLES R. WILLIAMSON  
Pharmacy Technician  
Applicant

Charles R. Williamson appeared with Lisa Stayton, pharmacy employer and his sister, to act upon his application for registration as a pharmacy technician and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the March 26, 2010 Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to approve Mr. Williamson's application for registration 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. Williamson, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Williamson 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.

EMORY F. HURST  
License No. 0202-005250

Emory F. Hurst appeared with Robert L. Runniger, pharmacist and co-owner of Runniger's Pharmacy; and Kathyanne Runniger, co-owner, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 1, 2010 Notice.

32

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Hurst a reprimand and impose a monetary penalty due to his failing to provide adequate security for the drug stock.

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

ROBERT L. RUNNINGER  
License No. 0202-004733

Robert L. Runninger appeared with Emory F. Hurst, pharmacist at Runninger's Pharmacy; and Kathyanne Runninger, co-owner of the pharmacy, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 1, 2010 Notice.

Closed Meeting:

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

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

Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Runniger a reprimand and impose a monetary penalty due to his failing to provide adequate security for the drug stock.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Runniger, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Runniger 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 3:30 p.m.

---

Cathy M. Reiniers-Day  
Deputy Executive Director

---

David C. Kozera, Chair

---

Date

DRAFT /UNAPPROVED

VIRGINIA BOARD OF PHARMACY  
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, May 6, 2010

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 was held at 8:30 a.m., on May 6, 2010, to consider the summary suspension of the registration of Jessica E. Thrower to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: John O. Beckner, Chair

MEMBERS PRESENT: Willie Brown  
Bobby Ison  
David C. Kozera  
Leo H. Ross  
Michael E. Stredler

STAFF PRESENT: Elizabeth Scott Russell, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
Eusebia L. Joyner, Disciplinary Program Specialist  
Wayne T. Halbleib, Assistant Attorney General  
Mykl Egan, DHP Adjudication Specialist

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

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

JESSICA E. THROWER  
Registration No. 0230-005129

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

Decision:

Upon a motion by Willie Brown and duly seconded by Leo Ross, the Board unanimously voted that with the evidence



---

presented, the practice as a pharmacy technician by Jessica E. Thrower poses a substantial danger to the public; and therefore, that the registration of Ms. Thrower to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Thrower for the indefinite suspension of her registration for not less than two years in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 8:45 a.m.

---

Cathy M. Reiniers-Day  
Deputy Executive Director

---

Eusebia L. Joyner  
Disciplinary Program Specialist

---

John O. Beckner, Chair for this meeting

---

Date

# Chart of Regulatory Actions in Progress

## Board of Pharmacy

Chapter	Action / Stage Information				
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<table border="1"> <tr> <td data-bbox="695 529 792 583"><u>Action:</u></td> <td data-bbox="792 529 1370 604">Repackaging in CSB's and BHA's Submitted: 3/31/10</td> </tr> <tr> <td data-bbox="695 604 792 659"><u>Stage:</u></td> <td data-bbox="792 604 1370 659">Emergency/NOIRA - <i>At Secretary's Office</i></td> </tr> </table>	<u>Action:</u>	Repackaging in CSB's and BHA's Submitted: 3/31/10	<u>Stage:</u>	Emergency/NOIRA - <i>At Secretary's Office</i>
<u>Action:</u>	Repackaging in CSB's and BHA's Submitted: 3/31/10				
<u>Stage:</u>	Emergency/NOIRA - <i>At Secretary's Office</i>				
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<table border="1"> <tr> <td data-bbox="695 667 792 772"><u>Action:</u></td> <td data-bbox="792 667 1370 772">Signing of automated dispensing devices in hospitals Submitted: 4/12/10</td> </tr> <tr> <td data-bbox="695 772 792 827"><u>Stage:</u></td> <td data-bbox="792 772 1370 827">Fast-Track - <i>At Secretary's Office</i></td> </tr> </table>	<u>Action:</u>	Signing of automated dispensing devices in hospitals Submitted: 4/12/10	<u>Stage:</u>	Fast-Track - <i>At Secretary's Office</i>
<u>Action:</u>	Signing of automated dispensing devices in hospitals Submitted: 4/12/10				
<u>Stage:</u>	Fast-Track - <i>At Secretary's Office</i>				
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<table border="1"> <tr> <td data-bbox="695 844 792 1012"><u>Action:</u></td> <td data-bbox="792 844 1370 1012">Drug donation program Submitted: 3/29/10  Extension of emergency regulation: 10/6/10</td> </tr> <tr> <td data-bbox="695 1012 792 1066"><u>Stage:</u></td> <td data-bbox="792 1012 1370 1066">Final - <i>At Secretary's Office</i></td> </tr> </table>	<u>Action:</u>	Drug donation program Submitted: 3/29/10  Extension of emergency regulation: 10/6/10	<u>Stage:</u>	Final - <i>At Secretary's Office</i>
<u>Action:</u>	Drug donation program Submitted: 3/29/10  Extension of emergency regulation: 10/6/10				
<u>Stage:</u>	Final - <i>At Secretary's Office</i>				

37  


**Agenda Item: Regulatory Action – Exempt action**

**Staff Note:** Included in your package are copies of:

- Amendments to requirements for maintenance of continuing education certificates are necessary for consistency with the Code of Virginia (§ 54.1-3314.1):
  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.
- An amendment to Section 690 C on controlled substance registration is necessary because there is an incorrect cite in regulation.

**Action:**

Motion to adopt amendments as presented in the agenda package as an action exempt from the Administrative Process Act process.

**Project 2431 – Exempt action**

**BOARD OF PHARMACY**

**Exempt action - CE retention**

**18VAC110-20-90. Requirements for continuing education.**

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);

2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology or drug therapy;  
or

3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.

C. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

D. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to

maintain, for ~~three~~ two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

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

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

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

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

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

Part 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, 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.

**Agenda Item: Adoption of a fast-track regulation**

**Staff Note:**

There is currently no fee for two administrative functions – verification of licensure and duplicate license/registration.

**Included in your packet:**

A draft of fast-track regulations to add fees sufficient to cover costs incurred

**Board action:**

Adoption of fast-track regulations

**Project 2432 – Fast-track action**

**BOARD OF PHARMACY**

**Addition of administrative fees**

**18VAC110-20-20. Fees.**

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

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

C. Initial application fees.

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

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

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

D. Annual renewal fees.

1. Pharmacist active license – 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

45

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

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

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

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

suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

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

47

<u>3. Duplicate license or registration</u>	<u>\$10</u>
<u>4. Verification of licensure or registration</u>	<u>\$25</u>

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

**18VAC110-50-20. Fees.**

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

B. Initial application fees.

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

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

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

48

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

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

E. Reinstatement fees.

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

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

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

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

F. Application for change or inspection fees.

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

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

H. For the annual renewal due on February 28, 2010, the following fees shall be imposed for a license or permit:

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

I. The fee for verification of license or permit shall be \$25.

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

Staff Note: A Petition for Rulemaking was received from:

David Byrd requesting promulgation of a regulation to add Tramadol and Tramadol/APAP to Schedule IV

Enclosed are:

A copy of the petition and the notice in the Register of Regulations

A copy of legislation introduced in the 2010 General Assembly (HB1165)

There were no comments on the petition

Action:     To either accept the petitioner's request or initiate rulemaking or to reject the request. Reasons for the decision must be stated.

2010 SESSION

INTRODUCED

10101226D

HOUSE BILL NO. 1165

Offered January 13, 2010

Prefiled January 13, 2010

A BILL to amend and reenact § 54.1-3452 of the Code of Virginia, relating to tramadol; add to Schedule IV.

Patrons—Phillips; Senator: Puckett

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

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

- Alprazolam;
- Barbital;
- Bromazepam;
- Camazepam;
- Chloral betaine;
- Chloral hydrate;
- Chlordiazepoxide;
- Clobazam;
- Clonazepam;
- Clorazepate;
- Clotiazepam;
- Cloxazolam;
- Delorazepam;
- Diazepam;
- Dichloralphenazone;
- Estazolam;
- Ethchlorvynol;
- Ethinamate;
- Ethyl loflazepate;
- Fludiazepam;
- Flunitrazepam;
- Flurazepam;
- Halazepam;
- Haloxazolam;
- Ketazolam;
- Loprazolam;
- Lorazepam;
- Lormetazepam;
- Mebutamate;
- Medazepam;
- Methohexital;
- Meprobamate;
- Methylphenobarbital;
- Midazolam;
- Nimetazepam;
- Nitrazepam;
- Nordiazepam;
- Oxazepam;
- Oxazolam;
- Paraldehyde;
- Petrichloral;

INTRODUCED

HB1165

2/4/10 10:17

59 Phenobarbital;  
60 Pinazepam;  
61 Prazepam;  
62 Quazepam;  
63 Temazepam;  
64 Tetrazepam;  
65 Triazolam;  
66 Zaleplon;  
67 Zolpidem;  
68 Zopiclone.

69 2. Any compound, mixture or preparation which contains any quantity of the following substances  
70 including any salts or isomers thereof:

71 Fenfluramine.

72 3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture,  
73 or preparation which contains any quantity of the following substances having a stimulant effect on the  
74 central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of  
75 such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the  
76 specific chemical designation:

77 Cathine (+)-norpseudoephedrine;

78 Diethylpropion;

79 Fencamfamin;

80 Fenproporex;

81 Mazindol;

82 Mefenorex;

83 Modafinil;

84 Phentermine;

85 Pemoline (including organometallic complexes and chelates thereof);

86 Pipradrol;

87 Sibutramine;

88 SPA (-)-1-dimethylamino-1, 2-diphenylethane.

89 4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture,  
90 or preparation containing any of the following narcotic drugs, or their salts calculated as the free  
91 anhydrous base or alkaloid, in limited quantities as set forth below:

92 Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

93 Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per  
94 dosage unit;

95 *Tramadol.*

96 5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture,  
97 or preparation which contains any quantity of the following substances, including their salts:

98 Butorphanol (including its optical isomers);

99 Pentazocine.

100 6. The Board may except by regulation any compound, mixture, or preparation containing any  
101 depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the  
102 compound, mixture, or preparation contains one or more active medicinal ingredients not having a  
103 depressant effect on the central nervous system, and if the admixtures are included therein in  
104 combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances  
105 which have a depressant effect on the central nervous system.

---

## PETITIONS FOR RULEMAKING

---

### TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

#### BOARD OF PHARMACY

##### Initial Agency Notice

Title of Regulation: 18VAC110-20. Regulations Governing the Practice of Pharmacy.

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Name of Petitioner: David P. Byrd.

Nature of Petitioner's Request: Promulgate a regulation to add Tramadol and Tramadol/APAP to Schedule IV because of the abuse problems and to have those drugs reportable to the Prescription Monitoring Program.

Agency's Plan for Disposition of the Request: The board will receive public comment on the petition for rulemaking and will review the petition and any comment at its meeting on June 2, 2010, to make a decision on whether to initiate rulemaking.

Public Comment Deadline: April 28, 2010.

Agency Contact: Elizabeth Scott Russell, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Henrico, VA 23233, telephone (804) 367-4456, FAX (804) 527-4472, or email [scotti.russell@dhp.virginia.gov](mailto:scotti.russell@dhp.virginia.gov).

VA.R. Doc. No. R10-42; Filed March 10, 2010, 9:48 a.m.

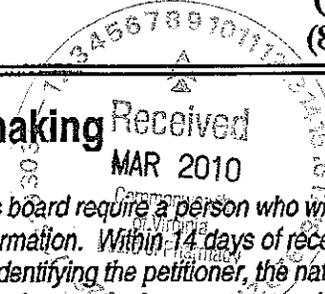
54



# 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 (52.2-4007) 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.) <b>BYRD, David P.</b>		
Street Address <b>395 ARCHA Street</b>	Area Code and Telephone Number <b>276-728-7787</b>	
City <b>Hillsville</b>	State <b>VA</b>	Zip Code <b>24343</b>
Email Address (optional) <b>dpyrd@embargmail.com</b>	Fax (optional) <b>276-398-2620</b>	

### 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.  
**Pey Act and Drug Control Act 7/1/09 54.1-3451**
2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.  
**To add Tramadol (Ultram<sup>®</sup>) & Tramadol/APAP (Ultracet<sup>®</sup>) to schedule IV status, because of the abuse problems and also so it would show up on the VA PDM Program for pain med review**
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.  
**54.1-2400**

Signature: **David P Byrd RPh** Date: **3/8/2010** **SS**



# 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,)

Haas, Eric, C

Street Address

3820 Ingalls Ave.

City

Alexandria

Email Address (optional)

ehaas2010@gmail.com

Area Code and Telephone Number

(571)970-4232 / (703)593-3340

State

VA

Zip Code

22302

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.

18VAC110-20-240

**B. Prescriptions.**

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Change the following: "All prescriptions shall be filed chronologically by date of initial dispensing."

New Language should be similar to the following: "All prescriptions shall be filed chronologically by date of initial dispensing or initial entry into pharmacy electronic record keeping system if such a system is employed for use in the pharmacy."

Rationale: Prescriptions are often placed into electronic record keeping systems for later dispensing, and retrieval and reassignment is a cumbersome process which is unnecessary and likely to promote errors in the patient record.



56

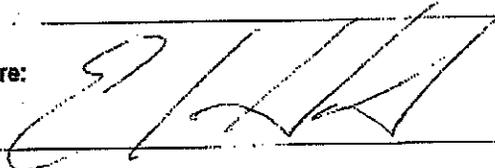


3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

§ 54.1-2400.6 To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title.

§ 54.1-2400.13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

Signature:



Date: 5-14-2010

57

July 2002

**§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.**

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; ~~or~~ and

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The compounding for human use of a drug product using an active ingredient not yet approved for use in the United States or otherwise deemed harmful by FDA; or

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, or (iii) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence

assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304 and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.



**§ 54.1-3408.01. Requirements for prescriptions.**

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

~~No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.~~

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

61

**Broken up into segments and some phrases highlighted for ease of reading and interpretation**

**CHAPTER 193**

*of identification. An Act to amend and reenact § 54.1-3420.1 of the Code of Virginia, relating to Schedule II drugs; proof*

[H 964]  
Approved April 7, 2010

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3420.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules ~~II~~ III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

① B. A pharmacist shall require proof of identity from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription before dispensing such drug, unless such person is known to the pharmacist.

② If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, the pharmacist shall record the full name and address of such person, regardless of whether the person seeking to take delivery of the drug is known to the pharmacist.

③ When proof of identity is required from a person seeking to take delivery of a drug pursuant to this subsection, the pharmacist shall make a photocopy or electronic copy of his proof of identity, or an electronic record documenting that proof of identity was provided.

④ The pharmacist shall keep records of the names and addresses and copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one year.

For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

1. must request proof of identity for all CII unless known to the pharmacist.
  - \* if known to the pharmacist, whether or not the patient, the person accepting delivery does not need to show proof of identity?
2. if not the patient, must record full name and address of person whether known to the pharmacist or not
  - \* requirement to record name and address but if known, do not need to request proof of identity?
3. photocopy, electronic copy or electronic record that proof was provided for only those persons not known to the pharmacist? what constitutes an electronic record that proof was provided? Can it just be an electronic log?
4. copies of proof of identity seems to exclude an electronic log and the language in the last part of segment 3?

# Assessing the Effectiveness of Sanctioning Reference Points

---

*Approved by the Virginia Board of Health Professions, May 4, 2010*

**Prepared by:**

VisualResearch, Inc.  
P.O. Box 1025  
Midlothian, VA 23113  
804.794.3144

**Prepared for:**

Virginia Department of Health Professions  
Virginia Board of Health Professions  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Richmond, VA 23233-4400

## Table of Contents

Introduction.....	1
Goals of the Effectiveness Study.....	1
Historical Background.....	2
SRP Implementation Timeline.....	3
Methods for Measuring the Effectiveness of Sanctioning Reference Points.....	4
Examining SRP Agreement Monitoring.....	6
SRP Training Issues.....	7
Additional Evaluation Issues.....	8
Anticipated Evaluation Obstacles.....	10
Appendices.....	11

65

## Introduction

The Virginia Board of Health Professions has recommended that the agency's Sanctioning Reference Points (SRP) be evaluated to determine whether the program has met the objectives set forth in 2001. In addition to measuring effectiveness, a study of this type should clearly identify potential improvements to the system, and recommend any additional changes related to future SRP operations. This document outlines specific methods for evaluating SRP effectiveness, and how any needed changes in SRP operations should be identified.

The original purpose of the SRP project was to positively impact the oversight and governance functions related to disciplining healthcare professionals. This presupposes an important question: how long should a new program be in place before a proper assessment can be made? The answer is not based only on a certain number of years, or even after a certain number of SRP worksheets have been collected. There are several reasons why now is an appropriate time to examine the overall SRP system:

1. Since the program was initially implemented by the Board of Medicine in 2004, the SRPs have been applied to a large number of cases (n=1,148 as of 1/1/2010).
2. Boards report a high agreement rate with recommended sanctions.
3. The majority of DHP health regulatory boards have adopted and implemented SRPs.
4. Boards have voiced some concerns relating to training needs, and there seems to be a misunderstanding of how to properly apply the SRP system in all cases (agreement rate monitoring shows worksheets not being filled out correctly in many cases).
5. Boards, because of their unique "cultures," have interpreted implementation of the system in different ways, and, from an agency-wide perspective, some unintended operational differences may be resulting.
6. Many other state and national organizations (other states, VA agencies, and professional groups) have expressed great interest in SRP effectiveness.<sup>1</sup>

For these reasons, BHP has asked VisualResearch, Inc. (VRI) to begin evaluating the SRP system. VRI was instrumental in developing the SRPs and has extensive experience evaluating programs similar in both nature and scope to the Virginia SRP system.

## Goals of the Effectiveness Study

The purpose of this study is to evaluate the SRP system against its own unique set of objectives. The SRPs were designed to aid board members, staff and the public in a variety of ways. An effectiveness study would seek to examine whether or not the SRPs were successful, and if not, what areas require improvement. Currently, the goals of this effectiveness study include:

- Striving toward consistency, proportionality and neutrality in sanctions
- Constraining undesirable outcomes of SRPs (increased workload, etc.)

---

<sup>1</sup> Researchers have made formal presentations to health and occupational regulatory boards in Colorado and South Carolina, and have presented at the Federation of State Medical Boards (FSMB), Council on Licensure, Enforcement and Regulation (CLEAR), Citizen Advocacy Center (CAC), Council of State Governments (CSG), Association of State and Provincial Psychology Boards (ASPPB), and the Virginia Board of Accountancy.

- Examining whether or not SRP training has been adequately provided
- Examining current agreement monitoring and board feedback practices
- Re-examining/modifying SRP worksheet factors and scoring weights
- Re-examining/modifying SRP sanction recommendation thresholds
- Determining how board polices fit within SRPs (CCA's, PHCOs, Formal Hearings)
- Identifying unintended consequences and outcomes of SRPs

## Historical Background

In April 2001, The Virginia Board of Health Professions (BHP) approved a work plan to conduct an analysis of health regulatory board sanctioning and to consider the appropriateness of developing historically-based sanctioning reference points for boards to use in disciplinary cases. Criticism had come from respondents, attorneys, public officials, the public, and others suggesting that sanctioning was too harsh, too lenient, or inconsistent over time. Some had indicated that sanctioning variation could be attributed to other undesirable influences, such as Board member ID or Board composition, respondent race or ethnicity, attorney presence, or geographical location of the Board hearing. The BHP decided that an analysis should be conducted to determine if these assertions were true, and what measures should be taken to rectify them.

Data collection and analysis began in 2002, and has continued in an effort to examine each individual health regulatory board. The results offer insight into the relative importance of each factor and show which respondent and case factors are influential in sanctioning. With this empirical information, eight SRP manuals have been developed for ten Boards (the three behavioral sciences Boards share one manual) with assistance and input from each Board and staff. The SRPs provide worksheets that score a respondent on a set of factors that can be tallied to arrive at a sanction recommendation that reflects past practice. Thus, the SRPs help ensure similarly situated respondents are handed down similar sanctions.

Recognizing the complexity and difficulty in sanction decision-making, Board members and staff have indicated that for any sanctioning reference system to be successful, it must be *“developed with complete Board oversight, be value neutral, be grounded in sound data analysis, and be totally voluntary”*—that is, the system is viewed strictly as a Board decision tool<sup>2</sup>. With this in mind, the Board of Health Professions cites the following purposes and goals for establishing Sanctioning Reference Points:

- Making sanctioning decisions more predictable
- Providing an education tool for new Board members
- Adding an empirical element to a process that is inherently subjective
- Providing a resource for Board staff and attorneys (both sides)
- “Neutralizing” sanctioning inconsistencies
- Validating Board member or staff recall of past cases
- Constraining the influence of undesirable factors—e.g., Board member ID, overall Board makeup, race or ethnic origin, etc.
- Helping predict future caseloads and need for probation services and terms
- Provide feedback to BHP and individual Boards

<sup>2</sup> Department of Health Professions Internal Committee & Staff, Fall 2001 organizational meeting.

67

## SRP Implementation Timeline

The implementation of Sanctioning Reference Points for Health Regulatory Boards has taken approximately seven years. It should be noted that during this time, researchers were performing a variety of other agency tasks. Therefore, SRP implementation did not require a continuous seven years of full time work. Below is a brief timeline of activities that concluded with SRP development for eleven VA Boards. It is anticipated that the remaining two Boards will implement in early 2010.

Spring 2001	Board of Health Professions adopts work plan to conduct systematic analysis of board sanctions and to derive reference points for board members and an educational tool for respondents and the public.
January 2002	Interviews with current and past board members, counsel, staff and members of the Attorney General's office to qualitatively glean information about the boards' past sanctioning, future goals, and expectations about uses for Sanctions Reference Points.
April 2002	Analyze results of interviews and present for feedback from respective boards and Board of Health Professions. In conjunction with boards and staff, develop and obtain approval from the boards on objective scaling for subjective factors.
May 2002	Finalize data collection instrument for obtaining sanctioning information from case files, minutes, notices. Data collection and keying begins.
October 2002	Compile, merge, clean databases.
December 2002	Determine statistical significant factors through multivariate analyses, report the results of analysis showing the relative importance of each factor, determine which factors the board wishes to retain as <i>appropriate</i> and exclude as <i>inappropriate</i> .
January 2003	Introduce board feedback into the statistical model and revise statistical models, use analysis to predict sanctioning outcomes, present results back to board members.
February 2003	Begin sanction reference point worksheet development for Medicine Board.
May 2003	Finalize sanctioning worksheets with sanction decision grids which provide for simultaneous consideration of offense, respondent, and prior record factors deemed appropriate by the board.
June 2003	Pharmacy data collection and analysis begins.
January 2004	Repeated the same steps as detailed above (for Medicine) for other boards.
January 2005	Beginning of ongoing monitoring of sanctioning worksheets for all implemented boards.
August 2004	Virginia Board of Medicine's Sanctioning Reference Points Manual is adopted. Training sessions are held for board members, staff, enforcement and adjudicative staff, the press, and private Bar. (Manual posted on the Board of Medicine's Guidance Document website)
December 2004	Pharmacy manual and worksheet complete
July 2005	Board of Dentistry adopts and begins implementation
May 2006	Board of Nursing adopts and begins implementation.
July 2006	Adapt methodology for boards with much smaller case volumes Funeral Directors & Embalmers, and Optometry. The same approach of gleaning data from the computer database, interviews, case files, minutes, notices, is applied. Smaller boards also use larger board's analysis to help determine which offense and respondent factors guide worksheet development. Resultant systems are tailored to the needs of the individual boards.
November 2006	Board of Veterinary Medicine adopts and begins implementation
March 2007	Board of Funeral Directors and Embalmers adopt and begin implementation.
November 2007	Board of Pharmacy adopts and begins implementation
January 2008	Adapt methodology for boards with similar culture: Counseling, Psychology, and Social Work. The same approach of gleaning data from the computer database, interviews, case files, minutes, notices, is applied. These boards also use larger board's analysis to help determine which offense and respondent factors guide worksheet development.
December 2008	Board of Optometry adopts and begins implementation
June 2009	Board of Counseling adopts and begins implementation Board of Psychology adopts and begins implementation Board of Social Work adopts and begins implementation
November 2009	Board of Physical Therapy adopts SRPs

## Methods for Measuring the Effectiveness of Sanctioning Reference Points

The focus of this study is to determine how well the SRPs have performed utilizing three objective criteria that provide a balanced conceptual framework for the study; consistency, proportionality, and neutrality.

### Consistency

*Are similarly situated respondents treated the same way in terms of sanctions handed down?*

Consistency in sanctioning attempts to address the following question: "To what extent do similar respondents and offenses receive similar sanctions?" One of the goals of SRPs is to make concepts like "similarly situated" measurable. For example, given a combination of offense and respondent factors on the Board of Medicine's Patient Care worksheet, a respondent falls within a certain grid cell. Being in the same grid cell carries the implication that those respondents are comparable in terms of factors deemed relevant in sanctioning, and hence, should receive similar penalties.

*What methods can be employed to evaluate consistency?*

The first method involves examining how a broad range of factors related to respondent and case characteristics (independent variables) predict sanctioning outcomes (dependent variables). Examples of factors that can potentially influence sanctioning include, but are not limited to: prior board history, substance abuse, gender, region, corrective action, attorney involvement, and patient injury. Depending on the presence of these factors, respondents could be eligible to receive sanctions ranging from "no sanction" to "loss of license".

A second method for evaluating consistency relies on examining SRP agreement rates. Before initial implementation, large samples of previously disposed cases were scored on the newly developed worksheets in order to test the accuracy of SRP recommendations. Another way researchers will evaluate consistency is to determine the degree to which agreement rates fall within the worksheet recommended ranges. Monitoring agreement with SRPs and departure reasons is a separate component of this evaluation.

### Proportionality

*Are the most serious cases getting the most serious sanctions? Conversely, are less serious cases getting less serious sanctions?*

Sanctioning Reference Points (SRP) provide an empirical point system that links offense and respondent characteristics to appropriate sanctions.<sup>3</sup> In order for rational sanctioning to occur, the proportionality of offense to sanction must be accurately represented by the point system. Inaccurate or unproven numerical proportions could lead to more serious offenders receiving less serious sanctions, and vice versa. Thus, the completed SRP worksheets must be evaluated to ensure that the point values are numerically sound.

---

<sup>3</sup> See *Sanctioning Reference Points Instruction Manual*, July 2004, Virginia Board of Medicine.

*What methods can be employed to evaluate proportionality?*

Using the prior history factors as an example, a methodology for determining proportionality can be explained. The worksheets have a point value assigned for a prior board order, with respondents receiving additional points if that prior order is similar to the current offense. A cumulative building of points for these factors ensures a more severe sanction for a respondent that not only has a prior record, but one that includes behaviors similar to the current case circumstances. The question becomes “Do the intended differences in sanctioning outcomes correspond to actual factors scored on a worksheet?” It is anticipated that higher scores on case type, respondent and prior record factors will be associated with an increased likelihood of receiving more severe sanctions (i.e. loss of license).

In order to answer the aforementioned question, data collection may be necessary to refine the terms that are part of a specific sanction in a specific case. Additionally, data on case circumstances may be needed to differentiate between the egregiousness of violations. Proportionality will rely mainly on those respondents who received sanctions at opposing ends of the continuum. “Middle ground” sanctioning thresholds, with their relatively wide ranges, will make it difficult to evaluate proportionality in any meaningful way.

### Neutrality

*Do “extra-legal” factors continue to affect sanctioning?*

Neutrality addresses the issue that sanctions could differ based on specific “extra-legal” characteristics of the respondent or case. For example, older respondents or those with attorneys could receive different sanctions even when other worksheet factors remain constant. For this reason, researchers will attempt to delineate the effects of any unwarranted disparities that the SRPs are intended to prevent—those resulting from the respondent’s gender, attorney involvement, or age.

*What methods can be employed to evaluate neutrality?*

Neutrality is traditionally the most difficult criteria to measure when differentiating among sanctioning decisions. For this phase of the efficacy study, researchers will employ an approach similar to what was used when SRPs were first developed. Beginning with cases that have already been closed using SRP worksheets, data will be collected on extra-legal factors such as gender, age, attorney representation and region. In order to gather these pieces of information, researchers will review case orders and minutes which show persons present at hearings and give information translatable to gender (referring to the respondent as “he” or “she”). Researchers will also obtain information from the department’s data collection system, L2K, which will provide the respondent’s date of birth (translatable to age) and region. Once data collection is complete, statistical analysis will be used in order to determine the presence of any “extra-legal” factors still influencing sanctioning. Data collection and analysis is expected to take six to eight weeks.

70

## Examining SRP Agreement Monitoring

*“Worksheets and coversheets are to be completed in all cases resolved by a Pre-Hearing Consent order or any informal conference including those conducted by special conference committees or agency subordinates. The resulting worksheets are collected and analyzed by VisualResearch, Inc. and quarterly reports are provided to the Board of Health Professions.”*

- Sanctioning Reference Points Manual, Board of Nursing

Each quarter, completed coversheets and worksheets should be obtained and logged into a database. These cases are to be analyzed based on overall agency agreement rate and by board. The database should include a variety of case factors: case number, board, case type, SRP recommendation, actual sanction handed down, whether the sanction handed down was a departure (high or low), and any cited departure rationale.

Currently, over one thousand worksheets have been submitted from various boards. The agency continues to have an overall agreement rate of approximately 80%. Each board with adequate cases for review should have an agreement rate comparable to the agency overall. For example, a board may have a low agreement rate due to the completion of very few worksheets and one departure.

The effectiveness study should incorporate the examination of the SRP worksheet collection process as well as other methods for reporting information back to BHP and individual boards. As stated above, the analysis of data from implemented boards was intended for report to BHP quarterly. Researchers would examine both the extent to which this is being done, and if individual boards are aware of their agreement rates.

Furthermore, the data used in the evaluation is only reliable and valid if the SRP worksheet data reported by boards is of high quality. Therefore, an assessment of the reliability and integrity of completed worksheets and coversheets should be included. This piece of the study would provide information regarding whether actual case files and worksheets and/or coversheets match up. Simultaneously, information regarding the accuracy and completeness of worksheets and coversheets could be gathered. This would entail a brief survey of the worksheets and coversheets returned for incorporation onto a board's reportable file of cases closed by violation using SRP worksheets.

Lastly, agreement rates for each board have been reported as an overall percentage of cases. This leaves many older “outlier” cases in the sample, giving a potentially biased average for those boards which implemented SRPs earlier in their program. Researchers encourage an examination of more valid methods of reporting. Other alternatives include:

Rolling Average – The percent of cases in agreement for a standard time period. For instance, the percent of cases that agreed in the past year (6 months, 18 months, etc). This method may allow for a relatively large amount of cases and reduce the number of older cases in the sample.

Quarterly- The rate of agreement on completed worksheets for a given quarter. This method would eliminate older cases from the sample, however using this method may not report any cases for certain quarters.

#### *Examining Agreement Monitoring - Departure Reasons*

In the Sanctioning Reference Points system, compliance is completely voluntary. SRPs are fundamentally guidelines; thus, boards use them as reference tools and may choose to sanction respondents outside the recommendation. In instances where the board feels a departure is necessary, it is encouraged to depart and provide a brief explanation as to the reason. During training, board members were informed that the departure reason provided would supply researchers with critical information on SRP accuracy and information for future changes to the SRP system.

Therefore, another purpose of monitoring the progress of the SRP agreement rates lies in the departure results. The three boards with the largest volume of cases (Medicine, Dentistry, and Nursing) implemented SRPs more than three years ago. Since that time no evaluation of departure reasons has been carried out. Researchers will evaluate departure results so as to recommend modifications to worksheets so that they reflect the most current practices.

#### **SRP Training Issues**

Upon adoption of the SRP manual as a guidance document, each board's members, Executive Director, and administrative staff were trained on its use. In 2004, DHP's administrative proceedings division, attorneys from the AG's office and the private Bar were trained in the Board of Medicine's SRP manual. Since full board training, some boards have new Executive Directors, while other boards have new support staff. It is not known to what extent any new staff has been trained on SRP use and procedure. Discussions with current board staff indicate very little, if any, training has occurred.

There has been significant turnover of board members since training began. The extent to which new members were trained by existing members or staff is unknown. During the five year period since the first manual was implemented, no board members or staff have been formally trained or re-trained by VisualResearch, Inc (VRI) staff. However, VRI maintains contact with board staff, providing consultation and problem solving as needed. Informally, VRI has provided ad hoc training to staff and continues to make efforts to improve SRP procedure.

This lack of formal training fosters potential problems in correctly completing the worksheets, choosing the appropriate recommended sanction, and proper handling of the completed worksheets and coversheets. These issues are those which are most critical to properly administering a sound SRP system.

## Additional Evaluation Issues

### *Formal Hearings*

The SRP system, as applied today, relates only to newly generated cases ending in violation. It does not apply to those cases which deal with compliance issues, actions by other boards, or mandatory suspensions. Additionally, in 2004, it was the opinion of the Attorney General's office to exclude the use of SRPs at formal hearings.<sup>4</sup>

An evaluation will include the possibility of broadening the scope of SRP use to include formal hearings. This evaluation would examine issues such as the current appeal rate for cases which closed using the SRP worksheet or examining the potential for other negative consequences of using SRPs at the formal stage. Also, an updated opinion from the Attorney General's office will be solicited, as the original opinion was given before any board had started using the SRPs.

### *Confidential Consent Agreements*

Legislation enacted in 2003 gave boards the ability to resolve certain allegations of practitioner misconduct by means of a Confidential Consent Agreement (CCA). CCAs could be used by any board in lieu of public discipline once certain criteria were met. For a case to be considered for a CCA, three conditions must be present:

- the case must involve minor misconduct and non-practice related infractions
- there can be little or no injury to a patient or the public
- there can be little likelihood of repetition by the practitioner

SRPs do not recommend sanctions for cases which end in a CCA. However, by statute, the existence of a past CCA may be considered in future disciplinary proceedings. The extent to which CCAs are scored as prior history when using an SRP worksheet should be evaluated as part of the effectiveness study.

The enactment of legislation regarding use of CCAs occurred while some boards were developing SRPs. Therefore, those boards do not have CCAs incorporated into each of their SRP systems. Consequently, it is possible that agreement rates are weighted by the worksheets' inclusion of cases that now have the potential for receiving a CCA. More specifically, when older boards were studied, all cases within a given time frame were analyzed. It is reasonable to expect that some of the cases analyzed and used to create the SRP worksheets would today receive a CCA, thus creating the potential for a biased worksheet. This effect of CCAs on sanctioning practice should be considered during this study with the goal of potentially updating older boards' worksheets.

The Boards of Medicine, Dentistry and Nursing were the first to implement SRPs, and researchers suggest that these boards be the first examined with regards to the effect of CCAs on worksheet performance.

### *Pre-Defined Sanctions*

The Board of Optometry removed certain violations with pre-defined sanctions from use on SRP worksheets. The following information appears at the top of Optometry's worksheet:

---

<sup>4</sup> Inter-Office Memorandum, Office of the Attorney General. "APA Inquiry Involving the Board of Medicine and Sanctioning Reference Points." Sept. 9, 2003.

The following violations do not qualify for a CCA and are prescribed the following sanctions:

- CE 2nd offense: \$300 fine first missing credit hour, \$200 each remaining hour
- CE 3rd or more: higher fines, additional sanctions, and pay hourly fees at a rate commensurate with 2nd time CE offenders
- PD 2nd offense: \$500 fine, pay renewal fees, reprimand
- PD 3rd offense: \$1000 fine, pay renewal fees, reprimand
- PD 4th or more: higher fines, additional sanctions, and pay renewal fees

Researchers will examine the effectiveness of this level of transparency by determining whether or not the number of violations indicated with pre-defined sanctions has changed. Researchers will also attempt to determine if other boards have begun using pre-defined sanctions since the implementation of SRPs. One of the reasons for this in-depth examination is to test whether or not these sanctions should be incorporated onto each board's worksheet.

#### *Dissemination of Materials*

The dissemination of completed worksheets and coversheets is a point of confusion within the SRP system. Early in the implementation process, it was decided that completed worksheets and coversheets were to be sent to the respondent with the final order, with the worksheet and coversheet being confidential under §54.1-2400.2 of the Virginia Code. Since that time, the question of what to do with completed worksheets has been a source of debate among board members, staff and attorneys. Researchers are aware of inconsistent practices among boards regarding this matter (see Appendix A). Researchers will evaluate the need for a standardized policy and incorporate any more recent decisions into training in an attempt to have all boards practicing in the same manner.

#### *Unintended Outcomes*

Researchers have been asked whether or not the SRPs have contributed significantly to the variety of disposition methods employed by DHP: violation, no violation, undetermined, CCA, etc. Currently, it is unknown if the implementation of SRPs has had any effect on the method or speed with which a case is processed. Some board staff have suggested that the number of informal conferences were decreasing due to SRPs, but no formal evaluation has been done to substantiate this. During the evaluation, researchers will examine the effect of SRPs on disposition method.

#### *Board Member and Staff Experiences*

Evaluating board member and staff experiences with the worksheets provides qualitative data from those actually using the SRPs in everyday practice. Researchers would develop a survey to be answered anonymously or by face-to-face interview. Probative questions regarding use and perceived effectiveness of the SRPs will be asked. Some questions might include:

- Do you feel SRPs had a positive or negative impact on case processing?
- In your experience, have you seen new board members make the transition to sanctioning respondents more easily?
- Do you feel that SRPs have improved an inherently difficult process?

74

- Do you feel there has been a lack of training?
- In your opinion, are the sanctioning recommendations too harsh? Too lenient?
- Do you feel your board's worksheet reflects current practice?
- Are the case types available for scoring the same case types presented?
- What can be done to improve the system?
- Do you feel the system is worthwhile?

Answers to such questions are relevant because disciplinary hearings consume a large portion of agency resources and sanctioning decisions have such a profound impact on healthcare practitioners and on the public's safety.

### **Anticipated Evaluation Obstacles**

As with any empirical evaluation, researchers should anticipate several obstacles. Should the boards be studied as separate entities, as they were when the SRPs were designed, small sample sizes may limit the availability of cases for study. However, many of DHP's smaller regulatory boards may provide useful input related to modifying SRP worksheets or procedures, even without being able to provide sufficient quantitative data.

The boards that have larger numbers of cases<sup>5</sup> (Medicine, Dentistry and Nursing) are defined by sanctioning cultures and practices that are different from smaller boards. This makes it difficult to add their data into the study without separating them from other boards. For instance, Nursing does not make use of monetary penalties as a general rule in sanctioning, whereas it is common in Dentistry. Likewise, certain factors appear on the Dentistry worksheet that do not appear on other boards' worksheets. For these reasons, it is advised to assess boards with larger sample sizes individually.

Additionally, the data collected by the agency does not always reflect the extra-legal factors that are ideal for examination. L2K, the agency's data management system, has no way to record certain features key to the concept of defining neutrality (for example, respondent gender or race). Additionally, more specificity on the types of terms given and the amounts of monetary penalties are not specified in a consistent and reliable format.

---

<sup>5</sup> See Appendix B.

# Appendices

76

**Appendix A: SRP Procedures Overview**  
 (as of July 2008)

	Medicine	Nursing	Nurse Aide	Dentistry	Vet Med	Pharmacy	Funeral	Optometry
SRP posted to the web as Guidance Document	yes	yes	yes	yes	yes	yes	yes	yes
Use of SRP referenced in the notice	yes	yes	yes	yes	yes	yes		yes
Use of SRP referenced in the Cover Letter sent with Final Order	yes			yes		yes		
Completed Worksheet sent with Final Order	yes			yes		yes		
Completed Coversheet sent with Final Order	yes			yes		yes		

77

**Appendix B: SRP Caseload and Agreement Rates for Implemented Boards (2004-2010)**

<b>Board</b>	<b>Total Number of Cases</b>	<b>Overall Agreement Rates</b>
BHP Overall	1148	80%
Medicine	115	72%
Dentistry	91	82%
Nursing (Nurses and CNAs)	839	82%
Funeral	16	75%
Veterinary Medicine	52	85%
Pharmacy	30	67%
Optometry	3	33%
Psychology	2	100%
Counseling	0	n/a
Social Work	0	n/a
Physical Therapy	0	n/a

78

NOV 13 2009

Pharmacy Coupons Pose Unnecessary Health Risks for Patients and Place  
Undue Burden on Pharmacists

DHP

November 10, 2009

Virginia Board of Pharmacy  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico, VA 23233-1463

Dear Board Members,

My name is Jonathan Carter and I am a student pharmacist at the Medical College of Virginia Campus of Virginia Commonwealth University. I am writing today to express my concern with the widespread use and abuse of pharmacy coupons. Such coupons, which promise gift cards of varying amounts with the filling of a new or transferred prescription, not only demean our great profession of pharmacy, but more importantly, pose a health risk to the patients who use them.

While working as an intern at CVS and Kmart pharmacies, I have frequently been disappointed to hear a patient explain to me that he or she does not know where his or her prescription is on file. In fact, in one instance, a previously-loyal patient whom we had not seen in months called our pharmacy in tears, exclaiming that she had no idea where any of her prescriptions were on file. She proceeded to beg my head pharmacist to call every pharmacy in a 10-mile radius to request any and all prescriptions for her and her family members so that she could have the safety and security that comes with filling all of her prescriptions with one pharmacist at one pharmacy.

My fear is that unfortunate occurrences similar to this one will continue to transpire as long as patients have access to these pharmacy coupons. This particular incident not only cost the patient unimaginable stress, but also resulted in the patient and her family members missing multiple days of necessary drug therapy for chronic disease states.

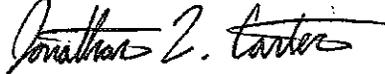
Another concern I have with the widespread use of these coupons is one that could jeopardize my future licensure as a pharmacist. As patients utilize more and more pharmacies, spreading their medications around, it becomes increasingly more difficult for pharmacists to perform duties outlined under the OBRA act of 1990. A satisfactory prospective and/or retrospective DUR process becomes impossible, especially if the patient is a cash customer (which a large portion of those using the coupons are). Because I may be liable for any negative health outcome that may result from me dispensing a medication to a patient, I will be forced to dispense every prescription with the fear that I may not have access to a serious drug interaction that may be present. While I can and

79

will take the time to question the patient about any concerns I have, it is most often the case that the patient cannot recall his or her other medications. As a student pharmacist in my final year of a PharmD program, this health risk to the patient is extremely concerning to me.

I understand that in economic situations such as the current one, it is advantageous for patients to find ways to save money and lower expenses, but I do not believe that these savings should come at the cost of their health. Because, in the end, complications from unfavorable drug therapy outcomes will cost the patient and the health care system much more than any gift card could ever cover. As a student pharmacist and pharmacy intern, and on behalf of every student pharmacist, pharmacist, and district pharmacy supervisor that I have spoken with regarding this issue, I implore you to take action to ensure that the use of these pharmacy coupons is prohibited in our great Commonwealth.

Sincerely,

A handwritten signature in cursive script that reads "Jonathan Carter".

Jonathan Carter  
PharmD Candidate, 2010  
Virginia Commonwealth University School of Pharmacy

30