FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 8, 2011
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:18 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, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr. Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: An amended agenda was presented and approved by the Board with one additional request from staff for guidance on the handling of a possible disciplinary matter.

APPROVAL OF MINUTES: The Board reviewed draft minutes for March 9, 2011 (board meeting); May 17, 2011 (Ad Hoc Committee, On-Hold Prescriptions); May 18, 2011 (Ad Hoc Committee, Pharmacy Inspections); and May 18, 2011 (Ad Hoc Committee, CQI Program). There was one minor correction to the minutes for May 17, 2011, in that the commencement time should be 12:35 P.M., instead of 12:35 A.M.

Motion: **The Board voted unanimously to approve the minutes as amended. (motion Kozera, second by Beckner)**

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

LEGISLATION:

- Legislation update

Ms. Yeatts discussed the legislative proposal for placing tramadol and carisoprodol into Schedule IV. In 2010, the Board denied a petition for rulemaking since there was hesitation to schedule drugs in rule versus legislation. Instead, the Board recommended a legislative proposal to place tramadol and carisoprol into Schedule IV. The legislative proposal was not carried by the Administration. There was discussion whether the Board wanted to again recommend the legislative proposal for the upcoming General Assembly session.

Motion:

The Board voted unanimously to recommend the legislative proposal to place tramadol and carisoprodol into Schedule IV. (motion Stelly, second by Ross)

REGULATIONS:

- Regulation update

Ms. Yeatts gave an update regarding the status of current regulatory action. The comment period for the proposed regulations to impose administrative fees for duplicate licenses and verifications closed on May 11, 2011, and the Board could adopt the proposed regulations later during this meeting. Additionally, she stated that the comment period for the NOIRA to amend regulations to address on-hold prescriptions closed later that day at 5pm and therefore, the Board cannot adopt proposed regulations until the September full Board meeting. The regulations to replace the emergency regulations regarding repackaging in a community service board or behavioral health authority are currently in the Secretary's office and the regulations regarding the elimination of an alarm system for certain emergency medical services agency are currently in the Governor's office.

- Fast- Track for CE Requirements:

Ms. Yeatts explained that the National Association of Boards of Pharmacy and the Accreditation Council for Pharmacy Education (ACPE) are collaborating to offer the CPE Monitor Service, an electronic system for pharmacists and pharmacy technicians to receive and track their completed continuing pharmacy education (CPE) credits. Because ACPE will cease providing a certificate of completion to the individual sometime in the next year and will solely provide electronic documentation of completion to the CPE Monitor Service, Ms. Yeatts stated that regulations 18 VAC 110-20-90 and 18 VAC 110-20-100 that require the provision and maintenance of an original certificate of completion need to be amended.

Motion:

The Board voted unanimously to adopt the fast-track regulatory amendments to Regulations 18VAC110-20-90 and 18VAC110-20-100 as presented regarding continuing education certificates. (motion Beckner, second by Kozera)

- Adoption of Proposed Regulations of New Administrative Fees:

Ms. Yeatts reported that the Board needed to consider adopting regulations for adding new administrative fees. The additions include a $10.00 fee for a duplicate license or registration and a $25.00 fee for verification of licensure or registration.

Motion:

The Board voted unanimously to adopt the proposed regulations for new administrative fees for duplicate licenses or registrations and verifications of licensure or registration. (motion Kozera, second by Beckner)

- Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reported that the Board has received three petitions for rulemaking concerning Regulation 18VAC110-20-490 which addresses automated dispensing devices. Because a petition for rulemaking requires at least a 21-day comment period, the Board cannot consider the petitions until the September 22, 2011 meeting.

- Guidance Document 110-11-Proof of Identity when Dispensing Schedule II Drugs:

Ms. Yeatts explained that the amendments to the proof of identity requirements found in § 54.1-3420.1 resulting from the passing of HB2256 will become effective July 1, 2011. Therefore, guidance document 110-11 would either need to be amended to reflect the statutory changes or repealed. After some discussion, the Board concluded that the guidance document should not be repealed since further clarification of the statute was needed, but it should be amended to conform to the statutory changes.

Motion:

The Board voted unanimously to amend guidance document 110-11 to conform to changes in § 54.1-3420.1, effective July 1, 2011, and for staff to amend the document accordingly. (motion Kozera, second by Beckner)

UPDATE ON ACTION ITEMS:

- Ad-Hoc committee for continuous quality improvement program

Ms. Juran provided an update regarding the ad-hoc committee meeting that was held on May 18, 2011, concerning the drafting of emergency regulations for pharmacies to implement a continuous quality improvement program as required by the passing of HB2220. Suggested key concepts to be included in the draft regulations have been identified by the committee and were listed in the committee meeting's minutes. Because emergency regulations become effective for one year once adopted and there is no opportunity for public comment, Ms. Yeatts explained that the Board may wish to consider adopting a notice of intended regulatory action (NOIRA) to give public a 30-day opportunity to

offer comment on the key concepts which may be included in the emergency regulations.

Motion:

The Board voted unanimously to adopt a NOIRA consistent with the key concepts identified in the minutes from the ad-hoc committee meeting for continuous quality improvement programs. (motion Beckner, second by Kozera)

- Ad-Hoc committee for on-hold prescriptions

Ms. Juran provided an update from the ad-hoc committee meeting held on May 17, 2011 and briefly reviewed the committee's suggested regulatory changes as outlined in the committee meeting's minutes. There was no Board action required at this time

- Ad-Hoc committee for routine inspection program

Sammy Johnson presented the ad-hoc committee's suggested amendments to Guidance Document 110-9 as determined during the May 18, 2011 ad-hoc committee meeting for the routine inspection program. The Board offered the following specific recommendations to the suggested amendments:

- Clarify the suggested language in Major Deficiency 17 regarding refill authorizations since not permissible for Schedule II drugs;
- Reword the suggested conditions for Major Deficiency 24 to read "Low volume defined as 15 or less hazardous drug CSP/week or as defined by USP. Review 2 months records."
- Add a 10% threshold to the conditions for Minor Deficiency 24; and,
- Add a condition to Minor Deficiency 38 to read "Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements."

The committee's other suggested amendments were accepted by the Board as presented.

Motion:

The Board voted unanimously to amend Guidance Document 110-9 as discussed. (motion Ross, second by Rhodes)

Mr. Johnson reminded the Board that the new inspection process has been "live" in community pharmacies since July 1, 2010, and has been piloted in hospital and other institutional pharmacies since July 1, 2010. Because Board staff and inspectors feel comfortable with the new inspection report for hospitals and other institutions, staff recommended that the Board consider going "live" with the new inspection process in all other pharmacies beginning July 1, 2011. Ms. Abernathy requested that staff notify pharmacists and pharmacy technicians of this decision prior to July 1.

Motion: **The Board voted unanimously to go "live" with the new inspection process in all pharmacies beginning July 1, 2011. (motion Kozera, second by Beckner)**

Action Item: **Board staff will send an email notification to all pharmacists and pharmacy technicians who have voluntarily provided an email address to the Board indicating that the new inspection process will go "live" in all pharmacies beginning July 1, 2011. Additionally, staff will post a similar notification on the Board's website.**

REPORTS: Dr. Elizabeth Carter, Director, DHP Healthcare Workforce Data Center, gave an update to the Board regarding the workforce surveys. Dr. Carter stated that any public feedback concerning the surveys would need to be received no later than July 1, 2011. She also requested a member of the Board of Pharmacy to consider serving on the workforce council.

Action Item: **The Board Chairman will appoint a member of the Board of Pharmacy to participate on the healthcare workforce council.**

MISCELLANEOUS:

- Methods for handling disciplinary matters- Review of statistics for key performance measures and the need to improve case clearance rate

  Ms. Juran reported the statistics for key performance measures in the third quarter of 2011. The clearance rate was reported at 41% (goal = 100%), the pending caseload older than 250 business days was 7% (goal = 25% or less), and the percent closed within 250 business days was 65% (goal = 90%). Ms. Reiniers-Day explained that the clearance rate was low partly due to a process which will no longer be used by staff. The process required cases which had technically been closed by the Board to be placed into a "pending closure" status during the thirty-day period appeal time. Ms. Reiniers-Day stated that other Boards do not use a "pending closure" status for this purpose, and that the Board's clearance rate in the third quarter of 2011 unofficially increased to 83% after eliminating the use of a "pending closure" status. Further, she stated that a review of cases closed for the time period April 1, 2011 to June 7, 2011 unofficially indicated a clearance rate of 96%, and she expected the Board to maintain a high percentage rate.

- Review of other Boards methods of delegating authority to professional staff

  Ms. Juran stated that the Boards of Nursing and Medicine have delegated authority to professional staff to process certain disciplinary matters. While the scope of delegated authority is rather broad for these Boards due to a greater need to efficiently process a higher volume of cases, Ms. Juran believed this Board's needs are more limited based on the number of disciplinary cases.

- Discussion of

  A handout was provided outlining the request for delegated

delegating authority to Board of Pharmacy professional staff

authority which included the following:

The Board of Pharmacy delegates to the Executive Director the authority to offer a prehearing consent order (PHCO) in the following circumstances:

1. Action taken by another state board of pharmacy. PHCO would require compliance with the other state's actions.

2. A single dispensing error with no patient harm involving an individual who is a minor or medically compromised, or a drug with a narrow therapeutic index. PHCO would require hours of continuing education in the subject of dispensing errors.

3. An inspection report as part of an investigation which resulted in the citing of deficiencies as identified in guidance document 110-9.

The delegation of authority to professional staff would also allow the Executive Director to offer confidential consent agreements for the following circumstances:

1. A single dispensing error with no patient harm, except as noted in #2 above. The CCA would require hours of continuing education in the subject of dispensing errors.

Additionally, it was requested that the Board delegate to the Executive Director the authority to close cases that have insufficient evidence of a violation of law or regulation.

The Board considered the request, and there was some discussion regarding the appropriate disciplinary action to be taken for a single dispensing error involving no patient harm. While Ms. Abernathy stated that she was comfortable with the concept of delegating authority, she believed that the act resulting in a dispensing error is the same no matter the patient or drug involved and therefore, she questioned whether the disposition of such cases should be the same barring any other violations of law. To aid the Board in possible future discussions on this topic, Ms. Juran offered to provide the Board with a historical perspective of statistics at the September meeting summarizing the Board's disposition of cases over the last year involving a single dispensing error involving no patient harm.

Action Item:

To aid the Board in possible future discussions, Ms. Juran will provide the Board with statistics at the September meeting summarizing the Board's disposition of cases over the last year

involving a single dispensing error with no patient harm.

Motion:

The Board voted nine to one to adopt a guidance document delegating authority to the Executive Director to handle certain disciplinary cases as requested for a six-month trial period with a report being provided by Ms. Juran at each full board meeting summarizing the disposition of cases during the trial period. (motion Kozera, second by Beckner; opposed Abernathy).

- Update of Guidance Document for use of agency subordinate

Ms. Yeatts reviewed suggestions for amending guidance document 110-37 regarding use of an agency subordinate explaining that the other boards within the agency have adopted such changes. Specifically, the Board of Nursing, who has actively used agency subordinates for several years, has found the changes to be very helpful. Ms. Juran reminded the Board that it has been interested in implementing agency subordinates and that the proposed changes to the guidance document would assist the process when in place.

Motion:

The Board voted unanimously to adopt the proposed changes as presented to guidance document 110-37 regarding the use of agency subordinates. (motion Abernathy, second by Ross)

- Request to waive regulation to allow acceptance of score transfer without obtaining additional hours of practical experience after failing NAPLEX three or more times

Ms. Juran discussed with the Board a situation where an individual licensed in another state, who did not pass NAPLEX until his fourth attempt, requested that he be allowed to obtain a pharmacist license in Virginia via score transfer without having to obtain the additional 1,000 hours of practical experience as required in Regulation 18VAC110-20-60. The Board believed the requirement to obtain additional hours of practical experience after having failed NAPLEX three times should apply to all applicants and therefore, denied the request to waive such requirement. It was stated that there is a mechanism in place for such an applicant and that he may apply for a pharmacist license in Virginia via license transfer or reciprocation.

- Board budget

Ms. Juran reported that she had been requested by the Finance Department to inform the Board that Dr. Cane has begun the formal process in the development of the agency's 2012-2014 biennium budgets. Ms. Juran provided the Board with a handout which outlined certain Board expenditures, excluding expenditures such as salaries, insurance, building rental, fiscal services, etc. She informed the Board that she did not believe the Board needed to request additional funds from Dr. Cane at this time.

REQUESTS FOR EXAMINATION ACCOMMODATION:

Motion for closed meeting:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia for the purpose of consideration and discussion of medical/mental health records contained in an accommodation request that are excluded from the Freedom of Information Act by Virginia Code Section 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Heather Hurley and David Gustin attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations. (motion by Beckner, second by Kozera).

Motion to certify the purpose of the closed meeting:

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 executive meeting were heard, discussed, or considered during the closed session just concluded. (motion by Beckner, second by Kozera).

Motions:

The Board voted unanimously to approve the examination accommodation request from Jamie Dalton allowing her twice the normally allotted amount of time for completing the examinations and a private room or partitioned area with limited distractions for completing the exams with a proctor appropriately monitoring her testing experiences. (motion by Kozera, second by Dabney).

The Board voted unanimously to approve the examination accommodation request from Michael Girgis allowing him to use a magnifying device when taking NAPLEX and authorizing the testing contractor to provide the examination in a larger computer font such as 16 point. The request for a paper format of NAPLEX was denied since the examination is not offered in a paper format as the security of the examination may be more easily compromised. (motion by Beckner, second by Kozera).

The Board held a working lunch from 1:55pm to 2:30pm

REPORTS:

- Report on Board of

Mr. Kozera reported that the Board of Health Professions was in the

Health Professions

process of recommending genetic counselors to become licensed under an advisory board of the Board of Medicine with an exemption for physicians and registered nurses who provide this type of service. Also, he stated that there is ongoing discussion on expanding the scope of practice for various types of licensees. The scopes of practice for pharmacists and pharmacy technicians are scheduled to be reviewed later this Fall. Additionally, the Board of Health Professions met with Neil Carter concerning sanction reference studies possibly addressing cases involving social media and the fact that if a licensee does not show for a disciplinary hearing should not be used as a scoring item. There was also a discussion whether a copy of the sanction reference worksheet must be included with the Order when provided to the licensee. Mr. Casway interjected that the agency's policy is still under development.

- Report on disciplinary matters

Ms. Reiniers-Day stated that, as of June 2, 2011, there were 280 cases docketed for the Board of Pharmacy. Three cases were at the entry level, 70 at the investigation level, 70 at the probable cause level, 11 at APD, five at the informal conference level, none at the formal hearing level and 121 at the pending closure level. These numbers include the cases docketed as a result of an inspection with an offered pre-hearing consent order.

Further, Ms. Reiniers-Day stated that all board members had been sufficiently exposed to disciplinary issues and the board could resume having two Special Conference Committees, meeting alternate months to provide monthly coverage. The first Committee included Mr. Kozera and Ms. Allen with Mr. Rhodes as the alternate; and the second Committee included Mr. Yi and Ms. Stelly with Ms. Shinaberry as the alternate. Ms. Reiniers-Day advised these board members that she would e-mail dates to them to begin the scheduling process.

- Report on licensure matters

Mr. Johnson reported that the board issued 877 licenses for the period of March 1 through May 31, 2001, including 110 pharmacist licenses and 505 pharmacy technician registrations. One pilot program was implemented at Dulles Urgent Care Center. The pilot utilizes the InstyMeds Automated Prescription Dispensing System.

- Executive Director's Report

Ms. Juran reported that in April she was involved in several discussions regarding whether pharmacists may compound 17 alph hydroxyprogesterone caproate, an injectable drug indicated to prevent pre-term labor. Pharmacies had previously compounded this drug for years at approximately $10-20 per dose, however, recently FDA granted KV Pharmaceuticals orphan drug status with

a 7-year exclusivity for manufacturing Makena. The initially announced price for Makena was $1500 per dose. Several groups including the US Congress initiated conversations with the manufacturer regarding the high cost for Makena which was ultimately reduced by approximately fifty percent. Additionally, the FDA announced that it would not enforce its enforcement provisions on any pharmacist compounding the drug when compounded in a safe and compliant manner. The Department of Medical Assistance Services concluded that it could not legally reimburse pharmacists for compounding 17 alpha hydroxyprogesterone caproate, but Board counsel advised that pharmacists may legally compound the drug within specific circumstances as identified in § 54.1-3410.2 of the Drug Control Act.

Additionally, Ms. Juran announced that DEA's second national take-back day was a success. DEA reported 376, 593 pounds of unwanted, unused, and potentially harmful drugs were collected nationwide, a 50% increase from the first initiative held last September. In Virginia, it was reported that 9,504.2 pounds were collected. DEA is planning a third take-back event to be held this Fall.

A letter of support, as requested, was sent in April to the Virginia Department of Health, Division of Immunization, for a grant funding opportunity. The grant is for developing or improving state or local public health immunization program relationships with pharmacies and the Board agreed to publish an e-newsletter article or send a blast email educating pharmacists and pharmacy technicians on this subject, if needed.

Ms. Juran asked Mr. Beckner to provide an update on the invitational meeting, the Pharmacy Transformation Conference, recently attended by Ms. Juran and Mr. Beckner. Mr. Beckner explained that this meeting was sponsored by the School of Pharmacy at the Virginia Commonwealth University. It was well-attended with several national speakers and the intent of the meeting was to begin a dialogue for what action may be necessary to review the current practice of pharmacy and implement possible changes consistent with any opportunities resulting from healthcare reform.

Ms. Juran reported that she attended the NABP Annual Meeting in May held in San Antonio, TX. She stated it was very informative and she reviewed the resolutions passed by the NABP voting members. Other travels will include Ms. Juran attending an invitational DEA Annual meeting later this month to be held in Ft. Worth, TX. The purpose of the meeting is to facilitate an exchange

of information between DEA and states that enforce controlled substance laws. Additionally, Ms. Juran will attend a one-day meeting in Chicago, IL in July, sponsored and paid for by NABP. It is designed to orient new executive officers to NABP processes.

Also, Ms. Juran stated that the Executive Director or his designee is required under statute to sit on the Board of Forensic Science and that she has recently been elected Chairman of the Board for the upcoming year beginning July 1, 2011.

Lastly, she reminded everyone that the date for the September full Board meeting has been changed to September 22, 2011.

RECONITION OF BOARD MEMBERS :

Mr. Yi and other members of the Board recognized the three Board members whose terms either had or were expiring and thanked them for their years of service and dedication to the Board and to the citizens of Virginia. Mr. Leo Ross' second full term expired on June 30, 2010 and Mr. Beckner will complete his second full term on June 30, 2011. Neither is eligible for reappointment. Additionally, Mr. Dabney will complete his first full term on June 30, 2011. He is eligible for reappointment.

ELECTION OF OFFICERS:

Mr. Kozera nominated Gill B. Abernathy for the office of Chairman, with a second from Mr. Rhodes. No other nominations were made. The Board voted unanimously to elect Ms. Abernathy as Chairman for the term July 1, 2011 through June 30, 2012.

Ms. Abernathy nominated David C. Kozera for the office of Vice-Chairman, with second from Mr. Ross. No other nominations were made. The Board voted unanimously to elect Mr. Kozera as Vice-Chairman for the term July 1, 2011 through June 30, 2012.

NEW BUSINESS:

There was no new business

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 a Consent Order. Additionally, it was moved that Cathy Reiniers-Day, Caroline Juran, Sammy Johnson, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Beckner, second by Kozera)

Motion to certify the purpose of the closed

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements

meeting: **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 Dabney)**

Motion: **The Board voted unanimously to accept the consent order as presented by Ms. Reiniers-Day in the matter of Thomas R. Eddy, Pharmacist. (motion by Kozera, second by Allen)**

ADJOURN: With all business concluded, the meeting adjourned at 2:50 P.M.

Gill B. Abernathy, MS, RPh, FPS
~~Brandon Yi, Board Chairman~~

Caroline D. Juran, Executive Director

9/20/11
Date

9/20/11
Date