FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 12, 2013
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15 AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
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
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, Director, DHP
Arne Owens, Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With ten 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 December 11, 2012 (Regulation Committee), December 12, 2012 (Full Board Meeting), December 18, 2012 (Special Conference Committee and Informal Conference Committee), January 14, 2013 (Telephone Conference Call), January 22, 2013 (Panel Formal Hearing), January 22, 2013 (Exam Committee), January 31, 2013 (Informal Conference Committee for Innovative (Pilot) Programs), February 1, 2013 (Ad Hoc Committee for Nonresident Pharmacies Sterile Compounding Surveys), February 4, 2013 (Telephone Conference Call), February 12, 2013 (Special Conference Committee and Informal Conference Committee) and February 25, 2013 (Telephone Conference Call).

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

PUBLIC COMMENTS: Tim Musselman representing the Virginia Pharmacist Association (VPhA) commented that his members are requesting guidance from the Board on sterile compounding issues which may assist compounding

pharmacies and hospital pharmacies in complying with legal requirements. Specifically, he indicated there is confusion regarding the board's expectations during pharmacy inspections and the processes to be used by the pharmacist for appropriately assigning beyond use dates and performing sterility tests. He suggested that the board form a workgroup which would represent compounding pharmacies, hospitals, and prescribers.

Cal Whitehead with Whitehead Consulting, LLC introduced himself and his colleagues to the board and announced that they will be serving as lobbyists for the Virginia Society of Health-System Pharmacists.

DHP DIRECTOR'S REPORT:

Dr. Cane reported that the three bills submitted by DHP and included in the Governor's package had all passed during the General Assembly session. The bill which eliminated the Psychiatric Board has been signed into law. The second bill adds two anabolic steroids to the Drug Control Act to conform to federal scheduling, and the third bill prohibits a licensee whose license has been suspended or revoked from engaging in practice pending appeal of the board's order. Dr. Cane also stated that the upcoming National Governors Association (NGA) meeting is being held at DHP on March 25, 2013. Four subgroups were created to focus on prescription monitoring, education, law enforcement, and drug disposal. The meeting on the 25th is designed to be a working meeting for these four subgroups. Dr. Cane then provided an update regarding her trip to the Virginia Pharmacist Association midyear conference that was held on February 23, 2013 in Roanoke, Virginia. Mr. Kozera recognized Dr. Cane for a job well done in providing the Rooke Lecture at the VPhA meeting.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2013 General Assembly session that may potentially impact the board or the profession of pharmacy.

TORNADO DRILL:

The Board participated in the state-wide tornado drill from 9:45am until approximately 9:55am.

- Regulatory Update

Ms. Yeatts reviewed with the board the status report for pending regulatory actions which was provided in the board agenda packet.

- Adoption of fast-track regulations resulting from regulatory reform:

Ms. Yeatts provided the board with a handout which contained a Notice of periodic review for chapters 20, 30, 40, and 50, one public comment, and staff's recommended changes to chapter 20. She indicated that the comment period for the Notice was November 5, 2012 through December 5, 2012 and that the board received one comment on December 5, 2012 which was general in nature. She proceeded to review staff's recommended change to 18VAC110-20-20 which would assist the agency in accommodating electronic renewal notices and encourage on-time payments by clarifying that the renewal fees may be paid at any time "up to" the expiration date. Suggested changes to 18VAC110-20-40 would allow the board to accept certification of pharmacy intern hours of practical experience from an ACPE-approved school of pharmacy when a state relies on the school to certify the hours. Suggested changes to 18VAC110-20-105 would remove the requirement that a pharmacy technician provide proof of continuing education (CE) when performing a late renewal of his registration and would simply require an attestation of

having obtained the required CE. Suggested changes to 18VAC110-20-270 would incorporate guidance from Guidance Document 110-22 which addresses conflicts between 18VAC110-20-270, 18VAC110-20-276, and 18VAC110-20-515. Suggested changes to 18VAC110-20-420 eliminates possible conflict with HIPAA by requiring labeling of drug drawer or tray simply in a manner that identifies the patient and his location without violating health privacy laws. Suggested changes to 18VAC110-20-425 would expand allowances for a robotic pharmacy system to dispense drugs in bar-coded compliance packaging. Suggested changes to 18VAC110-20-710 would remove potentially burdensome alarm requirements for teaching institutions possessing only Schedule VI drugs. Ms. Yeatts indicated these changes would follow the fast-track process since they are expected to be noncontroversial. After Executive Branch review and publishing in the Register, a 30-day public comment period will begin. If ten or more members of the public object to the regulatory changes then publication of the fast-track regulation will serve as the Notice of Intended Regulatory Action (NOIRA) and the standard rulemaking process will be followed. Ms. Shinaberry requested that in the future staff provide suggested regulatory changes to the members in advance of the meeting, if possible.

MOTION:

The Board voted to adopt the proposed fast-track regulatory amendments as presented by staff and that resulted from the periodic regulatory review required by the Governor to address overly burdensome regulations. (motion by Allen, second by Shinaberry) (Warriner abstained)

A member commented that it appears to take significantly more time for inspectors to perform sterile compounding inspections given the complexity of the subject. It was questioned whether licensing fees should be increased for those pharmacies performing sterile compounding. Ms. Juran indicated she is aware that a few states have considered this approach to address concerns with rising inspection costs associated with sterile compounding.

ACTION ITEM/ MOTION:

After discussion, the Board voted unanimously that staff should collect data on how much time is spent on performing routine inspections of pharmacies performing sterile compounding to determine if there is a validated concern for rising costs directly associated with sterile compounding and research what actions other states are taking to address cost increases. (motion Ellen, second Adams)

- Revenue, Expenditures and Cash Balance Analysis:

Ms. Yeatts reviewed with the Board the Revenue, Expenditures and Cash Balance Analysis that was conducted by the agency over the 2010-2012 biennium (July 1, 2010 through June 30, 2012). It was recommended by the agency that no fee increase be taken at this time.

INTRODUCTION:

Mr. Kozera called for the introduction of Mr. Paul Dalby who is the new Deputy Director for the Enforcement Division.

MISCELLANEOUS:

- Request for special considerations from Free Clinic of Franklin County, Inc.

Ms. Juran reviewed with the board the letter included in the agenda packet from the Free Clinic of Franklin County, Inc. that expressed concern for the cost associated with paying a pharmacist to operate the pharmacy. It indicated the clinic is in an area that is medically underserved, they cannot find pharmacists to volunteer in their clinic, they pay one pharmacist to operate the clinic's pharmacy, but that the cost is impacting services that could be provide to indigent patients. The clinic requested the ability for a licensed provider (MD, PA, FNP) to directly supervise pharmacy activities under the general supervision of a pharmacist who will be onsite at least once weekly or for the pharmacy technician to begin preparing medications 1-2 hours before the pharmacist arrives to supervise and approve the medications prior to dispensing. The board discussed current allowances in place for free clinics and requested staff to outline these provisions in a letter to the free clinic. The board also expressed concerns for drug security and lack of direct pharmacist supervision in the requested options. The board then asked the public present and those representing pharmacy associations to please assist this clinic in communicating the need for volunteer pharmacists.

MOTION:

The Board voted unanimously to deny the request from the Free Clinic of Franklin County, Inc. (motion by Rhodes, second by Stelly)

- Update on Sanctioning Reference Points evaluation and revision process:

Kim Langston, Research Associate with Visual Research, presented the Sanctioning Reference Points evaluation (SRP) that was completed for the Board of Pharmacy. Confidential consent agreements (CCAs), pre-hearing consent orders (PHCOs) and pre-defined sanctions are all new to the SRP since they were not commonly used during the development of the SRP. At this time, information regarding board cases is being transferred into a new database and the types of violation have changed since the implementation of the SRP. Ms. Langston stated that the board implemented the SRP process in 2007 and has currently completed seventy-six SRPs. Ms. Langston reported that Visual Research has been conducting interviews of select board members and staff to gain feedback and recommendations for the SRP process. She offered a summary of responses from the interviews that were conducted. She recommended to the Board that pharmacy technicians have their own worksheet and it could be presented with the revised pharmacist worksheet at the June board meeting.

MOTION:

The Board voted unanimously to approve the continuation of the Sanction Reference Points evaluation being conducted by Visual Research, Inc. (motion by Shinaberry, second by Allen)

- Adoption of Guidance Document 110-18

Ms. Juran reviewed with the board a handout with suggested revisions for Guidance Document 110-18 which is entitled, "Interpretation of administer to include preparation for administration." She indicated that the third paragraph should be deleted since the allowance for administering drugs in schools is now addressed in §54.1-3408 and this guidance may potentially conflict with schools' policies. Additionally,

Ms. Yeatts reported that the issue of drug administration is more appropriately addressed by the Board of Pharmacy since it enforces the Drug Control Act and that the Board of Nursing approved the reference to them being deleted.

MOTION: **The Board voted unanimously to amend Guidance Document 110-18 as presented. (motion by Warriner, second by Adams)**

- Adoption of amended Guidance Document 110-9:

The Board reviewed staff's suggested changes to Guidance Document 110-9 which was included in the agenda packet. Regarding Major Deficiencies 22 and 23, staff had received comment from certifying companies that it is standard practice to perform a hood certification no later than the last day of the month in which the certification is due. Ms. Juran explained that she was waiting on confirmation of this information from Eric Kastango, an expert on USP standards.

MOTION: **The Board voted unanimously to adopt amended Major Deficiencies 22 and 23 in Guidance Document 110-9 as presented, have staff report its findings from the USP expert at the June board meeting, and apply the guidance retroactively to any inspections citing this violation since the December 2012 full board meeting. (motion by Stelly, seconded by Allen)**

It was suggested that the proposed changes for Major 25c and Major 26a read to say "failed" instead of "negative". The amendments for Major 34 and Minor 42 concerning records were discussed, and it was recommended that no monetary penalty for deficiencies associated with CQI requirements be imposed until a later date.

MOTION: **The Board voted unanimously to amend the following deficiencies in Guidance Document 110-9:**

- **Major 25c by replacing the word "negative" with the word "failed";**
- **Major 26a as presented with the exception of replacing the word "negative" with the word "failed";**
- **Major 35 as presented; and,**
- **Major 34 and Minor 42 as presented with the exception that a monetary penalty will not be imposed until a later time.**

(motion by Rhodes, second by Munden)

- Request from staff for guidance regarding continued actions to address sterile compounding issues:

Ms. Juran requested guidance from the Board regarding continued actions to address sterile compounding issues. Ms. Juran stated that an ad-hoc committee was formed and met February 1, 2013 to review non-resident pharmacy compounding survey responses that were sent out in December. It was discussed that the same committee should meet again to continue the review of the survey responses, and a new committee should be formed, to include representation from VPhA, VSHP, and MSV, to develop consensus language for the full board to consider in the drafting of a guidance document on sterile compounding issues. Mr. Kozera instructed board members who are interested in participating on the committee to contact Ms. Juran and that he would appoint members to the ad hoc committee.

- Request from staff for guidance regarding whether drugs provided by a physician for an infusion pump constitutes dispensing or administering:

Ms. Juran requested guidance from the Board regarding whether the act of a physician providing a patient with an infusion pump containing drug constitutes administration or dispensing of a drug. Staff has been contacted by two physician offices who are seeking clarification as to whether the physician must obtain a dispensing license when providing a patient with an infusion pump containing drug.

MOTION:

The Board voted unanimously that the act of a physician providing a patient with an infusion pump containing drug which will administer doses after leaving the physician's office constitutes dispensing and that the physician will need to obtain a license to dispense. (motion by Stelly, second by Munden)

REPORTS:

- Report on Board of Health Professions:

Mr. Rhodes gave an update regarding previous and upcoming meetings with the Board of Health Professions. He stated that the Regulatory Research Committee met on February 5, 2013 and he gave an overview and discussed the minutes of the meeting with the Board.

- Report on Licensure Program:

Mr. Johnson reported that the Board issued 843 licenses and registrations for the period of December 1, 2012 through February 28, 2013, including 85 pharmacists, 133 pharmacy interns, and 481 pharmacy technicians. Inspectors conducted 262 facility inspections including 56 routine inspections of pharmacies: 16 resulted in no deficiency, 12 with deficiencies, and 28 with deficiencies and a consent order.

- 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 12, 2012; June 8, 2012; September 28, 2012; and March 8, 2012. For the final date, open cases are two at the entry stage; 55 at the investigation stage; 64 at the probable cause stage; 20 at the administrative proceedings division stage; 12 at the informal stage; six at the formal stage; and 101 at the pending closure stage.

Further, Ms. Reiniers-Day requested that the Board review the September 27, 2006, Board's guidance regarding the offering of a prehearing Consent Order associated with non-reporting to the Prescription Monitoring Program. She explained that the Guidance Document was put in place when reporting was required less frequently and the sanction was to immediately submit the reports as well as impose a $1,000 monetary penalty for each unreported period. The law has now been changed to require weekly reporting.

MOTION:

The Board voted unanimously to amend Guidance Document 110-06 to indicate that a prehearing Consent Order shall be offered with the sanction that the required reports be submitted immediately as well as impose a $250 monetary penalty for each unreported period to the

Prescription Monitoring Program. (motion by Adams; second by Allen)

- Executive Director's Reports:

Ms. Juran gave an update to the Board that the next DEA take-back event will be held April 27, 2013. The NABP annual meeting will be held May 18th through May 21st in St. Louis, MO and that Mr. Kozera, Ms. Allen, Ms. Warriner, Mr. Rhodes, Mr. Adams, Ms. Thornbury and herself were planning to attend. She reminded those attending that the deadline for the reduced hotel rate was April 27th. Ms. Juran also reported on the Healthcare Workforce Data Center forum held by Nursing, Dentistry and Pharmacy where the media and key stakeholders were invited to DHP to hear reports from recent surveys. The Board of Pharmacy reviewed reports from the 2011 pharmacy technician and pharmacist surveys. Ms. Juran stated that Mr. Kozera had recently appointed members to a new committee for the hearing of disciplinary cases related to inspection violations and continuing education audit violations. The two-member committee consists of Ms. Munden as chairman and Mr. Adams, with Ms. Warriner serving as an alternate member. The National Governors Association (NGA) meeting is being held at DHP on March 25, 2013 and it is open to the public. Ms. Juran also reviewed the expenditure report concerning the revenue for the Board of Pharmacy.

LUNCH:

The Board broke for lunch at approximately 12:45pm and presented former Board members Gill Abernathy and Brandon Yi with plaques of appreciation for their time and service to the Board of Pharmacy.

RECONVENE:

The Board reconvened at approximately 1:45pm.

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 Caroline Juran, Cathy Reiniers-Day, Howard Casway, 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 Allen, 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 Allen, second by Adams)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jonathan C. Spitler, Pharmacist (motion by Adams, second by Munden)

MOTION:

The Board voted unanimously to accept the Consent Order as

presented by Ms. Reiniers-Day in the matter of Jessica L. Malin, Pharmacy Technician (motion by Warriner, second by Rhodes)

ADJOURN: With all business concluded, the meeting adjourned at 2:25 pm.

David C. Kozera, Board Chairman

6/18/13
Date

Caroline D. Juran, Executive Director

6/18/13
Date