

(DRAFT/UNAPPROVED)

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

December 10, 2008
Second Floor
Conference Room 2

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

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

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Gerard Dabney
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT: Willie Brown

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Sandra Whitley Ryals, Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

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

APPROVAL OF AGENDA: Two additional sets of minutes, August 28, 2008 SCC and November 20, 2008 SCC, were added to the agenda to be approved. With no other changes to the agenda, the agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the September 3, 2008, Board meeting; August 28, 2008, Special Conference Committee; September 3, 2008, Panel, Formal Hearings; September 10, 2008, Telephone Conference Call; September 24, 2008, Special Conference Committee; September 25, 2008, Telephone Conference Call; September 29, 2008, Panel, Formal Hearing; November 13, 2008, Regulation Committee; and November 20, 2008 Special Conference Committee. With no changes to the minutes the minutes were approved as presented.

PUBLIC HEARING ON PROPOSED REGULATIONS: A public hearing was held on proposed regulations of the Board of Pharmacy, 18 VAC 110-20-10 et seq., resulting from the Board's

periodic review process. A copy of the transcript of the hearing will be maintained as part of the permanent record for regulation promulgation.

PUBLIC COMMENTS:

No additional public comments were received at this time.

DHP DIRECTOR'S REPORT:

Ms. Ryals provided the Board with an update on the Virginia Performs measures with statistics from the first quarter of FY2009. The Board of Pharmacy for this quarter was at 125% clearance rate which measures the numbers of cases closed in comparison with the numbers received. A clearance rate of over 100% is necessary to continue to decrease the backlog of any old cases. The age of pending caseload for Pharmacy was at 9% of open patient care cases (10 cases) over 250 business days. The percentage of cases closed within 250 business days for the last quarter was 77%. The agency goal for this measure is 90%, and the lower percentage probably represents the closing of older cases in the backlog. The Board's two licensure processing measures were at 97% for customer satisfaction, and 100% for issuance of license within 30 days of receipt of a completed application.

Ms. Ryals informed the Board of pending negotiations with VCU to streamline the Health Practitioners Intervention Program in an effort to reduce costs of the program. She stated that while the program was an excellent program, it had some components that were more related to treatment and that the department would be moving to a program that was a monitoring model. She stated that the Department currently spends approximately \$2 million a year for this program for a relatively small number of licensees, and that due to the current budget constraints, the Department is looking to reduce overall costs. Ms. Ryals stated that the program shall continue to be consistent with the core mission of the agency which is to ensure that licensed practitioners are competent and safe to practice. One of the cost savings measures for the program will be to eliminate payment by the Department for those persons who may have been suspended or revoked and are not practicing, and those practitioners who may be solely practicing in another state. It will continue to pay for persons applying for a license to include someone applying for reinstatement following a suspension or revocation for a period of time. The Department is putting a legislative proposal forward to assist with cost savings and make other improvements to include allowing participants to be charged a fee for the program, scale back the services to a monitoring program rather than a treatment program, and change the name of the program from "intervention" to "monitoring", as well as a number of other technical amendments.

Ms. Ryals also informed the Board that the Department was going forward with a legislative proposal related to the Prescription Monitoring Program. The proposal would eliminate the requirement for a signed patient release before a prescriber could query the system in favor of a notification consistent with what pharmacists currently must provide. The proposal will also allow for exchange of information between different state programs to assist with patients who cross borders to engage in doctor/pharmacy shopping.

Ms. Ryals also provided the Board with an overview and update of the Healthcare Workforce Data Center. She stated that Virginia is facing shortages of a number of different health care professionals, including pharmacists, but that there is a lack of accurate data on workforce. She stated that the Department has received a Governor's grant to establish the Workforce Data Center. The first year will be devoted to data collection and supply and demand issues related to physicians and nurses. After this other health care professions will be added. Ms. Ryals stated that several staff persons had been hired to begin this work, and an advisory council had been established to assist the Department. There had been one meeting of the advisory council, with a presentation at that meeting by the University of North Carolina Shepps Center's, NC Health Professions Data Center which provided information and recommendations to the Department and advisory council.

LEGISLATION UPDATE:

Bobby Ison provided the Board with a copy of a draft legislative proposal that VSHP will be seeking to allow hospital pharmacies to place certain multidose containers of other than oral medications into automated dispensing devices. He stated that this is being requested particularly for insulin because it is a more organized way of storing the various insulin products and assists the nurse in selecting the correct type to administer. The Board members did not express any concerns with this initiative.

REGULATION UPDATE:

- Change in Renewal Dates
- Drug Donation Program
- Standards of Conduct

Ms. Yeatts provided an update on the status of regulation processes of the Board.

The Board has emergency regulations with the changed expiration dates for facilities in effect until 9/22/09 and is currently in the NOIRA phase of adopting permanent replacements. The Board will be adopting proposed regulations later in this meeting, and there were no comments received on the NOIRA.

The Board has emergency regulations undergoing review by the Secretary of HHR.

The Board has completed the NOIRA phase for defining "unprofessional conduct" and now needs to adopt proposed regulations later in this meeting.

- Proposed regulations from periodic review
- Nuclear pharmacy fast-track rules

The Board is in a public comment period, and the public hearing was held earlier today. The Board at its next meeting will review and respond to public comments and adopt final regulations.

Regulations to conform the Board's regulations on nuclear pharmacies to new regulations of the Virginia Department of Health became effective on 12/11/08.

ADOPT PROPOSED
REGULATIONS ON
CHANGING EXPIRATION
DATES FOR FACILITIES:

The Board reviewed proposed regulations on changing expiration dates for most facilities to 2/28 annually and pharmacies and non-resident pharmacies to 4/30 annually. There were no changes made to the emergency regulations currently in effect.

Motion:

The Board voted unanimously to adopt as proposed regulations, the current language in the emergency regulations changing expiration dates and as included in the agenda package. (motion by Beckner, second by Stredler) Attachment 1.

ADOPT PROPOSED
REGULATIONS ON
UNPROFESSIONAL
CONDUCT:

The Board reviewed draft proposed regulations that had been recommended by the regulation committee and sent for comment to the various pharmacy associations. The regulation committee received no negative comments from any of the associations.

Motion:

The Board voted unanimously to adopt as proposed regulations defining unprofessional conduct the draft presented in the agenda package and as recommended by the regulation committee. (motion by Stredler, second by Ross) Attachment 2.

INTERPRETATION OF 54.1-
3434.1, NON-RESIDENT
PHARMACIES, NEW PIC
REQUIREMENT:

Ms. Russell advised the Board that she has received a number of applications with requests for the designated Virginia licensed pharmacist be allowed to be the Virginia PIC for multiple pharmacies. She has also received applications in which the Virginia licensed pharmacist who has been designated as PIC is not actively engaged in the practice of pharmacy at the pharmacy location and in fact may reside in another state. One example was an application for a pharmacy in Iowa, where the Virginia licensed PIC resides in Florida. She asked that the Board consider whether it wanted to apply the same standards to non-resident pharmacies as are applicable to resident pharmacies with respect to the PIC. With Virginia pharmacies, a pharmacist may not be PIC for more than two pharmacies (18 VAC 110-20-110), and must be actively engaged in the practice of pharmacy at the address of the pharmacy (§ 54.1-3434).

Ms. Russell also stated that she had been asked to waive the Virginia licensed pharmacist requirements entirely based on a limited scope of pharmacy services. Board counsel advised that

the Board could not provide a waiver for having a PIC licensed in Virginia because the Board does not have the authority to waive a statute.

Motion:

The Board voted unanimously to apply the same standard to non-resident pharmacy PICs as it does to resident pharmacy PICs, that is a pharmacist may not be PIC for more than one pharmacy, whether resident or non-resident, and the Virginia-licensed pharmacist designated as PIC of the non-resident pharmacy must be fully engaged in the practice of pharmacy at the location designated on the application. (motion by Ison, second by Stredler)

REQUEST FOR APPROVAL
OF THE ExCPT
EXAMINATION:

The Institute for Certification of Pharmacy Technicians (ICPT) requested that its Examination for Certification of Pharmacy Technicians (ExCPT) be approved by the Board of Pharmacy as a second approved examination that applicants could take in order to be registered as a pharmacy technician in Virginia. ICPT provided sufficient documentation to show that its examination meets the criteria set forth in 18 VAC 110-20-103. Rebecca Rabbit, Executive Director of ICPT, was present at the meeting. Ms. Russell stated that she received over 40 letters supporting the approval of this examination. Ms. Russell stated that with this examination, as with the Board's own examination, candidates would have to also complete a Board-approved training program.

Motion:

The Board voted 8 to 1 to approve the ExCPT examination as a Board approved examination pursuant to 18 VAC 110-20-103. Mr. Ison voted no. (motion by Beckner, second by Stredler)

2009 MEETING CALENDAR:

The dates for Board meetings for 2009 were set as follows:

- Wednesday, March 11, 2009
- Wednesday, June 10, 2009
- Wednesday, September 2, 2009
- Wednesday, December 16, 2009

BOARD OF HEALTH
PROFESSIONS REPORT:

Jennifer Edwards advised the Board that the Board of Health Professions was meeting on December 17, 2008, and that it had not met since the last meeting of the Board of Pharmacy. She will be reporting on BHP at the March meeting of the Board of Pharmacy.

EXECUTIVE DIRECTOR'S
REPORT:

- Contract with SMT for pharmacy technician examination

Ms. Russell reported that the Department entered into a new contract for the Board developed examination for pharmacy technicians. The previous contract expired June 30, 2008, but ICPT, the current contractor, had graciously agreed to extend the

current contract for six months to provide time to go through the competitive bidding process. A Request for Proposals was issued last spring, and four proposals were received. A committee comprised of Mr. Kozera, Mr. Yi, Caroline Juran, and herself, reviewed and scored the proposals. The contract was awarded to Schroeder Measurement Technologies (SMT) who will begin the examination administration on January 1, 2009. All needed data has been transferred from the current contractor, and SMT is on target to provide services the first of January.

- NABP News

Ms. Russell advised the Board that the November Board and NABP e-newsletter had gone out to all licensees and was on the website. She gave an update on recent NABP meetings including District II and the Fall Symposium.

- Renewal

Ms. Russell stated that the Board is currently in a renewal cycle for all pharmacists, pharmacy technicians and dispensing physicians. She stated that at the same time renewal notices were mailed out, new licenses were mailed to all facilities showing the extended expiration dates as well as an explanation as to the new date.

- PMP

Ms. Russell advised that Mr. Orr was not available to give a presentation that day on the prescription monitoring program. She stated that the PMP broke a record with 450 requests in one day the previous week.

Motion:

The Board voted unanimously to recognize Ralph Orr, Director for the Prescription Monitoring Program, for the excellent work he has done in implementing and promoting the PMP. (motion by Beckner, second by Edwards)

- Disciplinary and Licensing Report

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of December 9, 2008, and stated for patient care cases only there were 19 cases with 3 Priority B cases and 16 Priority C cases. For all BOP cases, there were 57 cases at the enforcement level, 68 cases at the probable cause level, 17 cases at the informal conference level, 1 case at the formal hearing level and 3 cases at the APD level.

Further, Ms. Reiniers-Day presented the Board's licensure report for the time period September 3, 2008, through December 9, 2008. The Board issued 20 controlled substance registration certificates for a total of 1,672; 12 medical equipment supplier permits for a total of 421; 6 non-resident pharmacy permits for a total of 541; 14 non-resident wholesale distributor permits for a total of 620; 1 non-restricted manufacturer for a total of 23; 1 permitted physician license for a total of 14; 22 pharmacy permits for a total of 1,663; 179 pharmacy intern registrations for a total of 1,494; 21 physician

selling controlled substance certificates for a total of 283; 1 restricted manufacturer permit for a total of 73; 1 warehouse permit for a total of 42; and 2 wholesale distributor permits for a total of 126. Additionally, she reported that both pharmacist licenses and pharmacy technician registrations exceed 10,000, in that 190 pharmacist licenses were issued with a total of 10,096, and 420 pharmacy technician registrations were issued for a total of 10,251.

APPROVAL OF CONSENT
ORDERS:

Motion for closed meeting:

The Board voted unanimously, to enter into closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding two Consent Orders. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Stredler, second by Yi)

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

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

Motion:

The Board voted unanimously to accept the consent orders as presented by Ms. Reiniers-Day in the matters of Ian Cooper, pharmacist, and April Cofer, pharmacy technician. (motion by Beckner, second by Yi)

ADJOURN:

With all business concluded, the meeting adjourned at 12:15 p.m.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date

Project 1311 - Proposed

BOARD OF PHARMACY
Changes in renewal dates for pharmacies and permitted facilities

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Permitted physician licensed to dispense drugs	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. Nonresident pharmacy	\$270
9. Controlled substances registrations (Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be \$50)	\$90
10. Robotic pharmacy system approval	\$150
11. Innovative program approval.	\$250

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

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

D. Annual renewal fees.

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

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

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

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

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

1. Pharmacist license	\$210
2. Pharmacist license after revocation or suspension	\$500
3. Pharmacy technician registration	\$35
4. Pharmacy technician registration after revocation or suspension	\$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	\$240
b. Physician permit to practice pharmacy	\$240
c. Medical equipment supplier permit	\$210
d. Humane society permit	\$30
e. Nonresident pharmacy	\$115
f. Controlled substances registration	\$180

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

1. Change of pharmacist-in-charge	\$50
2. Change of ownership for any facility	\$50
3. Inspection for remodeling or change of location for any facility	150

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|--|-------|
| 4. Reinspection of any facility | \$150 |
| 5. Board-required inspection for a robotic pharmacy system | \$150 |
| 6. Board-required inspection of an innovative program location | \$150 |
| 7. Change of pharmacist responsible for an approved innovative program | \$25 |

H. Miscellaneous fees.

- | | |
|-------------------------------|------|
| 1. Duplicate wall certificate | \$25 |
| 2. Returned check | \$35 |

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

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

18VAC110-50-20. Fees.

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

B. Initial application fees.

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

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

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

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a

license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

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

E. Reinstatement fees.

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

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

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

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

F. Application for change or inspection fees.

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

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

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

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

Project 1341 - Proposed

**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 disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient, or other conduct that results or could result in personal gain at the expense of the patient;

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

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered, and that such registration is current;

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