



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

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

Tentative Agenda of Meeting

December 12, 2007

9:00AM

TOPIC

PAGE(S)

Call to Order: Bobby Ison, Chairman

- Welcome and Introductions
- Reading of emergency evacuation script
- Approval of Agenda
- Approval of previous Board meeting minutes:
 - September 12, 2007 Board meeting
 - September 12, 2007 Regulation Committee meeting
 - October 10, 2007 Regulation Committee meeting
 - October 27, 2007 Pilot Committee informal conference

1-15

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.

Report of DPH Director, Sandra Whitley Ryals

Legislation:

- Legislative Update-Scotti Russell, Elaine Yeatts

n/a

Regulations: Elaine Yeatts

- Update on regulation processes
 - Pedigree rules
- Adoption of exempt change to remove inactive fee from PSD regs
- Petition for Rulemaking, Ken Dandurand, 18VAC110-20-515
- Adoption of proposed regulations, 18VAC110-20-10 et seq.

n/a

16

17-20

separate handout

Miscellaneous:

- Approval of guidance document on use of drop boxes
- Approval of revised guidance document on CE sanctions
- Discussion of whether "unprofessional conduct" needs to be defined in regulation-possible assignment to a subcommittee of the Regulation Committee if needed

21

22-25

26-56

Reports:

- Report on Board of Health Professions-Jennifer H. Edwards

- Executive Director's Report-Scotti Russell

 - Report on NABP Fall Legislative Conference
 - Report on NABP District II meeting
 - report on disciplinary program-Cathy Reiniers-Day
 - report on licensing -Caroline Juran
 - report on the prescription monitoring program-Ralph Orr

n/a

Consideration of consent orders (if any)

Adjourn

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

(DRAFT/UNAPPROVED)

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

September 12, 2007
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 9:20AM.

PRESIDING: Bobby Ison, Chairman

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

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
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

INTRODUCTIONS AND QUORUM: Board members and staff introduced themselves. Mr. Ison welcomed Gerard Dabney, newly-appointed citizen member of the Board of Pharmacy replacing Diane Langhorst. With ten 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 June 12, 2007 and July 26, 2007. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: Mr. Ison called for public comments and none were given at this time.

DHP DIRECTOR'S REPORT: Ms. Wingfield gave a brief report on behalf of Sandra Whitley Ryals, Director, DHP, who was unable to attend the Board meeting due to conflicting schedules. Ms. Wingfield welcomed the Board

to the new building and also welcomed Mr. Dabney on behalf of the Department and Ms. Ryals. She explained to the Board that due to current revenue shortfalls, agencies were being asked to cut budgets, and that one area that would be further restricted is out-of-state travel. Ms. Wingfield stated that new Board member training was being planned and a date would be forthcoming.

LEGISLATION UPDATE:

Ms. Yeatts provided a summary of the three legislative proposals being submitted for approval on behalf of the Board of Pharmacy. The first proposal is to remove from statute the specific expiration dates for renewal of licenses in order to allow the Board, in regulation, to stagger some expiration dates to better control staff workload. The second proposal is to seek authority for the Board to require topic-specific continuing pharmacy education programs with appropriate prior notice to pharmacists. The third proposal is the annual scheduling of controlled substances legislation to have Virginia controlled substances schedules conform to federal schedules.

REGULATION UPDATE:

- PPG

- NOIRA-periodic review

- Collaborative Practice

- Pedigree Regulations

- Petition for Rulemaking

- Petition for Rulemaking

Ms. Yeatts provided a summary of ongoing regulation processes. She stated that the fast track public participation guidelines regulations were final effective August 25, 2007.

She stated that the Board's NOIRA for changes to its general regulations pursuant to the recent periodic review had been published and the public comment period closed as of September 5, 2007.

Final regulations are at the Governor's office awaiting approval for publication.

The public comment on the proposed regulations ended August 10, 2007, and the Board will be acting on the comments and adopting final rules later in the agenda.

The Board received and published a petition for rulemaking from Sherry Fortune requesting that the Board allow an automated dispensing device in a long term care facility to be used only for stat and emergency box drugs and without a pharmacist review of new orders needed prior to removing drugs for administering. Ms. Fortune has since withdrawn the petition stating that she planned to comply with the current regulation.

The Board received and has sent for publication a petition for rulemaking from Ken Dandurand on behalf of MedNovations, Inc. to allow a non-resident pharmacy to use pharmacists not licensed in Virginia to provide outsourced pharmacy services to Virginia pharmacies. Comment on this petition will be received until

October 31, 2007. The Board may act on the petition at its December meeting.

FINAL PEDIGREE
REGULATIONS:

The Board reviewed the current proposed regulations for establishment of a pedigree system and public comment received during the comment period. The Board received comments from Anne Leigh Kerr, Pharmaceutical Research and Manufacturers of America (PhRMA); Elizabeth Gallenagh, Healthcare Distribution Management Association (HDMA); Martha Russell, Cardinal Health; and Michelle Cope, National Association of Chain Drug Stores (NACDS).

- ADR to ADR to office-based practitioner

HDMA requested an addition to 18 VAC 110-50-160 to include distribution from a manufacturer to an Authorized Distributor of Record (ADR) to one additional ADR then to an office based healthcare practitioner for the purpose of administering or dispensing to patients as a distribution for which a pedigree is not required.

Motion:

A motion was made and passed, to add language to 18 VAC 110-50-160 to exempt manufacturer to ADR to ADR to office-based practitioner from pedigree requirements. (Motion by Edwards, Second by Beckner)

- "Drop shipment"
- "Co-licensed partners" or "co-licensees"

There were comments from Cardinal and HDMA requesting different definitions of this term than in the proposed regulations.

There were requests from Cardinal and HDMA requesting that this term be added to definitions and included in 18 VAC 110-50-160 as a form of distribution not susceptible to counterfeiting, and include in the term "drop shipment". There was significant discussion related to the appropriate definition, the definition given by Cardinal versus the definition in the NABP model regulations. Ms. Russell stated that this was discussed at length during the promulgation process by the committee and these same interested parties, and that a determination was made at that time that a co-licensee was a secondary manufacturer of a product and, therefore, any distribution from a co-licensee would be considered distribution from a manufacturer and would be within the normal chain of distribution. For this reason, the term was deemed not necessary and not included in the proposed regulations.

Motion:

A motion was made and defeated, with a vote of 8 to 2, to add a definition of "co-licensee", as defined in the NABP model regulations, to the Board's final regulations and insert the term where appropriate in the regulations. (Motion by Abernathy, Second by Ross)

- "Authentication"

The Board reviewed comments by Cardinal related to authenticating a pedigree. Cardinal had asked that a definition be

added as well as an introductory paragraph establishing a requirement for authentication in 18 VAC 110-50-180. After discussion, the Board determined that a definition was not needed because everything in the definition offered by Cardinal was also listed in the paragraph suggested to be added to 18 VAC 110-50-180.

Motion:

A motion was made and passed, to add a new paragraph A to 18 VAC 110-50-180 that reads "Each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, shall affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred." (Motion by Beckner, Second by Edwards)

- General comment to adopt without change
- Add a "returns" section

The Board reviewed the comment by NACDS to adopt the proposed regulations without change.

Cardinal requested that the Board add a separate section to further clarify when a product could be "returned" without requiring a pedigree. Mr. Casway advised that applicability of returns of pharmaceutical products was already specified in the statute, and any expansion of allowable returns without a pedigree could be in conflict with law. There was discussion that returns to a third party returns processor provided the returns were for the purpose of proper disposal and not for further sale for use by the public would not constitute wholesale distribution by law in Virginia, and not require a pedigree.

- Clarification of authentication requirement

PhRMA requested that the Board insert clarifying language in 18 VAC 110-50-180 A (will now be 18 VAC 110-50-180 B), to ensure that a manufacturer or wholesale distributor would only have to provide authentication information for those distributions actually conducted by that manufacturer or wholesale distributor.

Motion:

A motion was made and passed, to add the phrase "only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor" in 18 VAC 110-50-180, now paragraph B. (Motion by Yi, Second by Kozera)

Motion:

A motion was made and passed, to adopt as final regulations the proposed regulations as amended by the Board today. (Motion by Beckner, Second by Yi)

SANCTION REFERENCE:

The Board reviewed the sanction reference manual and worksheet that had been developed for use by informal conference committees in determining sanctions by VisualResearch, Inc. A committee of the board met in July, reviewed the original

worksheet that had been developed several years ago, and made several modifications to the document. Neal Kauder, President of VisualResearch, was present to answer questions of the Board.

Motion:

A motion was made and passed, to adopt the manual and worksheet as a Board guidance document and to begin using this tool in informal conferences. (Motion by Ross, Second by Brown)

INSPECTION COMMITTEE
UPDATE:

Ms. Russell stated that the inspection committee met on July 26th and began the task of reviewing the inspection reports and identifying deficiencies for which the immediate consent order process could be used. She stated that the committee had also determined that these immediate consent orders in most cases should hold the pharmacy permit as the respondent rather than the PIC, staff pharmacist, or owner specifically. She advised that this committee would need to meet probably several more times before it was ready to make a recommendation to the full Board, but the goal would be to make a recommendation possibly by the March 2008 meeting.

TECHNICIAN
RESPONSIBILITY IN
DISPENSING ERROR CASES:

Ms. Russell explained that prior to registration of pharmacy technicians; the Board held only the checking pharmacist responsible for not assuring accuracy in cases involving dispensing errors, and when the registration process was initiated for pharmacy technicians, there was still sentiment on the part of the Board to only docket a case against the pharmacist. She stated that the Enforcement Division is receiving cases or noting in the investigation of cases that a pharmacy technician is identified as contributing to an error. She asked the Board to provide guidance as to whether to docket a case against both the pharmacy technician and the checking pharmacist in these type cases. After discussion, the Board, by consensus, agreed that cases should be docketed against both.

UPDATE GUIDANCE
DOCUMENT RELATED TO
UNREGISTERED
PHARMACY TECHNICIANS:

Ms. Reiniers-Day requested that, while the Board was discussing pharmacy technician cases, that it also discuss its previous guidance for issuance of a Confidential Consent Order (CCA) in cases where it is discovered that a person is performing pharmacy technician tasks without being registered with the Board or in an approved training program within the time limits for such training. Ms. Reiniers-Day suggested that the Board may want to consider increased sanctions for these cases since the requirement for technician registration has been in place over three years and pharmacists should be aware of the requirements, yet the Board is still receiving a number of these cases. There was some question as to jurisdiction over an unregistered person. Ms. Russell informed the Board that in most cases the unregistered persons performing technician tasks applied for registration and became

registered almost immediately once informed that they could not continue working as a pharmacy technician without being registered, so the Board then has jurisdiction to take disciplinary action. Most are already eligible for registration when the problem is discovered, but have just not yet made application. The Board agreed that it was time to move beyond the CCA for these cases and discussed appropriate sanctions.

Motion:

A motion was made and passed, to authorize staff to offer a pre-hearing consent order in these cases to both the pharmacy technician and the PIC, with the sanction of a reprimand to both and monetary penalty of \$50 for the pharmacy technician and \$250 for the PIC. (Motion by Beckner, second by Yi)

**ISSUE OF SCHEDULE II
PRESCRIPTIONS AND TWO
PRESCRIPTION NUMBERS:**

Ms. Russell stated that staff is frequently asked how to handle the dispensing of a Schedule II prescription in which a patient wants a portion billed to a third party and to pay cash for the remainder when the pharmacy computer system will not then indicate the dispensing of the total amount under the same prescription number. Some pharmacies have a method for working around the problem by giving the one prescription two different prescription numbers and dispensing each partial amount under the two numbers. There was significant discussion as to whether this is allowed; on the side of allowing this practice, there is the fact that a prescription number is not required by law, the hard copy record would show that the prescription was really only one prescription and not partially dispensed, a lot of dispensing software could not accommodate a split billing transaction or pharmacists did not know how to do it. On the side of not allowing this practice, the data submitted to the Prescription Monitoring Program (PMP) is not correct, the hard copy is not really the official dispensing record any longer, and the label may show the incorrect quantity if all the drug is put in one vial or, if using two labels, it will look as though two prescriptions were filled. The Board responded that the official dispensing record for the pharmacy would have to accurately reflect one prescription and the total quantity dispensed on that date for that one prescription and must otherwise meet any requirements of law to include accuracy of reporting to the PMP.

DROP BOXES:

Ms. Russell stated that staff has received requests from pharmacies that want to install a drop box for patients to leave new prescriptions after pharmacy hours. There was significant discussion related to security, location and access. The consensus of the Board was to allow this practice with some guidelines to ensure the security of the prescriptions and that patients would not be able to leave containers which contain drugs to be refilled. Ms. Russell offered to draft a guidance document to be considered at the December meeting and the Board agreed.

STAMPS FOR INITIALS:

Ms. Abernathy requested that the Board determine if initial stamps could be used for records requiring the initials of the "checking" pharmacist rather than handwritten initials which are frequently illegible. She stated that at her hospital, they had a policy in which pharmacist had stamps containing all three initials, so that the checking pharmacist could be more easily identified. She stated she found with hand initials, usually the pharmacist only used two initials, she has pharmacists with the same two initials, and after someone has to initial a hundred items in a day the checking pharmacist could often not be determined. She stated the stamp system worked well. It was discussed that stamps could be stolen and used by someone else or the pharmacist could give a pharmacy technician his stamp and not really check. These concerns were countered with the fact that a pharmacy technician could easily copy the hand initials of the pharmacist, and that this was not so different than a pharmacist's initials in a computer system being used by someone else.

Motion:

A motion was made and passed, to allow the use of stamps by pharmacists on records requiring the pharmacists' initials. (Motion by Beckner, second by Ross)

NEWSLETTER TOPICS:

Staff asked if the Board members had any ideas for the upcoming Board newsletter. The Board stated that some of the decisions made at this meeting should be included such as the increase sanction for not registering pharmacy technicians, pharmacy technicians being held jointly accountable for dispensing errors, the use of stamps for initials, reminders about upcoming renewals and CE requirements particularly for pharmacy technicians.

BOARD OF HEALTH
PROFESSIONS REPORT:

Ms. Edwards stated that she will attend her first Board of Health Professions meeting on September 25, 2007, and will have a report for the December meeting.

EXECUTIVE DIRECTOR'S
REPORT:

- NAPLEX
SUSPENSION
UPDATE

Ms. Russell gave an update on the NAPLEX suspension, stated that NABP is working diligently to have the examination back online by November 1, and is hopeful it will meet that date. She stated that at the time of suspension of the NAPLEX, Virginia had 65 applicants who had not yet taken it.

- NEW EMPLOYEES

Ms. Russell stated that the Board has two new part-time employees assisting with various functions. Ms. Russell introduced Sharon Davenport who will be handling Board meeting matters including contacting Board members related to meeting schedules and travel vouchers. Virginia Davis is assisting the Board with a special project involving preparing the Board's files to be scanned for record retention.

- UPCOMING MEETINGS

Ms. Russell stated that she will be attending the NABP Fall conference next week in Arlington, VA, and the District II meeting in October in Wilmington, DE, as part of her NABP responsibilities. Mr. Ross and Mr. Yi will also be attending the Fall Conference. Due to travel restrictions and because there had been no requests, no Board members are attending the District II meeting at Board expense. Ms. Edwards stated that she will be attending on behalf of her employer.

- DISCIPLINARY PROGRAM UPDATE

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that as of September 11, 2007, 208 cases were at the enforcement level, 55 cases were at the probable cause level, 6 cases were at the informal conference level, 3 cases were at the formal hearing level, 34 cases were at the APD level, 28 cases had either a Confidential Consent Agreement or pre-hearing Consent Orders pending for a total of 334 cases. Further, there were 249 cases at the Compliance Tracking level.

- LICENSING PROGRAM UPDATE

Ms. Juran presented the Board's licensing report and stated that the Board has issued approximately 800 licenses since the June 12, 2007, board meeting. The Board has issued 282 pharmacists licenses, 438 pharmacy technician registrations, 28 physician selling controlled substances licenses, 27 pharmacy permits, and 16 nonresident pharmacy registrations. Also, she stated that there has been concern regarding whether licensees know how to access proposed regulatory changes as it proceeds through the development processes. Therefore, staff will research whether a Notice of Intended Regulatory Action may be posted directly to the Board's website. If not, it will be determined if information may be posted on the Board's website under the "FAQ" (Frequently Asked Questions) section which would give instructions on how to readily access proposed regulatory information by either accessing state websites such as Town Hall, or through receiving notifications via one of the notification lists. Lastly, Ms. Juran mentioned that the next e-newsletter will be published in November 2007.

- PMP UPDATE

Mr. Orr reported on the PMP program. The Prescription Monitoring Program (PMP) now holds over 15.9 million records with about 1 million records being added each month. Mr. Orr discussed the number of registered users of the PMP; over 1000 total, with just over 300 pharmacists registered. He noted that, to date in 2007, the PMP processed over 13000 requests for information compared to 6333 in all of 2006. Mr. Orr stated that while the workload is increasing, response time still averages less than 30 minutes. He updated the Board on the new project the PMP has undertaken working with Virginia Commonwealth University's School of Medicine. The project is to develop a web-

based module training program on pain management practices, laws and regulations and the role of the PMP. The project will complete testing in September/October 2007 with the unveiling of the website on November 16, 2007. Mr. Orr invited the Board members to attend the Fall Conference being sponsored by the PMP on November 16, 2007, at the Perimeter Center.

APPOINTMENT OF
COMMITTEES

Mr. Ison appointed standing and ad hoc committees through June 30, 2008. The committee appointments are included as Attachment 1.

MEETING DATES

The calendar for full Board meetings has been set. There will be a Regulation Committee meeting on October 10, 2007. Dates for the CQI Committee, Drug Disposal Committee, and Inspection Committee will be set based on member and room availability, and the dates emailed to Board members. Mr. Beckner stated that Ukrops is having a pilot drug collection day at the Brook Run store on Tuesday, September 25th from 10AM until 2PM. He has coordinated with Lynn Rubenstein to be there. Mr. Beckner stated that after this trial run, he expects to have helpful information for the committee in developing a template for pharmacies that want to hold these programs.

ADJOURN:

With all business concluded, the meeting adjourned at 12:30 p.m.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

VIRGINIA BOARD OF PHARMACY
2007-2008

STANDING COMMITTEES

REGULATION	EXAMINATION	ITEM REVIEW	PILOT PROGRAM	SPECIAL CONFERENCE
Bobby Ison, Chair Dave Kozera Willie Brown Gill Abernathy Mickey Stredler Alternates: Citizen: Gerard Dabney Licensee: John Beckner any other Board member	Jennifer Edwards Brandon Yi John Beckner Mickey Stredler Scotti Russell	Nan Dunaway Jennifer Edwards Vicki Gwaltney Garrison Caroline Juran Sammy Johnson Scotti Russell	Bobby Ison, Chair John Beckner Alternates: Any pharmacist board member	Alternate between: Leo Ross Dave Kozera Jennifer Edwards Brandon Yi Alternates: Mickey Stredler Any other board member

AD HOC COMMITTEES

CQI	INSPECTIONS	DRUG DISPOSAL
Gill Abernathy, Chair John Beckner Mickey Stredler Jennifer Edwards Vicki Garrison Sammy Johnson	John Beckner, Chair Leo Ross Brandon Yi Mickey Stredler Bobby Ison Vicki Garrison Sammy Johnson	Dave Kozera, Chair Brandon Yi Jennifer Edwards John Beckner Tim Musselman

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
Minutes Of The Regulation Committee Meeting

September 12, 2007
Second Floor
Conference Center

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

CALL TO ORDER: The meeting was called to order at 1:15PM.

PRESIDING: Bobby Ison

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

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

18VAC110-20-10 ET SEQ This meeting was a working meeting to begin drafting proposed amendments to the current regulations subsequent to the periodic review and NOIRA. The committee reviewed issues related to and began drafting amendments for Parts I , II, and III of the regulations. No motions were made at this meeting. It was determined that based on the relatively small number of issues reviewed, and due to the target date of December 12, 2007 for Board adoption of proposed rules, that the October 10, 2007 committee date should be set aside for the Regulation Committee to continue its work, and that there would not be time to hold a second committee meeting that day.

ADJOURN: The meeting adjourned at 4:30 p.m.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

11

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING**

October 10, 2007
Second Floor
Conference Center

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

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

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT: Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
David C. Kozera
Michael E. Stredler

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst, DHP

18VAC110-20-10 ET SEQ This meeting was a working meeting to continue drafting proposed amendments to the current regulations subsequent to the periodic review and NOIRA. The committee reviewed issues related to and began drafting amendments for Parts IV through XVI of the regulations. No motions were made at this meeting. No public comment was received. The committee did accept a recommendation from staff that to split this set of regulations into two separate sets of regulations, with one set relating to licensure and requirements for pharmacist and pharmacy technicians, and the second set relating to requirements for pharmacy practice, pharmacies, and other facilities currently included in 18 VAC 110-20. Staff agreed to have draft amendments ready for full Board review and adoption at the December 12 meeting.

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

Elizabeth Scott Russell
Executive Director

Bobby Ison, Chairman

Date

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

October 22, 2007
Second Floor
Training Room 2

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 10:02am.
- PRESIDING:** Bobby Ison, Committee Chairman
- MEMBERS PRESENT:** John O. Beckner
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
- Vanetta Owens
License # 0201-003726
- Ms. Owens, Tim Koch, Allen Freeman and Virginia Tworek were present to discuss the application, received August 22, 2007, for approval of an Innovative (Pilot) program wherein filled prescriptions would be place in an automated finished prescription pick-up device at Wal-Mart Pharmacy #10-3214.
- Closed meeting:** Mr. Beckner moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to Section 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation and to act upon the application for approval of an Innovative (Pilot) program wherein filled prescriptions would be place in an automated finished prescription pick-up device at Wal-Mart Pharmacy #10-3214. Additionally, he moved that Caroline Juran and Scotti Russell attend the closed meeting because their presence in the closed meeting was deemed necessary.
- Reconvene:** Mr. Beckner moved, and the Committee voted 2-0 in favor of the motion, to reconvene an open meeting and to certify 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 application and statements concerning the proposed Innovative (Pilot) program, Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that the application for approval of an Innovative (Pilot) program wherein filled prescriptions would be place in an automated finished prescription pick-up device at Wal-Mart Pharmacy #10-3214 be approved contingent upon the following terms and conditions: Wal-Mart Stores East, LP shall notify the Board of the implementation date

of the program; Wal-Mart Stores East, LP shall implement the program at Wal-Mart Pharmacy #10-3214 and the device is approved for storing new prescriptions and refills; Wal-Mart Pharmacy #10-3214 may place the device outside the prescription department, but adjacent to or in close proximity for the one year period; After one year of operation, Wal-Mart Stores East, LP may apply to the Board for continuation of the program and pay a fee of \$200; The Board will review the program to determine continued safety, the need for further inspections, or the need for any modifications to the order; If continued operation is approved after one year, the device at Wal-Mart Pharmacy #10-3214 shall be moved to be part of the prescription department; After 6 months of operation, Wal-Mart Stores East, LP may petition for expansion of the use of the device in other locations as listed in the Application; Any additional locations approved by the Board shall also incorporate the device into the prescription department; Any moving of the original device at Wal-Mart Pharmacy #10-3214 to be part of the prescription department, as well as the installation of these devices at additional pharmacies would most likely constitute a remodeling of the prescription department requiring an application to the Board and subsequent inspection; Reports shall be submitted to the Board quarterly, with the first report due the last day of the third month after the implementation date and shall include the following information:

- a) number of prescriptions delivered to patients via the device;
- b) length and dates of any downtime associated with device;
- c) number of bags delivered to an incorrect patient;
- d) number of delivered bags containing the wrong drug;
- e) number of calls placed to a pharmacist for counseling when the prescription department is closed;
- f) and number and summary of problems or complaints received regarding use of device;

Upon a device error, the Board shall be notified and use of the device shall cease until the Board reauthorizes its use; Wal-Mart Stores East, LP shall adhere to all policies and procedures listed in the attachments of the Application; Wal-Mart Stores East, LP shall be subject to one random, unannounced inspection by the Board or its designated representatives, within the first year of implementation; This inspection is independent from any routine inspection of the pharmacy; Wal-Mart Stores East, LP shall be solely responsible for the payment of an inspection fee of \$150 to be paid to the Board within thirty days from the date of the inspection; Wal-Mart Stores East, LP shall notify the Board prior to implementing any modification to the approved Application and no modification shall be implemented until approved by the Board;

Reports of significant errors or other problems, or failure to comply with the terms and conditions described 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.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Ms. Owens unless a written request to the Board for a formal hearing on the decision of the aforementioned Innovative (Pilot) program is received from Ms. Owen 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 11:10am.

Caroline D. Juran
Deputy Executive Director

Bobby Ison
Chair

Date

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Project 1085 - none

BOARD OF PHARMACY
Elimination of inactive fee

18VAC110-30-15. Fees.

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

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

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

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

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

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

2. ~~The annual fee for renewal of an inactive license shall be \$45.~~

~~3.~~ The late fee for renewal of a license within one year after the expiration date is \$30 in addition to the annual renewal fee.

~~4.3.~~ The fee for reinstatement of a license expired for more than one year shall be \$210.

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

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

Part II

Licensure Requirements





COMMONWEALTH OF VIRGINIA Board of Pharmacy

6603 W. Broad Street, 6th Floor
Richmond, Virginia 23230-1712

(804) 662-9911 (Tel)
(804) 662-9943 (Fax)

Petition for Rule-making

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

Please provide the information requested below. (Print or Type)		
Petitioner's full name (Last, First, Middle Initial, Suffix.) Dandurand, Kenneth		
Street Address 316 Talbott Ave., Suite B	Area Code and Telephone Number 413-564-8100	
City Laurel,	State MD	Zip Code 20707
Email Address (optional) kdandur@clinpharm.com	Fax (optional) 413-564-8101	
Respond to the following questions:		
1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18 VAC 110-20-515. Remote prescription order processing for hospitals and long term care facilities. Section B 3		
2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Please see attached		
3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference. 54.1-3434-		
Signature: 	Date: 8/17/07	

Attachment

We are requesting that regulation 18VAC110-20-515 section B.3, be amended to allow a Virginia licensed non-resident pharmacy be allowed to remotely process a prescription by Pharmacists not licensed in Virginia but licensed in the State of Origin of the non resident licensed Pharmacy. This is consistent with what is currently allowed for mail order pharmacies outside the State of Virginia sending prescription medications to end users in Virginia as specified in 54.1-3434.1 Code of Virginia as well as regulation 18VAC110-20-276. Regulation 18VAC110-20-276 does not specify retail or hospital practice and allows for "...a check for accuracy on all processing done by the remote processor..." (section B.3), thus allowing processing by a non-resident pharmacy with pharmacists licensed in another State.

By allowing this amendment the State of Virginia will not compromise patient safety and maintain accountability as the non-resident pharmacy must follow Virginia regulations and would be licensed in the State they process orders. Currently close to 70% of hospitals nationwide do not provide 24 hour pharmacist review of all medication orders. These situations allow nurses to review and administer medications without pharmacists review. After-hours remote pharmacy service will provide this needed review in a licensed and professional manner in real time. The current shortage of pharmacists will prevent all hospital pharmacies from reviewing all patient medication orders prior to administration unless alternative methods are available. The method we are requesting is consistent with Joint Commission Accreditation of Healthcare Organizations (JCAHO) standards of prospective pharmacist review of medication orders.

Section of Regulation in the Petitioner Request

18VAC110-20-515. Remote prescription order processing for hospitals and long-term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;

4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;

5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;

6. Interpreting or acting on clinical data;

7. Performing therapeutic interventions;

8. Providing drug information to the medical or nursing staff of the hospital or long-term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long-term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long-term care facility may outsource certain order processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;

3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and

4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.

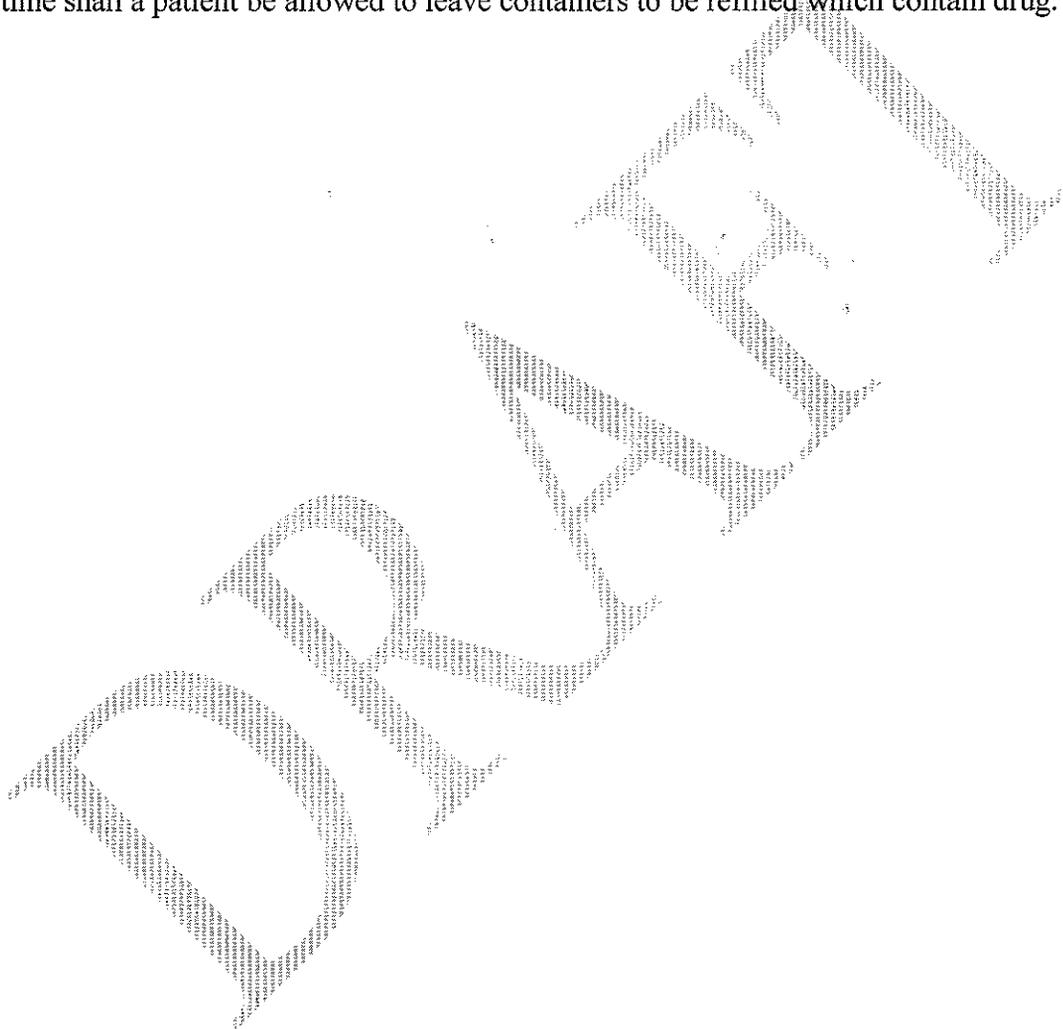
2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout that identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.

3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section provided the pharmacy establishes controls to protect the privacy and security of confidential records.

The Use of a Drop Box for the Collection of Prescriptions

A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box must be located in a visible area within the pharmacy and must be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. At no time shall a patient be allowed to leave containers to be refilled which contain drug.



The Board at the last meeting authorized different suggested sanctions in the form of a pre-hearing consent order for unregistered technicians practicing and the PIC allowing it. In the process of incorporating this into an existing guidance document and combining current 110-9 and 110-19, rather than creating a third new guidance document, we realized that the existing guidance documents relating to continuing education "second offenders" incorporated the suggested sanctions, but did not specifically authorize the offering of a PHCO. For this reason, staff is requesting that the Board adopt the revised guidance document for the record because of this additional change. The new draft is a combination of 110-9, 110-19, and the recommendations for changes to sanctions from the September meeting.

Both the old document for reference, as well as the new draft document are attached.

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CONFIDENTIAL CONSENT AGREEMENTS

OLD PRIOR
TO 9/07
MEETING

The following recommendations for use of CCAs are in addition to the recommendations for use of CCAs incorporated in revised *Guidance Document 110-26 Inspection Violations-Suggested Sanctions* and revised *Guidance Document 110-19 Continuing Pharmacy Education Requirement Violations*.

- For matters involving a pharmacist who has practiced without a license for less than six months (December 31st through June 30th), a CCA should be offered.
- For a first occurrence involving a pharmacist-in-charge allowing unlicensed persons to practice as pharmacy technicians, a CCA should be offered.
- For a first occurrence involving a registered pharmacy technician who practiced without being properly registered with the board or enrolled in an approved pharmacy technician training program, a CCA should be offered.
- CCAs may be recommended on a case by case basis by a SCC/ IFC during probable cause review.
- In following with the Agency's recommendation, once a Notice has been mailed, CCAs are no longer available for that particular matter.

CURRENT CE - MOVED

Virginia Board of Pharmacy

**INTO NEW
DRAFT
110-9**

**Guidance on
Continuing Pharmacy Education Requirements Violations**

Should a pharmacist or pharmacy technician not complete their continuing pharmacy education requirements and it is determined that this is the first time and that the conduct is not willful or intentional, the Board will offer a Confidential Consent Agreement ("CCA") that will allow them to immediately obtain the missing hours. Original documentation of said missing hours shall be returned with the signed CCA.

Should it be determined that the conduct is willful or intentional, or it is the second or more occurrence for this violation, the Board will proceed with an informal conference and shall consider the pharmacist's or pharmacy technician's previous continuing pharmacy education violations. Suggested sanctions for pharmacists previously adopted by the Board on November 27, 2000 and outlined in the original Guidance Document 110-19, included a \$100 monetary penalty for each missing hour and a \$300 monetary penalty for each fraudulent renewal certifying CE compliance in addition to completion of the missing hours with documentation submitted to the Board within 60 days of order entry.

Pharmacists and pharmacy technicians may request exemptions or extensions as provided in § 54.1-3314.1 of the Code of Virginia and 18VAC110-20-106 (C) of the Virginia Board of Pharmacy regulations. Should an extension be granted, the pharmacist or pharmacy technician must obtain the hours within the time frame allotted by the Board.

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NEW

Virginia Board of Pharmacy

**RECOMMENDATIONS FOR THE USE OF CONFIDENTIAL CONSENT AGREEMENTS AND
PRE-HEARING CONSENT ORDERS IN CE VIOLATIONS AND UNLICENSED PRACTICE
CASES**

The following recommendations for use of CCAs and pre-hearing consent orders are in addition to the recommended sanctions in *Guidance Document 110-26 Inspection Violations-Suggested Sanctions*.

Practicing without a required license or registration:

- For matters involving a pharmacist or pharmacy technician who has practiced on an expired license or registration for less than six months (December 31st through June 30th), a CCA may be offered. If the practice exceeds six months, the matter may be referred for a recommended pre-hearing consent order or for informal conference.
- For matters involving an unregistered person performing tasks restricted to pharmacy technicians when that person is not properly in an approved training program, a pre-hearing consent order may be offered to the PIC for a reprimand and a monetary penalty of \$250. A pre-hearing may also be offered to the unregistered person, if he or she applies for registration, for a reprimand and a monetary penalty of \$50. Subsequent matters involving the same conduct may be referred for an informal conference.

CE Violations:

- For matters involving a first-time failure, that is not willful or intentional, of a pharmacist or pharmacy technician to obtain the required hours of CE for one year, a CCA may be offered allowing them to immediately obtain the missing hours of CE and return the original documentation making up the missing hours along with the signed CCA.
- For matters involving a second failure to obtain required hours of CE, a failure covering CE missing for more than one year on an audit, or willful or intentional failure to obtain CE, a pre-hearing consent order may be offered with a monetary penalty of \$100 per missing hour and a \$300 monetary penalty for each fraudulent renewal certifying CE compliance. Such pre-hearing consent order shall also require the pharmacist or pharmacy technician to complete the missing number of hours and submit the original documentation to the Board within 60 days of order entry.
- Subsequent matters involving failure to obtain required CE may be referred for an informal conference.

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Unprofessional Conduct:

Note: The 2007 General Assembly amended the statutes related to grounds for denial or disciplinary action against a license by the Board of Pharmacy. The previous, very narrowly-defined, section related to "unprofessional conduct" was repealed and those activities specifically listed in 54.1-3316 (11) and (12) as grounds for disciplinary action. In addition 54.-3316 (4) was expanded to include unprofessional conduct "specified in regulations promulgated by the Board".

The question is whether the Board wants to consider promulgating regulations defining activities that may be considered unprofessional conduct for which disciplinary action may be taken.

Attached are a number of regulations from other boards and other states related to unprofessional conduct. Bear in mind that we only need to define those activities for which the Board may want to be able to deny or discipline a license where there is not already a ground listed in 54.1-3316.

§ 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.