

FINAL/APPROVED

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

September 8, 2010
Second Floor
Board Room 2

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

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

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT: Gill B. Abernathy
Jody H. Allen
John O. Beckner
Gerard Dabney
David C. Kozera
Robert M. Rhodes
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT: Caroline D. Juran, Acting Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant (business matters)
Eusebia Joyner, Administrative Assistant (disciplinary matters)

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

APPROVAL OF AGENDA: The agenda was approved as presented and amended by the Board to add minutes of the August 25, 2010, Special Conference Committee, and to add discussion of the formation of a committee to review hospital-related deficiencies and Regulation 18 VAC 110-20-490, in lieu of reviewing Guidance Document 110-9.

APPROVAL OF MINUTES: The Board reviewed draft minutes for June 2, 2010; June 17, 2010; June 30, 2010; July 13, 2010; and August 25, 2010. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments made at this time.

DHP DIRECTOR'S REPORT: Mr. Owens, on behalf of Dianne Reynolds-Cane, M.D., reported that the first National Drug Take-Back Day would be held on September 25, 2010, from 10 a.m. to 2.p.m. at participating drop-off sites throughout Virginia. This is a collaborative effort of state and local law enforcement agencies, coordinated by DEA, to collect

from the public any expired, unwanted, or unused pharmaceutical controlled substances and other medications for destruction. DHP has posted information on its website and intends to communicate this subject to its licensees to encourage participation. Additionally, Mr. Owens briefly stated that this agency is involved with discussions regarding healthcare reform, and reminded the Board members of an orientation meeting to be held on October 27, 2010, for all new board members of this agency.

LEGISLATION:

- 2011 Legislative Proposal

Ms. Yeatts stated that a draft bill adding tramadol and carisoprodol to Schedule IV and immediate precursors of amphetamine, methamphetamine, phencyclidine, and fentanyl to Schedule II had been submitted for the Governor's consideration. She then explained that the two legislative proposals discussed at the June 2010 Board meeting regarding compounding and an allowance for multiple prescriptions per order form were not submitted for administrative review, due to conflicts with the language.

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the permanent replacement of regulations for drug donation programs remains under administrative review and that the current emergency regulations will expire on October 6, 2010. Additionally, Ms. Yeatts stated regulations on the following subjects are under administrative review: emergency regulations for repackaging in community service boards and behavioral health authorities; signing of delivery record for automated dispensing devices in hospitals; and the addition of administrative fees and elimination of alarm system for certain emergency medical service agencies. Further, she reported that regulations regarding the following subjects became effective August 4, 2010: incorrect citation in 18 VAC 110-20-690; conformity with statute regarding maintenance of CE documentation; and conformity with DEA rules on e-prescribing.

- Response to petition for rulemaking regarding filing of prescriptions

Ms. Yeatts provided information on the petition received from Eric Haas requesting an amendment to 18 VAC 110-20-240 to allow prescriptions to be "filed chronologically by date of initial dispensing or initial entry into pharmacy electronic record keeping system if such a system is employed for use in the pharmacy." This proposed amendment would allow a prescription placed "on-hold", to be dispensed at a later time, to be filed by date of initial entry into the pharmacy's automated dispensing system, in lieu of filing chronologically by date of initial dispensing. The Board discussed the common practice of placing prescriptions "on-hold"; comment

was made that the practice may increase drug compliance and reduce the probability of a patient losing the prescription(s). Members expressed an interest in learning the requirements in other states. Ms. Juran stated that Ohio's regulations require the "on-hold" prescription to be entered into the pharmacy's automated data processing system when received, assigned a serial number, and permanently filed chronologically. Additionally, she stated that staff had received an email in the past from DEA with an informal opinion that while not directly prohibited by federal regulation, the practice of a pharmacy "holding" a patient's prescription(s) for dispensing at a later time was not recommended due to concerns for diversion. There was discussion to delay the decision-making process until more research could be performed regarding other states' requirements.

Motion:

The Board voted unanimously to deny the petition for rulemaking to amend Regulation 18 VAC 110-20-240, but agreed to query other states to determine their policies and/or rules for the filing of "on-hold" prescriptions and to revisit the request in December after additional information is obtained. (motion by Kozera, second by Beckner)

**UPDATE ON ACTION
ITEMS:**

• Pharmacy coupons

In response to the letter received by Jonathan Carter, a pharmacy student at VCU School of Pharmacy, requesting a prohibition on the use of pharmacy coupons and as requested by the Board at the June 2, 2010 board meeting, a survey of other states' restrictions on the use of pharmacy coupons was performed by NABP. Of the states that responded to the survey, Ms. Juran stated that she could only confirm that New York had current restrictions in place. New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise. Additionally, Mr. Yi stated that New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors. Board counsel stated a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. After further discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Motion:

The Board voted unanimously to take no action at this time regarding the request to prohibit the use of pharmacy coupons and to monitor the future use of these coupons. (motion by

Beckner, second by Kozer)

- Discussion regarding need for sending guidance document 110-27 to a new PIC now that attestation is included on the pharmacy permit application

Ms. Juran reported that staff had added the attestation to the pharmacy permit application, as requested at the June 2, 2010 board meeting, which requires the new pharmacist-in-charge to acknowledge having read and understood Guidance Document 110-27 and associated information regarding the inspection process. As a result, Ms. Juran asked if the Board wanted staff to continue mailing Guidance Document 110-27 along with the frequently asked questions (FAQs) regarding the pharmacy technician registration process after processing these submitted applications. The consensus was that staff should continue mailing the Guidance Document and the FAQs to ensure another opportunity for the PIC to read and understand the importance of the information contained within the document.

MISCELLANEOUS:

- Request from Allergan to discuss requirements for physician dispensing of topical drugs for aesthetic purposes

Ms. Juran stated that she; Scotti Russell, former Executive Director of the Board of Pharmacy; Scott Johnson and Tyler Cox of Hancock, Daniel, Johnson & Nagle, P.C.; and Pat Cannon, RN, Allergan, Inc., met on July 12, 2010. The meeting was to discuss current requirements for a physician to dispense drugs for aesthetic purposes. A formal request was then submitted to include this item on the September board meeting agenda to request an exemption from the security system and square footage requirements when dispensing topical Schedule VI drugs for aesthetic purposes. Ms. Juran explained that Regulation 18 VAC 110-30-20 already allows for the issuance of a limited-use license and that the Board has previously provided waivers of the 60 square feet requirement for the controlled substances selling and storage area when the scope, degree or type of services provided to the patient is of a limited nature and the inspector deems the square footage is sufficient for performing the limited purposes. There was discussion as to whether a security system should be required for protecting public safety when dispensing only topical Schedule VI cosmetic drugs and whether a limitation should be imposed on the number of drugs that could be dispensed by a physician when exempted from the security system requirement. After discussion, the Board determined it would delegate to the executive director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use.

Motion:

The Board voted unanimously to delegate to the executive

director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use. (motion by Ross, second by Kozera)

- Update on the inspection program

Ms. Juran provided an update on the new routine inspection program which went “live” with retail inspections in July 2010. In July and August 2010, 54 retail inspections were performed; 27% resulted in no deficiencies, 38% resulted in deficiencies but no monetary penalty, and 33% resulted in deficiencies with a monetary penalty. Ms. Juran explained that these statistics are similar to the statistics reported at the conclusion of the piloting phase of the retail inspections performed between January and June 2010. Additionally, she reported that, of the 18 deficiencies with a monetary penalty, five of the disciplinary cases have been closed through the signing of the pre-hearing consent order, payment of the monetary penalty and submission of corrective action; six were currently at the pending closure stage; one pharmacy requested an informal conference for further consideration of the matter; and six were pending a response from the pharmacy. Ms. Juran then reported that, as of July 2010, the new inspection program began the “pilot” phase in hospital/institutional pharmacies and three hospitals had been inspected to date. Each hospital inspection resulted in deficiencies with a monetary penalty.

- Formation of committee to review hospital pharmacy deficiencies listed in Guidance Document 110-9 and Regulation 18 VAC 110-20-490

Ms. Juran stated that some inspection areas and thresholds had been identified as needing clarification to ensure inspectors are properly inspecting hospital pharmacies for substantial compliance. One area of concern involves the inspections of the recordkeeping requirements for automated dispensing devices (ADDs) in hospitals as required in Regulation 18 VAC 110-20-490. Additionally, Ms. Abernathy had previously communicated with staff that this regulation may not be clearly written and that the monthly auditing process may be overly burdensome for hospitals with a large number of ADDs. The Board agreed that the formation of a committee to review hospital deficiencies listed in Guidance Document 110-9 and Regulation 18 VAC 110-20-490 for possible revision would be useful and the following board members volunteered to participate: Gill Abernathy, Jody Allen, Ellen Shinaberry, and Brandon Yi. The committee plans to meet in November and provide recommendations to the Board at the December 2010 Board Meeting

- Request from David Kozera

Mr. Kozera briefly expressed concern for opening disciplinary cases

to discuss opening
disciplinary case against
pharmacy permit or PIC

resulting from the new inspection program against the pharmacy permit instead of the pharmacist-in-charge. Discussions surrounded the requirement to report disciplinary action to NABP and the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB).

Action Item:

Mr. Kozera requested that staff research whether other states were reporting disciplinary action taken against a facility permit and Ms. Abernathy requested staff to contact the Centers for Medicare & Medicaid Services (CMS) or other appropriate persons to research whether reported disciplinary action taken against a facility permit would jeopardize a contract to receive government funds. Ms. Juran will report her findings at the December board meeting.

- Use of agency subordinates to hear disciplinary matters resulting from the new routine inspection process

Ms. Juran recommended the Board consider using an agency subordinate to expedite disciplinary matters resulting from the new routine inspection program as allowed in § 54.1-2400 and Regulation 18 VAC 110-20-15. Ms. Juran stated that Board of Nursing ("BON") has used agency subordinates for several years due to its high volume of cases and that BON staff has agreed to present information and offer training to the board members at the December 2010 Board Meeting. Also, BON staff has agreed to offer training to Board of Pharmacy staff for handling the administrative processes involved in using agency subordinates. Ms. Juran explained that the agency subordinate hears the matter and makes a recommendation to a panel or quorum of the Board who would then vote to approve or deny the subordinate's recommendation. She further reported that possible advantages to using an agency subordinate include: decreased cost and travel time associated with requiring two Board members to attend an informal conference committee meeting; increased consistency with recommendations when using a dedicated person to hear these matters; and faster scheduling of date for conferences since this requires only one person to participate. After discussion, the Board determined it would approve the use of an agency subordinate to hear disciplinary matters resulting from the new routine inspection process.

Motion:

The Board voted unanimously to approve the use of an agency subordinate to hear disciplinary matters resulting from the new routine inspection process and the annual CE auditing process. ((motion by Beckner, second by Kozera))

- Possible legislation proposal from VDH

Ms. Juran reported that the Virginia Department of Health has notified that Board that it may recommend a legislative proposal to amend §54.1-3303 C to include an allowance for prescribing Schedule VI antibiotics to other persons in close contact with a

diagnosed patient with chlamydia or gonorrhea.

- Discussion of vacancy for Board of Health Professions

Ms. Juran explained that there is currently a vacancy in the Board of Pharmacy's representation on the Board of Health Professions as allowed in §54.1-2507. She then directed any member who is interested in being appointed to the Board of Health Professions to inform her of this interest and complete the required document(s) found on the Secretary of the Commonwealth's website.

- Set board meeting dates for 2011

The following dates were chosen for holding full board meetings in 2011:

- March 9
- June 8
- September 7
- December 14

REPORTS:

- Report on Board of Health Professions

Ms. Juran discussed the information that was provided to her by Elizabeth Carter, Executive Director for the Board of Health Professions (BHP). Ms. Carter reported that BHP last met on May 4, 2010, and that the majority of BHP's current activities involve research into the need to regulate several "emerging" professions. Healthcare is evolving rapidly and the number of health professions seeking regulation is exploding in Virginia and nationally. Discussed at the May 4th meeting were the reviews on polysomnographers, community health workers/grand aides, surgical assistants and technologists, and genetic counselors. The General Assembly also assigned three studies to the BHP this year, two sunrise reviews for kinesiotherapists and laboratory scientists and laboratory technicians, and a review into the advisability of expanding medication aides into nursing homes. The BHP has also begun a review into the need for a new Allied Health Board within the Department of Health Professions or other means to help alleviate the burden placed on the Board of Medicine and Board of Nursing in Virginia to regulate professions outside of their traditional roles. Also, BHP is performing a formal research evaluation of Sanctioning Reference effectiveness.

- Acting Executive Director's report

Ms. Juran stated that the deadline for submitting applications for the Board's Executive Director position is September 28, 2010. It is anticipated that interviews will be held in October with a decision made later that month or in November. Additionally, the Board has a vacancy for an administrative office specialist and intends to advertise and fill this position as soon as possible.

Renee Watson, DHP Procurement Manager, provided information regarding issuance of a RFP for a contract administrator of the

Virginia Federal and State Drug Law Exam. She will contact staff later this year to schedule a committee meeting of the Board for reviewing submitted proposals. Participants on this committee are David Kozera, Brandon Yi, Caroline Juran, and Sammy Johnson. Ms. Juran then announced that John Beckner will be attending an upcoming NABP member forum meeting to be held at NABP headquarters in Mount Prospect, Illinois, on September 22-23, 2010. Expenses for this meeting were provided by NABP. This new meeting format consists of a one-day meeting, and the target audience will rotate triennially among board of pharmacy members, executive officers, and compliance officers from each active member board. It provides the participant an opportunity to discuss with their colleagues important and timely issues as well as learn about the latest enhancements to NABP programs and services. Ms. Juran also reported that the NABP District II meeting will be held October 29-31, 2010 in Cooperstown, New York.

NEW BUSINESS

There was no new business discussed.

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, it was moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Beckner, 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 Beckner, second by Yi)

Motion:

The Board voted unanimously to accept the consent orders as presented by Ms. Reiniers-Day in the matter of Rebekah H. Scott, pharmacy technician, and Robert B. Scott, pharmacist. (motion by Beckner, second by Kozera)

SUMMARY SUSPENSION:

Closed meeting:

Mr. Beckner moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711 (A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Cathy Reiniers-Day, Caroline

Juran, Eusebia Joyner, Sharon Davenport, Howard Casway, Wayne T. Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Beckner, second by Dabney)

TIA J. LATHON
Pharmacy Technician
Registration Number:
0230-014535

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

Reconvene:

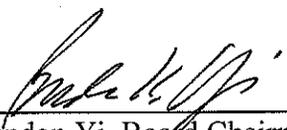
Mr. Beckner moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered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

Decision:

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

ADJOURN:

With all business concluded, the meeting adjourned at 1:30 p.m.



Brandon Yi, Board Chairman

12/15/2010

Date



Caroline D. Juran
Acting Executive Director

12/15/10

Date