FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 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
Ryan Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner
Sheila Elliott (arrived at 11:25AM)

MEMBERS ABSENT: Dinny Li

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 eight members present, a quorum was established.

APPROVAL OF AGENDA: An amended agenda was provided to the Board. Additionally, Ms. Shinaberry requested an additional item be added under new business – consideration for requiring mandatory continuing education for pharmacists on the topic of opioid use or abuse. The amended agenda was approved as presented, along with the request for the additional new business item.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the September 9, 2014 (Full Board Meeting), September 9, 2014 (Panel Formal Hearing), September 16, 2014 (Special Conference Committee), October 21, 2014, Special Conference Committee, and the October 28, 2014 (Panel Formal Hearing). Corrections were made to the September 9, 2014 full board

meeting minutes.

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

PUBLIC COMMENTS:

Andrew D. Howard, M.D., F.A.C.P. and Javit Thekkumkattil, Vice President, Pharmacy Operations and Clinical Services of Fresenius Medical Care, addressed the Board regarding their request to be able to service dialysis clinics in Virginia as alternate delivery sites. Dr. Howard commented on how it would be beneficial based on a 2008 federal Act that became effective in 2011 that pays for dialysis services under a bundled payment. He stated that 30% of the patients at their dialysis centers in Virginia are requesting that the drugs be delivered directly to their clinics instead of the patient's residence. Dialysis patients take an average of 10-12 medications per patient. Delivery to dialysis centers would also assist medicine reconciliation and help ensure patients receive their medications. Patients on average spend up to 18 hours a week in the clinic, at least 3 days a week, 4 hours a day. Pharmacist consultation would be provided to patients 24 hours, every day. Dr. Howard stated that a majority of the states are allowing the delivery of Schedule VI drugs to the dialysis clinics and they request that Virginia do the same.

Gill Abernathy, INOVA Health System, addressed the Board concerning the recommendation for amending guidance document 110-36 for compounding. Ms. Abernathy expressed concern for the recommendation prohibiting the use of "closed system transfer devices" (CSTD) to extend beyond use dates. She stated a prohibition would have significant financial implications for hospital pharmacies. She recommended the Board provide its reasoning to the public should it decide to prohibit use of CSTDs to extend beyond use dates.

Jamin Engle, Sentara Rockingham Hospital, stated that he disagreed with the use of CSTDs to extend the beyond use date. He stated that it is a safety concern and it can lead to a higher risk of contamination.

DHP DIRECTOR'S REPORT:

Dr. Brown updated the Board on the Governor's Taskforce on Prescription Drug and Heroin Abuse. It was found that the amount of deaths from drug abuse now exceeds the amount of deaths caused by automobile accidents. Dr. Brown stated that he is co-chairing the Education workgroup, Ms. Juran is co-chair for the Storage and Disposal workgroup, Ralph Orr, Director of the Prescription Monitoring Program serves as staff on the Data and Monitoring workgroup, Jamie Hoyle, Chief Deputy Director of DHP and Laura Rothrock, Executive Administrative Assistant to the Director serves as staff for the Taskforce. The first meeting was held in November and there is a second meeting scheduled later in December.

Regarding legislation, the bill for requiring criminal background checks for registered nurses and licensed practical nurses is moving forward. Earlier this year, research was conducted to see how many registered sex offenders are licensees of DHP. At this time, six or seven matches have been found and it is being reviewed whether or not these individuals self-disclosed this information during the application process. Dr. Brown announced the elimination of DHP's Human Resources Department in October and that the agency is now using the shared human resource services through the Department of Human Resources Management. Dr. Brown stated that this decision will save the agency over $100,000 a year.

REGULATORY ACTIONS:

- Regulatory Update:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet. She indicated final regulations regarding continuous quality improvement programs will become effective December 31, 2014.

LEGISLATIVE UPDATE:

Ms. Yeatts reported that the agency has submitted multiple bills for the upcoming General Assembly session. The five legislative proposals adopted by the Board will move forward.

Jody Allen excused herself briefly from the meeting at 10:00am.

CONIDERATION OF SCHEDULING ACTION RESULTING FROM PUBLIC HEARING:

The Board reviewed the issue heard earlier that morning during the public hearing for placing certain chemicals into Schedule I. Ms. Yeatts explained that if the Board approved placing the three chemicals into Schedule I via regulation that the scheduling action would remain in place for 18 months, unless a general law was passed during the General Assembly session to permanently place the chemicals into Schedule I.

MOTION:

The Board voted unanimously to approve placing the following chemicals into Schedule I:

- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA); cannabimimetic agent;**
- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB); cannabimimetic agent;**
- **3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA); substituted cathinone;**

(motion by Warriner, second by Thornbury) (Allen not present for vote)

REQUEST FROM FRESENIUS MEDICAL CARE TO PERFORM ALTERNATE DELIVERY OF CERTAIN

Ms. Juran presented a request from Fresenius Medical Care requesting approval for the use of dialysis clinics as alternate delivery sites. Ms. Juran referenced past board decisions regarding similar requests. There was some concern regarding the security of the drugs at the dialysis

DRUGS TO DIALYSIS CENTERS:

clinics since a prescriber would not always been on-site during hours of operation. Mr. Johnson stated that the clinics would have to obtain a controlled substances registration certificate and would be subject to routine inspections. Drug to be delivered to the clinics would be limited to Schedule VI dialysis drugs. It was discussed that the population receiving dialysis treatment may have specials needs such as difficulty in finding transportation and risk of drugs being stolen from residences.

MOTION:

The Board voted 4 to 3 to allow Fresenius Medical Care to provide alternate delivery of Schedule VI dialysis medications to its dialysis centers. (motion by Munden, second by Elliott; Allen not present for vote)

REQUEST FROM JOINT COMMISSION TO ACCEPT THEIR SCREENING CHECKLIST FOR SATISFYING INSPECTION REPORT REQUIREMENT IN §54.1-3434.1:

Ms. Juran reviewed with the Board a request from the Joint Commission to allow its screening checklist to be submitted by nonresident pharmacies in lieu of an inspection report from the resident regulatory body as required in §54.1-3434.1. It was stated that the checklist did not appear to inspect for compliance with USP Chapter 795 or general pharmacy standards regarding security, recordkeeping, etc. It was requested that staff inform the Joint Commission that it should consider including additional elements on its screening checklist.

Ms. Allen returned to meeting at 10:40am.

MOTION:

The Board voted unanimously to decline the request from the Joint Commission to allow its screening checklist to be submitted by nonresident pharmacies in lieu of an inspection report from the resident regulatory body as required in §54.1-3434.1. (motion by Thornbury, second by Allen)

REQUEST TO CONSIDER REQUIRING PTCB FOR PHARMACY TECHNICIAN REGISTRATION:

Ms. Shinaberry addressed the Board with information she had obtained while attending the NABP District Meeting regarding the certification and licensure of pharmacy technicians. She stated that other states vary in their educational requirements of pharmacy technicians. NABP does endorse the Pharmacy Technician Certification Board (PTCB) as a national standard for pharmacy technicians. It was stated that requiring PTCB certification may increase patient safety. It was suggested that this matter be referred to the Regulation Committee for further consideration. The Regulation Committee will tentatively meet in May. Should it recommend a statutory amendment to require PTCB certification, the full board could consider a legislative proposal in June.

MOTION:

The Board voted unanimously to refer the request to require PTCB certification for pharmacy technician registration to the Regulation Committee for further consideration. (motion by Allen, second by Logan)

CONSIDER AMENDING

A request was made by staff for the Board to consider amending

GUIDANCE DOCUMENT 110-34 REGARDING LICENSURE OF WHOLESALE DISTRIBUTORS AND MANUFACTURERS:

Guidance Document 110-34 to require wholesale distributors and manufacturers which hold new drug applications or abbreviated new drug applications to obtain licensure as a manufacturer or non-resident wholesale distributor, whichever is applicable, regardless of whether they physically posses or ship the drug. The Board previously provided guidance that licensure was not necessary if the facility did not physically possess or ship the drug. However, it is generally believed that while these facilities may not physically possess or ship prescription drugs, they still control the flow of distribution as the NDA or ANDA holder. Ms. Juran has received requests from the executive directors of the New York and Delaware Boards of Pharmacy to license these entities so they can comply with the requirements imposed by New York and Delaware. Ms. Yeatts offered minor edits to the proposed amendments to further clarify the intent of the guidance.

MOTION:

The Board voted unanimously to amend Guidance Document 110-34 as presented and amended. (motion by Warriner, second by Allen)

CONSIDER AMENDING GUIDANCE DOCUMENT 110-9 BASED ON RECOMMENDATIONS FROM AD HOC INSPECTION COMMITTEE:

On June 4, 2014, an Ad Hoc Inspection Committee met and recommended that the Board amend Major Deficiency 25A and Major Deficiency 26 within Guidance Document 110-9 to include gloved fingertip testing. During the full Board's review of Guidance Document 110-9 it was noted that Minor Deficiency 42 also needs amending based on the final continuous quality improvement regulations taking effect on December 31, 2014. It was suggested that pharmacists and pharmacy technicians should be provided a 6-month grace period to where the inspectors will use this time for educating and not sanctioning for noncompliance with CQI requirements. The Board also requested that staff alert licensees to the grace period and effective date for CQI regulations in the next newsletter.

MOTION:

The Board voted unanimously to amend Major Deficiency 25A and Major Deficiency 26 within Guidance Document 110-9 by including "gloved fingertip testing" and to amend Minor Deficiency 42, based on final CQI regulations becoming effective December 31, 2014, and to begin citing deficiencies for noncompliance with CQI requirements beginning July 1, 2015. (motion by Thornbury, second by Warriner)

Sheila Elliott arrived at 11:25am

REQUEST FROM STAFF FOR GUIDANCE REGARDING ACCEPTABLE SECURITY SYSTEMS IN WHOLESALE DISTRIBUTORS:

Ms. Juran presented a request to the Board from a wholesale distributor to allow them to use a combination of various security systems, in lieu of motion detectors covering all drug storage areas. She explained that the long standing interpretation of Regulation 18VAC110-50-40 has been that the facility's security system must utilize motion sensors and the sensors must cover all prescription drug storage areas as motion sensors have been revered as the "generally acceptable and suitable device". However, a wholesale distributor is requesting approval to use a layering of various security devices. Two representatives from the wholesale

distributor in question addressed the Board and presented background information on the use of "audio sensors" in their facility. The representative in charge of security for the company stated that audio sensors have been accepted in other states. He stated that the audio sensors fully cover the prescription drug storage areas in addition to other types of security devices used throughout the facility. He explained that the audio sensors assist a security company in evaluating false alarms that can often result from motion sensors detecting birds flying around in a large warehouse.

MOTION:

The Board voted unanimously to grant the request of the wholesale distributor to allow a layering of security system devices, e.g., door contacts, cameras, motion sensors, and audio sensors, throughout the facility and to not require motion detectors to cover all prescription drug storage areas. (motion by Warriner, second by Munden)

LUNCH:

The board had a working lunch at approximately 12:15pm and presented former board members R. Crady Adams, Robert M. Rhodes and Pratt Stelly with plaques of appreciation for their time and service to the Board of Pharmacy.

Meeting reconvened at approximately 1:10pm.

CONSIDER AMENDING GUIDANCE DOCUMENT 110-36 BASED ON RECOMMENDATIONS FROM COMPOUNDING WORKGROUP:

The Board reviewed a request to consider amending Guidance Document 110-36 based on recommendations from the Compounding Workgroup which met during the summer of 2014. The Board discussed the public comment received earlier regarding the recommendation to prohibit the use of closed system transfer devices (CSTD) to extend the beyond use date of a single dose vial. Ms. Shinaberry shared information received from Eric Kastango, Principal, Clinical IQ and from a microbiologist with the FDA. Both supported prohibiting the use of CSTDs to extend beyond use dates of single dose vials. Ms. Juran shared written comments provided by Becton, Dickinson and Company which supported the use of CSTDs to extend beyond use dates of single dose vials. Based on the conflicting information, it was suggested that the recommendation to prohibit use of CSTDs to extend beyond use dates of single dose vials be sent to the Regulation Committee in May for further review.

MOTION:

With the exception of the recommended amendment to prohibit use of closed system transfer devices (CSTD) to extend beyond use dates of single dose vials, the Board voted unanimously to adopt the amendments to Guidance Document 110-36 as presented and recommended by the Compounding Workgroup and to have the Regulation Committee in May further consider the recommendation to prohibit the use of CSTDs to extend beyond use dates of single dose vials. (motion by M. Elliott, second by Allen)

AMEND GUIDANCE DOCUMENT 110-12, BYLAWS:

To conform the Board's bylaws to recent changes in law regarding special conference committees, staff presented proposed amendments to Guidance Document 110-12.

MOTION:

The Board voted unanimously to amend Guidance Document 110-12 as presented. (motion by Munden, second by S. Elliott)

REQUEST TO MANDATE CE IN A SPECFIC TOPIC FOR PHARMACISTS:

In light of the Governor's Taskforce on Prescription Drug and Heroin Abuse, Ms. Shinaberry recommended the Board be proactive in educating pharmacists and consider requiring pharmacists to obtain in 2015 up to 2 hours of continuing education (CE) in the subject of opioid use or abuse. Ms. Juran explained that 54.1-3314.1 provides the Board authority to require pharmacists to obtain up to 2 hours of CE in a specific topic if the Board informs pharmacists prior to January 1 of the year in which the requirement is imposed. The requirement applies only for a single year, does not apply to pharmacy technicians, and does not require pharmacists to obtain additional hours of CE. It simply requires, of the 15 hours to be obtained by a pharmacist, that a specific number of hours be obtained in a specific topic. It was suggested that Board staff could publish the requirement in the next newsletter and inform all pharmacists in writing prior to January 1, 2015.

MOTION:

Pursuant to 54.1-3314.1, the Board voted unanimously to require pharmacists to obtain at least one hour of continuing education (CE) in the subject of opioids use or abuse during the 2015 calendar year and prior to renewing his license to practice in 2016. (motion by Warriner, second by Logan)

REPORTS:

- Chairman's Report:

Ms. Shinaberry reported that the District I & II meeting held in Williamsburg in October was a success. She thanked Ms. Juran and Ms. Warriner for their hard work in organizing the meeting. Ms. Shinaberry spoke about her recent trip to the NABP Interactive Forum held December 2nd -3rd in Mt. Prospect, Illinois. She stated it was a great networking opportunity where pharmacists from all over the United States and Canada met and discussed topics affecting boards such as collaborative practice agreements and conflict of interest.

- Report on Board of Health Professions:

Ms. Shinaberry provided an update regarding recent activities of the Board of Health Professions. Ms. Shinaberry stated that 12 new members were appointed to the Board of Health Professions. They are currently discussing job placements for veterans, heroin and prescription drug abuse, and consideration of a mid-level provider license. Scope of practice for dental hygienists and telemedicine are the upcoming topics of review.

- Report on NABP/AACP Districts 1 & 2 Meeting:

Ms. Warriner praised the Board for the outstanding turnout for the NABP/AACP Districts 1 & 2 Meeting held in Williamsburg, VA. The meeting was October 5th -7th and was held at the Williamsburg Lodge. Ms. Warriner thanked all members involved in the planning and organizing of the meeting. She stated it was her understanding that the meeting had the highest attendance in the past eight years. The 2015 Districts 1 and 2 Meeting will be held in New Hampshire. A final report will be sent to them with any suggestions that this Board may have for them.

- Report on NABP Taskforce:

Ms. Allen reported on her trip she took for the NABP Taskforce held in Chicago, October 22nd -23rd. The meeting consisted of examining robberies and thefts of pharmacies. They reviewed actions taken by other state boards and collaborated on how to form a model state act that may modify security to help ensure the safety of pharmacists.

- Report on Licensure Program:

Mr. Johnson reported the Board currently licenses over 36,000 individuals and facilities. The Board issued 1,115 licenses and registrations for the period of September 1, 2014 through November 30, 2014, including 199 pharmacists, 317 pharmacy interns, and 412 pharmacy technicians. Inspectors conducted 439 facility inspections including 200 routine inspections of pharmacies: 69 (34%) resulted in no deficiency, 53 (27%) with deficiencies and 78 (39%) with deficiencies and a consent order. While there was an increase in inspections resulting in a consent order over the previous quarter, this is the fourth consecutive quarter where deficiencies and a consent order have been below 40%. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies including "repeat" deficiencies. Of the 78 inspections that resulted in a consent order, four pharmacies had 5 or more minor deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

- 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 March 25, 2014; June 3, 2014; September 9, 2014; and December 8, 2014. For the final date, the number of open cases are two at the entry stage; 78 at the investigation stage; 105 at the probable cause stage; 11 at the administrative proceedings division stage; 4 at the informal stage; three at the formal stage; and 158 at the pending closure stage.

- Executive Director's Report:

Ms. Juran reported to the Board that a request had recently been received from the National Transportation Safety Board (NTSB) regarding its safety study concerning the risk of drug-induced impairment in transportation accidents. The NTSB requested all Boards of Medicine and Pharmacy to remind its licensees of the importance of routinely discussing with patients the effect their diagnosed medical conditions or

prescribed drugs may have on their ability to safely operate a motor vehicle. In response to the request, the Department of Health Professions has placed on alert on the Board of Pharmacy's website, along with other websites of those boards that license prescribers. She also reported that the November e-newsletter was published, emailed to those licensees that have provided an email address to the Board, and is now available on the board's website. The piloting of the physician selling inspection process is moving forward. Ms. Juran stated that she is currently co-chairing the Storage and Disposal Workgroup as a part of the Governor's Prescription Drug and Heroin Abuse Taskforce. She and the Workgroup are currently researching whether the Board needs to promulgate regulations to support the new federal drug disposal regulations. Ms. Juran and Mr. Johnson are working with the NABP, along with the executive directors of the Arkansas, Oklahoma and Louisiana Boards of Pharmacy to develop recommendations for a more uniform inspection report. Additionally, Ms. Juran and Mr. Johnson will be traveling to Mt. Prospect, IL in January for a Verified Pharmacy Practice (VPP) Inspection Committee Meeting to finalize recommendations for a more uniform inspection report. Ms. Juran also stated she will be participating on the NABP Legislative Taskforce being held in Mt. Prospect, IL on January 20th-21st. Travel costs for NABP meetings recently attended by members and staff and those scheduled in January have been paid for by NABP.

Ms. Juran left the meeting at this time due to illness.

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 Cathy Reiniers-Day, Jim Rutkowski, 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 Munden, 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 Munden, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Rianna Lynn Hodgen, pharmacy technician (motion by Allen, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as

presented by Ms. Reiniers-Day in the matter of Jerri Denice Mallory, pharmacy technician (motion by Thornbury, second by Logan)

ADJOURN: With all business concluded, the meeting concluded at approximately 3:05pm.

Ellen B. Shinaberry, Chairman

3/24/15
DATE:

Caroline D. Juran, Executive Director

3/24/15
DATE: