FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 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 9:16 AM.

PRESIDING: David C. Kozera, Chairman

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

MEMBERS ABSENT:
Pratt P. Stelly
Rebecca Thornbury

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
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: With no changes to the agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the October 1, 2012 (Full Board Meeting), October 24, 2012 (Special Conference Committee and Informal Conference Committee), November 6, 2012 (Special Conference Committee and Informal Conference Committee), November 20, 2012 (Telephone Conference Call), November 28, 2012 (Informal Conference Committee for Innovative Pilot Programs), and November 29, 2012 (Panel Formal Hearing). There was a suggestion to add the list of standing committees to page 7 under the "Scheduling of 2013 dates for full board meetings".

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

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

DHP DIRECTOR'S REPORT: Dr. Cane discussed with the Board the three legislative proposals that made it into the governor's package. The first one pertains to the elimination of the Psychiatric Board since they have never met. The second proposal is regarding prohibiting a Department of Health Professional licensee from being able to practice on a suspended or revoked license. The third proposal concerns the adding of anabolic steroids to the Drug Control Act. Dr. Cane attended the Milbank Conference which is made up of state legislators and agency heads to discuss how to reduce the abuse of prescription drugs. The Southwest Drug Abuse Summit was held November 14th in Wytheville, Virginia and Dr. Cane and Ralph Orr from the Prescription Monitoring Program attended. In January, the NGA will meet and Arne Owens, Deputy Director of the Department of Health Professions is presiding as Chair and will be working directly with Caroline Juran and Ralph Orr.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that the emergency regulations for continuous quality improvement programs (CQI) went into effect on October 1, 2012 and that they will expire in one year but may be extended for an additional six months after expiration. The proposed regulations for CQI to replace the emergency regulations will be presented to the Board for adoption. The comment period for the notice of intended regulatory action (NOIRA) addressing the hours of continuous work by pharmacists closed on October 10, 2012. The proposed regulations for continuous work hours was drafted by the Regulation Committee at the December 11, 2012 meeting, and will be presented to the Board for adoption. The adopted regulations for administrative fees for duplicate licenses and verifications are currently at the Secretary's Office.

- Adoption of proposed regulations for CQI to replace emergency regulations:

Ms. Shinaberry discussed the proposed regulations that the committee recommended to replace the emergency regulations.

MOTION: **The Board voted unanimously to adopt the proposed continuous quality improvement program (CQI) regulations as recommended by the Regulation Committee. (motion by Warriner, second by Adams)**

- Adoption of proposed regulations for working conditions for pharmacists:

Ms. Shinaberry gave the Board an overview of the committee's recommendation for regulations concerning the working conditions for pharmacists. After being reviewed and discussed, the Board was asked to make a motion regarding the proposed regulations.

MOTION: **The Board voted to adopt the proposed regulations as recommended by the Regulation Committee regarding working conditions for pharmacists. (five in favor, three opposed; motion carried)**

- Adoption of fast-track regulations resulting from regulatory reform:

Ms. Yeatts recommended to the Board to consider adopting the fast-track regulations resulting from regulatory reform. Fast-track regulations are less restrictive, there is no comment period and it is reviewed internally. Three major regulations that were included in the governor's reform package for review are concerning the physician's selling, collaborative practice agreements, and wholesale distributors.

MOTION:

The Board voted unanimously and the motion was carried, to adopt fast-track regulations regarding physicians selling controlled substances.

MOTION:

The Board voted unanimously and the motion was carried, to adopt fast-track regulations regarding collaborative practice agreements.

MOTION:

The Board voted unanimously and the motion was carried, to adopt fast-track regulations regarding wholesaler distributors.

UPDATE ON ACTION ITEMS:

- Discussion of "authorized generics"

Ms. Juran gave an overview of the research that she obtained by the Board's request at the October 1, 2012 board meeting concerning "authorized generics". Ms. Juran stated that she conducted a fourteen state survey through the NABP, with seven states agreeing that an "authorized generic" would be considered a equivalent, and seven states did not agree. A newsletter that was posted by the Kentucky Board of Pharmacy included a section from the Orange Book, 32nd edition, that the FDA does consider an authorized generic as an approved equivalent. Ms. Juran state that the Board could accept that "authorized generics" would be considered an equivalent as stated by the Orange Book and they could adopt a Guidance Document or not accept the "authorized generics" as a substitution drug.

MOTION:

The Board voted unanimously to adopt a guidance document that deems "authorized generics" as being an equivalent substitution as stated in the 32nd edition of the FDA Orange Book, and have staff reference this information in the next newsletter. (motion by Warriner, second by Shinaberry)

ADDTION TO AGENDA:

Mr. Kozera stated that there was going to be an addition to the agenda after the consideration of consent orders to include ethics training by Howard Casway, counsel for the Board.

MISCELLANEOUS:

- Update on actions taken regarding pharmacies performing sterile compounding, staff request for additional guidance:

Ms. Juran gave the Board an update of actions that staff was taking regarding sterile compounding pharmacies located outside and within Virginia. A survey was sent out to all non-resident pharmacies that will need to be submitted by December 28, 2012. This survey will indicate whether that pharmacy is sterile compounding and if they are complying with USP 757 standards. All documentation will be reviewed by an ad-hoc committee made up by Board members and Board staff. Ms. Juran also requested guidance from the Board by giving additional feedback or input concerning the regulation of sterile compounding pharmacies.

- Consideration of possible legislative amendments regarding licensure and renewal process of non-resident pharmacies and compounding:

Ms. Juran stated that there was possible consideration of amendments to legislation regarding licensure and renewal of non-resident pharmacies that are sterile compounding. The FDA invited Ms. Juran and Howard Casway to a meeting of all fifty states to discuss the issues with sterile compounding pharmacies. This meeting will be held December 19, 2012 in Silver Spring, Maryland, and she and Mr. Casway will be attending. The Board suggested that staff conduct a survey through NABP concerning the other state's processes of sterile compounding pharmacy licensure and renewal. Sherry Garvin, representing Leesburg Pharmacy addressed the Board, and stated she believed Virginia had adequate laws in effect regarding both compounding and sterile compounding. Her main concern was drugs that were being compounded for physician's in-office use and what alternate drugs would be offered if a pharmacy could not compound these anymore. She also stated that non-resident pharmacies do ship compounded drugs for resale when Virginia law prohibits it. Ms. Garvin stated she did not support legislation separating the types of compounding conducted within a pharmacy. Bill Rice from South River Compounding Pharmacy addressed the Board stating that the compounding pharmacies in Virginia have not had any major issues and that he believes the legislation that is currently in place is adequate. He feels the issue lie with the non-resident pharmacies that are sterile compounding. Sonny Currin representing Rx3 Compounding Pharmacy, discussed his concerns and recommended that the inspectors and Board give more guidance to the pharmacies in Virginia that are sterile compounding so that they can ensure compliance with state and federal laws and regulations. The Board requested that anyone that would like to give input concerning amending the legislation for compounding, to please submit it in writing to Board staff for review.

- Adoption of amendments to guidance document 110-9

Mr. Johnson gave the Board an overview of the proposed amendments made to Guidance Document 110-9 that refers to inspection deficiencies. The changes made to the Guidance Document reflected primarily around sterile compounding.

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiency 20 with additional changes made to the wording under section 20a by omitting "checking" and adding "final verification" and to section 20b by omitting "checking" and adding "final verification". (motion by Rhodes, second by Allen)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiencies 22 and 23 and added the wording to Major 22 under conditions "Review 2 most recent reports". (motion by Allen, second by Munden)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiency 25. (motion by Adams, second by Rhodes)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiency 26. (motion by Allen, second by Adams)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to**

Major deficiency 33. (motion by Munden, second by Rhodes)

MOTION: **The Board voted unanimously to adopt the proposed amendments to Minor deficiency 30 and adding under law/regulation citations "54.1-3410.2". (motion by Rhodes, second by Adams)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Minor deficiency 31 and 32. (motion by Munden, second by Allen)**

REPORTS:

- Report on Board of Health Professions: Mr. Rhodes gave an update to the Board regarding previous and upcoming meetings with the Board of Health Professions. ?????

- Report on Licensure Program: Mr. Johnson reported that the Board issued 1,047 licenses and registrations for the period of September 1, 2012 through November 30, 2012, including 148 pharmacists, 299 pharmacy interns, and 457 pharmacy technicians. Inspectors conducted 251 facility inspections including 72 routine inspections of pharmacies: 23 resulted in no deficiency, 9 with deficiencies, and 40 with deficiencies and a consent order. One innovative (pilot) program for the utilization of the InstyMeds automated dispensing device in an immediate care center was approved by an informal conference committee.

- Report on Disciplinary Program:

- Executive Director's Reports: Ms. Juran reviewed with the Board the agency fiscal report and asked if they would like a copy provided to them at each board meeting. She stated that the Board's expenses are relatively steady and that is has been in good financial standing for several years. Leo Ross, former Board member, attended the International Pharmaceutical Federation Centennial Congress in Amsterdam back in October. Board members Cynthia Warriner, Crady Adams, Ellen Shinaberry and Robbie Rhodes attended the NABP District 1&2 meeting in SkyTop, Pennsylvania with Ms. Juran back in mid-October. The collaborative practice agreements were a huge topic of discussion at the meeting including expansion of pharmacist allowances under these agreements. An informative presentation was given by the Assistant Surgeon General of the US, Scott Giberson, who is also a pharmacist. District II discussed the bylaws associated with becoming 201c and passed resolution that NABP needs to encourage state boards to require accreditation of pharmacies that perform sterile compounding. Another resolution discussed was to prohibit the "under 5% allowances" except for emergencies which appears to be creating gray market concerns. Ms. Juran also attended the first Tri-Regulator meeting in Washington, DC, which is a meeting of the NABP, National Council of State Boards of Nursing and the Federation of State Medical Boards. Ms. Juran spoke of the upcoming General Assembly session that will begin this January and anticipates it will be very busy and will be reviewing many bills that the Department of Health Professions will be following.

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, Sammy Johnson 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 Adams)

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 Adams)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Brian Burns, Pharmacy Technician (motion by Warriner, second by Munden)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of William Wimbish, Jr. , Pharmacist (motion by Warriner, second by Allen)

REPORT FROM ENFORCEMENT DIVISION:

Faye Lemon, Director of the Enforcement Division, updated the Board on the inspection process, and what procedures were taking place for inspecting the current active compounding pharmacies in Virginia. There have been seventy compounding pharmacies identified, and they have been split into two groups for inspection. The first portion of inspections will be completed by the end of December. So far, thirty-six have been completed within this timeframe. The second half of the inspections will need to be completed by the end of January. Out of this group, three have been conducted. Five out of the seventy compounding pharmacies have been identified as "nuclear" compounding. Ms. Lemon reports that the pharmacy inspectors consist of three full time pharmacists and one part-time or temporary pharmacist. Interviews for the Northern Virginia pharmacy inspector will be taking place this Friday. Ms. Lemon is also anticipating a fifth pharmacy inspector will be hired in the near future and will be a floater inspector that will assist with all regions, primarily Northern Virginia.

PRESENTATION BY BOARD COUNCIL REGARDING BOARD MEMBER ETHICS:

Howard Casway, Board Council, reviewed with the Board a power-point presentation of possible conflicts that the members could have while serving on the Board and what situations to avoid.

ADJOURN:

With all business concluded, the meeting adjourned at 3:32 pm.

David C. Kozera, Board Chairman

3/12/13
Date

Caroline D. Juran, Executive Director

3|12|2013
Date