

FINAL/APPROVED

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

March 24, 2015  
Second Floor  
Board Room 4

Perimeter Center  
9960 Mayland Drive  
Henrico, Virginia 23233-1463

**CALL TO ORDER:** The meeting was called to order at 9:02am

**PRESIDING:** Ellen B. Shinaberry, Chairman

**MEMBERS PRESENT:** Jody H. Allen  
Melvin L. Boone, Sr.  
Michael Elliott  
Sheila Elliott  
Dinny Li  
Ryan Logan  
Empsy Munden  
Cynthia Warriner

**MEMBERS ABSENT:** Rebecca Thornbury

**STAFF PRESENT:** Caroline D. Juran, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Jamie Hoyle, Chief Deputy 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.

**APPROVAL OF AGENDA:** Ms. Juran requested that the Board consider an amendment to Guidance Document 110-9 as an additional agenda topic. The agenda was amended and approved as requested.

**APPROVAL OF MINUTES:** The Board reviewed draft minutes for the December 4, 2014 (Telephone Conference Call), December 9, 2014 (Public Hearing for Scheduling Certain Controlled Substances), December 9, 2014 (Full Board Meeting), December 16, 2014 (Special Conference Committee), January 22, 2015 (Special Conference Committee), February 5, 2015 (Formal Hearing) and March 11, 2015 (Special Conference Committee).

**MOTION:** The Board voted unanimously to approve the minutes as presented.

**(motion by Warriner, second by Allen)**

**PUBLIC COMMENTS:**

John Beckner, representing the National Community Pharmacists Association, discussed with the Board his concerns with pharmacy benefit managers (PBMs) and the lack of oversight which impacts patient care. He stated that this warrants further discussion and requested that the Board refer the agenda topic of PBMs to the Regulation Committee for further review.

Alexander Pytlarz, representing the Virginia Pharmacists Association (VPhA), addressed the Board regarding Guidance Document 110-36 "Compliance with USP Standards for Compounding". Mr. Pytlarz requested that the Board consider adopting the guidance document as presented as it accurately represents the compounding working group's recommendation.

Susan Schriener, clinical pharmacist, Virginia Oncology Associates, encouraged the Board to consider their request for the dispensing physicians at their locations to be able to use a camera-facilitated prescription verification process.

H. Otto Wachsmann, Jr., pharmacist, Stoney Creek Pharmacy, expressed concerns regarding physicians dispensing as the physicians may not have sufficient time to devote to the accuracy verification process. He also stated that he had concerns with the PBMs and their impact on the services of rural pharmacies. He stated the credentialing process has become an issue and is taking too much time away from safely dispensing medication.

Scott Johnson, General Counsel, Medical Society of Virginia (MSV), thanked the Board for including his letter within the meeting agenda and stated he was ready and willing to be a resource if necessary regarding the issue involving PBMs.

David Creecy, pharmacist, Poquoson Pharmacy, stated his concerns regarding PBMs and wanted to reiterate on Mr. Beckner's comments. Mr. Creecy brought to the Board's attention the access issues, how there are no standards and there is consistent changes. He also disagrees with the constant credentialing process and how many times independent pharmacies have to be re-accredited. Mr. Creecy also stated he too has issues with camera verification of prescriptions and that the rules should stay constant across the board.

Tim Musselman, Executive Director, Virginia Pharmacist Association (VPhA), addressed concerns regarding the length of time that some of the draft regulations have been either at the Secretary's office or the Governor's office. He also expressed concerns with the issue of physicians dispensing using a camera to verify dispensed prescriptions as the process did not appear to provide adequate supervision as required in regulation. Mr. Musselman also stated that he often receives negative

comments from VPhA membership regarding PBM practices. He encouraged the Board to address the issue and consider regulating PBMs to the extent that is consistent with the Board's jurisdiction.

Hunter Jamerson, Counsel, Epic Pharmacies, stated that he concurred with the concerns expressed by the VPhA on the matter of PBMs as PBMs are effectively unregulated. He stated many community pharmacies are having a difficult time with the credentialing process, it is creating a patient access issue, and that the patients are the ones who are ultimately suffering. He expressed concern for the PBMs ability to designate drugs in a specialty tier, often requiring these drugs to be dispensed by mail order pharmacies owned by the PBMs, and concerns for mail order pharmacies to satisfy a bona fide pharmacist-patient relationship.

DHP DIRECTOR'S REPORT:

Dr. Brown was unable to attend the meeting due to a scheduling conflict. Jamie Hoyle, Chief Deputy Director, DHP, provided the Director's report. Ms. Hoyle began by offering her gratitude to Ms. Juran and Ms. Yeatts for their participation in a successful legislative session. She stated that the department was increasing their efforts in providing training for staff and investigators. Training for board members on disciplinary topics will be held in September. Ms. Hoyle reported that the Citizen Advocacy Center was contracted to conduct an audit of the Health Practitioners Monitoring Program (HPMP). They are beginning their audit with a focus on nursing and medicine cases. A report with findings and recommendations will be available in May.

REPORT:

VCU SCHOOL OF  
PHARMACY:

Ms. Shinaberry stated that the Board recently invited the deans of the Virginia schools of pharmacy to provide a report to the Board of their activities during one of the 2015 full board meetings. Joseph T. DiPiro, Dean, VCU School of Pharmacy and Tom Reinders, Associate Dean for Admissions and Student Services, appeared this day and provided the Board with a handout outlining current information regarding the school of pharmacy. Currently, there are 70 faculty members, 140 PharmD students, 85 graduate students and satellite programs located at Inova-Fairfax in Virginia. Dean DiPiro also addressed the multiple achievements made by faculty and staff. He reported there have been ongoing position recruitments at the school. A center for compounding practice and research has been added to the school and they are currently recruiting for a director of the program. Regarding the VCU School of Pharmacy class of 2018, it is 64% female, 36% male, mean age of 23 years, 76% Virginia residents and 97% hold baccalaureate degrees. Currently, the school of pharmacy meets all 30 standards of accreditation, and was commended in two areas of teaching methods and assessments regarding faculty collegiality to develop new methods of teaching. The accreditation has been extended a full 8 years until 2023 by the Accreditation Council for Pharmacy Education Board (ACPE).

REGULATORY ACTIONS:

- LEGISLATIVE UPDATE:

Ms. Yeatts reported that this was a busy General Assembly session. She reviewed the handout in the agenda packet and indicated that several bills submitted by DHP were passed. Ms. Yeatts also stated that the majority of the agency's bills are pharmacy-related and many will require action by the Regulation Committee. Unless otherwise authorized, bills passed will become effective July 1, 2015. Ms. Yeatts and Ms. Juran confirmed for Ms. Warriner, therefore, that the requirement to perform a perpetual inventory of hydrocodone-containing products takes effect July 1, 2015 when the State law placing hydrocodone-containing products into Schedule II becomes effective.

- REGULATION UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet.

- AMENDMENT OF 18VAC 110-20-727; PHARMACISTS REPACKAGING FOR CLIENTS OF A CSB OR BHA:

Ms. Yeatts stated that staff recently identified an error in 18VAC 110-20-727 as there is no section G, H or J in 18VAC 110-20-725. She requested that the Board amend 18VAC 110-20-727 regarding pharmacists repackaging for clients of a CSB or BHA.

**MOTION:**

**The Board voted unanimously to amend 18VAC 110-20-727 as presented regarding pharmacists repackaging for clients of a CSB or BHA. (motion by Munden, second by Allen)**

NEW BUSINESS:

DISCUSS CONSTITUENT CONCERN RAISED WITH SENATOR WARNER'S OFFICE REGARDING PHARMACY BENEFIT MANAGER OVERSIGHT:

Ms. Juran provided an overview of the letter sent from Senator Mark Warner to Ms. Shinaberry requesting an appropriate response to concerns with PBMs that were expressed by John Frye, Pharmacist, Rocky Mount Family Pharmacy. In the letter, Mr. Frye states the PBM discriminates against independent pharmacies by requiring a different credentialing process than that which required for larger chain pharmacies. During the discussion, members acknowledged that not all PBM activities are within the Board's legal scope of authority. There was some focus of discussion on patient safety, security of the prescription department, and patient access to drugs. It was suggested that the NABP PBM Task Force Report be utilized as a resource. Ms. Shinaberry stated that the request for the Regulatory Committee to review this matter should be more general in nature and not limited to specific subjects.

**MOTION:**

**The Board voted unanimously to refer the concerns of pharmacy benefit manager oversight to the Regulation Committee in May for a more thorough review. (motion by Munden, second by M. Elliott)**

CONSIDER OF ADOPTION OF  
NOIRA FOR DRUG  
DISPOSAL

Ms. Juran reviewed with the Board the Drug Enforcement Administration's (DEA) final ruling regarding the disposal of pharmaceutical controlled substances. Ms. Juran stated that currently a pharmacy may collect and dispose of controlled substances under federal regulations, however, there is no direct authority for the Board to regulate this process or address issues of non-compliance. It was recommended that the Board adopt a Notice of Intended Regulatory Action (NOIRA) which would directly authorize the Board to regulate the drug disposal process in accordance with federal regulation.

**MOTION:**

**The Board voted unanimously to adopt a NOIRA requiring compliance with the federal rules regarding the collection and disposal of controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010. (motion by S. Elliott, second by Li)**

CONSIDER USE OF  
CAMERA-FACILITATED  
PRESCRIPTION  
VERIFICATION PROCESS BY  
PRACTITIONERS OF THE  
HEALING ARTS TO SELL  
CONTROLLED  
SUBSTANCES:

Ms. Juran reviewed with the Board a request made by Virginia Oncology Associates that would allow their physicians licensed to dispense drugs to use a camera-facilitated prescription verification process. The process is somewhat akin to the Walgreens camera verification system that the Board previously deemed met compliance with regulation, albeit there are differences. Ms. Juran suggested that if the Board could not reach consensus on whether the verification process met compliance with current regulation, it could consider recommending that Virginia Oncology Associates apply for an innovative "pilot" program. Among the concerns voiced by the Board: lack of supervision of the person assisting the physician with the dispensing process; camera not interfaced with dispensing software; communications sent via email; lack of drug security; lack of process for ensuring correct drugs are placed in the correct patient's bag. No action was taken on the matter. It was recommended that Virginia Oncology Associates consider strengthening the intended verification process prior to possibly applying for an innovative pilot program.

STAFF REQUEST TO  
CONSIDER PARTICIPATING  
IN THE MULTISTATE  
PHARMACY  
JURISPRUDENCE  
EXAMINATION (MPJE):

Ms. Juran requested that the Board consider moving from Virginia contracting to administer its own Federal and State Drug Law Exam (FSDLE) to participating in the NABP Multistate Pharmacy Jurisprudence Examination (MPJE). Currently, Virginia is one of three states that do not participate in the MPJE. The contract with the current testing administrator expires in June 2015 and can be extended for only one additional year prior to issuing a Request for Proposal (RFP) for a testing administrator. Ms. Juran explained that staff workload has steadily increased in recent years while resources remain limited. Overseeing the administration of the jurisprudence examination is labor-intensive and costly due to the number of meetings required for exam development. Staff has also noticed fewer companies have been bidding on the examination contracts, possibly due to the relatively small number of

exams administered annually. She then provided a brief comparison between the MPJE and FSDLE.

**MOTION:**

**The Board voted unanimously to extend the contract for the Virginia FSDLE for one year and approve staff working with NABP to transition to the MPJE. (motion by S. Elliott, second by Munden)**

AMEND GUIDANCE  
DOCUMENT 110-36

Ms. Juran discussed the proposed amendment to Guidance Document 110-36 to more accurately reflect the recommendation offered by the Compounding Work Group which met during the summer of 2014.

**MOTION:**

**The Board voted unanimously to amend Guidance Document 110-36 as presented. (motion by Warriner, second by Boone)**

AMEND GUIDANCE  
DOCUMENT 110-9

Ms. Juran discussed the proposed amendment to Guidance Document 110-9 which is consistent with the current inspection report.

**MOTION:**

**The Board voted unanimously to adopt the amendment to Guidance Document 110-9 as presented. (motion by Munden, second by Warriner)**

IDENTIFY SUBJECTS FOR  
POSSIBLE 2016  
LEGISLATIVE PROPOSALS:

- IMAPACT OF DRUG  
SUPPLY CHAIN  
SECURITY ACT
- PHARMACIST  
ACCESS TO PMP

It was requested that the Board identify subjects for possible 2016 legislative proposals. The Drug Supply Chain Security Act prohibits boards of pharmacy from licensing third party logistic providers (3PL) as wholesale distributors. Additionally, it preempts state pedigree requirements that differ from the federal track and trace requirements. Thus, Virginia law may need amending. Another subject discussed involves limitations on when pharmacists may access the PMP. This subject is being discussed within the Governor's Task Force on Prescription Drug and Heroin Abuse. Ralph Orr, Program Director for the PMP stated that the PMP committee was meeting later this month and will consider drafting a legislative proposal to allow pharmacists to have broader access to the PMP and not simply when presented a prescription for dispensing or when serving as a physician's delegate.

REPORTS:

CHAIRMAN'S REPORT:

Ms. Shinaberry gave a brief report on upcoming events. May 16<sup>th</sup>-May 20<sup>th</sup> is the NABP 111<sup>th</sup> Annual meeting being held in New Orleans, Louisiana. She and Ms. Juran will be attending. Ms. Shinaberry stated that anyone who would like to provide comments on any of the resolutions that will be voted on at the meeting should send those comments to Ms. Juran by April 30<sup>th</sup>. She also congratulated current and past members and staff for being selected to receive the NABP Fred T. Mahaffey award during the awards dinner to be held on May 19<sup>th</sup>. This award is presented to a board that has substantially contributed to the protection of the public health and welfare through the enforcement of state and federal laws and regulations. Virginia is specifically recognized for its efforts to address concerns with compounding.

**BOARD OF HEALTH  
PROFESSIONS:**

Ms. Shinaberry gave an update on the Board of Health Professions. The last meeting was cancelled due to snow, however; the review committee is scheduled to meet next month to discuss scope of practice for dental hygienists.

**PRESCRIPTION  
MONITORING PROGRAM:**

Ralph Orr, Program Manager for the Prescription Monitoring Program (PMP), gave an overview of the program's current activity. Mr. Orr stated as of now, 5696 pharmacists are registered and 199 pharmacist delegates are registered. In the year 2014, 25% of all requests were made by pharmacists. Currently 1.1 to 1.2 million prescriptions records are being processed monthly. Mr. Orr stated that the PMP is planning an archive system to reduce the size of the program's database to increase speed and efficiency. The retention schedule will be 2 years active, 3 years inactive and after 5 years removed from database. Mr. Orr stated that they are working on a project to place morphine equivalent score information on the PMP. This will include the conversion score which is calculated by strength. This may help practitioners when looking at patients records and preventing an overdose. The higher the score, the higher the overdose risk. He also discussed the automatic registration of pharmacists on the PMP. Those pharmacists that are not already registered will become automatically registered and be sent an email to activate their account. There are currently 13,500 licensed pharmacists and it is crucial that pharmacists add or update their email address by August. Mr. Orr stated that the Board of Medicine is giving money to help develop a resource website which will assist practitioners on how to use the morphine daily dose scores, access the PMP and information on the collaborative process.

**LICENSURE PROGRAM:**

Mr. Johnson reported the Board currently licenses 34,066 individuals and facilities. The Board issued 848 licenses and registrations for the period of December 1, 2014 through February 28, 2015. Inspectors conducted 302 facility inspections including 151 routine inspections of pharmacies: 35 (23%) resulted in no deficiency, 56 (37%) with deficiencies and 60 (40%) with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

**DISCIPLINARY PROGRAM:**

**EXECUTIVE DIRECTOR'S  
REPORT:**

Ms. Juran congratulated the Board again on being selected to receive the Fred T. Mahaffey award that is given every year at the NABP annual meeting. Ms. Juran discussed her involvement with the Governor's Task Force on Prescription Drug and Heroin Abuse. A third meeting of the Storage and Disposal Workgroup will convene in mid-April. The minutes and agendas for all Task Force and Workgroup meetings can be accessed on the DHP homepage. One of the focal points for the Storage

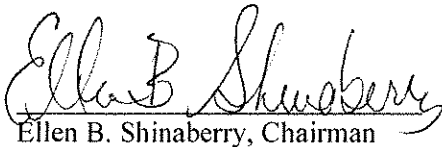
and Disposal workgroup has been to find ways to increase drug collection boxes at law enforcement agencies throughout Virginia. Ms. Juran stated that she and Mr. Johnson attended an NABP meeting in January to consider amendments to the Verified Pharmacy Provider inspection report. The goal was to modify the VPP to present a more uniform inspection report that could potentially be adopted by all 50 states. NABP intends to release this document at the annual meeting. Ms. Juran also stated that she participated on the NABP Law and Legislative Committee in January. Pharmacy renewals have gone smoothly which includes renewals from December, February and April. The 50-State Intergovernmental meeting hosted by the FDA was last week in which she and Mr. Johnson both attended. There was excellent discussion regarding the draft MOU for interstate compounding. Ms. Juran reported that she served as a panelist for the draft information sharing documents, to include the proposed changes to their 20.88 agreement. She also stated that Virginia is fortunate to have a good working relationship with FDA and that several members of Board staff, herself included, and inspectors are commissioned with the FDA which allows them to receive non-public information from the FDA. Ms. Juran also addressed the possibility for the board to send renewal notices via email later this year. Several other boards have utilized this process for several years now and it has reduced their mailing costs. The individual or facility would receive an email that would alert them to go online and renew their license or permit. If the license is not renewed within a specified time period, a paper renewal notification will be mailed to the licensee.

CONSIDERATION OF  
CONSENT ORDERS

There were no consent orders for consideration at this time.

ADJOURN:

With all business concluded, the meeting concluded at approximately 12:10pm.

  
Ellen B. Shinaberry, Chairman

  
Caroline D. Juran, Executive Director

10/15/15  
DATE:

6/15/15  
DATE: