COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

Tentative Agenda of Meeting

September 3, 2008

9:00AM

TOPIC	PAGE(S)

Call to Order: David Kozera, Chairman

- Welcome and Introductions
- Reading of emergency evacuation script
- Approval of Agenda
- Approval of previous Board meeting minutes: 1-70
  - June 4, 2008 Board Meeting
  - June 4, 2008 Formal Hearings-Panel
  - June 17, 2008 Ad Hoc Committee-Drug Donation
  - June 19, 2008 ICC-Robotic Pharmacy System
  - June 25, 2008 SCC
  - July 1, 2008 TCC
  - July 17, 2008 SCC
  - July 23, 2008 Ad Hoc Committee-Drug Donation
  - July 31, 2008 SCC
  - August 14, 2008 TCC

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

DHP Report: Sandra Whitley Ryals, Director 71-72

Legislation:

- update on legislative proposals-Scotti Russell, Elaine Yeatts

Regulations: Elaine Yeatts

- Update on regulation processes 73
- Adopt emergency regulations on drug donation program 74-77
- Adopt exempt PPG regulations 78-86
- Adopt proposed regulations on unprofessional conduct 87-89

Miscellaneous:

- Approval of changes to Guidance Document 110-25 90-91

Reports:

- Report on Board of Health Professions-Jennifer H. Edwards
- Executive Director's Report-Scotti Russell
  - award of Technician Examination Contract
  - report on disciplinary program-Cathy Reiniers-Day
  - report on licensing, inspections, website-Caroline Juran

Consideration of consent orders (if any)

Formal Hearing: Richard B. Lakes 92-93

Adjourn

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

Following lunch, a panel of the Board will convene for the purpose of conducting formal hearings.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 4, 2008
Second Floor
Conference Room 2

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

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

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Jennifer H. Edwards
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT: Gerard Dabney

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Howard M. Casway, Senior Assistant Attorney General
Emily Wingfield, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

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

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

APPROVAL OF MINUTES: The Board reviewed draft minutes for the March 12, 2008, Board Meeting; March 12, 2008, CQI Committee Meeting; March 18, 2008, Summary Suspension Telephone Conference Call; April 16, 2008, Summary Suspension Telephone Conference Call; May 1, 2008, Summary Suspension Telephone Conference Call; and May 13, 2008, Summary Suspension Telephone Conference Call. With no changes to the minutes, they were approved as presented.

PUBLIC COMMENTS: There were no public comments.

ELECTIONS: Dave Kozera was unanimously elected Chairman for the term July 1, 2008 through June 30, 2009 (nomination by Stredler, second by

Brown). Mickey Stredler was unanimously elected Vice-Chairman for the same term. (nomination by Yi, second by Ross).

REPORT:
DHP Director, Sandra W. Ryals

Ms. Ryals reported to the Board that Virginia had been named one of the best governed states, ranked in the top 3 with an overall score of A- and the only state to receive a full A ranking in human resources.

She also reported that Governor Kaine has begun a new initiative related to one-stop shopping via a web portal for the formation of businesses.

Ms. Ryals gave the Board an update on the three measures for the DHP performs initiatives. She reported that the Board of Pharmacy had received a 98% approval rating in the customer satisfaction category and a 100% rating for issuing initial licenses within 30 days of receipt of a complete application. She reported that with respect to the patient care cases completed in 250 working day measure, the department has made significant progress, but still has work to do to meet this goal. She stated that a lot of work has been done and is ongoing to clean up the old case load, measures being implemented to prevent the reoccurrence of such a backlog, and efficiency measures taken to process new cases within the timeline. Neal Kauder, with Visual Research, is working with the department to use some of the same tools that were developed nationally, for use by the court system, to measure and report outcomes related to the processing of cases at DHP. Specifically, we will be looking at clearance rates, time to disposition, and age of active pending caseload. These measures will be able to be broken out by board as well as shown for the department as a whole. At a future meeting once these measures are in place, she will provide a demonstration for the Board.

Lastly, Ms. Ryals briefly described the department initiative to ultimately go paperless and the move to a new product to assist with this initiative called Documentum.

LEGISLATION UPDATE:

Ms. Yeatts explained the process for development of legislative proposals. She stated that the Board would be reviewing draft legislation today, and if it wanted to go forward with the proposals, it should pass a motion to pursue the legislative proposal. The proposals are then sent to interested parties for comment, and then to the Secretary's office for a recommendation. Ms. Yeatts stated that the proposal could become part of the Governor's legislative package; the Department could receive permission to seek a patron to put in a bill, or possibly not receive approval to proceed.

- Mandatory reporting

The Board reviewed a draft legislative proposal that had been

developed and recommended by the CQI committee that will require reporting of certain known information to the Board of Pharmacy. Similar to current requirements for hospitals in §54.1-2400.6, the proposal would require pharmacy owners, pharmacist, pharmacy interns, and pharmacy technicians to report certain information, gained within their professional capacity, about a pharmacist, pharmacy intern, or pharmacy technician, to include possible impairment, incompetence, negligence, substance abuse or diversion, or unethical, fraudulent or other unprofessional conduct.

The Board requested that "employed by the pharmacy" be removed from subsection A1.

Motion:

The Board voted unanimously to approve the draft legislative proposal as amended and forward it to the Director for inclusion in the agency's legislative submissions (motion by Beckner, second by Stredler; Attachment A).

- CQI requirement

The Board reviewed a draft legislative proposal to require pharmacies to have a continuous quality improvement program in place to analyze dispensing errors and make process improvements based on the analysis to reduce the possibility of errors. The proposal was recommended by the CQI committee. The draft would also require that the Board promulgate regulations to further define the elements of such a program. The Board members requested that the draft be more descriptive of the purpose of a CQI program, and that the description clearly require some action by the pharmacy as a result of analyzing errors. It was also requested that the federal law citation for the Patient Safety Act of 2005 and subsequent regulations be included in the draft. Additionally, the Board wanted to require that the CQI program apply to non-resident pharmacies.

Motion:

The Board voted unanimously to approve the draft legislative proposal with the amendments requested by the Board and forward it to the Director for inclusion in the agency's legislative submissions (motion by Abernathy, second by Brown; Attachment B).

- Scheduling

Ms. Russell stated that a placeholder bill would be put in to address any final scheduling changes from DEA before the 2009 session. There are several drugs that are in the proposed stage of scheduling, but have not yet been made final.

REGULATION UPDATE:

- NOIRA Unprofessional

Ms. Yeatts stated that the NOIRA to allow the Board to propose

Conduct

rules defining unprofessional conduct has just been approved by the Governor's office for publication, and that the publication date will be June 9 with public comment until July 9. The Board can then adopt proposed regulations at the September meeting. Ms. Russell stated that staff would have draft regulations ready to be discussed and adopted at that meeting. She further reminded the Board that it had briefly discussed the content of the regulations at a previous meeting, and had requested staff bring draft regulations to this meeting, as there did not appear to be sentiment on the part of the Board to have the Regulation Committee meet for this purpose first. There was agreement by the Board members that the Regulation Committee did not need to meet.

- Proposed Regulations resulting from the periodic review

Ms. Yeatts stated that the proposed regulations and the package had been sent to the Department of Planning and Budget for its review, and that she and Ms. Russell had met with DPB representatives to go through the regulation changes and it is expected that DPB's analysis will be completed soon. She further explained the subsequent review process by the Secretary and Governor before we could publish the proposed changes for public comment.

- Fast-Track regulations related to nuclear pharmacies

In response to a request from the Virginia Department of Health that the Board of Pharmacy amend its rules related to nuclear pharmacy to conform to changes made in VDH rules, Ms. Yeatts, Ms. Juran and Ms. Russell met with Mike Welling, VDH representative, to discuss the requested changes. After some discussion with Mr. Welling, staff and Mr. Welling agreed upon suggested changes to better conform the Board of Pharmacy regulations with VDH regulations and requirements of the U. S. Nuclear Regulatory Commission. Several of the current regulations were outdated and in conflict. Requirements for nuclear pharmacists to certify credentials to the Board of Pharmacy are duplicative since VDH is already ensuring the proper qualifications before it licenses the facility to handle radioactive material. The board reviewed a draft of amendments to the current regulations that will satisfy VDH concerns and remove any duplication of effort in licensing. Ms. Yeatts stated that because all changes were not due to non-conformity with other law or regulation, it did not meet the criteria for an exempt change, but that the changes did meet the criteria for a fast-track process.

Motion:

The Board voted unanimously to adopt the draft changes as presented and proceed with the fast-track process (motion by Abernathy, second by Beckner; Attachment C).

- Exempt change to volunteer practice regulation

The Board reviewed a draft exempt amendment to 18VAC110-20-75 to conform Board regulations to new statutory provisions for

volunteer practice.

Motion:

The Board voted to adopt the exempt amendment to the regulation (motion by Beckner, second by Kozera; Attachment D).

- Emergency regulations to establish new renewal dates

The Board reviewed draft emergency amendments to both 110-20 and 110-50 to establish license expiration dates for all facilities as a result of legislation that takes effect July 1, in which the expiration dates are removed from statute. Currently, all licenses issued by the Board expire on December 31 annually. This has created excessive workload on staff during this time of year. The legislation was sought for the purpose of being able to more evenly distribute this workload. The proposed language would have pharmacy permits and non-resident pharmacy registrations expire on April 30 annually, and all other facility permits, licenses, or registrations expire on February 28 annually. This is a relatively even split of the numbers, still allows for the collection of all renewal fees in the next fiscal year, and provides a little additional time for non-resident pharmacies to meet new requirements of law to have a Virginia licensed PIC designated.

Motion:

The Board voted unanimously to adopt the emergency regulations as presented (motion by Beckner, second by Yi; Attachment E).

MISCELLANEOUS:

- Request from the Virginia Department of Health concerning expedited family planning

The Virginia Department of Health (VDH) asked the Board of Pharmacy to review a protocol for expediting the initiation of contraception when a client comes to the clinic seeking contraception, but the clinic is not able to have a complete physical examination done on that day. VDH is requesting an interpretation from the Board of Pharmacy as to whether a new protocol for an "expedited" visit would satisfy the requirements of § 54.1-3303 related to a bona fide prescriber-patient relationship for the purpose of having contraception started at the time of that first visit. Jim Burns, MD, Deputy Commissioner for Public Health Programs and CIO was present for this discussion. Dr. Burns previously provided the Board with a copy of the protocol and associated form. Dr. Burns stated that under the protocol, if a client comes in seeking or needing contraception, but the clinician (prescriber, either a physician or nurse practitioner) is not able to perform a full physical examination that day, the nurse will measure height and weight of the patient, take their blood pressure, and obtain a history from the patient. The history includes all the items listed on the form. The clinician will then review the documentation of the nurse, and make a determination of the appropriateness for prescribing and dispensing contraception at that time. A follow-up appointment will be scheduled not later than three months from that date, and if contraception is dispensed, only the amount needed for the time until the follow-up visit will be dispensed, not to exceed a three-month supply. Clients will only be afforded this opportunity once. If they do not make the follow-up visit, further contraception will not be provided. In response to questions of the Board members, Dr. Burns provided the following additional information. The nurse conducting the preliminary examination and history will be an RN. The nurse does ask about history of blood clots. The clinician will personally do any dispensing and the protocol will be amended to include that information.

Motion:

The Board voted unanimously that the expedited family planning protocol submitted by the Virginia Department of Health (VDH) for prescribing and dispensing prescription contraception is in the best interest of public health, and in conformity with §54.1-3301 and § 54.1-3303 of the Code of Virginia, satisfies the requirements for establishment of a bona fide prescriber-patient relationship, provided the following is assured:

1. **The protocol is followed and this approval is limited to this particular situation;**
2. **The patient and prescriber are both on site at the time of prescribing;**
3. **The RN performs certain physical examination functions to include weight, height, and blood**

pressure, takes a history that includes history of blood clots, and documents findings;

4. **The prescriber reviews the documentation by the RN and makes an assessment whether prescription contraception should be prescribed at that time;**
5. **The follow-up examination with the prescriber is scheduled as soon as possible and the quantity of contraception provided is limited to the time of the follow-up visit not to exceed 90 days; and**
6. **This protocol is only allowed once per patient.**

(motion by Yi, second by Brown; Attachment F)

- Flavoring of Medications

Staff informed the Board that it received frequent calls asking if the addition of flavoring agents to prescription medications constituted "compounding", if the pharmacist would need permission from the prescriber to flavor, and if a pharmacist could flavor a prescription product dispensed by another pharmacy. There was discussion that while this most likely did meet the strict definition of compounding, it was fairly common practice and in most cases in the best interest of the patient by promoting compliance in taking the medication. There were no motions in this matter.

- Guidance Document 110-36, compliance with USP 797

Staff informed the Board that it had already received two requests for extensions from complying with the physical standards of USP 797, and asked how it wanted to handle such requests. Mr. Ison provided a brief summary of the changes to this chapter from the 2004 version, that were published in December 2007, and which took effect June 1, 2008 The current guidance document requires compliance by June 30, 2008. The Board has already given pharmacies a one-year extension to be in compliance, and it considers that pharmacies should have at least complied with the 2004 requirements, if not the 2007 which primarily relate to changes with respect to chemotherapy drug storage in the clean room. Discussion centered on reviewing requests for extensions on a case by case basis, or providing for a blanket one-time extension. It was determined that the blanket extension in the guidance document would be the best way to go, because it would be equitable, and also more efficient. Different deadlines were discussed, but it was considered that four months should be sufficient for any pharmacy to comply as they have been aware of this since at least 2004. It was also requested that the guidance document provide a statement continued non-compliance would be subject to disciplinary action by the Board. The Board discussed assessing a monetary penalty as probably the appropriate action vor this violation, and questioned how much could be assessed. Mr. Casway advised that the Board could assess a monetary penalty not to exceed $5000 per violation, but could impose less. There was

discussion as to what constituted a single violation. The violation is the act of compounding a sterile preparation under conditions that do not meet standards, so conceivably each preparation prepared could constitute a separate violation.

Motion:

The Board of Pharmacy voted unanimously to amend its guidance document to provide for a one-time extension on compliance with physical standards of USP 797 for all pharmacies until October 31, 2008. No further extensions will be allowed, and pharmacies not in compliance by this deadline may be imposed a monetary penalty not to exceed $5000 per violation (motion by Edwards, second by Ross).

- Insulin in Pyxis machines

The Board Chairman tabled this issue until such time as he is able to obtain additional information.

REPORTS:

- BHP Report
  Jennifer Edwards

Ms. Edwards provided a brief update on the Board of Health Professions. At the last meeting, VDH reported to BHP that Title VI of federal law requires any health care providers that receive any federal funds to provide appropriate language services to patients. Providers cannot pass on these costs to patients. VDH does offer services by interpreters by phone 24-7. It also has some routine documents translated on its website.

Additionally VDH is requesting assistance from DHP in promoting its message of hand washing as a deterrent to transmission of communicable diseases.

- Executive Director's Report
  Scotti Russell

  - NABP Annual Meeting

Ms. Russell reported that she, Bobby Ison (voting delegate), Jennifer Edwards, Brandon Yi and Leo Ross attended the meeting held May 17-21 in Baltimore, Maryland. Ms. Edwards, Mr. Yi, and Mr. Ross were not compensated by the Department for their attendance. She reported the following NABP initiatives announced during this meeting:

- NABP has developed a list of websites not recommended for online drugs. The Board will link its website to it.

- The Task Force on Patient Safety issued its report, and has recommended language for CQI programs, and for forms for pharmacies to use to self-audit. This will be helpful to this board if we have legislation passed that needs to be implemented.

- The resolutions were passed as follows:
  1. NABP is to collaborate with stakeholders to develop statutory authority to establish a behind-the-counter class of drugs.
  2. NABP will encourage national standards for tall-man lettering for look-alike drugs.
  3. NABP will encourage uniform standards for pharmacy interns and work with AACP and ACPE to determine a uniform date within the pharmacy curriculum to begin internship registrations.
  4. NABP will establish a task force on uniform prescription labeling requirements.
  5. NABP will establish a task force to study the feasibility of standardizing education and training for pharmacy technicians.
  6. NABP will establish a task force to review medication collection and disposal programs.
  7. NABP will look at ways to inform constituents about the critical nature of abuse of prescription medications by teens and how pharmacists can assist with this effort.

Ms. Russell reported on the following educational sessions held at the meeting:

- Educational sessions:
  1. Program on Teen addiction of prescription and OTC drugs
  2. State and Federal Regulatory Update
     - Pharmacy Technician and Training Act of 2008-grant act-no money
     - E-Prescribing-for Medicaid published-DEA still has not published, NCPCP 8.1
     - Proposed Patient Safety Rule-protections with PSO, privileged and confidential
     - Online Pharmacy Consumer Protection Act
  3. Pedigree Update, speaker from the FBI and Elisa Bernstein from FDA on RFID, etc.
  4. Medicaid Fraud Tamper Resistant Pads
  5. How to Investigate an Internet Pharmacy-defense attorney-VA
  6. Compounding Update-USP

She stated that Virginia was mentioned as a model in two separate continuing education sessions. In one session, "How to Investigate An Internet Pharmacy", the speaker, a defense attorney, touted Virginia as being the only state that had a law (§ 54.1-3303) he would find difficult to defend a client against, in a case involving either prescribing or dispensing in an internet scheme. In a separate session, a representative from USP mentioned that Virginia is the only state that has laws and regulations that set standards for sterile compounding in physician offices.

Additionally, Virginia's prescription monitoring program has a very good reputation nationally. Representatives from three states approached her asking for information and contacts they could use in establishing programs for their states.

- Diane Langhorst

Ms. Russell informed the Board that Ms. Langhorst had not been able to make a Board meeting to receive her plaque since her decision not to seek reappointment to the Board last year. She stated that she had not wanted Ms. Langhorst to go without her plaque any longer so had mailed it to her. She read a card to the Board from Ms. Langhorst, thanking the Board for remembering her in this way, and thanking the Board members for their service to the public.

- Disciplinary Update
  Cathy Reiniers-Day

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of June 3, 2008, and stated that there were 174 cases at the enforcement level, 172 cases at the probable cause level, 11 cases at the informal conference level, 4 cases at the formal hearing level and 8 cases at the APD level. She also provided a more detailed breakdown of the stages and the number of cases of each priority at that stage. Further, for cases at the probable cause level that are now 250+ days, 8 cases are priority B and 41 cases are priority C. Ms. Reiniers-Day reminded the Board that the days counted for the 250+ cases included all stages that the case has been in. Since the March Board Meeting, the Board has closed 70 cases.

- Licensing Update
  Caroline Juran

Ms. Juran reported that the Board issued 661 licenses since the Board meeting held in March. The majority of those licenses issued were for pharmacy interns and pharmacy technicians. Additionally, Ms. Juran reported that Board staff sent a letter in early May to the 541 non-resident pharmacies currently registered with the Board notifying them that the General Assembly passed a law, effective July 1, 2008, which may affect non-resident pharmacies. Specifically, the law will require each non-resident pharmacy to designate to the Board the name and license number of a Virginia licensed pharmacist in charge. This person will be responsible for ensuring compliance with Virginia laws. This requirement does not apply to non-resident pharmacies providing services as a pharmacy benefit manager. Also, the law will require certification by NABP as a Verified Internet Pharmacy Practice Site (VIPPS), or certification by a substantially similar program approved by the Board, if the non-resident pharmacy dispenses more than 50 percent of its total prescription volume pursuant to prescriptions received as a result of solicitation on the Internet, to include solicitation by e-mail. Last, Ms. Juran informed the Board that Ms. Russell was nominated by staff for the Governor's Career Achievement Award. This award is presented to one individual

employed by the Commonwealth who has a record of consistent achievement over time that has significantly improved the efficiency and effectiveness of Commonwealth operations. As a result of her nomination, she was recently recognized by Ms. Ryals and agency staff at a DHP agency event and was congratulated on her many contributions and outstanding performance during the last 30 years of service with the Commonwealth.

- PMP Update
  Ralph Orr

Mr. Orr provided the Board with updated program statistics. The program continues to grow with registrations increasing monthly for both the PMP Data Center and the Online Pain Management Course. Mr. Orr gave highlights of presentations the program has participated in to include a one-day seminar in Norfolk that had an outstanding turnout of providers. He asked the Board to put a note on their calendar for early November 2008 for a Fall Conference to be held in northern Virginia. Mr. Orr reported that the program is very close to finalizing the procurement of software that will allow for 24/7 access to PMP information. It is expected that this enhancement to the system may be available in early fall, with a marketing campaign to be made prior to the implementation date to inform Virginia healthcare providers of this new feature. The enhancement to the program software will provide access to those pharmacies that are open 24 hours a day and on weekends when the PMP is not normally staffed to process requests. Another feature of the 24/7 access is that a response to the request should be received within a minute or less.

FORMAL HEARING

MEMBER ABSENT:

Mr. Beckner left the meeting at approximately noon and was not present for the hearing.

ROBERT A. DAVIS
Pharmacist License #0202-205379

A formal hearing in the matter of Robert A. Davis was held to discuss his petition for reinstatement of his pharmacist license that was mandatorily suspended on November 10, 2004, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Davis appeared and was not represented by counsel.

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

Robert A. Davis testified on his own behalf.

Mr. Kozera and Mr. Ross stated that they work for CVS/pharmacy and didn't know Mr. Davis. Therefore, they could make a fair and impartial decision in this matter. There were no objections from Mr. Davis and the remaining board members.

Closed Meeting:

Mr. Kozera moved, and the Board voted unanimously, to enter into closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Robert A. Davis. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene:

Mr. Kozera moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Yi moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, amended by the Board and read by Mr. Casway (Attachment # 1).

Mr. Kozera moved, and the Board voted unanimously, that Mr. Davis' petition for reinstatement be granted and that his license be reinstated with terms and conditions (Attachment G).

ADJOURN:

With all business concluded, the meeting adjourned at 2:25 p.m.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

Department of Health Professions
2009 Session of the General Assembly

DHP-PHA-#enter proposal number

A bill to enact § 54.1-3316.1 of the *Code of Virginia* to require reporting of known information relating to the practice of pharmacy to the Board.

Be in enacted by the General Assembly:

1. That § 54.1-3316.1 of the *Code of Virginia* is enacted as follows:

§ 54.1-3316.1. Mandatory reporting

A. Every pharmacy owner, pharmacist, pharmacy intern, and pharmacy technician shall report to the Board of Pharmacy within 30 days the following information of which he may become aware in his professional capacity:

1. That a pharmacist, pharmacy intern, or pharmacy technician is in need of treatment or has been committed or admitted as a patient at a health care institution, for treatment of substance abuse or a psychiatric illness that may render that person a danger to himself or the public.

2. Any evidence that indicates a reasonable probability that a pharmacist, pharmacy intern, or pharmacy technician (i) is or may be professionally incompetent; (ii) has or may have engaged in intentional or negligent conduct that causes or is likely to cause injury to a patient or patients; (iii) is or may be mentally or physically unable to engage safely in the practice of his profession; (iv) has or may have engaged in unethical, fraudulent or unprofessional conduct as defined in §54.1-3316 and Board regulations; or (v) has or may have engaged in substance abuse or diversion of prescription drugs. Such evidence shall include, but is not limited to, denial or termination of employment, restrictions imposed on employment, or voluntary resignation in order to avoid investigation or termination.

B. No person shall be obligated to report any matter to the Board if the person has actual notice that the matter has already been reported to the Board.

C. Any person making a report required by this section, providing information pursuant to an investigation, or testifying in a judicial or administrative proceeding as a result of such report shall be immune from any civil liability resulting therefrom unless such person acted in bad faith or with malicious intent.

Department of Health Professions
2009 Session of the General Assembly

DHP-PHA-#enter proposal number

A bill to enact § 54.1-3434.03 and amend and reenact §54.1-3434.1 of the *Code of Virginia* to require pharmacies licensed in Virginia to have a program for continuous quality improvement for the purpose of reducing dispensing errors.

Be in enacted by the General Assembly:

1. That § 54.1-3434.03 of the *Code of Virginia* is enacted and §54.1-3434.1 is amended and reenacted as follows:

§ 54.1-3434.03. Continuous Quality Improvement Program

Every pharmacy shall have a program for continuous quality improvement. The Board of Pharmacy shall promulgate regulations to further define required elements of the program. Such program shall be deemed in compliance with this section if it (i) complies with Board regulations, (ii) provides for a systematic, ongoing process of analysis of dispensing errors and uses findings to formulate an appropriate response and develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors, and (iii) provides for voluntary reporting to a patient safety organization as defined by the United States Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41, 42 USC 216, 299b-21 through 926, 42 USC 299b-21 through 299b-26).

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the

inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies pursuant to §54.1-3434.03 of this chapter.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

2. That the Board shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the Board may provide for a delayed implementation date in regulation.

Project 1359 - none

BOARD OF PHARMACY
Nuclear pharmacies

Part V
Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

~~A. A permit to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist as defined in 18VAC110-20-230. In emergency situations, in the absence of the nuclear pharmacist, he may designate one or more other qualified pharmacists to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals for the immediate emergency and shall document such withdrawals in the control system.~~

~~B. Pharmacies providing ordinary pharmacy services in addition to radiopharmaceutical services shall comply with all regulations applicable to pharmacies in general. Pharmacies providing only radiopharmaceutical services shall comply with all regulations related to physical standards, sanitary conditions and security.~~

~~C.~~ Nuclear pharmacies shall ~~have adequate space and equipment, commensurate with the scope of services required and provided and in compliance~~ comply with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health related to the staffing and operation of the facility.

~~D.~~ B. Radiopharmaceuticals are to be dispensed only upon an order from a ~~practitioner~~ prescriber authorized to possess, use and administer radiopharmaceuticals.

1. Orders shall originate at an institution or healthcare facility licensed to receive and possess radiopharmaceuticals, and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by fax, or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, but must include the name of the agent.

~~E.~~ C. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of §54.1-3410.1 B of the Code of Virginia.

~~F.~~ D. The immediate inner container shall be labeled with: (i) the standard radiation symbol; (ii) the words "Caution--Radioactive Material"; and (iii) the serial number assigned to the order.

~~G. The amount of radioactivity shall be determined by radiometric methods for each individual dose immediately prior to dispensing.~~

~~H.~~ E. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

18VAC110-20-230. ~~Qualification as a nuclear pharmacist.~~ (Repealed)

~~In order to practice as a nuclear pharmacist, a pharmacist shall possess the following qualifications:~~

~~1. Meet Nuclear Regulatory Commission (NRC) standards of training for medically used or radioactive by-product material.~~

~~2. Have received a minimum of 200 contact hours of didactic instruction in nuclear pharmacy.~~

~~3. Attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an approved school of pharmacy.~~

~~4. Submit to the board an affidavit of experience and training meeting the requirements of subdivisions 1, 2 and 3 of this section; documentation of NRC approval as an authorized nuclear pharmacist; or documentation of certification as a nuclear pharmacist by the American Pharmaceutical Association Board of Pharmaceutical Specialties.~~

Exempt Regulation
House Bill 1222

BOARD OF PHARMACY
Restricted volunteer license

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of §54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization ~~with no paid employees~~ that sponsors the provision of health care to populations of underserved people ~~throughout the world~~ shall:

1. File a complete application for registration on a form provided by the board at least ~~15~~ five business days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of §54.1-3301 of the Code of Virginia.

Emergency Regulation
House Bill 1129

BOARD OF PHARMACY
Renewal dates

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 ~~(Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be $50)~~	$90
10. Robotic pharmacy system approval	$150
11. Innovative program approval.	$250
If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	
12. Approval of a pharmacy technician training program	$150
13. Approval of a continuing education program	$100

D. Annual renewal fees.

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

8. Nonresident pharmacy – due April 30	$270
9. Controlled substances registrations – due February 28	$90

10. Innovative program continued approval based on board order not to exceed $200 per approval period.

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

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

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

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115
f. Controlled substances registration	$180

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50

2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

~~I. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license, permit or registration:~~

~~1. Pharmacist active license~~	~~$50~~
~~2. Pharmacist inactive license~~	~~$25~~
~~3. Pharmacy technician registration~~	~~$15~~
~~4. Pharmacy permit~~	~~$210~~
~~5. Physician permit to practice pharmacy~~	~~$210~~
~~6. Medical equipment supplier permit~~	~~$140~~
~~7. Humane society permit~~	~~$20~~
~~8. Nonresident pharmacy~~	~~$210~~
~~9. Controlled substances registrations~~	~~$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

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

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

E. Reinstatement fees.

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

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

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

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

F. Application for change or inspection fees.

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

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

H. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license or permit:

1. Nonrestricted manufacturer permit	$210
2. Restricted manufacturer permit	$140
3. Wholesale distributor license	$210

4. Warehouser permit	$210
5. Nonresident wholesale distributor	$210

Family Planning Expedited Visit Protocol
6/4/08

Purpose: The goal of the family planning expedited visit is to improve pregnancy planning and prevent unintentional and unplanned pregnancy. The family planning expedited visit is an abbreviated family planning visit designed to remove client barriers for accessing contraceptive methods. The expedited visit process is designed for implementation in the clinical and non-traditional settings. These clinical settings may include but are not limited to: STI, Pregnancy Test, Immunization, Pediatric, Teen, WIC, Walk In, and mobile clinical settings. The expedited visit form will serve as the family planning encounter and should be entered as a visit into WebVISION.

Criteria for using the family planning expedited visit form

- A clinician (MD or NP) must be present at the site and is responsible for dispensing.
- The contraceptive method selected must be available for dispensing.
- The expedited visit form must be completed.
- The client must receive a scheduled appointment for a comprehensive family planning visit within 90 days of the expedited visit. The return visit will include a comprehensive history, physical assessment, evaluation of the birth control method, client centered counseling and the required educational components of family planning.
- Only three cycles may be dispensed.
- Only one expedited visit will be permitted per patient.

Steps for completing the VDH Family Planning Expedited Visit

- Have the client complete as much of the form as possible.
- The nurse must review the form with the client and obtain clarifying information.
- The nurse will sign and date the form.
- The clinician on site will be given the completed form for review.
- The clinician is not required to actually see or examine the client on site, but may elect to.
- Clinician will elect to prescribe or decline to prescribe a birth control method based on client information, clinical judgment and protocol(s). The quick start process should be utilized whenever possible. Signature of the clinician is required on the form.
- If a method is ordered the nurse will provide: 1) method specific counseling and education, 2) provide a back up contraceptive method to be used if appropriate, 3) provide information on emergency contraception.
- Initiate referrals as identified.
- Schedule the client for a return comprehensive family planning visit within 90 days of the expedited visit..
- Nurse will enter: "follow up required," the return appointment date, and sign and date the form.
- The completed form will be added to the patient's medical record.

Family Planning Expedited Visit **DATE:** _____

Name: _____

Address: _____

DOB: _____ **Age:** _____

Race/Ethnicity (circle): W B Asian American Indian Alaska Native Pacific Islander Multiracial Hispanic Non-Hispanic Other

LMP: _____/_____/_____ **ALLERGIES:** _____

Using any kind of birth control? Yes No
If yes, what? _____

Smoke? Yes No **Drink alcohol?** Yes No
List Current Medications/dosage/start date (include OTC & Street Drugs)

_____

_____

Urine Pregnancy Test today: POSITIVE NEGATIVE N/A

Problems since LMP?

Nausea	Y	N	_____
Vomiting	Y	N	_____
Bleeding	Y	N	_____
Cramping	Y	N	_____
Other	Y	N	_____

Have you been to a medical provider since LMP? Yes No
If yes, why? _____

_____

OB History: G _____ P _____
Date of last pregnancy: _____
Pregnancy complications: _____
Future pregnancy plans: _____

Contraceptive History:

OCs	Y	N	_____
DEPO	Y	N	_____
OrthoEvra	Y	N	_____
IMPLANTS	Y	N	_____
IUDs	Y	N	_____
Condoms/foam	Y	N	_____
Other	Y	N	_____

Comments:

Referral (circle)? WIC DSS BabyCare FP Plan First

Other: _____

QUICK START

BP: _____

WT: _____

Last Intercourse (date)?

_____

If unprotected & 5 days or less, offer EC

Medical History:

Hypertension?	Y	N
Heart disaese?	Y	N
Diabetes?	Y	N
Blood clots?	Y	N
Chest pain?	Y	N
Breast CA?	Y	N
Cervical CA?	Y	N
Abnormal Pap	Y	N
Migraine HA?	Y	N
Seizures?	Y	N
Liver disease?	Y	N
Vag Bleeding?	Y	N
Breast feeding?	Y	N

Other: _____

Dispense:

_____ X 1 pack

NuvaRing X 1 month

DMPA 104 SQ X 1

EC _____

Other _____ X 1 month

Clinician: _____

MD, NP, CNM, PA

RN follow-up: _____

_____

F/U appt:

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: ROBERT A. DAVIS, PHARMACIST
License No. 0202-205379

ORDER

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110, 54.1-2400(11) and § 54.1-2409 of the Code of Virginia (1950), as amended ("Code"), a formal administrative hearing was held before the Board of Pharmacy ("Board") on June 4, 2008, in Henrico County, Virginia, to receive and act upon the application to reinstate the license of Robert A. Davis to practice as a pharmacist in the Commonwealth of Virginia. Said license was mandatorily suspended by an Order of the Department of Health Professions entered on November 10, 2004, pursuant to § 54.1-2409 of the Code, due to the suspension of Mr. Davis' license to practice pharmacy in the State of Texas. The case was prosecuted by James E. Schliessmann, Assistant Attorney General. Howard M. Casway, Senior Assistant Attorney General, was present as legal counsel for the Board. Mr. Davis was present and was not represented by counsel. The proceedings were recorded by a certified court reporter.

Upon consideration of the evidence presented, the Board adopted the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

The Board finds that:

1. Robert A. Davis held license number 0202-205379 to practice pharmacy in the Commonwealth of Virginia. Said license was mandatorily suspended on November 10, 2004.

2. On August 4, 2004, Mr. Davis' license to practice pharmacy in the State of Texas was suspended for diverting controlled substances for his personal use and for use by his wife pursuant to fraudulent prescriptions purportedly authorized by several physicians.

3. Mr. Davis' license to practice pharmacy in Texas was reinstated on probation with terms on February 7, 2007, and documents and interviews provided to the Board indicate he

is in compliance with the Order. Records provided confirm that Mr. Davis entered into the Texas Pharmacy Recovery Network Program on June 29, 2004, and that he is compliant with the Program. Further, he attends Alcoholics Anonymous meetings three to four times a week and has had no positive urine drug screens. Since April 1, 2007, he has been employed as a pharmacist and is supervised and monitored by the pharmacist-in-charge at the pharmacy where he is currently employed. It is Mr. Davis' intention to relocate to Virginia and to seek employment with his current employer.

CONCLUSIONS OF LAW

Finding of Fact #2 constitutes a violation of § 54.1-3316(10) *[formerly § 54.1-3316(9)]* of the Code. The matter of Mr. Davis' application for reinstatement of his pharmacist's license is properly before the Board.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the application to reinstate the license of Robert A. Davis be, and hereby is, GRANTED subject to the following terms and conditions:

1. Mr. Davis shall remain in compliance with the terms and conditions set forth in the Agreed Board Order of the Texas State Board of Pharmacy entered November 1, 2006.

2. Should Mr. Davis relocate to Virginia, he shall not practice until he has entered into the Health Practitioners Intervention Program ("HPIP"), pursuant to Chapter 25.1 of Title 54.1 of the Code of Virginia (1950), as amended, and 18 VAC 76-10-10, et seq., of the Regulations Governing the Health Practitioners' Intervention Program and has provided the Board with documentation of entry into a HPIP Recovery Monitoring Contract ('RMC"). After entry into HPIP, Mr. Davis shall comply with all terms and conditions for the period specified in the RMC.

3. Any violation of the terms and conditions of HPIP or any of the terms and conditions stated in this Order shall be reason for revoking the license of Mr. Davis, and an administrative proceeding shall be held to decide whether his license shall be revoked. Mr.

Davis shall be noticed to appear at an administrative hearing at such time as the Board is notified that:

a. Mr. Davis is not in compliance with the terms and conditions specified by the HPIP, or has been terminated from participation in HPIP, or

b. Mr. Davis has successfully completed the above-referenced period of participation in HPIP. Upon receipt of evidence of Mr. Davis' participation in and compliance with HPIP, the Board, at its discretion, may waive his appearance before the Board, relating to the HPIP contract only, and conduct an administrative review of this matter, or

c. Any violation of the other terms and conditions of the Order.

As provided by Rule 2A:2 of the Supreme Court of Virginia, Mr. Davis has thirty (30) days from the service date in which to appeal this decision by filing, in writing, a Notice of Appeal with Elizabeth Scott Russell, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, Virginia, 23233-1463. The service date shall be defined as the date Mr. Davis actually received this decision or the date it was mailed to him, whichever occurred first. In the event this decision is served upon him by mail, three (3) days are added to that period.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Elizabeth Scott Russell
Executive Director

ENTERED: June 19, 2008

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

Wednesday, June 4, 2008
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:30 p.m.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Gill Abernathy
Willie Brown
Jennifer H. Edwards
David C. Kozera
Mickey Stradler
Brandon K. Yi

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

QUORUM: With seven members of the Board present, a quorum was established.

JAMES Q. UNDERWOOD
License Number 0202-006303

A formal hearing was held in the matter of James Q. Underwood following the summary suspension of his pharmacist license on March 28, 2008, and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

William Clay Garrett, Assistant Attorney General, prosecuted the case with the assistance of Amanda E. Mitchell, DHP Adjudication Specialist.

Susan Beasecker, DHP Compliance Case Manager, and Donna Whitney, HPIP Outreach Program Manager and Case Manager, appeared and testified on behalf of the Commonwealth.

Mr. Underwood appeared with Lisa Lawrence, Esquire.

Mr. Underwood testified on his own behalf.

Closed Meeting:

Mr. Kozera moved, and the Panel voted 7-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of James Q. Underwood. Additionally, he moved that Scotti Russell and Howard Casway attend the closed meeting.

Reconvene:

Mr. Kozera moved, and the Panel voted 7-0, 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.

Decision:

Mr. Yi moved, and the Panel voted 7-0, to adopt the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett and modified by the Panel and read by Mr. Casway (Attachment 1).

Mr. Kozera moved, and the Panel voted 7-0, that Mr. Underwood's license be continued on indefinite suspension.

MELISSA T. MOORE
Registration # 0230-012153

A formal hearing was held in the matter of Melissa T. Moore following the summary suspension of her pharmacy technician registration on May 6, 2008, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Moore was not present at the hearing. The Panel proceeded in Ms. Moore's absence as the Notice of Formal Hearing dated May 6, 2008, was mailed to Ms. Moore's legal address of record, both regular and certified mail. Mr. Ison ruled that adequate notice was provided to Ms. Moore and the hearing proceeded in her absence.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

CLOSED MEETING:

Mr. Kozera moved, and the Panel voted 7-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the

Code of Virginia for the purpose to reach a decision in the matter of Melissa T. Moore. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, and Howard Casway attend the closed meeting.

RECONVENE:

Mr. Kozera moved, and the Panel voted 7-0, 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.

DECISION:

Mr. Yi moved, and the Panel voted 7-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, and read by Mr. Casway. (Attachment #2)

Mr. Kozera moved, and the Panel voted 7-0, that Ms. Moore's pharmacy technician registration be revoked.

SUSAN A. VIPPERMAN
Registration # 0230-003617

A formal hearing was held in the matter of Susan A. Vipperman following the summary suspension of her pharmacy technician registration on May 6, 2008, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Vipperman was not present at the hearing. The Panel proceeded in Ms. Vipperman's absence as the Notice of Formal Hearing dated May 6, 2008, was mailed to Ms. Vipperman's legal address of record, both regular and certified mail. Mr. Ison ruled that adequate notice was provided to Ms. Vipperman and the hearing proceeded in her absence.

Mr. Schliessmann prosecuted the case with the assistance of Amanda E. Mitchell, DHP Adjudication Specialist.

DECISION:

Mr. Yi moved, and the Panel voted 7-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessman (Attachment 3).

Mr. Kozera moved, and the Panel voted 7-0, that Susan A. Vipperman's pharmacy technician registration be revoked.

ADJOURN: With all business concluded, the meeting adjourned at 6:15 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

Attachment 1
Board of Pharmacy
Formal Hearings - Panel
June 4, 2008

James Q. Underwood

Findings of Fact:

- James Q. Underwood, III, was issued License No. 0202-006303 to practice as a pharmacist by the Board on July 28, 1981. Said license was summarily suspended pursuant to an Order of the Board entered on March 28, 2008.
- Pursuant to an Order of the Board entered November 6, 2006 ("Board's Order"), Mr. Underwood's license was reinstated on the condition that he enter into and comply with the terms and conditions of the Health Practitioners Intervention Program ("HPIP"). On November 20, 2006, he entered into a Participation Contract with HPIP. On December 19, 2006, he entered into a Recovery Monitoring Contract, including term #6 in which he agreed "to refrain from practice until approved to return to work in a health profession by HPIP staff." On March 6, 2008, Mr. Underwood was urgently dismissed from the program for non-compliance due to his employment as a pharmacist with CVS/pharmacy #7577 without authorization from HPIP. According to information provided by CVS Corporate offices, Mr. Underwood was employed with CVS/pharmacy from December 14, 2007, until terminated on March 6, 2008, initially in training and later, as a staff pharmacist, without on-site supervision.
- In an interview with the Board's compliance case manager on March 14, 2008, Mr. Underwood, when asked if HPIP gave him permission to work, stated that he had not been given permission to work by HPIP. He further indicated that he and his psychiatrist "decided it was time and this should have been done a long time ago."
- Mr. Underwood testified that he left repeated messages with his HPIP case manager regarding his prospective employment but never heard anything back from him and never attempted to contact any other HPIP staff. As a result, having heard nothing to the contrary from HPIP, Mr. Underwood, purportedly with his psychiatrist's concurrence, began employment with CVS/pharmacy on December 14, 2007. Mr. Underwood further testified that he left employment with CVS/pharmacy on March 7, 2008, based upon four patient complaints that were made to his supervisor over a two-month period.
- As reflected in his testimony, Mr. Underwood steadfastly maintained that he had acted appropriately in returning to work without approval from HPIP when, in fact, the terms of the HPIP contract and the Board Order were clear and unequivocal to the contrary.

Conclusions of Law:

The Board concludes that Finding of Fact #2 constitutes a violation of Term No. 1 of the Board's Order.

Sanction:

The Virginia Board of Pharmacy, effective upon entry of this Order, hereby ORDERS that the pharmacist license of James Q. Underwood, III, be CONTINUED on INDEFINITE SUSPENSION.

Attachment 2
Board of Pharmacy
Formal Hearings - Panel
June 4, 2008

Melissa T. Moore

Findings of Fact :

- Melissa T. Moore holds registration number 0230-012153 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia that shall expire on December 31, 2008. Said registration was summarily suspended on May 1, 2008.
- Based upon representations of James E. Schliessmann, Assistant Attorney General, and Commonwealth's Exhibit No. 3, the presiding officer ruled there was adequate notice and the panel of the Board proceeded with the hearing in Ms. Moore's absence.
- Pursuant to Mr. Moore's admission, during the course of her employment as a pharmacy technician at CVS/pharmacy #7593, Christiansburg, Virginia, between December 2007, and February 2008, she diverted between 3,500 and 4,000 dosage units of hydrocodone/APAP 10/650 (Schedule III). As a result, her employment was terminated and she was arrested and charged in the General District Court of Montgomery County, Virginia, with felony embezzlement.

Conclusions of Law:

- Finding of Fact #3 constitutes a violation of § 54.1-3316(9) of the Code.

Sanction:

- The registration of Melissa T. Moore be, and hereby is, REVOKED.

Attachment 3
Board of Pharmacy
Formal Hearings - Panel
June 4, 2008

Susan A. Vipperman

Findings of Fact:

- Susan A. Vipperman was issued Registration Number 0230-003617 to practice as a pharmacy technician by the Board on February 13, 2004. Said registration was summarily suspended pursuant to an Order of the Board entered on May 6, 2008.
- Based upon the representations of James E. Schliessmann, Assistant Attorney General, and Commonwealth's Exhibits #1 and #3 i.e., the Notice of Formal Hearing and Statement of Particulars, and the Affidavit of Mailing, the presiding officer ruled that adequate notice was provided to Ms. Vipperman and the hearing proceeded in her absence.
- Between February 15, 2008 and March 20, 2008, by Ms. Vipperman's own admission, during the course of her employment as a pharmacy technician at CVS/pharmacy #5505, Abingdon, Virginia, she diverted oxycodone 15mg (Schedule II) from the pharmacy stock for her own personal and unauthorized use. Ms. Vipperman self-administered the diverted medication both during and following her shifts.

Conclusions of Law:

- The Board concludes that Finding of Fact #3 constitutes a violation of § 54.1-3316(4) and (9) of the Code.

Sanction:

- The registration of Susan A. Vipperman be and hereby is REVOKED.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR DRUG DONATION PROGRAM

June 17, 2008
Second Floor
Board Room 3

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of drafting emergency regulations to establish a prescription drug donation program as required by 2008 House Bill 85 was called to order at 10am.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT:
John Beckner
Jennifer H. Edwards
Timothy S. Musselman
Bill Hancock
Keith Kittinger
Rachel Cain

MEMBERS ABSENT: Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
Sandra Whitley Ryals, Deputy Director, DHP
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst
Sammy Johnson, Deputy Director of Enforcement

DISCUSSION: The committee was comprised of several members of the Board of Pharmacy, a representative of the Department of Medical Assistance Services (DMAS), a representative from the Virginia Pharmacists Association, and two pharmacists who work for pharmacies providing services to long term care facilities. There were also interested parties present representing several groups including associations that represent the different long term care facilities and the Virginia Trial Lawyers Association. Steve Pearson representing the Virginia Trial Lawyers Association spoke about his concerns that the language in the statute providing immunity from liability to pharmaceutical manufacturers was too broad and may encourage manufacturers to try to use it to avoid complete product liability, when he considered that the intention of the language was to prevent any additional liability for manufacturers just by virtue of the fact that someone may receive a drug that had been previously dispensed through such a program. He plans to seek legislative clarification, but wanted the Board to also interpret the statute in this manner in its emergency regulations.

There were two other concerns discussed by the committee that may require legislation to fix. The first is that there is no immunity

from liability for persons participating in the program. Second, the language excepting drugs paid for by Medicaid and Medicare was left in the statute. For such a program to be successful, this needs to be removed. Rachel Cain, DMAS, will check with her agency and determine if there can be amendments to the statute to allow donation of drugs paid for by Medicaid or Medicare when there is no possibility of return of the drugs for credit to either of those payors. Once DHP receives a response from DMAS, staff will draft a legislative proposal to take care of these two issues.

The committee reviewed Maryland's laws and regulations for its program as well as Ohio's. Ohio does not permit donations by consumers if the donated drug has ever been in the possession of the consumer, essentially limiting donated drugs to institutional settings. It was generally decided that for such a program in Virginia to work and not put the person accepting donated drugs in a position of being in violation of federal law by accepting Schedule II-V controlled substances, that collection sites for donated drugs should be restricted to permitted pharmacies. The collecting pharmacy would need to register with the Board, but no fee would be assessed for this registration. The registration would enable the Board to be able to publish a list of collection locations. The collecting pharmacy could directly dispense donated drugs to patients of free clinics or other clinics serving the indigent, or could transfer the collected drugs to another pharmacy in a free clinic or serving a free clinic. There would be requirements for recordkeeping for accountability purposes, and requirements for separate storage within the prescription department to ensure security and proper use of these collected drugs. While such program will allow for consumers to donate drugs, it was recognized by the committee that such donations will be severely limited due to safety concerns about drug integrity. Any donated drug will still have to meet packaging requirements as set forth in the statute, and the pharmacist screening the drug for acceptability will need to determine whether the integrity can be ensured. Staff will draft proposed regulations for the committee to review at its next meeting mid-July.

ADJOURN: The meeting was adjourned at approximately 2:30PM.

Elizabeth Scott Russell
Executive Director

Dave Kozera, Chairman

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

June 19, 2008
Second Floor
Board Room 1

Department of Health Professions
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A meeting of an informal conference committee of the Board of Pharmacy was called to order at 10:25am.

PRESIDING: Bobby Ison, Committee Chairman

MEMBERS PRESENT: John O. Beckner

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director

Dana Anderson
License # 0201-001251

Mr. Anderson, Michael Nyame-Mireku, Dominic Conti, and Terry Farnsworth were present to discuss the application, received April 25, 2008, for approval of a robotic pharmacy system wherein a pharmacist would be required to check or verify accuracy of only a reduced percentage of drug dispensed by the robot at Virginia Hospital Center Arlington Pharmacy.

Decision: After consideration of the application and statements concerning the robotic pharmacy system, Mr. Ison stated that the Committee approved the robotic pharmacy system for a period of three years from the date of implementation, contingent upon verifying references and receiving favorable responses, and contingent upon other terms and conditions. Mr. Ison stated that possible terms and conditions may include:

1. Virginia Hospital Center Arlington Pharmacy shall notify the Board of the implementation date of the program;

2. Pharmacists shall verify accuracy of 100% of all data entered into the packaging and overwrapping robots and will be responsible for transferring drug from stock bottles into the pill box canister after verifying accuracy of selected drug; Pharmacy technicians may transfer drug into the phialbox used for overwrapping, but pharmacists shall verify the accuracy of all selected drugs; Pharmacists shall document the verification of drugs during the packaging and overwrapping process by recording their initials/name in the robotic pharmacy system, and such documentation shall be maintained in an accessible format for 3 years from the date of packaging/overwrapping; Packaging and labeling, including the appropriate beyond-use date, shall conform to Board of Pharmacy regulations and to current USP-NF standards;

3. Pharmacists shall perform a daily check of drugs picked by the robot for 100% of all patients' bins for the initial 2 weeks from

implementation of said program; After two weeks of perfect accuracy while performing 100% check, the pharmacy may move to a 10% check in which pharmacists shall perform a daily random check of medications picked by the robot for 10% of all patients' bins and 10% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found. If the robot picks an incorrect medication, the hospital shall immediately institute a 100% check of all patients' bins or doses and shall immediately report this problem to the Board. This 100% check procedure shall continue until the Board allows the pharmacy to return to a reduction in checking.

4. All records for the robot shall be maintained on the premises for at least three years. These records shall include, but are not limited to packaging logs, random patient check logs, and copies of the quality assurance reports sent to the Board. All records shall be available for review by the Board or its designated representative;

5. Quality assurance reports showing the accuracy of the robot shall be forwarded to the Board for the three-year time period by the last day of the months of March, June, September, and December. These reports shall include but are not limited to, a summary of all discrepancies found during that quarter plus a cumulative summary since approval of the application. The reports shall indicate the total number of doses picked by the robot which were checked in conducting the 10% patient bin check, 10% cart updates check, and 10% first dose check; and, the total number of doses dispensed by the robot during the same time period. The reports shall also include notification for any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution. Unanticipated downtime shall be immediately reported to the Board. Additionally, the report shall include discrepancies on the packaging portion of the robotic system. After six months of operation under this order with no reports of the robot picking the wrong drug, Virginia Hospital Center Arlington Pharmacy may petition the board to consider reducing the 10% pharmacist check requirement;

6. Virginia Hospital Center Arlington Pharmacy shall be subject to one random, unannounced inspection by the Board or its designated representatives, within the three-year period. This inspection is independent from any routine inspection of your pharmacy. Virginia Hospital Center Arlington Pharmacy shall be solely responsible for the payment of an inspection fee of $150.00, to be paid to the Board within thirty days from the date of the statement of monies owed that will be mailed following the inspection;

7. Any operational changes or modifications to the robot system shall be approved by the Board prior to initiation of the

modification;
8. Reports of significant robot errors or failure to comply with the terms and conditions of the waiver as set forth above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

ADJOURN: With all business concluded, the meeting adjourned at approximately 1:15pm.

Caroline D. Juran, Deputy Executive Director

Bobby Ison, Chairman

Date

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

Wednesday, June 25, 2008
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	David C. Kozera, Committee Chairman
MEMBERS PRESENT:	Brandon K. Yi
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
MANZEL FELZER Registration # 0230-011874	Manzel Felzer appeared with Lisa Strucko and Martha Porter, pharmacists at Leesburg Pharmacy; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 28, 2008 Notice.
Closed Meeting:	Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Manzel Felzer. 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 their presence would aid the Committee in its deliberations.
Reconvene:	Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.
Decision:	After consideration of the evidence and statements concerning the allegations, Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law

and sanctions as stated in Attachment 1.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Mr. Felzer unless a written request to the Board for a formal hearing on the allegations made against him is received from Mr. Felzer within such time. If service of the Order is made by mail, three 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.

MARTHA PORTER
License #0202-205070

Martha Porter appeared with Lisa Strucko, pharmacist and Manzel Felzer, pharmacy technician, at Leesburg Pharmacy; to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 28, 2008 Notice.

Closed Meeting:

Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Martha Porter. 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 their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 2.

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

from Ms. Porter within such time. If service of the Order is made by mail, three 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.

JAREN OUTLAW
Registration #0230-0048831

Ms. Outlaw was scheduled to appear at 9:00 a.m. to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 28, 2008 Notice that was mailed to Ms. Outlaw's legal address of record, both regular and certified mail.

The Committee recommended that this case be heard at a formal hearing.

NELSON TIDWELL
License #0202-007302

Nelson Tidwell appeared with William Dean, current Pharmacist-In-Charge at Rx Services and William Hancock, Omnicare Area Director; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 28, 2008 Notice.

Closed Meeting:

Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Nelson Tidwell. 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 their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Yi moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 3.

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

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

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

Attachment 1
Minutes - Board of Pharmacy
Special Conference Committee
June 25, 2008

Manzel Felzer

Findings of Fact and Conclusions of Law:

- Manzel Felzer holds registration number 0230-011874 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia.
- During the course of Mr. Felzer's employment as a pharmacy technician at Leesburg Pharmacy, Leesburg, Virginia, he violated § 54.1-3316(7), § 54.1-3321(A)(4) and (5) and § 54.1-3462(1) of the Code in that on December 21, 2007, by his own admission, he compounded Rx #155421 for amlodipine 1.25 mg/ml suspension containing 0.68 grams of amlodipine powder rather than the required 0.068 grams of amlodipine powder. The prescription bottle was mislabeled as containing amlodipine 1.25 mg/ml.
- The veterinarian reported that, due to the cat consuming ten times the amount of the medication on three occasions, it "significantly contributed" to the death of the patient.

Sanction

- It is hereby ORDERED that Manzel Felzer be issued a REPRIMAND. Further, the Board ORDERS that Mr. Felzer will successfully complete six (6) hours of continuing pharmacy education in the subject of compounding.

Attachment 2
Minutes - Board of Pharmacy
Special Conference Committee
June 25, 2008

Martha Porter

Findings of Fact and Conclusions of Law:

- Martha Porter holds license number 0202-205070 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- During the course of Ms. Porter's employment as a pharmacist at Leesburg Pharmacy, Leesburg, Virginia, she violated § 54.1-3316(7), § 54.1-3320(A)(1), and §54.1-3462(1) of the Code, and 18 VAC 110-20-270(C) of the Board of Pharmacy Regulations, in that on December 21, 2007, by her own admission, she dispensed Rx #155421 for amlodipine 1.25 mg/ml suspension containing 0.68 grams of amlodipine powder rather than the required 0.068 grams of amlodipine powder. The prescription bottle was mislabeled as containing amlodipine 1.25 mg/ml.
- The veterinarian reported that, due to the cat consuming ten times the amount of amlodipine on three occasions, it "significantly contributed" to the death of the patient.

Sanction

- It is hereby ORDERED that Martha Porter be issued a REPRIMAND. Further, the Board ORDERS that Ms. Porter shall successfully complete four (4) hours of continuing pharmacy education in the subject of compounding.

Attachment 3
Minutes - Board of Pharmacy
Special Conference Committee
June 25, 2008

Nelson D. Tidwell

Findings of Fact and Conclusions of Law:

- Nelson D. Tidwell holds license number 0202-007302 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- During the course of Mr. Tidwell's employment as the pharmacist-in-charge of Rx Services, Williamson Drug Company, Inc., Abingdon, Virginia, he violated § 54.1-3316(6) and (7), § 54.1-3320, and § 54.1-3434 of the Code, in that between May and August, 2007, he allowed an individual who was not licensed as a pharmacist to perform the duties of a pharmacist.

Sanction:

It is hereby ORDERED that Nelson D. Tidwell be issued a REPRIMAND.

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

Tuesday, July 1, 2008

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

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

TIME & PURPOSE: After an attempt to schedule a regular meeting failed, pursuant to § 54.1-2408.1 of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:35 a.m., on July 1, 2008, to consider the summary suspension of the license of Mildred L. Smith to practice as a pharmacist.

PRESIDING: Dave Kozera, Chairman

MEMBERS PRESENT:
John Beckner
Willie Brown
Bobby Ison
Michael E. Stredler
Brandon Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
James Schliessmann, Assistant Attorney General
Amanda Mitchell, DHP Adjudication Specialist

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

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

MILDRED L. SMITH
License Number 0202-206361

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

Decision:

Mr. Stredler moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacist by Mildred L. Smith poses a substantial danger to the public; and therefore, that the license of Mildred L. Smith, to practice as a pharmacist be summarily suspended.

Mr. Beckner moved, and the Board voted 6-0 in favor of the motion, that a Consent Order be offered to Ms. Smith for the indefinite suspension of her license in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:20a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Dave Kozera, Chairman

Date

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

Wednesday, July 17, 2008
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	David C. Kozera, Committee Chairman
MEMBERS PRESENT:	Leo H. Ross
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
DARLENE SMITH Pharmacy Technician Applicant	Darlene Smith appeared to discuss her application for registration as a pharmacy technician and allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 2, 2008 Notice.
Closed Meeting:	Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Darlene Smith. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.
Reconvene:	Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.
Decision:	After consideration of the evidence and statements concerning the allegations, Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law

and sanctions as stated in Attachment 1.

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

MARK L. BLANTON
License #0202-010024

Mark L. Blanton appeared with Charles Midkiff and Rachel Reardon, Attorneys; and Clint E. Blanton; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2008 Notice.

Closed Meeting:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Mark L. Blanton. 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 their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 2.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Mr. Blanton unless a written request to the Board for a formal hearing on the allegations made against him is received from Mr. Blanton within such time. If service of the

Order is made by mail, three 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.

CLINT E. BLANTON
License #0202-011355

Clint E. Blanton appeared with Charles Midkiff and Rachel Reardon, Attorneys; and Mark L. Blanton; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 29, 2008 Notice.

Closed Meeting:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Clint E. Blanton. 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 their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 3.

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

ADJOURN:

With all business concluded, the meeting adjourned at 5:00 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

Attachment 1
Minutes - Board of Pharmacy
Special Conference Committee
July 17, 2008

Darlene Smith

Findings of Fact and Conclusions of Law:

- Pursuant to a completed application received by the Board on August 13, 2007, Darlene P. Smith applied for registration as a pharmacy technician in the Commonwealth of Virginia.
- Ms. Smith violated § 54.1-3316(9) *[formerly § 54.1-3322(7)]* of the Code in that she was convicted of the following violations of Virginia drug law:
    - On June 5, 1981, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of possession of drug paraphernalia.
    - On November 30, 1981, she was convicted in the General District Court for the City of Norfolk, Virginia, of one count of possession of drug paraphernalia and one count of possession of marijuana.
    - On April 19, 1984, she was convicted in the General District Court for the City of Norfolk, Virginia, of one count of possession of marijuana.
- Ms. Smith violated § 54.1-3316(11) *[formerly § 54.1-3322(7)]* of the Code in that she was convicted of multiple felonies and misdemeanors involving moral turpitude. Specifically:
    - On September 14, 1979, she was convicted in the City of Norfolk, Virginia, of one count of petit larceny, a misdemeanor.
    - On October 31, 1979, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of petit larceny, a misdemeanor.
    - On July 29, 1980, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of petit larceny, a misdemeanor.
    - On March 3, 1981, she was convicted in the City of Norfolk, Virginia, of three counts of concealment, all misdemeanors.
    - On June 5, 1981, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of larceny, third offense, a felony.
    - On January 8, 1982, she was convicted in the City of Norfolk, Virginia, of one count of concealment, a misdemeanor.
    - On January 11, 1982, she was convicted in the City of Norfolk, Virginia, of one count of concealment, a misdemeanor.
    - On April 5, 1984, she was convicted in the Circuit Court for the City of Virginia Beach, Virginia, of one count of larceny, third offense, a felony.
    - On June 27, 1984, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of concealment, a felony.
    - On July 17, 1984, she was convicted in the Circuit Court for the City of Virginia Beach, Virginia, of one count of concealment, a felony.
    - On July 29, 1988, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of larceny, a felony.
    - On August 23, 1988, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of larceny, a felony.

- On September 8, 1988, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of one count of larceny, a felony.
- On September 15, 1988, she was convicted in the City of Norfolk, Virginia, of one count of assuming a false name, and one count of larceny, both misdemeanors.
- On October 19, 1994, she was convicted in the General District Court for the City of Virginia Beach, Virginia, of one count of larceny, a misdemeanor.
- On May 9, 1995, she was convicted in the Circuit Court for the County of Chesapeake, Virginia, of one count of grand larceny, a felony.
- On August 30, 1995, she was convicted in the Circuit Court for the City of Norfolk, Virginia, of two counts of concealment and one count of failure to appear, all felonies.
- On September 11, 1995, she was convicted in the Circuit Court for the County of Chesapeake, Virginia, of one count of petit larceny, third offense, a felony.
- On February 4, 2002, she was convicted in the Circuit Court for the City of Virginia Beach, Virginia, of one count of petit larceny, third offense, a felony.
- On December 9, 2003, she was convicted in the Circuit Court for the County of Chesapeake, Virginia, of one count of probation violation, a felony.

- Ms. Smith stated to the Committee that she has changed her life and is no longer involved with the same people as when she received the convictions. Additionally, she stated that she is aware that her criminal record will follow her for the rest of her life.
- The last offense she was arrested for was committed in July 2001.

Sanction

- The application of Darlene P. Smith for registration as a pharmacy technician be APPROVED and that Ms. Smith be placed on PROBATION under the following terms and conditions:
- The period of probation shall begin on the date that this Order is entered and shall continue INDEFINITELY. Ms. Smith may petition the Board to end her probation after not less than five (5) years of employment as a pharmacy technician.
- All reports required by this Order shall be submitted in writing to the Board office with the first report being received no later than thirty (30) days following the date that this Order is entered. Subsequent reports must be received every other month by the last day of the months of January, March, May, July, September, and November until the probation ends. Ms. Smith is fully responsible for ensuring that required reports are properly submitted and received by the Board in a timely manner.
- Ms. Smith shall provide written notification to the pharmacist-in-charge ("PIC") of each location where she works that her pharmacy technician registration is on probation and provide the PIC with a copy of this Order in its entirety. Within ten of days of notifying the PIC of her probation, she shall forward to the Board a copy of the written notification she gave the PIC.
- Ms. Smith shall direct her employer to provide a written job performance evaluation to the Board every other month, as set forth in term #2.
- Every other month, Ms. Smith shall submit self-reports which must include her current address and current employment, if any.
- Ms. Smith shall request that her parole/probation officer provide the Board with a report every other month, as set forth in term #2, describing her compliance with the conditions of her parole/probation.
- Ms. Smith shall provide the Board with a certified true copy of her Final Court Order upon completion of her parole/probation or upon final disposition of charges.

- Ms. Smith shall immediately inform the Board if she is charged with any felony or a misdemeanor.
- Ms. Smith shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code. Any violation of these terms of probation or of any law or regulation affecting the practice of pharmacy technicians in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of her registration and an administrative proceeding shall be convened to determine whether such registration shall be suspended or revoked

Attachment 2
Minutes - Board of Pharmacy
Special Conference Committee
July 17, 2008

Mark L. Blanton

Findings of Fact and Conclusions of Law:

- Mark L. Blanton holds license number 0202-010024 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- During the course of Mr. Blanton's employment as pharmacist-in-charge of K Mart Pharmacy # 3705, Wise, Virginia, he violated § 54.1-3316(1), (2), (7) and (13), § 54.1-3432, and § 54.1-3434 of the Code, and 18 VAC 110-20-190(C) of the Board of Pharmacy Regulations, in that between December 2006, and December 2007, he allowed an unlicensed non-employee access to the prescription department between one and three times a week. In December 2007, this individual was caught stealing a 100 count bottle of hydrocodone/APAP (Schedule III), and admitted to diverting between 70 and 80 bottles of hydrocodone of various strengths between April 2007, and December 2007. As a result of these actions, Mr. Blanton's employment was terminated.
- Mr. Blanton stated to the Committee that he made an error in judgment.

Sanction

- It is hereby ORDERED that Mark L. Blanton be issued a REPRIMAND. Further, the Board ORDERS that:
- Mr. Blanton will successfully complete five (5) hours of continuing pharmacy education in the area of drug security between July 31, 2008, and September 30, 2008, with documentation of satisfactory completion submitted to the Board by October 31, 2008. Said hours shall be in addition to the fifteen (15) hours required for the renewal of his license.
- Mr. Blanton shall be assessed a monetary penalty of Five Hundred Dollars ($500.00) to be paid to the Board within ninety (90) days from the date this Order is final. If the monetary penalty is not received within the prescribed deadline, an additional One Hundred Dollars ($100.00) will be assessed weekly, up to a maximum of One Thousand Dollars ($1,000.00). Failure to pay the full fee plus the additional assessed penalty within thirty (30) days of the date the maximum penalty may be assessed shall constitute grounds for the suspension of the license of Mr. Blanton, and an administrative proceeding will be convened to determine whether such license shall be suspended.
- Mr. Blanton shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code. Any violation of these terms or of any law or regulation affecting the practice of pharmacy in the Commonwealth of Virginia shall constitute

grounds for the suspension or revocation of his license and an administrative proceeding shall be convened to determine whether such license shall be suspended or revoked.

Attachment 3
Minutes - Board of Pharmacy
Special Conference Committee
July 17, 2008

Clint E. Blanton

Findings of Fact and Conclusions of Law:

- Clint E. Blanton holds license number 0202-011355 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- During the course of Mr. Blanton's employment as a pharmacist with K Mart Pharmacy # 3705, Wise, Virginia, he violated § 54.1-3316(1), (2) and (13) of the Code, and 18 VAC 110-20-190(C) of the Board of Pharmacy Regulations, in that between December 2006, and December 2007, he allowed an unlicensed non-employee access to the prescription department. In December 2007, this individual admitted to diverting between 70 and 80 bottles of hydrocodone/APAP (Schedule III) of various strengths. As a result of these actions, Mr. Blanton's employment was terminated.
- Mr. Blanton stated to the Committee that he made an error in judgment.

Sanction:

- It is hereby ORDERED that Clint E. Blanton be issued a REPRIMAND. Further, the Board ORDERS that:
- Mr. Blanton will successfully complete five (5) hours of continuing pharmacy education in the area of drug security between July 31, 2008, and September 30, 2008, with documentation of satisfactory completion submitted to the Board by October 31, 2008. Said hours shall be in addition to the fifteen (15) hours required for the renewal of his license.
- Mr. Blanton shall be assessed a monetary penalty of Two Hundred Fifty Dollars ($250.00) to be paid to the Board within ninety (90) days from the date this Order is final. If the monetary penalty is not received within the prescribed deadline, an additional One Hundred Dollars ($100.00) will be assessed weekly, up to a maximum of One Thousand Dollars ($1,000.00). Failure to pay the full fee plus the additional assessed penalty within thirty (30) days of the date the maximum penalty may be assessed shall constitute grounds for the suspension of the license of Mr. Blanton, and an administrative proceeding will be convened to determine whether such license shall be suspended.
- Mr. Blanton shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code. Any violation of these terms or of any law or regulation affecting the practice of pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of his license and an administrative proceeding shall be convened to determine whether such license shall be suspended or revoked.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR DRUG DONATION PROGRAM AND DRUG DISPOSAL

July 23, 2008
Second Floor
Board Room 1

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of drafting emergency regulations to establish a prescription drug donation program as required by 2008 House Bill 85 was called to order at 10am.

PRESIDING: David C. Kozera, Committee Chair

MEMBERS PRESENT:
John Beckner
Jennifer H. Edwards
Timothy S. Musselman
Keith Kittinger
Rachel Cain
Major Robert Tavenner, Virginia State Police joined the meeting at approximately 1PM for the discussion of a drug disposal program.

MEMBERS ABSENT: Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst
Sammy Johnson, Deputy Director of Enforcement

REVIEW OF DRAFT REGULATIONS: The ad hoc committee of the Board of Pharmacy for drafting regulations to establish the drug donation program met Wednesday, July 23 and completed work on draft regulations which will go to the Board on September 3 for adoption as emergency regulations. In summary the regulations allow any pharmacy to register as a drug donation site. Such sites will be able to collect donated drugs; re-dispense donated drugs to free-clinic patients themselves; or transfer the drugs to another site, such as a free clinic pharmacy, for re-dispensing.

DISCUSSION OF POSSIBLE LEGISLATION NEEDED: There were a couple of issues identified that may need to be corrected in statute. First, the Virginia Trial Lawyers Association feels that the provision in subsection D of §54.1-3411.1 giving immunity to pharmaceutical manufacturers is too broad. The organization is concerned that the immunity could extend beyond problems that occurred within the donation program itself, and does not want to have a law that would give manufacturers an argument against all product liability. The representative, Steve Pearson, requested that the Board include a paragraph in its regulations limiting the immunity. Mr. Casway agreed to further discuss this with Mr. Pearson and provide guidance to the Board in

September, but his initial advice was that the limitation needed to be in statute, not regulation. In either case, it is anticipated that the Virginia Trial Lawyers Association will be seeking a change in the statute next session.

The second issue is that the language in subsection C, which is not new language, expressly prohibits the donation of any drugs paid for by Medicare Part D or Medicaid. The primary source for donated drugs in any drug donation program will be from long term care facilities, and if the majority of these patients are Medicaid or Medicare Part D patients, then the donation program will not really get off the ground. CMS does not want drugs donated if the drugs can be returned to the pharmacy for re-sale, and a credit given. However, according to the two long term care pharmacists on the committee, there are many instances where drugs cannot be credited, and these are the drugs that they would like to be able to donate. Rachel Cain, DMAS representative to the committee had a directive from CMS related to drugs at "nursing facilities" not being able to be donated, and DMAS is suggesting that the phrase "in nursing facilities" be added to subsection C. However, this may not resolve the problem of an express prohibition in statute. Board counsel suggested that the wording in that paragraph could be re-written in the positive to say something to the effect that "Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated unless such donation is prohibited." Ms. Cain was not able to advise at this time if this language would satisfy her department or CMS.

DISCUSSION OF 2008 HB86 AND ESTABLISHMENT OF A PROGRAM TO COLLECT AND DISPOSE OF UNWANTED DRUGS

The ad hoc committee with representation of the state police began discussion of the issue of a drug disposal program. Delegate Landes, the patron of HB86 had asked that this bill be carried over until 2009 to provide the Virginia State Police and the Board of Pharmacy an opportunity to explore the different methods being used throughout the country and make a recommendation for Virginia. The ad hoc committee reviewed a comprehensive report put together following a study by a large stakeholder group in Oregon. The report includes a listing of the different types of current pilots and programs in the Unites States and one in British Columbia, issues and barriers to such programs, and cost estimates of the different types of programs.

The Oregon group put together proposals based on available data for five different types of programs as follows. In the options, "controlled drugs" is defined as DEA controlled substances (Schedule II-V). "Non-controlled drugs" is defined as other non-DEA controlled substances (Schedule VI in Virginia). The fifth option which involves direct return to a reverse distributor is not currently available in the U.S., because of the prohibition of consumer return of controlled drugs.

1. Drop boxes in participating pharmacies for non-controlled drugs and controlled drugs taken to local law enforcement.
Problems: pharmacy personnel having to take time to sort out the controlled drugs that cannot be accepted, consumers unwilling to take to two separate places.
Cost: 803,403 Year 1, and 658,403 annually thereafter

2. Secured drop boxes in participating pharmacies for non-controlled drugs, and controlled drugs mailed to law enforcement by the consumer in a pre-paid mailer provided by the pharmacist.
Problems: the pharmacist would have to take time to assist persons in determining if a drug was controlled and provide the mailer if there were controlled drugs; potential for diversion from the mailbox.
Benefit: less burden on the consumer.
Cost: 1,150,806 Year 1, and 825,806 annually thereafter

3. Secured drop boxes, similar to a mailbox, located outside of local law enforcement agencies. In this option, the local police are tasked with separating the controlled from non-controlled drugs, destroying the controlled as they would evidence, and sending the non-controlled to a private hazardous waste disposal company for destruction.
Problems: additional workload on local law enforcement too much to absorb, ability of law enforcement personnel to properly separate, possible diversion from the drop off boxes, discomfort of consumers in bringing medications to local law enforcement office.
Cost: 1,467,565 Year 1, and 1,322,566 annually thereafter

4. Mailers provided for consumers to mail all unwanted drugs to the state police. Pharmacies to stock pre-paid mailers. State police would separate the controlled drugs and destroy them as evidence and ship the non-controlled to a private hazardous waste vendor.
Problems: additional workload on state police too much to absorb, ability of state police personnel to properly separate.
Benefits: minimal pharmacy personnel time involved.
Costs: 875,195 Year 1, and 835,195 annually thereafter

Of the four options, the ad hoc committee felt that there was less opportunity for consumer confusion and for diversion with Option 4 where everything is mailed to the state police. Major Tavenner stated that in Virginia, for Option 3, drop boxes could be placed at area offices, but that these offices were not always easily accessible to consumers. Some area offices serve multiple counties and could mean a significant drive for some people. Additionally, the area offices are not manned at all times, are sometimes in remote locations, and VSP has experienced some problems with break-ins at these locations. He had concerns about theft of the drop boxes from these locations.

It was decided that over the next couple of weeks, staff of the Department of Health Professions and the State Police will meet and put together a summary for Delegate Landes with recommendations for a program in Virginia and a cost estimate, based on the Oregon research, extrapolated as best possible to the population in Virginia. The Department of Environmental Quality (DEQ) will also be consulted as there are EPA and DEQ laws that such programs must take into account as well as federal DEA regulations that prohibit the return of Schedule II-V controlled substances to entities other than law enforcement personnel.

ADJOURN: The meeting was adjourned at approximately 2:30PM.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Chairman

Date

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

Thursday, July 31, 2008
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	John O. Beckner, Committee Chairman
MEMBERS PRESENT:	Leo H. Ross
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
STEVEN YI License Number 0202-011157	Steven Yi appeared with Donna Whitney, HPIP Case Manager, to discuss his petition for reinstatement of his pharmacist license and to review allegations that he may have violated portions of the Board's laws and regulations as stated in the July 11, 2008 Notice.
Closed Meeting:	Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Steven Yi. 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 their presence would aid the Committee in its deliberations.
Reconvene:	Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.
Decision:	After consideration of the evidence and statements concerning the allegations, Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law

and sanctions as stated in Attachment 1.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Mr. Yi unless a written request to the Board for a formal hearing on the allegations made against him is received from Mr. Yi within such time. If service of the Order is made by mail, three 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 W. KELLY
License Number 0202-001592

Robert W. Kelly appeared with John W. Swezey, his attorney; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 10, 2008 Notice.

Closed Meeting:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Robert W. Kelly. 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 their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ross moved, and the Committee voted 2-0 in favor of the motion, to close this case with no violation.

ADJOURN:

With all business concluded, the meeting adjourned at 12:55 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

John Beckner, Chair

Date

Steven S. Yi

Findings of Fact and Conclusions of Law:

- Steven S. Yi held license number 0202-011157 issued by the Board to practice pharmacy in the Commonwealth of Virginia. Pursuant to an Order of the Board entered on February 17, 2004, said license was summarily suspended. Subsequently, a Consent Order was entered on March 1, 2004, that continued his license on indefinite suspension due to his diversion and personal use of various Schedule II drugs.
- Pursuant to an application received by the Board on February 4, 2008, Mr. Yi applied for the reinstatement of his license to practice as a pharmacist in the Commonwealth of Virginia.
- Mr. Yi attended outpatient treatment at the Kolmac Clinic, Silver Spring, Maryland, from September 11, 2007, to October 30, 2007. The Clinical Director reports that he continues to attend the aftercare program with regular attendance and a high commitment to the recovery process.
- Mr. Yi signed a Participation Contract with the Health Practitioners Intervention Program ("HPIP") on May 31, 2007, and a Recovery Monitoring Contract on November 9, 2007, with an expected completion date of November 30, 2012.
- Mr. Yi stated to the Committee that he currently attends International Doctors in Alcoholics Anonymous ("IDAA"), Caduceus, and/or Narcotics Anonymous meetings four (4) to five (5) times per week. Additionally, he stated that he has a sponsor and is currently on step 4 of a 12-step program.
- Donna Whitney, HPIP Case Manager, stated to the Committee that Mr. Yi has been compliant with the terms and conditions of his HPIP contract. Since November 9, 2007, he has submitted to 27 urine drug screens and all had negative results. Ms. Whitney further stated that HPIP is advocating for the reinstatement of Mr. Yi's license to practice as a pharmacist in the Commonwealth of Virginia and once HPIP approves him to return to work he would face additional restrictions including having a peer monitor and a worksite monitor as well as an increase in the number of drug screens.
- Mr. Yi has demonstrated to the Committee that he is safe and competent to practice pharmacy in the Commonwealth of Virginia.

Sanction

- It is hereby ORDERED that the license of Steven S. Yi to practice pharmacy in the Commonwealth of Virginia shall be REINSTATED, subject to the following terms and conditions:
- Mr. Yi shall comply with all terms and conditions for the period specified by HPIP.
- Mr. Yi shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code. Any violation of these terms and conditions of this Order, or of any law or regulation affecting the practice of pharmacy in the Commonwealth of Virginia, shall constitute grounds for the suspension or revocation of his license and an administrative proceeding shall be convened to determine whether such license shall be suspended or revoked. Mr. Yi shall be noticed to appear at an administrative hearing at such time as the Board is notified that:
    - He is not in compliance with the terms and conditions specified by HPIP, or has been terminated from participation in HPIP, or
    - There is a pending investigation or unresolved allegations against him involving a violation of law, regulation or any term or condition of this Order, or

- He has successfully completed the above-referenced period of participation in HPIP. Upon receipt of evidence of Mr. Yi's participation in and compliance with HPIP, the Committee, at its discretion, may waive Mr. Yi's appearance before the Committee, and conduct an administrative review of this matter.

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

Thursday, August 14, 2008

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

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

TIME & PURPOSE: After an attempt to schedule a regular meeting failed, pursuant to § 54.1-2408.1 of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:40 a.m., on August 14, 2008, to consider the summary suspension of the registrations of Jacqueline Gallo and Kevin Rivera to practice as pharmacy technicians.

PRESIDING: Michael E. Stredler, Vice Chairman

MEMBERS PRESENT:
Gill Abernathy
John Beckner
Bobby Ison
Leo Ross
Brandon Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
James Schliessmann, 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 two possible summary suspension cases. The Board members stated that they would not have been able to attend.

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

JACQUELINE GALLO
Registration #0230-012187

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

Decision:

Mr. Beckner moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Jacqueline Gallo poses a substantial danger to the public; and therefore, that the registration of Jacqueline Gallo, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Gallo for the indefinite suspension of her registration in lieu of a hearing.

KEVIN RIVERA
Registration #0230-009415

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

Decision:

Mr. Yi moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Kevin Rivera poses a substantial danger to the public; and therefore, that the registration of Kevin Rivera, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Mr. Rivera for the indefinite suspension of his registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 8:55a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Michael E. Stredler, Vice Chairman

Date

Virginia Department of Health Professions

Sandra Whitley Ryals, Director

Patient Care Disciplinary Case Processing Times: Quarterly Performance Measurement, Q4 2004 - Q4 2008

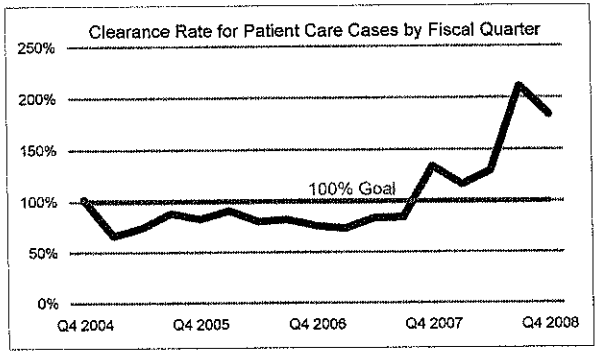
"To enhance the delivery of safe and competent health care by licensing qualified health care professionals, enforcing standards of practice, and providing information to both practitioners and consumers of health care services."
DHP Mission Statement

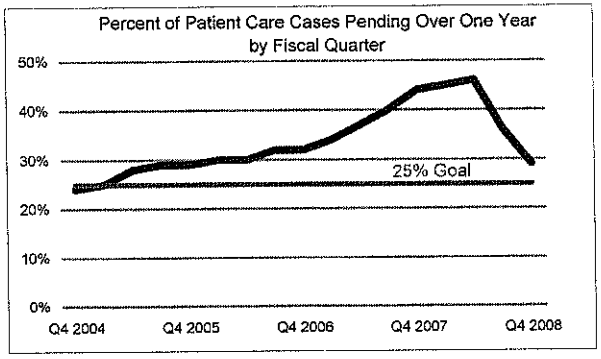
In order to uphold its mission relating to discipline, DHP continually assesses and reports on performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on the Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. These three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload; Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement. The following pages show the KPMs by board, listed in in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

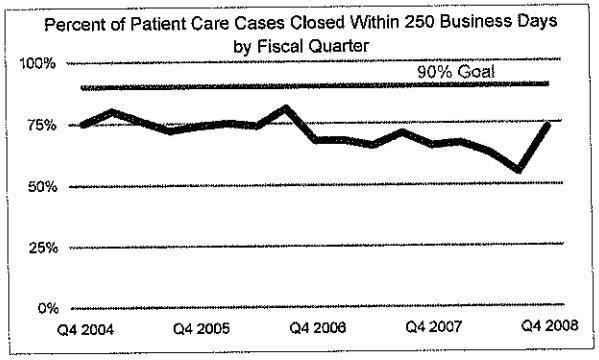
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to achieve a 100% clearance rate of allegations of misconduct by the end of FY 2009 and maintain 100% through the end of FY 2010. The clearance rate increased dramatically over the last year, hovering around 200% over the last two quarters; DHP is resolving double the amount of cases it receives. For the last quarter shown, there were 780 patient care cases received and 1,432 closed.

Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to reduce the percentage of open patient care caseload older than 250 business days to no more than 25% by the end of FY 2010. The percent of cases pending over 250 business days has dropped dramatically over the last year, falling from 45% to 29%. For the last quarter shown, there were 2,194 patient care cases pending, with 636 pending over 250 business days.

Time to Disposition - the percent of patient care cases closing within 250 business days for cases received within the immediately preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes undue influence of the oldest cases on the measure. The goal is to resolve 90% of complaints related to patient care within 250 business days by the end of FY 2010. The percent of cases resolved within 250 business days jumped to 73% during the last quarter (up from 55% in the previous quarter). For the last quarter shown, there were 1,201 patient care cases closed, with 876 closed within 250 business days.







Submitted: 8/15/2008

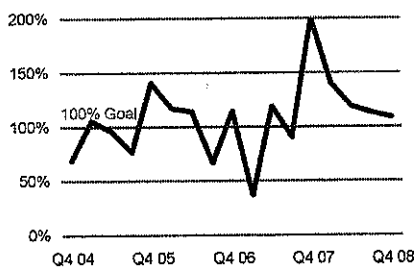
Prepared by: VisualResearch, Inc.

Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Pharmacy - In Q4 2008, the clearance rate was 109%, the Pending Caseload older than 250 business days was 25% and the percent closed within 250 business days was 72%.

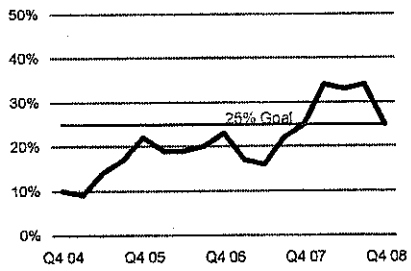
Q4 2008 Caseloads:
Received=47, Closed=51
Pending over 250 days=35
Closed within 250 days=33

Clearance Rate

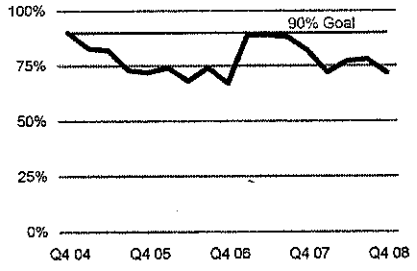


Age of Pending Caseload

(percent of cases pending over one year)



Percent Closed in 250 Business Days



Board of Pharmacy

Current Regulatory Actions

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Changes in renewal dates for pharmacies and permitted facilities Stage: Emergency/NOIRA - *At Secretary's Office*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Standards of conduct Stage: NOIRA - *Register Date: 6/9/08* *Board to adopt proposed regulations on 9/3/08*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Periodic review Stage: Proposed - *At Governor's Office*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Changes to nuclear pharmacy rules Stage: Fast-Track - *At Secretary's Office*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Registration of restricted volunteer licensees Stage: Final - *Register Date: 7/7/08* *Effective 8/6/08*

DRAFT REGULATIONS FOR ESTABLISHMENT OF A DRUG DONATION PROGRAM

18VAC110-20-10 Definitions

...

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

...

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

~~A.~~ Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of §54.1-3411.1 A of the Code of Virginia. Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

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

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

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

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

PART XVII PRESCRIPTION DRUG DONATION PROGRAM

18VAC110-20-740. Drug donation sites.

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

B. A pharmacy that chooses to continue as a registered drug donation site may renew registration every two years on the date of initial registration.

18VAC110-20-750. Eligible drugs.

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

1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, as set forth in § 54.1-3411.1, subdivision A2; and

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

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

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

2. Drugs that in the professional judgment of the pharmacist appear to be adulterated or misbranded;

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

4. Drugs that may only be dispensed under a restricted distribution system for safety reasons to include drugs that may only be dispensed to a patient registered with the drug manufacturer; and

5. Drugs that have been previously compounded.

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

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

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long term care facility or other facility where drugs are administered to that patient, if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

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

2. A statement that the donor intends to voluntarily donate the prescription drug for re-dispensing;

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

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

5. The date of donation;

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

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

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

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

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

E. Prior to transferring or re-dispensing donated drugs, a pharmacist shall perform a final check of any donated drug for eligibility and shall:

1. Remove the donor's patient specific information from previous labeling or render unreadable such information;

2. If transferring, ensure that all other labeling needed for product identification and eligibility determination by the dispensing pharmacy is legible and remains on the original container.

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

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

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

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

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

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

3. The date of transfer.

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

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

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

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

B. The pharmacy re-dispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing fee for each such drug re-dispensed, not to exceed the current Medicaid dispensing fee.

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

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

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

A. A drug donation site in possession of donated prescription drugs that expire or otherwise become ineligible for re-dispensing shall dispose of such drugs in compliance with 18 VAC110-20-210.

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

18VAC110-20-800. Records

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

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

C. Storage of records.

1. Transfer, dispensing, and disposal records may be stored in an electronic database or record or as a scanned image;

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

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

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

Agenda Item: **Regulatory Action – Adoption of Exempt Regulation Public Participation Guidelines**

Staff Note:

SB 734/HB 1167 enacted by the 2008 General Assembly require the Department of Planning and Budget (DPB) to draft model Public Participation Guideline regulations and for all agencies to either adopt the model as an exempt action or modify the model and adopt as a fast-track action. We have worked with for several months to revise the model so it is acceptable to DHP boards and have been told that any changes will be very carefully scrutinized.

Recommended Action:

It is recommended that the Board adopt the model PPG regulations as an exempt action.

There must also be a motion to repeal Chapter 10, which is the current regulation for Public Participation Guidelines.

Project 1485 - Final

BOARD OF PHARMACY
Model Public Participation Guidelines

CHAPTER 10
PUBLIC PARTICIPATION GUIDELINES (REPEALED)

~~Part I~~
~~General Provisions~~

18VAC110-10-10. ~~Purpose.~~ (Repealed.)

~~The purpose of this chapter is to provide guidelines for the involvement of the public in the initial formation and development, amendment or repeal of regulations of the Board of Pharmacy. The guidelines do not apply to regulations exempted or excluded from the provisions of the Administrative Process Act. These rules seek to expand participation by providing for electronic exchange with the public and thereby increasing participation, reducing costs, and improving the speed of communication.~~

18VAC110-10-20. ~~Definitions.~~ (Repealed.)

~~The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:~~

~~"Administrative Process Act" means Chapter 40 (§2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.~~

~~"Board" means the Board of Pharmacy.~~

~~"Notification lists" means lists used by the board to notify persons pursuant to these rules. Such lists may include electronic lists maintained through the Virginia Regulatory Town Hall or lists maintained by the board.~~

~~"Person" means an individual, a corporation, a partnership, an association, a governmental body, a municipal corporation, or any other legal entity.~~

~~"Regulation" means any statement of general application, having the force of law, affecting the rights or conduct of any person, adopted by the board in accordance with the authority conferred on it by applicable laws.~~

~~Part II~~
~~Mailing List~~

18VAC110-10-30. ~~Composition of notification lists.~~ (Repealed.)

~~A. The board shall maintain lists of persons who have requested to be notified of the initial formation, development, amendment or repeal of regulations.~~

~~B. Any person may request to be placed on a notification list by indicating so electronically or in writing to the board. The board may add to a list any person it believes will serve the purpose of enhancing participation in the regulatory process.~~

~~C. The board may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.~~

~~D. The board shall periodically request those persons on the notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the lists. Persons who elect to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there has been no response to the request from the board, such persons shall be deleted from the list.~~

18VAC110-10-40. ~~Documents to be sent to persons on the notification lists.~~ (Repealed.)

~~A. Persons on the notification lists, as described in 18VAC110-10-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:~~

~~1. A notice of intended regulatory action.~~

~~2. A notice of the comment period on a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.~~

~~3. A notice soliciting comment on a final regulation when the regulatory process has been extended.~~

~~B. Notification of the adoption of a final regulation and copies of the regulation shall be posted on the board's website prior to the 30-day adoption period.~~

~~C. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation otherwise adopted in accordance with this chapter.~~

~~Part III~~

~~Public Participation Procedures~~

18VAC110-10-50. ~~Petition for rulemaking.~~ (Repealed.)

~~A. As provided in §2.2-4007 of the Code of Virginia, any person may petition the board to develop a new regulation or amend an existing regulation.~~

~~B. A petition shall include but need not be limited to the following:~~

~~1. The petitioner's name, mailing address, telephone number, and, if applicable, the organization represented in the petition.~~

~~2. The number and title of the regulation to be addressed.~~

~~3. A description of the regulatory problem or need to be addressed.~~

~~4. A recommended addition, deletion, or amendment to the regulation.~~

~~C. The board shall receive, consider and respond to a petition within 180 days and shall have the sole authority to dispose of the petition.~~

~~D. Nothing herein shall prohibit the board from receiving information from the public and proceeding on its own motion for rulemaking.~~

18VAC110-10-60. ~~Notice of Intended Regulatory Action.~~ (Repealed.)

~~A. Except as provided in §2.2-4012.1 of the Code of Virginia, the board shall issue a notice of intended regulatory action (NOIRA) whenever it considers the adoption, amendment or repeal of a regulation. The NOIRA shall state the purpose of the action and a brief statement of the need or problem the proposed action will address.~~

~~B. The NOIRA shall indicate whether the board intends to hold a public hearing on the proposed regulation after it is published. If the board does not intend to hold a public hearing, it shall so state in the NOIRA.~~

~~C. If prior to the close of the 30-day comment period on the NOIRA, the board receives a request for a public hearing on the proposed regulation from at least 25 persons or if the Governor directs the board to hold a public hearing, such a hearing shall be scheduled.~~

18VAC110-10-70. ~~Notice of Comment Period.~~ (Repealed.)

~~A. The board shall issue a notice of comment period (NOCP) whenever it proposes to initiate, amend or repeal a regulation. The NOCP shall indicate that copies of the~~

~~proposed regulation are available electronically or from the board and may be requested in writing from the contact person specified in the NOCP.~~

~~B. The NOCP shall indicate that copies of the statement of substance, issues, basis, purpose, and estimated impact of the proposed regulation may also be requested in writing.~~

~~C. The NOCP shall make provision for comments pertaining to the proposed regulation by regular mail, facsimile or electronic means. With the exception of comment received at a scheduled public hearing, oral comment shall not be accepted.~~

18VAC110-10-80. ~~Notice of meeting.~~ (Repealed.)

~~A. At any meeting of the board or advisory committee at which the formation, amendment, repeal, or adoption of a regulation is anticipated, the subject shall be described in a notice of meeting, which has been posted electronically on the Virginia Regulatory Town Hall and transmitted to the Registrar of Regulations for inclusion in the Virginia Register.~~

~~B. If the board anticipates action on a regulation for which an exemption to the Administrative Process Act is claimed, the notice of meeting shall indicate that a copy of the proposed regulation may be requested from the board at least two days prior to the meeting. A copy of the regulation shall be made available to the public attending such meeting.~~

18VAC110-10-90. ~~Public hearings on regulations.~~ (Repealed.)

~~The board shall conduct a public hearing during the 60-day comment period following the publication of a proposed regulation or amendment to an existing regulation unless, at a noticed meeting, the board determines that a hearing is not required.~~

18VAC110-10-100. ~~Periodic review of regulations.~~ (Repealed.)

~~A. The board shall conduct a periodic review of its regulations consistent with an executive order issued by the Governor and with §2.2-4007.1 of the Code of Virginia to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.~~

~~B. Such review may be conducted separately or in conjunction with other meetings or hearings.~~

~~C. Notice of the proceeding shall be transmitted to the Registrar of Regulations for inclusion in the Virginia Register and shall be sent to the notification lists identified in 18VAC110-10-30.~~

~~Part IV~~

~~Ad Hoc Committees~~

18VAC110-10-110. ~~Appointment of committees.~~ (Repealed.)

~~A. The board may appoint an ad hoc committee whose responsibility shall be to assist in the review and development of regulations for the board.~~

~~B. The board may appoint an ad hoc committee to provide professional specialization or technical assistance when the board determines that such expertise is necessary to address a specific regulatory issue or need or when groups of individuals register an interest in working with the agency.~~

18VAC110-10-120. ~~Limitation of service.~~ (Repealed.)

~~A. An ad hoc committee that has been appointed by the board may be dissolved by the board when:~~

~~1. There is no response to the Notice of Intended Regulatory Action; or~~

~~2. The board determines that the promulgation of the regulation is either exempt or excluded from the requirements of the Administrative Process Act.~~

~~B. An ad hoc committee shall remain in existence no longer than 18 months from its initial appointment unless the board determines that the specific regulatory need continues to exist beyond that time. The board may authorize the ad hoc committee to continue for an additional specified period of time to complete the task for which it was appointed.~~

CHAPTER 11
PUBLIC PARTICIPATION GUIDELINES

Part I
Purpose and Definitions

18VAC110-11-10. Purpose.

The purpose of this chapter is to promote public involvement in the development, amendment or repeal of the regulations of the Board of Pharmacy. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§2.2-4000 et seq. of the Code of Virginia).

18VAC110-11-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative Process Act" means Chapter 40 (§2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Agency" means the Board of Pharmacy, which is the unit of state government empowered by the agency's basic law to make regulations or decide cases. Actions specified in this chapter may be fulfilled by state employees as delegated by the agency.

"Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency.

"Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by §2.2-3707 C of the Freedom of Information Act.

"Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action.

"Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.

"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation.

"Person" means any individual, corporation, partnership, association, cooperative, limited liability company, trust, joint venture, government, political subdivision, or any other legal or commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.

"Regulation" means any statement of general application having the force of law, affecting the rights or conduct of any person, adopted by the agency in accordance with the authority conferred on it by applicable laws.

"Regulatory action" means the promulgation, amendment, or repeal of a regulation by the agency.

"Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested parties established by the agency for the purpose of assisting in regulatory actions.

"Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia Department of Planning and Budget at www.townhall.virginia.gov, which has online public comment forums and displays information about regulatory meetings and regulatory actions under consideration in Virginia and sends this information to registered public users.

"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published under the provisions of Article 6 (§2.2-4031 et seq.) of the Administrative Process Act.

Part II
Notification of Interested Persons

18VAC110-11-30. Notification list.

A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency.

B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier.

C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list.

E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list.

F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.

18VAC110-11-40. Information to be sent to persons on the notification list.

A. To persons electing to receive electronic notification or notification through a postal carrier as described in 18VAC110-11-30, the agency shall send the following information:

1. A notice of intended regulatory action (NOIRA).

2. A notice of the comment period on a proposed, a reproposed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents.

3. A notice soliciting comment on a final regulation when the regulatory process has been extended pursuant to §2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

B. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation or regulatory action.

Part III
Public Participation Procedures

18VAC110-11-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with §2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to §2.2-4012 E of the Code of Virginia.

18VAC110-11-60. Petition for rulemaking.

A. As provided in §2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.

B. A petition shall include but is not limited to the following information:

1. The petitioner's name and contact information;

2. The substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections; and

3. Reference to the legal authority of the agency to take the action requested.

C. The agency shall receive, consider and respond to a petition pursuant to §2.2-4007 and shall have the sole authority to dispose of the petition.

D. The petition shall be posted on the Town Hall and published in the Virginia Register.

E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.

18VAC110-11-70. Appointment of regulatory advisory panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

18VAC110-11-80. Appointment of negotiated rulemaking panel.

A. The agency may appoint a negotiated rulemaking panel (NRP) if a regulatory action is expected to be controversial.

B. An NRP that has been appointed by the agency may be dissolved by the agency when:

1. There is no longer controversy associated with the development of the regulation;

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act; or

3. The agency determines that resolution of a controversy is unlikely.

18VAC110-11-90. Meetings.

Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with §2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.

18VAC110-11-100. Public hearings on regulations.

A. The agency shall indicate in its notice of intended regulatory action whether it plans to hold a public hearing following the publication of the proposed stage of the regulatory action.

B. The agency may conduct one or more public hearings during the comment period following the publication of a proposed regulatory action.

C. An agency is required to hold a public hearing following the publication of the proposed regulatory action when:

1. The agency's basic law requires the agency to hold a public hearing;

2. The Governor directs the agency to hold a public hearing; or

3. The agency receives requests for a public hearing from at least 25 persons during the public comment period following the publication of the notice of intended regulatory action.

D. Notice of any public hearing shall be posted on the Town Hall and Commonwealth Calendar at least seven working days prior to the date of the hearing. The agency shall also notify those persons who requested a hearing under subdivision C 3 of this section.

18VAC110-11-110. Periodic review of regulations.

A. The agency shall conduct a periodic review of its regulations consistent with:

1. An executive order issued by the Governor pursuant to §2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and

2. The requirements in §2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses.

B. A periodic review may be conducted separately or in conjunction with other regulatory actions.

C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.

Project 1341

BOARD OF PHARMACY

Standards of conduct

18VAC110-20-25. Unprofessional conduct.

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

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

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

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

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

5. Entering into a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to, sexual misconduct with a patient, or other actions that result in personal gain to the detriment of the patient;

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

7. Failing to appropriately handle known dispensing errors in a manner that protects the health and safety of the patient, including but not limited to, determining whether the patient consumed the incorrect drug or in an incorrect manner, and if so, ensuring that the prescriber is notified;

8. Delegating a task related to the practice of pharmacy to a person who is not adequately trained, or licensed or registered, to perform such task;

9. Failing to adequately supervise non-pharmacist personnel engaged in activities related to the practice of pharmacy;

10. Failing to ensure that pharmacy interns and pharmacy technicians are registered, and that such registration is current, as required in law and regulation; or

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

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

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

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;

2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;

3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;

4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;

5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;

6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;

7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;

8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;

9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;

10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;

11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;

12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;

13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or

14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

Guidance Document 110-25

Life of a Prescription When the Prescriber Is No Longer In Practice

The Board has been requested on numerous occasions to give guidance to pharmacists on whether to refill prescriptions with authorized refills when the prescriber is no longer in practice. The reason for cessation of practice may include, but are not limited to, relocation, retirement, death, suspension or revocation of license, and long-term illness. There is nothing in the Drug Control Act that specifically addresses this issue. The law does state that no prescription shall be filled which does not result from a bona fide physician-patient relationship. The law does not address whether a prescription can be "refilled" without this relationship.

At the point in time when the prescription was written and refills authorized, it is assumed that a bona fide relationship existed and that the prescriber envisioned that the patient could safely receive the authorized refills without further intervention on his part. However, while still in practice, the prescriber would be available for consultation should questions or problems arise. Once the prescriber retires, is suspended, moves from the area, etc. he is no longer available for consultation, and there is no longer a relationship should a problem occur.

The Board believes that, in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the validity of refilling these prescriptions should be left to the professional judgment of the pharmacist. Each prescription should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. At the same time, each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write new prescriptions for any required drugs.

Adopted by the Board of Pharmacy on October 5, 1999

Virginia Board of Pharmacy

Guidance Document 110-25

Life of a Prescription When the Prescriber Is No Longer In Practice

Whenever a prescriber is no longer in practice due to death, extended illness, retirement, relocation, suspension or revocation of the license by the relevant licensing board, or other reason, pharmacists question whether they can fill or continue to refill prescriptions that were written prior to the cessation of practice. There will be prescriptions which have been filled, but for which there are still valid refills remaining. There will probably also be prescriptions written prior to the ceasing of practice, but not yet presented to a pharmacy for filling by the patient for any number of reasons. This could include Schedule II prescriptions written with "do not fill until *<future date>*" instructions.

While there is nothing in law that specifically addresses this issue, §54.1-3303 does state that no prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship. At the point in time when the prescription was written and refills authorized, it is assumed that a bona fide relationship existed and that the prescriber envisioned that the patient could safely receive the authorized refills without further intervention on his part. However, while still in practice, the prescriber would be available for consultation should questions or problems arise. Once the prescriber retires, is suspended, moves from the area, etc. he is no longer available for consultation, and there is no longer a relationship if a problem occurs.

The Board believes that, in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the decision to fill or refill these prescriptions should be left to the professional judgment of the pharmacist. Each prescription should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. At the same time, each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write new prescriptions for any required drugs. In cases where a license is denied, suspended, revoked, or restricted, in whole or part, because of illegal or inappropriate prescribing practices, the pharmacist must carefully evaluate the prescription and any remaining refills to determine if the prescription actually resulted from a bona fide practitioner-patient relationship at the time written, and if it was written for a legitimate medical purpose.

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: RICHARD B. LAKES, PHARMACIST
REINSTATEMENT APPLICANT
License No. 0202-004156

NOTICE OF HEARING

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110 and § 54.1-2400(11) of the Code of Virginia (1950), as amended ("Code"), Richard B. Lakes is hereby given notice that in accordance with § 2.2-4024 of the Code, a formal administrative hearing will be held before the Board of Pharmacy ("Board"). The hearing will be held on September 3, 2008, at 11:00 a.m., at the Department of Health Professions, Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 201, Richmond, Virginia, at which time Mr. Lakes will be afforded the opportunity to be heard in person or by counsel.

At the hearing, Mr. Lakes has the following rights among others: the right to representation by counsel, the right to have witnesses subpoenaed and to present witnesses on his behalf, the right to present documentary evidence, and the right to cross-examine adverse witnesses. If Mr. Lakes desires any witnesses to appear on his behalf, he shall notify the Director of Administrative Proceedings, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300, Richmond, Virginia 23233, giving the names and addresses of the witnesses, at least fifteen (15) days prior to the date of the hearing in order that subpoenas may be issued.

The purpose of the hearing is to act upon the request for reinstatement of Mr. Lakes' license to practice pharmacy in the Commonwealth of Virginia, which was mandatorily suspended by Order of the Department of Health Professions entered March 30, 2007, pursuant to § 54.1-2409 of the Code, and to inquire into evidence that Mr. Lakes may have violated certain laws governing the practice of pharmacy in Virginia, as more fully set forth in the Statement of Particulars below.

As the applicant, the burden of proof shall be upon Mr. Lakes to provide evidence satisfactory to the Board that he is prepared to resume the competent practice of pharmacy pursuant to § 54.1-3316(7) of the Code and 18 VAC 110-20-80 and 18 VAC 110-20-90 of the Board of Pharmacy Regulations. Pursuant to § 54.1-2409 of the Code, reinstatement of Mr. Lakes' license requires the affirmative vote of three-fourths of the members of the Board in attendance at the hearing.

STATEMENT OF PARTICULARS

The Board alleges that Mr. Lakes may have violated § 54.1-3316(7) and (11) of the Code in that he was found guilty in the Circuit Court of Albemarle County, Virginia, on August 30, 2006, of twelve (12) counts of possession of child pornography, all felonies. The sentencing order for these twelve (12) counts was entered on January 16, 2007, and amended on September 18, 2007. Pursuant to the plea agreement in the criminal case, seven (7) counts of possession of child pornography have been continued until April 2010 with the dismissal of these counts contingent upon Mr. Lakes' good behavior. These convictions formed the basis for the mandatory suspension of his license pursuant to § 54.1-2409 of the Code.

FOR THE BOARD

Elizabeth Scott Russell
Executive Director

ENTERED: August 11, 2008