

(DRAFT/UNAPPROVED)

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

October 1, 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: David C. Kozera, Chairman

MEMBERS PRESENT: R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

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 ten members present, a quorum was established.

INTRODUCTION OF NEW BOARD MEMEBERS: Mr. Kozera welcomed two new members to the Board of Pharmacy, Rebecca Thornbury and Cynthia Warriner.

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

APPROVAL OF MINUTES: The Board reviewed draft minutes for the June 12, 2012 (Full Board Meeting), June 29, 2012 (Special Conference Committee and Informal Conference Committee), July 24, 2012 (Formal Hearing), August 22, 2012 (Special Conference Committee and Informal Conference Committee), and September 18, 2012 (Special Conference Committee and Informal Conference Committee).

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

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

DHP DIRECTOR'S REPORT:

Dr. Cane commended those who participated in the collaboration of the National Governors Association's (NGA) policy grant application for \$45,000 to reduce prescription drug abuse. Virginia, along with six other states, was recently awarded the grant and discussions have begun for identifying ways to reduce prescription drug abuse. Dr. Cane also commented on the successful turnout for the New Board Member Orientation that was held at the Department of Health Professions on Friday, September 28, 2012. She stated that the orientation appeared very informative to the new and existing Board members. It included a panel presentation which discussed the effectiveness of the boards and the responsibilities that the members are to assume.

REPORT ON ENFORCEMENT
ACTIVITIES:

Faye Lemon, Director of the Enforcement Division at DHP, provided an overview of the activities occurring within the division. Ms. Lemon introduced Pamela Twombly as one of the new Deputy Directors for Enforcement, Wanda Jackson, Case Intake Manager who oversees pharmacy cases, and Vicki Garrison, Pharmacy Inspector, who recently served as acting Deputy Director for Enforcement and assisted in supervising the inspection program. Ms. Lemon explained that the Enforcement Division has authority in statute to inspect and investigate. Their department conducts facility-related inspections for the Boards of Pharmacy, Veterinarian Medicine, and Funeral. In addition to inspections, investigations are conducted by the Enforcement Division based on complaints received by the agency. These cases are submitted to each individual board once the investigation is complete, to determine if a violation has taken place. Ms. Lemon reported that the amount of pharmacy cases increased from 317 in 2011 to 573 in 2012. She speculated that the increase may be a result of the pharmacy inspection process which was fully implemented in July 2011. She further stated that she is recruiting for the vacant pharmacy inspector position in northern Virginia. When asked about the type of training the inspectors/investigators receive, Ms. Lemon stated that it takes at least 18 months to completely train the individual. Internal training is provided in addition to training from outside entities such as the Council on Licensure, Enforcement and Regulation (CLEAR).

NABP-REPORT ON THE
IMPLEMENTATION OF THE
PARE EXAMINATION:

Elizabeth Scott (Scotti) Russell, NABP Government Affairs Manager, presented to the Board an outline regarding the implementation of the PARE Examination (Pharmacist Assessment for Remediation Evaluation). Ms Russell explained that this exam could be utilized by the boards of pharmacy to evaluate competency of pharmacists wishing to reinstate a license following a suspension or revocation. The Board could also use the exam, if warranted, to evaluate competency of a pharmacist with a lapsed license who has not practiced for a significant number of years.

The PARE exam is computer-based, consisting of 210 questions with a maximum testing time of 4.5 hours. The cost of the exam is \$250.00 that would be paid by the licensee directly to NABP. The content areas of the exam are focused 50% in medication safety and practice of pharmacy, 25% in professional ethics and pharmacy judgment and 25% on clinical

pharmacy practice. Details regarding the registration process were provided by Ms. Russell. The testing site would be determined by the board. She indicated that the PARE exam has not been administered to date, but that several boards of pharmacy have expressed interest to require the examination in the near future.

CHAIRMAN'S REPORT:

Mr. Kozera provided a report of the NABP Interactive Member Forum that he attended on September 19th and September 20th. The meeting provided an opportunity for the various states to share issues of concern and best practices occurring within their states. Some of the discussed topics included pharmacy technician educational requirements; licensure prerequisites such as criminal background checks; strategies for addressing drug shortages; and, current and future uses of the prescription monitoring programs.

REPORT ON LICENSURE PROGRAM:

Mr. Johnson reported that the Board issued 1,383 licenses and registrations for the period of June 1, 2012 through August 31, 2012, including 400 pharmacists, 156 pharmacy interns, and 645 pharmacy technicians. Inspectors conducted 328 facility inspections including 110 routine inspections of pharmacies: 33 resulted in no deficiency, 17 with deficiencies, and 60 with deficiencies and a consent order. There are currently five active innovative (pilot) programs, one pilot program pending approval, and three applications for pilot programs to be scheduled for reviewed by an informal conference committee.

REPORT ON DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of December 12, 2011; March 12, 2012; June 8, 2012, and September 28, 2012. For the final date, open cases are 62 at the investigation stage; 46 at the probable cause stage; 25 at the administrative proceedings division stage; 12 at the informal stage; two at the formal stage; and 88 at the pending closure stage.

Due to a position vacancy in the Administrative Proceedings Division, there is a backlog of cases which may result in the percentage of patient care cases closed within the required 250 business days to decrease for the next few reports. Recruitment for the position is underway and staff reassignments have been implemented to address the backlog.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran reported that she received approval to travel to the NABP/AACP District 1 & 2 meeting that will be held in Skytop, Pennsylvania on October 14th through 16th. Other board members who had expressed interest in attending were identified as Ms. Shinaberry, Mr. Adams, Ms. Warriner, Mr. Rhodes, and Ms. Allen. Additionally, Ms. Juran stated that she will attend the Tri-Regulator meeting to be held in Washington DC October 17th and 18th. This will be the first-ever meeting of National Association of Boards of Pharmacy, Federation of State Medical Boards, and the National Council of State Boards of Nursing. Even though it is recognized that while each association is different, there is a common regard for protecting the public through state licensure activities. By collaborating, there are potential benefits to be

gained in order to better protect the public health, safety and welfare. It will also recognize the value of involving a broader constituency as issues emerge and encourage other health care regulatory representatives to participate in relevant and pertinent issues. Ms. Juran also stated that the October newsletter was just recently disseminated. She highlighted that the July newsletter had an article referencing “red flags” that a pharmacist should consider when evaluating a suspicious prescription. On October 20th, Ms. Juran will be presenting at the Virginia Society of Health Systems Pharmacists Fall Seminar in Norfolk. Effective as of September 28, 2012, Pallavi Lee resigned as the pharmacy inspector for the Northern Virginia Region. The Enforcement Division has begun recruitment for this position. Ralph Orr, Program Manager for the PMP (Prescription Monitoring Program), is now the chairman for the PMP steering committee. In addition, the PMP Interconnect has currently 26 states that have committed with the NABP. Ten of those states are currently actively sharing data. New Mexico is the most current state to go live with the program but is only sharing data with Arizona at this time. They are to expand to other states later this month. Kentucky is hopefully in the process of becoming active in the near future. Ms. Juran also reported on the White House Subcommittee of Forensic Science meeting that she recently attended on behalf of the Virginia Forensic Science Board. The Office of the President is interested in establishing national standards in some fashion and invited certain states to attend the recent meeting to discuss how the states vary with respect to oversight for forensic science.

REPORT ON HEALTH
PRACTITIONER
MONITORING PROGRAM
(HPMP):

Dr. Penelope Ziegler, Medical Director, VCU-Health Practitioner Monitoring Program (HPMP) and Peggy Wood, Program Manager, Health Practitioner Monitoring Program (HPMP), gave an overview of the program to the Board. Dr. Ziegler stated that the Board of Pharmacy was the third largest Board with participants. The most common diagnosis for the practitioners in the program is substance abuse which is at 90%. Data collected indicate that the physicians’ substance of choice to abuse is alcohol, while nurses and pharmacists primarily abuse prescription drugs. Other diagnoses within the HPMP are psychiatric disorders and physical conditions. The HPMP evaluates the practitioner by assessing their condition and creates a treatment plan based off their diagnosis. The Virginia HPMP was established in 1997 by the General Assembly and was formerly known as the Health Practitioners Intervention Program (HPIP). The name of the program was changed in 2009 to the Health Practitioners Monitoring Program (HPMP). It is operated by Virginia Commonwealth University (VCU), Department of Psychology under memorandum of agreement with the Department of Health Professions. The program consists of staff and a medical director from VCU. HPMP monitors the treatment of the impaired licensee to determine if and when a recovered licensee may resume practice in the applicable profession and under what restrictions. Failure to comply with the monitoring may be cause for dismissal from the program. Dr. Ziegler explained that health care practitioners can be referred to the HPMP program by a board order, DHP staff (investigator), colleagues, peer assistance programs, physicians or therapists. The Board of

Pharmacy has the third largest group of participants, after the Boards of Nursing and Medicine. There are 36 pharmacy licensees in the program as of August 31, 2012. Admissions to the HPMP program since 2003 for the Board of Pharmacy have been a total of 160 practitioners. Dr. Zeigler stated that the pharmacists have a 60% positive outcome with completion of the program, while pharmacy technicians' success rate is less than 20%.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an update of ongoing regulatory processes. She stated that the emergency regulations related to implementation of continuous quality improvement (CQI) programs became effective October 1, 2012 and will be in place until September 30, 2013. A notice of intended regulatory action (NOIRA) for the replacement regulations for CQI has recently been published. Public comment on the NOIRA will be accepted from October 8, 2012 until November 7, 2012. Ms. Juran reminded the Board of its previous decision in 2011 to not impose a monetary penalty for noncompliance on this issue within the first 6 months of the emergency regulations becoming effective. As of April 1, 2012, a monetary penalty could be imposed if the Board establishes such monetary penalty at its next meeting.

Ms. Yeatts also reported that the proposed regulations for automated dispensing devices are currently at the Secretary's office. The regulatory amendments that address on-hold prescriptions are currently at the Governor's office, and the public comment period for the NOIRA regarding the number of continuous hours worked by pharmacists closes October 8, 2012.

- Adoption of proposed regulations for changes to run dry requirement for automated counting devices:

The Board discussed draft proposed regulatory amendments to Regulation 18VAC110-20-355, prepared by staff, for run-dry requirements for automated counting devices. Soumi Saha, Government Relations and Regulatory Affairs Coordinator for Kaiser Permanente addressed the Board concerning how the run-dry requirements affect their pharmacies. Ms. Saha explained that the drugs that were being dispensed by the automated counting devices were fast-moving and did not stay in the cells for extended periods of time. Mr. Kozera suggested that in section C5b of the draft proposed regulation that the phrase “,with a record made of the run dry date,” be added following the phrase “The bin has been “run dry””.

MOTION:

The Board voted 9-1 to adopt the proposed regulatory amendments of Regulation 18VAC110-20-355 regarding the run dry requirement for automated counting devices as amended by Mr. Kozera. (motion by Stelly, second by Allen)

After further discussion, it was determined that the approved regulatory amendment to Regulation 18VAC110-20-355 did not adequately address the need to remove recalled drug product if the automated counting

device stored slow-moving drugs.

MOTION:

The Board voted unanimously to reconsider and amend the prior motion regarding run-dry requirements for automated counting devices.

(motion by Allen, second by Adams)

A recommendation was made to add language to section C5 “or if a recalled drug is known to remain in the bin” following the phrase “...in the last three months”.

MOTION:

The Board voted unanimously to adopt the proposed regulatory language, as amended in sections C5b and C5, of Regulation 18VAC110-20-355 regarding run dry requirements for automated counting devices.

(motion by Allen, second by Adams)

**ADOPTION OF GUIDANCE
DOCUMENT DISPENSING
AUTHORIZED GENERICS:**

Ms. Juran indicated that staff has received calls from pharmacists requesting guidance as to whether a pharmacist may dispense an authorized generic for a prescription written for a Schedule II branded drug product or if a new prescription written for the authorized generic would be necessary. Because authorized generics are identical to the branded drug and are not recognized as a therapeutically equivalent drug product in FDA’s Orange Book and Virginia’s laws regarding substitution appear to only address substitution with a therapeutically equivalent drug product as identified in the Orange Book, it is unclear what actions the pharmacist must take. A draft guidance document prepared by staff was presented for the Board’s consideration. The Board expressed concerns for how the patient would know that an authorized generic had been dispensed since the labeling requirement for the phrase “generic for” as listed in Regulation 18VAC110-20-330 would not apply.

ACTION ITEM:

The Board requested staff to survey the other state boards of pharmacy to determine how they are addressing the issue of dispensing authorized generics and to report back at the December full board meeting for further consideration.

**REQUEST TO OFFER
COMMENT TO BOARD OF
HEALTH PROFESSIONS
REGARDING PHARMACIST
SCOPE OF PRACTICE
REVIEW:**

Dr. Elizabeth Carter, Executive Director for the Board of Health Professions, requested comments from the Board regarding the recent pharmacist scope of practice review. Dr. Carter stated that public comment was obtained from July 2012 to August 2012 for suggestions on how broadening a pharmacist’s scope of practice can help improve patient care. She requested from the Board feedback regarding the possible expansion of a pharmacist’s scope of practice. Tim Musselman, Executive Director for the Virginia Pharmacists Association, stated that they were drafting legislative language for the upcoming General Assembly Session to expand allowances for collaborative practice agreements to include a provision for pharmacists to initiate drug therapy. The physician would set perimeters for the pharmacist and any implementation of drug therapy would be post-diagnosis. The Board did not express any significant concerns for the possible expansion to

pharmacist's scope of practice as discussed.

Additionally, Dr. Carter distributed the survey conducted for pharmacy technicians. She requested that the Board submit any comments to Ms. Juran no later than October 12, 2012.

AMEND GUIDANCE
DOCUMENT 110-36
REGARDING USP
STANDARDS:

Following the June board meeting, staff identified a conflict between the recordkeeping requirements in USP and Guidance Document 110-36. Additionally, the inspectors had expressed concerns for allowing certain records to be maintained off-site since it could impact the timely completion of the inspection report. The allowance to maintain certain records electronically appeared sufficient for addressing any storage concerns for records. The Board reviewed the draft amendments to Guidance Document 110-36, prepared by staff, regarding USP standards.

MOTION:

The Board voted unanimously to approve the amendments, as presented, to Guidance Document 110-36 regarding USP standards.. (motion by Warriner, second by Allen)

CONSIDERATION OF
REQUEST FOR A MEMBER
TO PARTICIPATE
TELEPHONICALLY AT
CERTAIN BOARD
MEETINGS:

Staff had been approached by a member for guidance regarding whether a board member could participate via telephone at board meetings if inclement weather prevented travel. Counsel reviewed the statutory allowances with the Board and advised that the board should determine if it is comfortable with members participating via telephone in compliance with the law. Mr. Casway explained that as an appointed member it is advisable that members make every effort to attend in person barring emergency circumstances or sickness. The Board was supportive of allowing a member to participate via telephone under emergency circumstances only in compliance with 2.2-3708.1.

GUIDANCE FROM COUNSEL
REGARDING LEADERSHIP
ROLES IN PROFESSIONAL
ASSOCIATION AND
APPEARANCES OF
POSSIBLE CONFLICTS OF
INTEREST:

Mr. Casway discussed the possible appearance of conflict of interest when a Board member is serving in leadership roles in professional associations. Mr. Casway stated that the member needs to determine if he can serve on the Board and the association without any inappropriate conflicts, and he may want to reconsider before agreeing to become a member of any legislative or regulatory committee of a professional association. Mr. Casway also reviewed with the Board prohibitions to discuss Board issues outside of properly noticed meetings.

REVIEW OF DRAFT BYLAWS
OF NABP DISTRICT 2:

Ms. Juran presented the Board with the draft bylaws for NAPB District 2 and asked the members to review the information and submit feedback. Also, Ms. Juran stated that if any member wishes to be on the Board of Directors for the NABP District 2 to let her know. All comments needs to be submitted by October 12, 2012.

SCHEDULING OF 2013
DATES FOR FULL BOARD
MEETINGS:

The Board reviewed suggested dates for the upcoming 2013 full board meetings. The tentative dates selected were March 12, 2012, June 18, 2013, September 10, 2013 and December 12, 2013. Mr. Kozera also announced the appointed members to the standing committees for the year 2013.

CONSIDERATION OF
CONSENT ORDERS:

**MOTION FOR 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 a Consent Order. Additionally, it was moved that Caroline Juran, 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 deliberation. (motion by Allen, second by Warriner)

**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 Allen, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of James T. Marrow, Pharmacist. (motion by Warriner, second by Stelly)

ADJOURN:

With all business concluded, the meeting adjourned at 4:10pm.

David C. Kozera, Board Chairman

Caroline D. Juran, Executive Director

Date

Date