

**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.

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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.

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- 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.

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 United 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.

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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
Myki 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 Myki 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.

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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

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

Sandra Whitley Ryals, Director

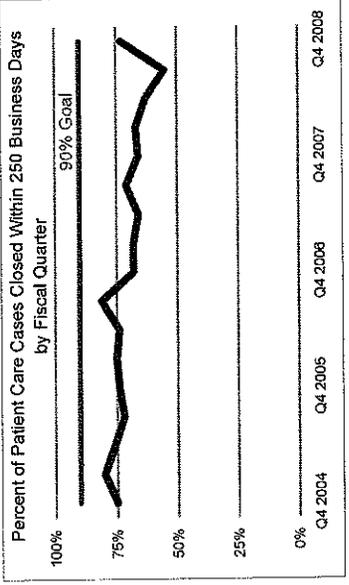
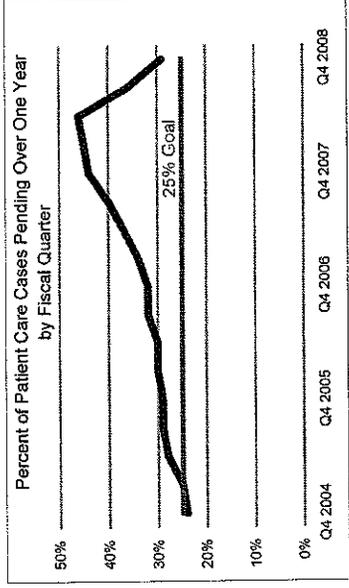
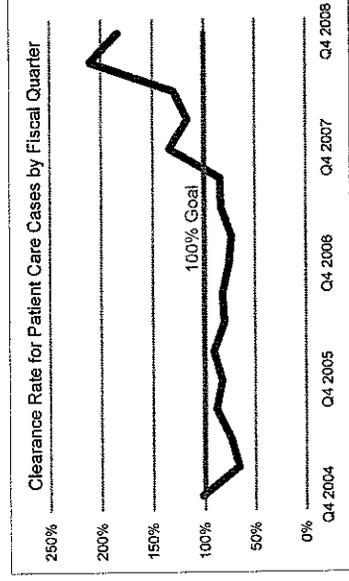
"To enhance the delivery of safe and competent health care by licensing qualified health care professionals, enforcing standards of practice, and providing information to both practitioners and consumers of health care services."
DHP Mission Statement

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 Performance 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 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, 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 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.



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%.

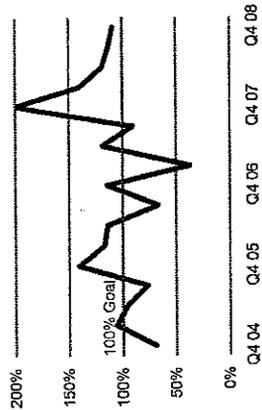
Q4 2008 Caseloads:

Received=47, Closed=51

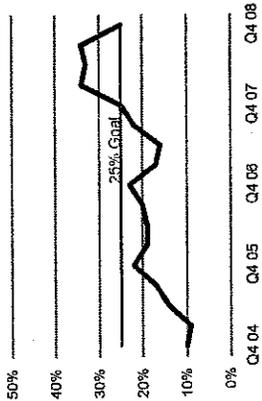
Pending over 250 days=35

Closed within 250 days=33

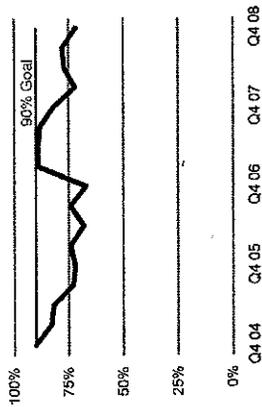
Clearance Rate



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]	<table border="1" style="width: 100%;"> <tr> <td style="width: 10%;"><u>Action:</u></td> <td>Changes in renewal dates for pharmacies and permitted facilities</td> </tr> <tr> <td><u>Stage:</u></td> <td>Emergency/NOIRA - <i>At Secretary's Office</i></td> </tr> </table>	<u>Action:</u>	Changes in renewal dates for pharmacies and permitted facilities	<u>Stage:</u>	Emergency/NOIRA - <i>At Secretary's Office</i>
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Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<table border="1" style="width: 100%;"> <tr> <td style="width: 10%;"><u>Action:</u></td> <td>Registration of restricted volunteer licensees</td> </tr> <tr> <td><u>Stage:</u></td> <td>Final - <i>Register Date: 7/7/08</i> <i>Effective 8/6/08</i></td> </tr> </table>	<u>Action:</u>	Registration of restricted volunteer licensees	<u>Stage:</u>	Final - <i>Register Date: 7/7/08</i> <i>Effective 8/6/08</i>
<u>Action:</u>	Registration of restricted volunteer licensees				
<u>Stage:</u>	Final - <i>Register Date: 7/7/08</i> <i>Effective 8/6/08</i>				

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.

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 re-proposed, 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 repropoed 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.

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.

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