

DRAFT/UNAPPROVED

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

March 26, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER: The meeting was called to order at 9:05 a.m.
- PRESIDING: Jody Allen, Chairman
- MEMBERS PRESENT: Ellen B. Shinaberry, Vice-Chairman
Cradly R. Adams
Ryan K. Logan
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner
Dinny Li - arrived at 10:19 a.m.
- STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
- QUORUM: With nine members present, a quorum was established.
- WELCOME: Ms. Allen welcomed David E. Brown, D.C., newly appointed Director of the Department of Health Professions; Ryan K. Logan, newly appointed member of the Board of Pharmacy; and James Rutkowski, Assistant Attorney General, recently assigned as counsel for the Board of Pharmacy. Ms. Allen also welcomed two pharmacy students in the audience from Hampton University and Virginia Commonwealth University
- APPROVAL OF AGENDA: Ms. Allen indicated that the conflict of interest training program would not be shown following adjournment of the business portion of the meeting because the audio-visual equipment was currently inoperable. The tentative agenda was otherwise approved by the Board as presented.
- APPROVAL OF MINUTES: The Board reviewed the draft minutes. It was noted that the December 12, 2013 Full Board Meeting minutes had two corrections. On page 4, "pan" should be changed to "plan" and on page 11, "Rhoades" was misspelled.

MOTION:

The Board voted unanimously to amend the December 12, 2013 full board meeting minutes by changing “pan” to “plan” on page 4 and changing “Rhoades” to “Rhodes” on page 11 and to approve the minutes as otherwise presented for the following meetings: December 12, 2013 (Public Hearing on Regulations for Continuous Quality Improvement Programs); December 12, 2013 (Full Board Meeting); December 12, 2013 (Panel of the Board Formal Hearing); December 17, 2013 (Special Conference Committee and Informal Conference Committee); January 21, 2014 (Special Conference Committee and Informal Conference Committee); January 27, 2014 (Telephone Conference Call); February 5, 2014 (Special Conference Committee and Informal Conference Committee); February 18, 2014 (Telephone Conference Call); February 20, 2014 (Informal Conference Committee); February 26, 2014 (Panel Formal Hearing); and March 7, 2014 (Ad Hoc Committee on Guidance for Suggested Disciplinary Action and Monetary Penalties Resulting from Routine Inspections of Physicians Licensed to Dispense). (motion by Warriner, second by Stelly)

The Board was provided an additional handout of the draft minutes from the March 11, 2014, Informal Conference Committee for an Innovative (Pilot) Program.

MOTION:

The Board voted unanimously to approve as presented the minutes of the March 11, 2014 Informal Conference Committee for an Innovative (Pilot) Program. (motion by Munden, second by Shinaberry)

**RECONSIDERATION OF
PREVIOUSLY APPROVED
MINUTES:**

Ms. Juran stated she had recently been made aware of an inaccuracy in the previously approved minutes from the November 25, 2013, Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense and asked that the Board consider the suggested changes on page 39A of the agenda packet.

MOTION:

The Board voted unanimously to amend the previously-approved minutes for the November 25, 2013 “Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense” by replacing the sentence “He indicated that VPhA is not happy with the routine pharmacy inspection process and that it has decayed the relationship between VPhA and the Board” with the sentence “Speaking as an individual, Mr. Davis stated that he is currently not happy with the routine pharmacy inspection process and he feels that it has decayed the relationship between Virginia pharmacists and the Board.” (motion by Shinaberry, second by Warriner)

PUBLIC COMMENTS:

There were no public comments received at this time.

DHP DIRECTOR'S REPORT:

Dr. Brown introduced himself and provided the board members with his background information. He also expressed his pleasure at being appointed Director of the Department of Health Professions.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2014 General Assembly session that may potentially impact the board or the profession of pharmacy.

- Regulatory Update

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 45 of the agenda packet. She stated the modifications to regulatory requirements for automated dispensing devices for a less burdensome process became effective February 27, 2014, as did the regulatory amendments for less restrictive and burdensome record-keeping for on-hold prescriptions. She also reported the regulatory amendments to conform to changes in the Code for collaborative practice agreements will likely become effective April 23, 2014.

- Adoption of Final Regulations for CQI

Ms. Yeatts stated that the Board needs to adopt the proposed final regulations for continuous quality improvement (CQI) regulations to replace the emergency regulations that expired on September 30, 2013. She explained the request for an extension was never approved and therefore, there are currently no regulations in place. The Board had a lengthy discussion regarding suggested changes provided in the one written comment received during the public comment period. It was unclear to the Board what, if any, ramifications would result by adopting the proposed final regulations with the suggested change.

MOTION:

A motion to amend and adopt the proposed final regulations for continuous quality improvement programs by changing the definition of "actively report" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error" was made by Shinaberry and seconded by Warriner, but then was rescinded by both.

MOTION:

The Board voted unanimously to table the discussion and refer the adoption of the final proposed regulations for continuous quality improvement programs to the regulation committee with direction to specifically consider whether documenting as collected for reporting affords protections under federal regulations and the appropriateness of requiring errors to be reported to a patient safety organization within 30 days of identifying the error. (motion by Stelly, second by Adams)

- Reconsideration of Regulation 18 VAC 110-20-500 regarding EMS

Ms. Yeatts stated that there were several comments from Virginia EMS agencies requesting that the Board reconsider the previously adopted draft of fast-track regulatory action to amend Regulation 18 VAC 110-20-500. She indicated the draft language has not yet been submitted for Executive

branch review and Board Chairman has referred the matter to the Regulation Committee. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, offered brief comments and stated she would provide more detailed comments at the upcoming regulation committee meeting. Sam Dahl, Executive Director for the Northern Virginia EMS Council, introduced himself and indicated he will provide comments to the Regulation Committee. Joey King with the Northern Virginia EMS Council provided his insight on the needs of EMS agencies throughout Virginia and looks forward to working with the Board to achieve 1:1 exchange of Schedule VI drugs.

- Request from the Department of Corrections to Amend 18 VAC 110-20-590 to Allow Floor Stock of Certain Drugs

Ms. Yeatts discussed with the Board the request from the Department of Corrections to amend 18 VAC 110-20-590 to allow floor stock of certain drugs in the correctional facilities similar to allowances in other types of facilities, e.g., long term care. She reviewed the suggested amendments provided by staff. Ms. Yeatts stated the amendments could be adopted as a fast-track regulatory process.

MOTION:

The Board voted unanimously to amend Regulation 18 VAC 110-20-590 as presented to allow floor stock of certain drugs in correctional facilities and that the amendments be adopted under the fast-track regulatory process. (motion by Munden, second by Rhodes)

- Action on Petition for Rulemaking – Pharmacy Coupons

Ms. Yeatts reviewed with the Board the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Ms. Yeatts referenced the action taken by the Board in 2010 when a similar petition was received and board counsel advised that a prohibition of coupons may be a possible restraint of trade. The Virginia Pharmacist Association and the Academy of Managed Pharmacy Care submitted comment in favor of the recently received petition. Ms. Yeatts stated the Board could reject the petition and give the petitioner a reason as to why it was rejected; accept and adopt a Notice of Intended Regulatory Action (NOIRA), or reject the petition but refer the matter to the regulation committee for further consideration. Ms. Warriner and Mr. Rhodes expressed concern for the practice. Ms. Shinaberry referenced ISMP's position of concern for the practice and a recent review of this practice by the Department of Justice.

MOTION:

A motion was made to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration. (motion by Warriner, second by Adams)

MOTION:

A motion was made to table the discussion regarding the petition for rulemaking to prohibit pharmacy coupons until the June full board

meeting. (motion by Adams, second by Munden) (5 :5 vote, motion failed)

MOTION:

As previously motioned by Warriner and seconded by Adams, the Board voted unanimously to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration.

MISCELLANEOUS:

- Request from Containment Technologies Group, Inc. to Amend Guidance Document 110-36

Ms. Juran reviewed a letter that was received from Hank Rahe, Director Technology with Containment Technologies Group, Inc. that requests the Board to amend the response to question #24 in Guidance Document 110-36. Within the letter, Mr. Rahe provided information from the United States Pharmacopeia (USP) confirming that the current USP chapter <797> does not specifically require certifying companies to comply with guidelines published by the Controlled Environment Testing Association (CETA). Rather, chapter <797> states certifying companies shall comply with certification procedures “such as” those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006).

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented on page 103 of the agenda packet. (motion by Stelly, second by Shinaberry)

- Request from Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to Accept their Accreditation or Assessment In Lieu of Inspection Report from Regulatory or Licensing Agency of the Jurisdiction
- DEA Open Public Comment Period for Proposed Rule to Move Hydrocodone Combination Products to Schedule II

Ms. Juran discussed the requests from the Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to accept their accreditation in lieu of the inspection report from the regulatory board or licensing agency of the jurisdiction. She indicated the Board Chairman has referred this matter to the Ad Hoc Committee for Inspections for further consideration.

Ms. Juran reviewed DEA’s notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II. She stated that in January 2013 an FDA Advisory Committee recommended the drugs be moved to Schedule II based on an 8-factor analysis and the potential for severe psychological and physical abuse. Ms. Juran asked if the Board would like to offer comment to DEA during the open comment period which ends April 28, 2014. David Creasy, pharmacist-owner of Poquoson Pharmacy, stated his concerns for patient care and access to the drug if moved to Schedule II. He indicated he is not in favor of the change at this time but perhaps down the road when e-prescribing is more fully utilized.

MOTION:

A motion was made to provide comment to DEA in support of rescheduling hydrocodone combination products from Schedule III to II. (motion by Adams, second by Stelly) (3 in favor, 7 opposed; motion failed)

No further action was taken on the subject.

- Ad Hoc Committee Report on Guidance for Suggested Disciplinary Action and Monetary Penalties Resulting from Routine Inspections of Physicians Licensed to Dispense

Ms. Shinaberry provided a report of the ad hoc committee's recommendations. The committee met on March 7, 2014, to discuss a ticketing program for practitioners of the healing arts to sell controlled substances that would mirror the pharmacy inspection guidance within Guidance Document 110-9. Ms. Shinaberry discussed the consensus of the committee and Mr. Johnson briefly reviewed the committee's recommended major and minor deficiencies and associated monetary penalties in the draft guidance document. Ms. Warriner noted a minor deficiency regarding the lack of equipment for non-sterile compounding in compliance with USP standards should be added to the draft guidance document.

MOTION:

The Board voted unanimously to adopt the guidance document as amended to establish suggested disciplinary action for major and minor deficiencies cited during routine inspections of practitioners of the healing arts to sell controlled substances. (motion by Warriner, second by Adams)

MOTION:

The Board voted unanimously to accept the following recommendations made by the ad hoc committee:

- **The Board will pilot this process for approximately 12 months beginning this summer, if possible;**
- **Strongly recommend that the physicians be present during the pilot inspection for educational purposes;**
- **No monetary penalties will be imposed by the inspector for any deficiencies cited during the pilot;**
- **The Board is to send written notification to all licensed practitioners of the healing arts to sell controlled substances prior to the implementation of the pilot to alert them of the pilot and educating them of ways to avoid being cited deficiencies.**

(motion by committee, second by Warriner)

- Board Member Request to Consider 24-Hour Advanced Notice of Routine Pharmacy Inspections

In lieu of unannounced routine inspections, Ms. Shinaberry requested the Board consider directing inspectors to provide a 24- hour notice prior to performing a routine inspection, similar to processes used by accrediting bodies. Ms. Shinaberry explained that providing advance notice would allow the pharmacist-in-charge an opportunity to be present during the inspection which may decrease the possibility of cited deficiencies as the PIC would be more aware of the location of required recordkeeping, allow the opportunity to schedule additional staff which could facilitate the inspection process and minimize distractions for the pharmacist practicing pharmacy that day, and possibly make the inspection process more palatable to the licensees. Ms. Yeatts stated that the agency has had

a longstanding policy to conduct unannounced inspections and that inspection policies should be uniform within the agency. A request made many years ago by the Board of Veterinary Medicine to announce inspections was denied by the agency director at that time. Paul Dalby, Deputy Director, Enforcement Division, stated that providing advance notice for a specific timeframe may shackle the inspectors and unplanned events may prevent the inspector from performing the inspection within the specified time. He agreed that providing notice may help improve compliance at that moment, but that unannounced inspections may create a culture of compliance. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, commented that a 30-day window notice could be helpful, but not really if it prevents staff from taking time off during that time period. Hunter Jamerson, Esquire, Macaulay & Burtch, P.C., stated he has noticed the informal conference hearings often deal with location of records and believes a quarterly notification could be helpful, more efficient, and make the inspection process more palatable for licensees. Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA), stated the ability to schedule additional staffing may prevent risk to patient care.

ACTION ITEM:

Ms. Allen suggested that staff research whether a written or verbal policy exists within the agency to perform routine inspections unannounced and request Dr. Brown, Director, DHP, to consider a policy to provide advance notice when performing routine inspections.

- Staff Request to Amend Guidance Document 110-9 to Include Deficiency Regarding Gloved Fingertip Sampling
Ms. Allen advised the board members that she has already referred the matter to the ad hoc inspections committee.
- 2015 Possible Legislative Proposals
Ms. Allen advised the board members that she has already referred the matter to the Regulation Committee.

REPORTS:

- Report on Board of Health Professions
Mr. Rhodes gave an update of previous and upcoming meetings with the Board of Health Professions. He reported that February 25, 2014, was the last meeting held. Some of the topics discussed included the PMP pamphlet, sanction reference points, budget, healthcare workforce and military credentialing as part of the National Governors Association policy grant.
- Report on Planning of the NABP/AACP District 1 & 2 Meeting
As Chairman of NABP District 2, Ms. Warriner updated the Board on the progress of the planning for the NABP/AACP District 1 & 2 meeting that is being hosted by Virginia October 5-7, 2014, at the Williamsburg Lodge. She reported that Alan Dow, M.D., Assistant Vice President of Health Sciences for Interprofessional Education and Collaborative Care, Virginia Commonwealth University, is the scheduled keynote speaker. He will also participate in a panel discussion with a pharmacist and nurse

on interprofessional development. She stated a planning committee is holding telephone conference calls about every two weeks for the planning of the event.

- Report on Licensure Program:

Mr. Johnson reported the Board issued 859 licenses and registrations for the period of December 1, 2013, through February 28, 2014, including 121 pharmacists, 142 pharmacy interns, and 492 pharmacy technicians. He also reviewed the number of current active licenses and certifications. Mr. Johnson informed the Board that the renewal process has begun for nonresident pharmacies. The Virginia Code was amended effective July 1, 2014, requiring nonresident pharmacies to submit a current inspection report when renewing the registration. A nonresident pharmacy that engages in sterile or non-sterile compounding must provide an inspection report that indicates compliance with USP-NF standards for sterile and non-sterile compounding. Inspectors conducted 351 facility inspections including 196 routine inspections of pharmacies: 57 resulted in no deficiency; 74 with deficiencies; and 65 with deficiencies and a consent order. Guidance Document 110-9, which was amended at the December 12, 2013, Board Meeting, modified several major deficiencies and established new minor deficiencies. Mr. Johnson stated that 33% of the inspections for the current period resulted in a consent order compared to 41% for the prior reporting period. He reviewed the report of Major & Minor Inspection Deficiencies.

- 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 June 14, 2013; September 9, 2013; December 10, 2013; and March 25, 2014. For the final date, open cases were none at the entry stage; 74 at the investigation stage; 89 at the probable cause stage; 11 at the administrative proceedings division stage; ten at the informal stage; five at the formal stage; and 176 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 Second Quarter 2014. Specific to the Board of Pharmacy, the clearance rate was 78%, the Pending Caseload older than 250 days was 18%, and the percent closed within 250 business days was 89%.

- Executive Director's Report:

Ms. Juran stated that DEA will host another prescription drug take-back event on Saturday, April 26, 2014. Additionally, she reported that she and board counsel attended a two-day intergovernmental meeting hosted by FDA on March 20-21, 2014, to discuss the new federal compounding requirements found in the Drug Quality and Security Act signed by the President in November 2013. She reported that it was a very informative meeting and that the Board may need to consider a possible legislative proposal on the subject at the upcoming Regulation Committee meeting. She also reminded the members of their legal obligation to complete conflict of interest training every two years. Members were asked to provide staff with certificates of completion of the training program by

April 15, 2014. She stated she is planning to attend the NABP Annual Meeting in Phoenix, AZ this May and that she has been awarded a travel grant of \$1500. Mr. Rhodes and Ms. Warriner indicated they hope to attend the meeting as well.

CONSIDERATION OF
CONSENT ORDERS:

There were no consent orders to be considered at this time.

NEW BUSINESS:

There was no new business.

ADJOURN:

With all business concluded, the Board adjourned at 2:01 p.m.

Jody H. Allen, Chairman

Caroline D. Juran, Executive Director

Date: _____

Date: _____

DRAFT