

(DRAFT/UNAPPROVED)

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

December 12, 2013
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:20am.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT: Ellen B. Shinaberry, Vice-Chairman
Cradly R. Adams
David Kozera
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner
Dinny Li - arrived at 9:30am

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Dianne Reynolds-Cane, Director, DHP – arrived 11:30am
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Wayne Halbleib, Assistant Attorney General- arrived 12:45pm
Carrie Mitchell, Assistant Attorney General- arrived 12:45 p.m.
Allyson Tysinger, Assistant Attorney General-arrived 12:45pm
Mykl Egan, Adjudication Specialist

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 September 9, 2013 (Regulation Committee regarding Emergency Medical Services Agencies), September 10, 2013 (Full Board Meeting), October 7, 2013 (Informal Conference Committee), October 15, 2013 (Panel Formal Hearing), October 17, 2013 (Special Conference Committee and Informal Conference Committee), November 7, 2013 (Telephone Conference Committee), November 12, 2013 (Special Conference Committee and Informal Conference Committee), November 25, 2013 (Regulation Committee), and November 25, 2013 (Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispensed). Mr. Adams recommended a correction in the September 10, 2013 Full Board Meeting minutes under the subject of

possible disciplinary action against PICs following documented drug loss. The word "PIC" in the sentence "Mr. Adams stated that during his research, he discovered that in the first six months of the year 2013, only nine disciplinary actions, resulting from drug losses, were taken against a PIC." should be changed to read "pharmacist or pharmacy technician".

MOTION:

The Board voted unanimously to approve the minutes as presented, to include the amendment of the September 10, 2013 Full Board Meeting minutes. (motion by Adams, second by Kozera)

PUBLIC COMMENTS:

No public comments were received at this time.

DHP DIRECTOR'S REPORT:

Due to a conflict, Dr. Cane was unable to attend the meeting at the time the Director's report was provided. Arne Owens, Chief Deputy Director of DHP, provided the Director's report in her absence. Mr. Owens stated that the plan to reduce prescription drug abuse has been submitted to the National Governor's Associations (NGA). Virginia was also awarded another grant by the NGA that will focus on the transition of veterans and active military into the civilian or public sectors of certain healthcare fields. The grant will focus primarily on the occupations of licensed practical nurses, physical therapy assistants, and emergency medical technicians. The study will research the type of licensing, education and credentialing military and veterans will need to transition into these types of positions. The study will last a year and will conclude January of 2015. The first interagency meeting will be held January 8, 2014. Additionally, Delegate Stolle has requested the review of certain professionals transitioning from the military to healthcare. The review includes pharmacy technicians. Ms. Allen expressed appreciation to both Mr. Owens and Dr. Cane for the past four years of their service.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 44 of the agenda packet.

REGULATORY UPDATE:

- ADOPTION OF COMMENT TO DEA ON PROPOSAL TO PLACE TRAMADOL INTO SCHEDULE IV:

Ms. Yeatts explained that the DEA had published a notice of proposed rulemaking to place tramadol into Schedule IV and that a public comment period was open until January 3, 2014. She further explained that the Board had supported legislative proposals in Virginia in 2010, 2011, and 2013 to place tramadol into Schedule IV of the Drug Control Act. She then stated a draft of public comment on page 45 of the agenda packet was provided for their consideration.

MOTION:

The Board voted unanimously to approve staff submitting the public comment as presented to the DEA which supports placing tramadol into Schedule IV. (motion by Munden, second by Rhodes)

- ADOPTION OF AMENDED GUIDANCE DOCUMENT

A handout was provided which included a draft version amending Guidance Document 110-17 and a letter from NABP dated 11/27/13

110-17 TO CONFORM
WITH NEW MINIMUM
SCORE REQUIREMENTS
FOR TOEFL IBT:

regarding TOEFL iBT passing standards increase. Ms. Yeatts explained that because NABP recently notified the Board of an increase to the minimum passing score of the TOEFL iBT, the Board would need to amend Guidance Document 110-17 to conform to the new standard. The Board requested staff to research the total score a candidate could receive in each of the four sections and follow up with them in an email.

MOTION:

The Board voted unanimously to amend Guidance Document 110-17 as presented. (motion by Kozera, second by Adams)

- ADOPTION OF
AMENDED
GUIDANCE
DOCUMENT 110-22
TO CONFORM WITH
REGULATORY
AMENDMENT OF
18VAC 110-20-27:

A handout containing the current Regulation 18VAC110-20-270 and a draft amending Guidance Document 110-22 was provided. Ms. Yeatts explained that the guidance previously captured in Guidance Documents 110-22 regarding which pharmacist to hold responsible for a dispensing error had recently been incorporated into regulations during the last periodic review, effective September 2013. If the Board believes the examples provided in Guidance Document 110-22 are still beneficial, then the Board should amend the document to conform to current regulations. In lieu of the draft language in the introductory paragraph provided in the handout, Ms. Yeatts recommended the following: "To improve compliance with regulations and assist in determining which pharmacist to hold responsible for a dispensing error, the Board offers the following guidance on current dispensing practices and required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product."

MOTION:

The Board voted unanimously to amend Guidance Document 110-22 as presented with the amended language for the introductory paragraph as suggested by Ms. Yeatts. (motion by Warriner, second by Stelly)

- REPORT FROM THE
AD HOC COMMITTEE
FOR DRUG
DIVERSION AND
RESPONSIBILITY OF
PHARMACIST-IN-
CHARGE TO
PROVIDE ADEQUATE
SAFEGUARDS:

Ms. Yeatts and Ms. Warriner provided background regarding the Regulation Committee of the Board which met on November 25, 2013 to discuss the responsibility of the pharmacist-in-charge in providing adequate safeguards concerning drug diversion. The recommendations to the Board included entering the name of the pharmacist(s)-in-charge in the finding of facts for those cases that involve drug diversion and also to amend Guidance Document 110-27 to add a new section regarding diversion, theft and loss of controlled substances. The amendments to the guidance document would also include suggestions for best practices for safeguarding against diversion of controlled substances.

MOTION:

As recommended by the Regulation Committee, the Board voted unanimously to list the name of the pharmacist(s)-in-charge in the Finding of Facts in disciplinary cases involving drug diversion. (motion by Regulation Committee, second by Munden)

Ms. Juran indicated staff would correct any typographical errors found in the proposed amendments of Guidance Document 110-27. Mr. Adams

recommended adding as a suggested best practice, “Have full and timely access to all reports relating to inventories, invoices, and audits”.

MOTION:

The Board voted unanimously to amend Guidance Document 110-27 as recommended by the Regulation Committee, following the correction of typographical errors, and to include the suggested best practice to “Have full and timely access to all reports relating to inventories, invoices, and audits”. (motion by Warriner, second by Munden)

MOTION:

The Board voted unanimously to make an additional amendment to Guidance Document 110-27 to include the Board’s new policy to list the name of the pharmacist(s)-in-charge in the Findings of Fact in those disciplinary cases involving drug diversion. (motion by Adams, second by Munden)

MISCELLANEOUS:

- REPORT FROM THE AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHARMACIES AND PHYSICIANS LICENSED TO DISPENSE:

An Ad Hoc Committee of the Board met on November 25, 2013 to discuss suggested disciplinary action resulting from routine inspections of pharmacies and physicians licensed to dispense. The following recommendations were made by the committee:

- Amend Guidance Document 110-9 as presented in the agenda packet
- To take no action at this time regarding the consideration of suggested penalty for repeat deficiencies
- To take no action at this time regarding the consideration of reduced monetary penalties imposed against free clinic pharmacies, however, to hear more on this subject at the December full board meeting

Regarding the consideration for directing inspectors to provide an expedited pre-hearing consent order to physicians licensed to dispense, following a routine inspection with certain deficiencies, the committee recommended the following:

- To implement a process similar to the process used for routine pharmacy inspections
- To reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 to identify deficiencies and suggested monetary penalties for routine inspections of physician licensed to dispense
- Issuing pre-hearing consent orders against the individual physician licensed to dispense. If a common stock of drugs is maintained, then it is recommended that the pre-hearing consent order is issued to the designated responsible practitioner for that practice.

Mr. Johnson briefly reviewed the numerous recommended amendments to Guidance Document 110-9.

MOTION:

The Board voted unanimously to amend Guidance Documents 110-9 as recommended by the ad hoc committee, effective December 12, 2013. (motion by Stelly, second by Adams)

Based upon the ad hoc committee's recommendations, the Board did not take any action concerning disciplinary sanctions for repeat deficiencies.

MOTION:

The Board voted unanimously to reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 which will list suggested monetary penalties for certain deficiencies, following a routine inspection of physicians licensed to dispense. (motion by Warriner, second by Rhodes)

- REQUEST FROM FREE CLINICS FOR REDUCED MONETARY PENALTIES RESULTING FROM ROUTINE PHARMACY INSPECTIONS:

Linda Wilkinson, Executive Director of the Virginia Association of Free Clinics and Amy Yarcich, Executive Director of Rx Partnership, discussed with the Board the impact of the current monetary penalties against free clinic pharmacies. Ms. Wilkinson stated that there are 60 free clinics in Virginia and 26 of those clinics have pharmacies. Out of the 26 clinics, 9 were cited during a routine inspection and sanctioned with a monetary penalty. At least 4 of those free clinic pharmacies did not have a backup system for the pharmacy alarm. Ms. Yarcich requested that the Board consider lowering the monetary penalty for free clinic pharmacies since all services rendered to patients are free and they have a difficult time getting funding. She also stated that education from the inspector or Board would be welcomed so that they would be able to comply for future inspections.

The Board expressed appreciation for the services provided by the free clinics; however, there was consensus that all dispensing locations should be held to the same standard. Additionally, the Board reminded Ms. Wilkinson and Ms. Yarcich that any pharmacy may refuse to pay the suggested monetary penalty imposed by the inspector and may request an informal conference with the Board for further consideration of the matter. If mitigating circumstances exist, it is the committee's prerogative to adjust the suggested sanction. The Board concluded the discussion that no action should be taken at this time to reduce the monetary penalties imposed against a free clinic pharmacy following a routine pharmacy inspection wherein certain deficiencies were cited.

OLD BUSINESS:

- REQUEST FROM VPHA TO RECONVENE AD HOC COMMITTEE ON

Ms. Juran stated that she had shared the public comment provided at the September full board meeting by Loyd V. Allen, Jr., Ph.D., R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and Remington: The Science and Practice of Pharmacy, with Rick

**STERILE
COMPOUNDING:**

Schnatz, Manager Compounding and Healthcare Standards for the U.S. Pharmacopeial Convention (USP). Ms. Juran then reviewed the response provided by Mr. Schnatz, and found in the agenda packet, which indicates USP posted an Accelerated Revision on November 22, 2013 to clarify chapter <795>. The intent of the revision was to clarify that the beyond-use date in the table “BUD by Type of Formulation” is specific for nonsterile preparations and users should refer to General Chapter <797> *Pharmaceutical Compounding- Sterile Preparation* for standards on sterile compounding. Ms. Juran also shared that Mr. Schnatz indicated that Dr. Allen had resigned from the USP expert committee for personal and professional reasons.

The Accelerated Revision appeared to negate Dr. Allen’s concern with question #4 in Guidance Document 110-36. The comments expressed by Dr. Allen for questions number 2, 6, and 16 within Guidance Document 110-36 appeared commentary in nature. The Board stated that if USP amends its chapters on these subjects, then it could certainly consider amending its guidance at that time. For these reasons, the Board reached consensus that it did not need to reconvene the ad hoc committee on compounding at this time.

REPORTS:

- **CHAIRMAN’S REPORT**

Ms. Allen recognized two students of the VCU School of Pharmacy in the audience and encouraged other students to attend future Board meetings.
- **BOARD OF HEALTH PROFESSIONS**

Mr. Rhodes indicated the last meeting had been cancelled and that there was nothing to report at this time.
- **NABP/AACP DISTRICT 1 AND 2 MEETING**

Ms. Warriner reported on the attendance at the NABP/AACP District 1 and 2 meeting held in October in Maine. She reviewed the information provided on pages 83-86 in the agenda packet, to include the resolutions passed at the meeting.
- **LICENSURE PROGRAM**

Mr. Johnson reported that the Board issued 907 licenses and registrations for the period of September 1, 2013 through November 30, 2013, including 152 pharmacists, 178 pharmacy interns, and 460 pharmacy technicians. Mr. Johnson also reviewed the number of current active licenses, certifications, and registrations. Inspectors conducted 422 facility inspections including 195 routine inspections of pharmacies: 69 resulted in no deficiency, 47 with deficiencies, and 79 with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies.
- **DISCIPLINARY PROGRAM**

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of March 8, 2013; June 14, 2013; September 9, 2013; and December 10, 2013. For the final date, open cases are five at the entry stage; 71 at the investigation stage; 85 at the probable cause stage; 9 at the administrative proceedings division stage; 12 at the informal stage; five at the formal

stage; and 137 at the pending closure stage.

Further, Ms. Reiniers-Day provided the Board with the agency's Patient Care Disciplinary Case Processing Times for the Quarterly Performance Measurement for the First Quarter 2014. Specific to the Board of Pharmacy, the clearance rate was 116%, the Pending Caseload older than 250 days was 13%; and the percent closed within 250 business days was 98%.

- EXECUTIVE DIRECTOR'S REPORT

Ms. Juran reported that the executive officer forum hosted by NABP in September was excellent. She served as a panelist and provided a presentation regarding actions Virginia has taken to address compounding. The NASCSA meeting held in October was informative. Discussion topics included prescription monitoring programs (PMP), synthetic cannabinoids, research chemicals (bath salts), increased access to naloxone for overdose treatment. Additionally, Ralph Orr, Director of the VA PMP was elected President. Ms. Juran reported that Mr. Johnson and Mr. Orr attended a prescription drug forum in Tennessee hosted by the US Attorneys General. Mr. Johnson also presented in October at the Virginia Society of Health Systems Pharmacists annual meeting. Ms. Beckman will attend the NABP inspector forum later this month. Attendees for most of these meetings received travel grants to offset expenses. Also, Ms. Juran stated she had provided a presentation in October to a visiting Chinese delegation interested in learning about regulatory oversight of drugs. Ms. Juran provided an update on the planning for the 2014 NABP/AACP District 1 and 2 meeting which will be held at the Williamsburg Lodge October 5-7, 2014. She provided current statistics for the PMP requests processed to date and reported that Virginia is now interoperable with 14 other states. Ms. Juran reminded board members to participate in the Tri-Regulator Webinar Series on compounding. Eric Kastango and Kate Douglass are the presenters. The tri-regulators include members of the National Association of Boards of Pharmacy, the Federation of State Medical Boards, and the National Council of State Boards of Nursing. Lastly, she reported that she was seeking travel approval to serve as a panelist at the upcoming educational conference hosted by the International Academy of Compounding Pharmacists.

NEW BUSINESS:

Mr. Adams suggested that staff mail the newly revised Guidance Document 110-27 to all current pharmacists-in-charge (PICs) in Virginia. After some discussion, the Board concluded it would be appropriate to mail this particular guidance document to all PICs.

MOTION:

The Board voted unanimously to direct staff to mail the newly revised Guidance Document 110-27 to all pharmacists-in-charge in Virginia. (motion by Adams, second by Rhodes)

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 Consent Orders. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, 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 Shinaberry, 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 Shinaberry, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jennifer Wild Hoerrner, Pharmacist (motion by Kozera, second by Warriner)

MOTION:

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

SUMMARY SUSPENSION:

DOUGLAS A. HARRIS
Pharmacist
License Number:
0202-006176

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.

MOTION FOR CLOSED MEETING:

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 and that Caroline D. Juran, Cathy Reiniers-Day, and Eusebia Joyner attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Shinaberry, 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 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 Shinaberry, second by Warriner)

MOTION:

The Board voted unanimously in favor of the motion that, according to the evidence presented, the continued practice by Douglas A. Harris as a pharmacist poses a substantial danger to the public; and therefore, the license of Douglas A. Harris to practice as a pharmacist shall be summarily suspended and that a Consent Order be offered to

**Mr. Harris for the revocation of his license in lieu of a hearing.
(motion by Stelly, second by Rhoades)**

ADJOURN:

With all business concluded, the Board adjourned at 4:30 p.m.

Jody H. Allen, Chairman

Caroline D. Juran, Executive Director

Date: _____

Date: _____

DRAFT UNAPPROVED