

(DRAFT/UNAPPROVED)

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

September 9, 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 9:10am
- PRESIDING:** Ellen B. Shinaberry, Chairman
- MEMBERS PRESENT:** Jody H. Allen  
Melvin L. Boone, Sr.  
Michael Elliott  
Sheila K. W. Elliott  
Dinny Li  
Ryan K. Logan  
Empsy Munden  
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  
Jamie Hoyle, Chief Deputy Director, DHP  
James Rutkowski, Assistant Attorney General  
Elaine J. Yeatts, Senior Policy Analyst, DHP  
Heather Hurley, Administrative Assistant
- QUORUM:** With ten members present, a quorum was established.
- APPROVAL OF AGENDA:** Ms. Shinaberry noted two corrections in the tentative agenda: the minutes from August 14, 2014 were from a special conference committee meeting, not an informal conference committee meeting; and, a panel of the board will convene at 1:30pm or immediately following adjournment of the meeting, whichever is later, not at 2pm as listed on the tentative agenda. The tentative agenda was approved as amended.
- APPROVAL OF MINUTES:** The Board reviewed draft minutes for the June 3, 2014 (Informal Conference Committee-Innovative Pilot Program), June 4, 2014 (Public Hearing on Proposed Regulations for Administrative Fees for Duplicate Licenses and Verification), June 4, 2014 (Full Board Meeting), June 4, 2014 (Ad Hoc Inspection Committee), June 5, 2014 (Special Conference Committee), July 9, 2014 (Telephone Conference Call), July 22, 2014 (Panel Formal Hearing), July 29, 2014 (Special Conference Committee

and Informal Conference Committee), July 29, 2014 (Telephone Conference Call), August 14, 2014 (Special Conference Committee), and August 20, 2014 (Special Conference Committee).

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

**PUBLIC COMMENTS:** Alexander Pytlarz, pharmacist practicing in northern Virginia, thanked the board for addressing compounding issues during the recent compounding working group meetings and asked the board to support the recommendations captured in the compounding working group report.

Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA), provided comment on the agenda topic regarding interruptions when administering flu vaccinations. He asked the board to not restrict under what conditions vaccines may be administered, but to provide a balanced approach while acknowledging the raised concerns. He also offered assistance from VPhA to address the issue.

**REGULATORY ACTIONS:**

- **Regulatory Update:** Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet.
- **Adoption of Final Regulations for Administrative Fees:** Mr. Yeatts briefly reviewed the proposed regulations indicating no comment was received during the public comment period ending 7/18/14.

**MOTION:** **The board voted unanimously to adopt the proposed final regulations for administrative fees for duplicate licenses and license verifications. (motion by Warriner, second by Allen)**

- **Discussion of Amended 2015 Legislative Proposals: Virginia Licensure for Outsourcing Facilities, Pharmacies that Compound Human Drugs, and Wholesale Distributor Notification of Suspicious Ordering:** Ms. Yeatts reported that the provision for compounding for office use in the legislative proposal primarily addressing outsourcing facilities and adopted by the board in June was recently amended based on a recommendation from the compounding working group. The proposal now includes language allowing pharmacies to provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry if there is a critical need to treat an emergency condition. Additionally, she noted that the paragraph regarding labeling requirements for compounded products for office use that was originally stricken in the proposal adopted by the board will need to remain to address the now proposed emergency provision. Ms. Yeatts explained that it may be early December before notification is received from the Governor as to whether the legislative proposal is approved for introduction in the upcoming General Assembly session.

**The board voted unanimously to support amending the outsourcing**

**MOTION:**

**facility legislative proposal by including language for pharmacies to provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry if there is a critical need to treat an emergency condition primarily addressing outsourcing facilities and by keeping the paragraph regarding labeling requirements for compounded products for office use that was originally stricken in the proposal adopted by the board in June. (motion by Warriner, second by Allen)**

Ms. Yeatts reviewed the current language for the legislative proposal regarding wholesale distributor notification of suspicious ordering. The board offered no changes or comments.

Ms. Juran provided a brief update on this matter and indicated that staff intends to begin piloting the process in October.

**OLD BUSINESS**

- Update on Revising Physician Selling Drugs Inspection Process:

**NEW BUSINESS**

- Request to Use Numbered Stamps during Pharmacist Verification:

The Board discussed a request from a pharmacist to allow for the use of numbered rubber stamps which are cross referenced to pharmacist initials in lieu of handwritten pharmacist initials. The board took into consideration an allowance approved by the board in September 2007 to allow for the use of stamps to capture pharmacist initials. There was consensus to not approve the current request as the 2007 allowance appeared to provide a reasonable alternative to capturing handwritten pharmacist initials. Additionally, there was concern for the need to maintain an additional record, as outlined in the request, for cross referencing the pharmacist's initials as it appeared unnecessarily burdensome and could be misplaced. No action was taken by the board on this request.

- Concerns for Pharmacy Workflow Interruptions when Administering Influenza Vaccines:

The Board discussed concerns raised by a pharmacist regarding workflow interruptions in a community pharmacy when administering flu shots. Specific concerns included: expectations by some community pharmacies that a pharmacist must interrupt or rush through other activities to administer vaccines with little to no wait time for the patient regardless of staffing levels; and, the amount of time spent outside the prescription department administering vaccines, in lieu of supervising staff, answering prescriber telephone calls, and counseling patients.

**The Board expressed concern for the issues raised by the pharmacist and directed staff to advise the pharmacist in writing of the following information:**

**ACTION ITEM:**

- **§54.1-3434 and Regulation 18VAC110-20-110 B indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, and that if the**

owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations;

- the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit;
- the Board included an article entitled *Concern for Contemporary Practice: Evidence Requested* in the February 2013 board e-newsletter which addressed similar concerns;
- a summary of responsibilities of the pharmacist-in-charge found in Guidance Document 110-27; and,
- instructions for filing a complaint when evidence exists regarding possible patient harm resulting from contemporary pharmacy practice or any violation of law, to include abridging the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, or any decision overriding such control of the PIC or other pharmacist on duty.

The Board discussed the impact on facility security systems that currently utilize 2G cellular technology. The use of 2G technology is currently sunseting. Industry is moving toward the use of 3G/4G. Any devices using 2G technology after December 31, 2016 will no longer work. Staff explained that some newer security systems using 2G technology will only require a minor upgrade to transition to 3G/4G while some older security systems will need a significant upgrade or replacement.

- Guidance for Security Systems Transitioning from 2G to 4G and if it Necessitates Submission of a Remodel Application:

**ACTION ITEM:**

The Board offered the following direction to staff:

- send letter to facilities alerting them to sunset of 2G technology;
- advise permit holder to contact alarm company to determine what actions, if any, will be necessary to upgrade security system;
- if upgrade requires only a change to the circuit board, then a remodel application does not need to be submitted to the board office;
- if upgrade requires a replacement of the alarm panel, then a remodel application and fee must be submitted to the board office;
- advise facilities whose security system uses cellular technology to maintain documentation on file indicating if 3G/4G technology is currently being used, or if and when an upgrade was performed, and what the upgrade entailed;
- emphasize importance of ensuring security system operates at

**all times when activated and that action must be taken, when applicable, prior to December 31, 2016 when the 2G Sunset is complete;**

- **publish an article on this subject in an upcoming board e-newsletter.**

Ms. Juran reported that staff had received an inquiry from VDH as to who and under what conditions may someone access dispensed drugs maintained and delivered to a local health department under the alternate delivery provisions of 18VAC110-20-275. In researching the matter staff realized Guidance Document 110-3 should be amended to reflect current regulatory language and additional guidance could be provided to further clarify who may access alternate delivery drugs at a health department.

- Request from VDH for Guidance for Accessing Alternate Delivery Drugs

**The Board voted unanimously to amend Guidance Document 110-3 as presented. (motion by Munden, second by Allen)**

The following dates were selected for 2015 Full Board Meetings: 3/24/15; 6/16/15; 9/29/16; and, 12/1/15.

The following dates were selected for 2015 tentative Regulation Committee Meetings: 5/11/15 and 11/3/15.

#### **MOTION:**

- Dates for 2015 Full Board Meetings and Tentative Regulation Committee Meetings

#### **REPORTS**

- **DHP Director's Report:** Due to a scheduling conflict, Dr. Brown was unable to provide a report to the board.
- **Chairman's Report:** Ms. Shinaberry welcomed the three newly-appointed board members. She then announced her appointments to the standing committees as indicated on a handout.

#### **ACTION ITEM:**

**Because the law now allows a special conference committee to address permit holders, there was consensus to rename the "Informal Conference" standing committee as listed on the handout the "Inspection Special Conference" standing committee.**

- **Report on Board of** A brief report was provided by Elizabeth Carter, Executive Director of

Health Professions: the Board of Health Professions. It was stated that Ms. Shinaberry was recently appointed by the Governor to the board, along with 11 others. There are 18 member positions on the board. The next scheduled meeting of the board is September 25, 2014. The board will review the scope of practice for dental assistants and dental hygienists.

- Report on Compounding Workgroup: Ms. Allen provided a brief report regarding the two meetings recently held by the compounding working group as required in the enactment clause of HB 1035 passed during the 2014 General Assembly session. The goal of the group was to explore and clarify issues related to the compounding of drugs for human and animal use and provide a report to the Chairmen of the House of Delegates' Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2014. She indicated the report has been sent to Secretary Hazel for his review prior to submission to the legislators.

**ACTION ITEM:**

**There was consensus for staff to provide a copy of the compounding working group's report to the board members on November 1<sup>st</sup>, following submission to the Chairmen of the House of Delegates' Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health.**

- Report on Planning of NABP/AACP Districts I & II Meeting: Ms. Warriner provided a brief update on the planning for the NABP/AACP Districts I & II meeting being held in Williamsburg, Virginia, October 5, 2014 through October 7, 2014. Ms. Warriner requested that board members provide possible roundtable discussion topics and possible resolutions to Ms. Juran by September 20, 2014.

- Report on Licensure Program: Mr. Johnson reported the Board currently licenses over 35,000 individuals and facilities. The Board issued 1,408 licenses and registrations for the period of June 1, 2014 through August 31, 2014, including 480 pharmacists, 104 pharmacy interns, and 579 pharmacy technicians. Between June 1, 2014 and August 31, 2014, inspectors conducted 503 facility inspections including 198 routine inspections of pharmacies: 70 (35%) resulted in no deficiency, 71 (36%) with deficiencies and 57 (29%) with deficiencies and a consent order. This is the third consecutive quarter where deficiencies and a consent order have been below 40%. This may be attributed to educational efforts by the inspectors and amendments made to Guidance Document 110-9 at the December 12, 2013 board meeting that modified several major deficiencies and established new minor deficiencies. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies including "repeat" deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

Mr. Johnson reported that the Item Review Committee met in August to

develop new questions for the Virginia Federal and State Drug Law Exam.

Mr. Johnson reported that the Board is conducting its annual random audit of compliance with continuing education requirements by pharmacists and pharmacy technicians. In lieu of requesting, from those being audited, the submission of original certificates for all continuing education obtained in 2012 and 2013, the board will request NABP to provide information regarding any ACPE-approved CE maintained by the NABP CPE Monitor program for those being audited. If the information provided by NABP does not indicate full compliance with CE requirements, the licensee will be asked to submit original CE certificates to the board office to complete the auditing process.

- 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 10, 2013; March 25, 2014; June 3, 2014; and September 9, 2014. For the final date, open cases are none at the entry stage; 61 at the investigation stage; 106 at the probable cause stage; three at the administrative proceedings division stage; 13 at the informal stage; three at the formal stage; and 131 at the pending closure stage.

- Executive Director's Report:

Ms. Juran provided an overview of the internal process to be used should the board, in consultation with the Department of Forensic Science, need to consider scheduling a chemical into Schedule I or II pursuant to §54.1-3443. She provided a similar report to the Forensic Science Board in August. Several announcements regarding DEA-related matters were highlighted: national take-back day Sept 27<sup>th</sup>, 10am-2pm; recent teleconference announcing publication of final federal rules for drug disposal. She reported a blast email will soon be sent to licensees regarding DEA's final rule, effective October 6, to reschedule hydrocodone combination products from CIII to CII. She provided an update on meetings recently attended or to be attended in the near future: July 17 and 18<sup>th</sup>, Mr. Johnson, Ms. O'Halloran, and Ms. Juran traveled to Rockville, MD to attend a 2-day USP training program hosted by USP; Mr. Johnson will participate in additional sterile compounding training Sept 16-17 with expenses paid by NABP; Ms. Allen was appointed to the NABP taskforce to address pharmacy robberies and internal/external theft and will attend a meeting October 22-23 with expenses paid by NABP; Ms. Juran has been appointed to the NABP Committee on Law Enforcement/Legislation and will attend a meeting in January with expenses paid by NABP; Ms. Juran has been invited to participate on an Advisory Committee on Compounding Best Practices put together by the Pew Charitable Trust and will attend a meeting on October 9<sup>th</sup> with expenses paid by Pew; staff offered two presentations at the VPhA annual

meeting August 3-5<sup>th</sup>; and, staff will offer two presentations at the VSHP meeting in October. She reported an e-newsletter was published in July to further educate licensees on compliance with laws and regulations.

## SUMMARY SUSPENSIONS

DAVID O. COX  
Pharmacy Technician  
Registration Number:  
0230-020185

Corie Tilman Wolf, 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:

**Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by David O. Cox as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of David O. Cox to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Mr. Cox for the revocation of his pharmacy technician registration.**

TIHESA N. ELLIOTT  
Pharmacy Technician  
Registration Number:  
0230-014828

Corie Tilman Wolf, 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:

**Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Tihesa N. Elliott as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Tihesa N. Elliott to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Elliott for the revocation of her pharmacy technician registration.**

KILEY J. KESSLER  
Pharmacy Technician  
Registration Number:  
0230-023259

Corie Tilman Wolf, 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:

**Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Kiley J. Kessler as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Kiley J. Kessler to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Kessler for the revocation of her pharmacy technician registration.**

ADJOURN:

With all business concluded, the meeting concluded at approximately 1:10pm.

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Ellen B. Shinaberry, Chairman

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Caroline D. Juran, Executive Director

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DATE:

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