FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 12, 2012
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Gill B. Abernathy, Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
David C. Kozera
Dinny Li
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Brandon K. Yi

MEMBERS ABSENT: Ellen B. Shinaberry

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
Dianne Reynolds-Cane, Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: An amended agenda was provided and approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the March 13, 2012 (Full Board Meeting), April 12, 2012 (Telephone Conference Call), April 30, 2012 (Special Conference Committee and Informal Conference Committee), May 2, 2012 (Panel Formal Hearing), May 2, 2012 (Regulation Committee- Pharmacy Working Conditions), and May 15, 2012 (Special Conference Committee and Informal Conference Committee.

MOTION: **The Board voted unanimously to approve the minutes as presented. (motion by Stelly, second by Allen)**

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

DHP DIRECTOR'S REPORT: Dr. Cane reported that suggestions for legislative proposals will need to

be submitted to the Secretary's Office by August. She also reported that she has been conducting a weekly progress check of the regulations that are currently at the Governor's Office. Arne Owens, Chief Deputy Director, DHP, and Ralph Orr, Director, Prescription Monitoring Program (PMP), visited the Department of Health and Human Resources in Washington, DC to discuss the PMP with regards to interoperability between states (interstate data sharing between PMP programs). Dr. Cane also spoke on new policies being set forth by the agency that will help decrease traveling expenses.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that the comment period for the changes to the "run-dry" requirement for automated dispensing devices is now closed. Emergency regulations for Continuous Quality Improvement Programs (CQI) are at the Governor's Office. The proposed amendments to address on-hold prescriptions and the final regulations for repackaging in the Community Service Boards and Behavioral Health Authorities are also at the Governor's Office (emergency regulations for CSB's and BHA's expire 6/18/12). The proposed regulation for administrative fees for duplicate licenses and verification are at the Secretary's Office.

- Re-adoption of the proposed regulations for automated dispensing devices:

Ms. Yeatts indicated that staff did not make any substantive changes, but did reorganize the proposed regulations for automated dispensing devices to improve readability. Therefore, she requested that the Board review the changes. Ms. Yeatts stated that the Board would need to re-adopt the proposed regulations.

MOTION:

The Board voted unanimously to adopt the proposed regulations as presented for automated dispensing devices.
(motion by Yi, second by Allen)

REGULATORY COMMITTEE REPORT:

- Recommendation on Petition for Rulemaking, Kristen Barratt, Pharmacist

Ms. Yeatts presented to the Board Ms. Barratt's Petition for Rulemaking concerning professional work environment. Ms. Yeatts stated that the Board could either deny the petitioner's request for amendments and state the reason why the request was denied, or accept the request and initiate rulemaking by adopting a Notice of Intended Regulatory Action (NOIRA). Ms. Juran discussed the research that staff conducted and provided to the Regulation Committee. The Regulation Committee's motion was for the Board to accept the request and adopt a NOIRA.

MOTION:

The Board voted unanimously to approve the Regulation Committee's recommendation to accept the petition for rulemaking and adopt a Notice of Intended Regulation Action regarding the number of continuous hours a pharmacist may work and required breaks.

- Recommendation regarding request from *The Pharmacy Alliance* on pharmacy working conditions

Ms. Allen discussed with the Board the request from The Pharmacy Alliance concerning pharmacy working conditions and the Regulation Committee's recommendation. The Committee recommended the following: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and other pharmacists to submit evidence to the Board that the identified practices referred to the Committee can or have created patient harm; publish an article in the Board's e-newsletter expressing concerns for contemporary practices and restating the relevant sections of §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

MOTION:

The Board voted unanimously to approve the Regulation Committee's recommendation regarding *The Pharmacy Alliance's* request concerning pharmacy working conditions.

MISCELLANEOUS:

- Request to discuss length of time associated with and access to final orders:

Mr. Adams presented to the Board his concerns regarding pharmacists who have past disciplinary actions on their licenses and are having a difficult time getting employment as a result. Notices and Orders are public information and kept on record for eighty-five years. Mr. Casway explained that changes would necessitate the General Assembly amending the Administrative Process Act, Freedom of Information Act, title 54.1 and possibly other sections of law. Additionally, changes to the state record retention requirements and agency policy would be necessary. Mr. Kozera commented that many violations are also reportable to the National Practitioner Databank and therefore, a violation would also exist in its records.

MOTION:

A motion was presented and subsequently withdrawn by Mr. Adams for the Board to consider a process to expunge certain case violations from a pharmacist's license.

MOTION:

A new motion was made that the Department of Health Professions reconsider how it displays public information on its website with a focus of discussion on violations occurring in excess of twenty years. (motion by Adams, died for lack of a second)

- Define "annual" and "semiannual" in guidance document 110-36

To further clarify the Board's expectations regarding when media fill testing must be performed, Ms. Juran requested that the Board review staff's suggested changes to Guidance Document 110-36 concerning the definitions of "annual" and "semiannual". It was suggested the terms

"annual" and "semiannual" be defined to mean every twelve and six months, respectively. Additionally, she indicated that the information in the document was somewhat outdated and the other suggested changes as presented in the draft document were to simply update the information.

MOTION: **The Board voted unanimously to adopt the amended Guidance Document 110-36 as presented.**
(motion by Rhodes, second by Munden)

- Establish threshold for compliance in guidance document 110-9

The Board discussed whether a threshold was appropriate when determining compliance with annual and semiannual requirements for media fill testing found in Major Deficiencies 25 and 26 in Guidance Document 110-9. Mr. Adams believed a 60-day threshold was too long.

MOTION: **A motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9, but without the suggested 60-day threshold. (motion by Adams, died for lack of second)**

MOTION: **A new motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9 which included the suggested 60-day threshold. (motion by Yi, died for lack of second)**

MOTION: **The Board voted unanimously to amend Major Deficiencies 25 and 26 in Guidance Document 110-9 to include the following thresholds when determining compliance:**

- **Major Deficiency 25 = 14-day threshold added, i.e., inspector will not cite deficiency until 15 days after the required due date of the semi-annual media fill testing for high-risk level CSPs;**
- **Major Deficiency 26 = 30-day threshold added, i.e., inspector will not cite deficiency until 31 days after the required due date of the annual media fill testing for low and medium-risk levels. (motion by Rhodes, second by Adams)**

- Evaluation and revision of Sanction Reference Point System:

Neal Kauder presented to the Board a slide presentation reviewing the suggested evaluation and revision process of the Sanction Reference Point System (SRPS). The Board adopted the SRPS in guidance document 110-21 in September 2007 and he recommended that it may be time to evaluate its effectiveness and determine if it remains consistent with Board policies. He stated that other boards such as Medicine and Nursing have recently concluded this evaluation process which did result in some changes.

MOTION: **The Board voted unanimously that the Board of Health Professions evaluate the effectiveness of the Board of Pharmacy's Sanction Reference Point System. (motion by Kozera, second by Yi)**

REPORTS:

- Report on Workforce Survey

Dr. Elizabeth Carter, Director, DHP's Healthcare Workforce Data Center, presented the draft workforce survey results. The survey was conducted of pharmacists during the recent licensure renewal cycle. Dr. Carter reported that 90% of online renewing pharmacists responded to the survey. This survey included various questions that were responded to by pharmacists located in all regions of Virginia. Data and percentages were compiled based off of the number of pharmacists who participated in the survey and location of these individuals. While draft results were shared with the Board members, these results remain embargoed and will not be available for the public until the full analysis is completed. Dr. Carter indicated that it is anticipated that final results of the pharmacist workforce survey will be released to the public in the next few months. A release date for the draft results of the pharmacy technician workforce survey was not indicated.

- Report on Board of Health Professions

Mr. Rhodes stated that the full board meeting of the Board of Health Professions scheduled for May was cancelled, and therefore, he did not have anything to report at this time.

LICENSURE PROGRAM

Mr. Johnson reported that the Board issued 918 licenses and registrations for the period of March 1, 2012 through May 31, 2012, including 129 pharmacists, 82 pharmacy interns, and 538 pharmacy technicians. Inspectors performed 300 facility inspections including 110 routine inspections of pharmacies: 28 resulted in no deficiency, 25 with deficiencies, and 57 with deficiencies and a consent order. There are currently two active innovative (pilot) programs, one pilot program pending approval, and three pilot programs to be renewed for an extension .

DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of September 19, 2011; December 12, 2011; March 12, 2012; and June 8, 2012. For the final date, open cases are 37 at the investigation stage; 50 at the probable cause stage; 31 at the administrative proceedings division stage; five at the informal stage; one at the formal stage; and 89 at the pending closure stage.

Further, Ms. Reiniers-Day informed the Board that one case received the previous week had already accrued the 250 business days while at the enforcement level. The case was already at the APD level to draft an informal notice.

Ms. Reiniers-Day also stated that Rose Dematteo, the new Compliance Case Manager, was quickly reviewing all the compliance cases so that all the cases could be current.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran thanked Ms. Abernathy and Mr. Kozera for serving as Chairman and Vice-Chairman, respectively, during the past year. Additionally, she acknowledged Ms. Abernathy whose second full term

as board member expires June 30, 2012 and Mr. Brandon Yi whose first full term expires June 30, 2012. Ms. Juran then reported that Dave Kozera, Leo Ross, and she attended the 108th NABP Annual Meeting held in Philadelphia in May and highlighted several presentations offered at the meeting. She reminded the members that the 2012 General Assembly passed a law to implement the National Precursor Log Exchange (NPLEx) effective January 1, 2013. She has been working with the Virginia State Police (VSP) and Appriss to coordinate implementation efforts. She indicated that a letter from the VSP will be sent within the next two months to all pharmacies and retailers selling pseudoephedrine informing them of the law and the process for implementing this free technology. Additionally, Ms. Juran briefly reported that Elaine Yeatts, Sammy Johnson, and she participated on the anaphylaxis workgroup for drafting anaphylaxis guidelines for schools that must stock epinephrine for anaphylaxis treatment. She then reported that a new part-time employee has been hired, Laura Rothrock. She is assisting Mr. Johnson with the handling of possible disciplinary matters resulting from the inspection program or continuing education audit. Additionally, she stated that the pharmacist inspector for the northern Virginia region, Scott Arnott, is retiring as of July 1. Lele Pallavi, pharmacist investigator, has been transferred into this position and is currently training with Mr. Arnott. Additional meetings in which Ms. Juran will be participating or offering presentations include the Pharmacy Workforce Center meeting to be held June 18th and the 131st VPhA Annual Convention this August.

ELECTION OF OFFICERS:

MOTION: **The Board voted unanimously to elect Mr. Kozera as Chairman for the term July 1, 2012 through June 30, 2013. (motion by Rhodes, second by Allen)**

MOTION: **The Board voted unanimously to elect Ms. Allen as Vice-Chairman for the term July 1, 2012 through June 30, 2013. (motion by Adams, second by Munden)**

NEW BUSINESS:

- Request from staff for guidance regarding nine-month allowance in regulations 18VAC 110-20-101 D and 18VAC 110-20-111 C

Board staff requested the Board to confirm its understanding that the nine month allowance for pharmacy technicians as stated in regulations 18VAC 110-20-101 D and 18VAC 110-20-111 C is restricted to nine continuous months from the date of enrollment in a Board-approved pharmacy technician training program.

MOTION FOR CLOSED MEETING: **The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(7) of the Code of Virginia for the purpose of obtaining advice from Board Counsel that is excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Elaine Yeatts and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the**

Board in its deliberations.

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 closed meeting were heard, discussed or considered during the closed meeting.

MOTION:

The Board voted unanimously to adopt a Guidance Document that clarifies regulations 18VAC 110-20-101 D and 18VAC 110-20-111 C in that the nine-month allowance to perform tasks restricted to a pharmacy technician prior to obtaining registration as a pharmacy technician begins on the first enrollment date in a Board-approved pharmacy technician training program and ends nine consecutive months later, regardless of whether the person completes the program or enrolls in a different program during those nine months. (motion by Kozera, second by Adams)

- Request for guidance regarding when more than one pharmacist is involved with the dispensing process

Counsel advised staff that a conflict may exists between Regulations 18VAC 110-20-270 and 18VAC 110-20-276 and advised that the Board opine and provide guidance to staff as to which pharmacist should be held responsible for an error when the dispensing involved more than one pharmacist. Al Carter with Walgreens addressed the Board concerning remote processing allowances in Regulation 18VAC110-20-276 and explained that several pharmacists are involved in the dispensing process as allowed in regulation. Each pharmacist is assigned a duty and if an error is made during the dispensing, the pharmacist responsible for that individual task can be identified. However, Regulation 18VAC110-20-270 indicates that the pharmacist shall verify accuracy in all respects and take responsibility for the entire transaction. Three dispensing scenarios were discussed: one pharmacist performing all dispensing functions and taking responsibility for the entire transaction; two pharmacists involved at one pharmacy location, one performing data entry verification and one performing drug product verification; and, two pharmacists involved at multiple pharmacy locations performing central or remote processing. Ms. Juran also discussed that recordkeeping requirements of 18VAC 110-20-255 may apply to some of these scenarios.

MOTION FOR CLOSED MEETING:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(7) of the Code of Virginia for the purpose of obtaining advice from Board Counsel that is excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and

that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Elaine Yeatts and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.

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 closed meeting were heard, discussed or considered during the closed meeting.

MEMBERS ABSENT FROM CLOSED SESSION:

Jody H. Allen

MOTION:

The Board voted unanimously to have staff draft a guidance document to include information on: the three dispensing scenarios discussed; identifying which pharmacist would be held responsible for a dispensing error in each scenario; suggested best practices for complying with Regulations 18VAC110-20-270, 18VAC110-20-276, and 18VAC110-20-255; and, to further clarify potential conflicts with the regulations during the next periodic regulatory review. (motion Kozera, second by Adams, Allen abstained)

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, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.

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 closed meeting were heard, discussed or considered during the closed meeting.

MOTION:

The Board voted unanimously to approve the following examination requests of Hope Pierpoint: extended time by one and a half times the normally allotted time; a pop-up calculator provided on the

computer at the testing center; and, a room with limited distractions for completing the exams with a proctor appropriately monitoring her testing experiences. (motion by Adams, second by Stelly)

APPROVAL OF CONSENT ORDERS

Motion for a closed meeting

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding two Consent Orders. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, 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 Kozera, second by Rhodes)

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

Motions

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Rachel J. Mitchell, pharmacy technician. (motion by Kozera, second by Stelly)

Further, eight Board members voted affirmatively with one abstaining to accept the Consent Order as presented by Ms. Reiniers-Day and amended in the matter of Morgan R. Tripke, pharmacy technician. (motion by Yi, second by Allen)

ADJOURN:

With all business concluded, the meeting adjourned at 3:35pm.

Gill Abernathy, Board Chairman

10/1/12
Date

Caroline D. Juran, Executive Director

October 1, 2012
Date