FINAL/APROVED

VIRGINIA BOARD OF PHARMACY
DRAFT/ MINUTES OF BOARD MEETING

September 20, 2011
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10 AM.

PRESIDING: Gill B. Abernathy, Chairman

MEMBERS PRESENT:
Crady R. Adams
Jody H. Allen
Gerard Dabney
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly

MEMBER ABSENT: Brandon K. Yi

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 (business portion)
Rachel Baer, Assistant Attorney General (formal hearings)
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Eusebia Joyner, Disciplinary Program Specialist

QUORUM: With nine members present, a quorum was established.

INTRODUCTION OF NEW BOARD MEMBERS: Ms. Abernathy welcomed two new members to the Board of Pharmacy, R. Crady Adams and Empsy Munden.

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for June 8, 2011 (Board Meeting); July 25, 2011 (Telephone Conference Call); August 16, 2011 (Panel Formal Hearing); and August 25, 2011 (Ad Hoc Committee, Continuous Quality Improvement). There was an amendment made to the June 8, 2011 full board meeting minutes to include on page 10 the allowable circumstances for compounding

17 alpha hydroxyprogesterone caproate.

Motion: **The Board voted unanimously to approve the minutes as amended. (motion by Kozera, second by Dabney)**

PUBLIC COMMENTS: There were no public comments offered at this time.

DHP DIRECTOR'S REPORT: Dr. Cane reported that the Department of Health Professions (DHP) was presented with the Council on Licensure, Enforcement and Regulation (CLEAR) Regulatory Excellence Award at the September 9, 2011 annual meeting that was held in Pittsburgh, for its development of the Sanctioning Reference Points (SRP) program. Dr. Elizabeth Carter (Director, Board of Health Professions) and Neil Carter (Visual Research) developed the SRP program which is the first tool of its kind to standardize sanctions.

Arne Owens reported on DEA's National Take-Back Day, the last one bringing in approximately five tons of unwanted drugs statewide. The next National Take-Back Day is scheduled for October 29, 2011, and DHP will take part in publicizing the event. Mr. Owens highlighted a booklet which had been distributed by Board staff to the Board, "A Roadmap for Local Communities in Virginia" to host a successful drug take-back program. The Office of the Attorney General published this booklet in order to assist local communities in organizing their own programs.

REGULATIONS: Ms. Yeatts provided a status update of the Board's current regulatory packages. The proposed regulations for administrative fees for duplicate licenses and verifications are at the Secretary's Office and the proposed regulation to eliminate the requirement for an alarm system for certain EMS agencies is at the Governor's Office.

- Emergency Regulations for CSBs, BHAs, and Crisis Stabilization Units

Additionally, Ms. Yeatts stated the emergency regulations for CSBs, BHAs, and crisis stabilization units will expire December 19, 2011. Ms. Yeatts explained that the Board could consider requesting a six-month extension of the emergency regulations, since the permanent replacement regulations will not become effective prior to December 19, 2011. This would extend the emergency regulations to June 18, 2012.

Motion: **The Board voted unanimously to request that the emergency regulations for CSBs, BHAs, and crisis stabilization units be extended for 6 months until June 18, 2012. (motion by Rhodes, second by Shinaberry)**

- Adoption of Proposed Regulations for On-Hold

Ms. Yeatts reported that a Notice of Intended Regulatory Action (NOIRA) was published for public comment on May 9, 2011, for

Prescriptions

the proposed regulations concerning on-hold prescriptions. Responses were received until June 8, 2011. All responses received supported amending regulations. Additionally, she reported that a committee of the Board met on May 17, 2011 to draft proposed regulations on the subject. Ms. Yeatts requested that the Board review the received public comments and the draft proposed regulations as recommended by the committee and consider adopting proposed regulations either as recommended or with amendments.

Motion:

The Board voted unanimously to adopt the proposed regulations for on-hold prescriptions as recommended by the committee. (motion Rhodes, second by Dabney)

- Adoption of Emergency Regulations for Continuous Quality Improvement:

Ms. Yeatts reminded the Board that § 54.1-3434.03, recently enacted, requires the Board to promulgate emergency regulations for implementing continuous quality improvement programs (CQI) in all pharmacies. She also stated that a taskforce representing various areas of pharmacy practice met on May 18, 2011 and August 25, 2011 to draft proposed emergency regulations. At the August meeting, the committee requested staff to research whether current statutory language for peer review would offer pharmacists confidentiality protections; if not, what action could be taken to create such protections; and if the effective date of the rules could be delayed to provide an educational period for the licensees. Ms. Juran reported that Board counsel indicated current peer review language does not appear to provide civil protections and that an interested stakeholder could seek a legislative amendment, if desired. Mr. Casway then stated that the rules could not defer the effective date for implementing the requirements, but that it would be the Board's decision as to whether it would impose a sanction for a violation of non-compliance. It was recommended that pharmacies should have an opportunity to implement the CQI programs prior to being issued a sanction for non-compliance. It was stated that many pharmacies, including hospitals and retail chains, already have a CQI program in place or report to a patient safety organization (PSO). Additionally, James Pickral, representing the Virginia Pharmacist Association, indicated that many independent pharmacies also currently have either a CQI program or report to a PSO. After discussion, the Board agreed to direct inspectors during a routine inspection to cite non-compliance with these requirements as a comment only for six months from the date authorizing the publishing of the emergency regulations.

Motion:

The Board voted unanimously to direct inspectors during a routine pharmacy inspection to record on the inspection report non-compliance regarding § 54.-3434.03 and the CQI

emergency regulations as a comment only and to not impose a monetary penalty for non-compliance with these requirements for six months from the date authorizing the publishing of the emergency regulations. (motion Kozera, second by Allen).

Action Item:

The Board agreed to consider amending Guidance Document 110-9 at a future board meeting to include a possible monetary penalty for non-compliance of § 54.-3434.03 and the CQI emergency regulations when cited during an inspection after the first six-month period from the date authorizing the publishing of the emergency regulations.

The Board also discussed the term "dispensing error". It was determined a dispensing error occurs after the final verification of the pharmacist, regardless of whether the drug has been delivered to the patient or not. The fact that a drug incorrectly prepared was verified to be accurate by the pharmacist and made ready for delivery to the patient is sufficient to constitute a dispensing error. Lastly, it was noted in the proposed definition of "dispensing error", section 3, that "medication" and "wrong", were not the correct terms to use. It was suggested that "drug" and "incorrect" be used instead.

Motion:

The Board voted unanimously to adopt the emergency regulations as required by § 54.-3434.03 regarding continuous quality improvement programs and as recommended by the taskforce, with amendments to the definition of "dispensing error", section 3, using "drug" instead of "medication" and "incorrect" instead of "wrong". (motion by Allen, second by Rhodes)

Motion:

To afford another opportunity to receive public comment, the Board voted unanimously to adopt a second Notice of Intended Regulatory Action (NOIRA) for the permanent replacement regulations regarding continuous quality improvement programs. (motion by Stelly, second by Adams)

- Consideration of Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reviewed with the Board three petitions for rulemaking regarding monthly audit requirements in Regulation 18 VAC 110-20-490. The petitioners indicated that current auditing requirements are overly burdensome, because improvements in technology since this regulation became effective could potentially automate or eliminate some of the manual processes currently required. Ms. Yeatts indicated twenty-one public comments were received, all supporting an amendment to the regulation. Ms. Yeatts stated that the Board must either approve the petitions for rulemaking and adopt a Notice of Intended Regulatory Action (NOIRA) or deny the petition and state the reason for denial.

Motion:

The Board voted unanimously to approve the petitions for rulemaking regarding automated dispensing devices, but to expand the petition to include all of Regulation 18VAC 110-20-490 and adopt a Notice of Intended Regulatory Action. (motion by Adams, second by Kozera)

- Review "Run Dry" Requirement for Automated Counting Devices:

Ms. Juran reported that Delegate Chris Jones had indicated in a recent conversation with her that the "run dry" requirement in Regulation 18VAC 110-20-355 may currently be overly burdensome. He explained to Ms. Juran that there is an increasing trend to use automated counting devices to more securely store certain slow-moving drugs which do not inherently empty from the bin every sixty days. Ms. Juran stated she reviewed the other states' regulations for automated counting devices and none had a "run dry" requirement. Alan Friedman representing Kaiser Permanente addressed the Board with his concerns for the regulation. He explained that current counting devices rely on gravity to empty the device to ensure the "first drug in" is the "first drug out", unlike the baker cells used in past when the "run dry" requirement was put in place. He believes the "run dry" requirement is no longer necessary and the Board should consider either eliminating the requirement or requiring an annual "run dry".

Motion:

The Board voted unanimously to refer the review of the "run dry" requirement in Regulation 18VAC 110-20-355 to the regulation committee and for it to collect further information for consideration by the Board. (motion by Munden, second by Rhodes)

UPDATE ON ACTION ITEMS:

- Statistics Regarding Delegated Authority:

Ms. Juran and Ms. Reiniers-Day discussed with the Board the use of the delegated authority to review cases that was approved during the June 8, 2011 board meeting. Ms. Reiniers-Day reported the past year's history for the Board in that, for the time period September 1, 2010 to August 31, 2011, for patient care cases involving a medication error, ten pre-hearing consent orders were entered and fifty confidential consent agreements were entered. All ten pre-hearing consent orders involved a child's medication error. Ms. Reiniers-Day further advised that since the June 8, 2011, board meeting, she and Ms. Juran discussed six cases, with two being handled as pre-hearing consent orders and four being handled as confidential consent agreements.

Action Item:

The Board requested that Board staff monitor the number of medication error cases involving pediatric patients received for

the next six months and provide the Board with this information.

MISCELLANEOUS:

- Request for Consideration of Amending Guidance Document 110-9, Major 24 regarding Definition of "Low Volume":

Ms. Juran reminded the Board that USP Chapter 797 allows sterile compounding of hazardous drugs in an area not physically separated from other preparation areas if the compounding of hazardous drugs is limited to a "low volume". To offer guidance to the inspectors, the Board had defined "low volume" at the June board meeting to mean no more than 15 compounded hazardous preparations per week or as defined by USP. Subsequent to the June board meeting the Board received a letter from Hank Rahe, Technical Director, Containment Technologies Group, Inc., requesting the Board amend the definition of "low volume" in Guidance Document 110-9, Major 24, to place the burden of proof on the manufacturer of the engineering control to state the low-volume benchmark based on independently produced data and studies. Mr. Rahe was present at the board meeting and offered comment that with the use of a Containment Aseptic Compounding Isolator (CACI) a much larger volume of hazardous drugs can be compounded safely compared to a Class II biological safety cabinet.

Motion:

The Board voted unanimously to refer the request for amending the definition of "low volume" in Guidance Document 110-9, Major 24, to the regulation committee for further review and for Board staff to obtain any additional information from industry experts for consideration by the committee and full Board. (motion by Shinaberry, second by Allen)

- Request for Guidance for Reconciliation of Perpetual Inventories:

Staff requested guidance from the Board concerning "reconciliation" during a perpetual inventory of Schedule II drugs as required in Regulation 18VAC 110-20-240. The Board discussed that the perpetual inventory record should accurately reflect the "physical count" of the Schedule II drug on-hand at the time of inventory. Additionally, the Board agreed that reconciliation involves a comparison of the "physical count" and the "theoretical count" and that a recording must be made explaining any difference between the two counts. The Board agreed to clarify these expectations in Guidance Documents 110-9 and 110-16.

Motion:

The Board voted unanimously to amend Guidance Document 110-9, Major Deficiency 15, and Guidance Document 110-16 to clarify that the perpetual inventory record must accurately

indicate the "physical count" of the Schedule II drug on-hand at the time of inventory and that the "reconciliation" required at least monthly means to record an explanation for any difference between the physical count and the theoretical count. (motion Kozera, second by Adams)

- Review Joint Commission's Study Recommendations

Ms. Juran briefly shared with the Board the study reports that were presented to the Joint Commission on Health Care on September 19, 2011. The two studies resulted from the General Assembly referring the following bills to be studied: HB 1961, HB 1966, and SB 878. No action was taken by the Board at this time.

- Concerns Regarding 15-Minute Prescription Guarantee Dispensing Policies by Pharmacists and ISMP:

Ms. Juran reviewed with the Board a letter received from a pharmacist expressing concerns for his employer, Harris Teeter Pharmacy, intending to implement a "15-minute Prescription Guarantee" in August 2011, similar to the policy previously implemented by Rite Aid Pharmacy. The letter references another letter from the Institute for Safe Medication Practices (ISMP) sent to the National Association of Boards of Pharmacy (NABP) requesting NABP "explore and assist members in employing methods to eliminate inducements to consumers that insinuate or promise prescriptions will be dispensed within timeframes that may compromise patient safety." This letter from ISMP was shared with the Board, along with NABP's response to ISMP. In that response, NABP expressed a shared concern and requested ISMP share verifiable information to identify and substantiate concerns noted by ISMP. During the discussion of the letters, Board counsel advised that prohibiting a pharmacy from offering a 15-minute prescription guarantee might be construed by the U.S. Federal Trade Commission as a restraint of trade absent an express statutory provision authorizing the Board to restrict/prohibit this practice. The Board expressed concerns for the 15-minute prescription guarantee policy and that it would like to review any information provided by ISMP to NABP for future consideration of this matter.

Motion:

The Board voted unanimously to draft a letter to NABP expressing concern for the "15-minute prescription guarantee" policy and requesting that any information provided by ISMP be shared with the Board for future consideration of this matter. (motion Rhodes, second by Kozera)

- Schedule Dates for 2012 Full Board Meetings:

Ms. Juran stated that meeting dates for the full board meetings needed to be scheduled for the upcoming year. The dates agreed upon were March 13, 2012, June 12, 2012, September 19, 2012 and December 12, 2012.

REPORTS:

- Report from PMP: Carolyn McCann, Deputy Director, Prescription Monitoring Program (PMP), addressed the Board on upcoming changes that will be taking place. On October 19, 2011, the reporting system will shut down for a system upgrade and reopen on October 24, 2011 to accept new data. Ms. Yeatts reviewed a legislative proposal submitted by the PMP to Dr. Cane for consideration. Additionally, she stated on October 1, 2011 regulatory changes regarding reporting requirements will go into effect, and data will be rejected after January 1, 2012 if the new format is not utilized.

- Chairman's Report-Announcement of Committee Appointments: Ms. Abernathy reviewed with the Board the upcoming committee appointments for the 2011/2012 year.

- Report on Board of Health Professions: Robbie Rhodes reported that the Regulatory Research Committee met on July 29, 2011 to receive public comment on the scope of practice of nurse practitioners. Comments that were received supported nurse practitioners being given autonomous prescription authority. On October 14, 2011, the committee will meet for a round table discussion regarding nurse practitioners' scope of practice and team delivery. The August 2, 2011 full board meeting was cancelled and the next meeting is scheduled for October 24th. There have also been several recent appointments made to the Board of Health Professions and these new appointees will be attending the October 24th meeting.

- Report on Licensure Program: Mr. Johnson reported that the Board issued 1,230 licenses for the period of June 1, 2011 through August 31, 2011, including 397 pharmacists and 586 pharmacy technicians. Inspectors performed 293 facility inspections including 89 routine inspections of pharmacies: 18 resulted in no deficiency, 23 with deficiencies, and 48 with deficiencies and a consent order. No new applications for innovative (pilot) programs were received. There are currently three active pilot programs: Institutional Pharmacy Solutions, Tech Bar Code Scan (Omnicare), and Dulles Urgent Care Center – InstyMeds Automated Dispensing Systems.

- Report on Disciplinary Program: Ms. Reiniers-Day reported that, as of September 19, 2011, there were 233 open cases docketed for the Board, as follows: entry-two; investigation-64; probable cause-90; administrative proceedings division-two; informal-15; formal-two; and pending closure-58.

  Ms. Reiniers-Day also reviewed the Quarterly Performance Report for the fourth quarter (April 1, 2011 through June 30, 2011) regarding patient-care cases that indicate a clearance rate of 93%, pending caseload greater than 250 business days of 8% and 96% closure rate within 250 business days.

Action Item:

The Board requested that, for future meetings, Board staff provide a trend report to review the tracking of cases, to include the number of cases opened and closed.

- Executive Director's Report

Ms. Juran reported that there will be a USP Live Webinar named "Compounding Total Parenteral Nutrition Preparations: A 2011 Investigation of Bacterial Outbreak" to discuss factors that resulted in the contamination of compounded TPNs that caused an outbreak of serratia marcescens earlier this year that killed nine people. Registration is full at this time, but that USP will re-air at a later date on their website for free. Ms. Juran also stated that she will be attending the NABP Executive Forum, September 21–22, 2011 in Chicago and that she will be leading the panel discussion on physician dispensing requirements. She will also attend the NABP/AACP-District 1 & 2 Meeting, October 20-22, 2011 in Boston, along with Ms. Allen, Mr. Adams, Ms. Munden, Ms. Shinaberry, and Mr. Leo Ross. Additionally, she was invited to participate this upcoming January on NABP's Task Force to review and recommend revisions to the Controlled Substances Act. She also reported that DEA had issued a notice of intent to temporarily schedule three synthetic cathinones under temporary scheduling provisions to avoid any hazards to public safety.

NEW BUSINESS:

There was no new business at this time.

CONSIDERATION OF CONSENT ORDERS:

There were no consent orders for consideration.

REQUESTS FOR EXAMINATION ACCOMMODATION:

Motion for closed meeting:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia for the purpose of consideration and discussion of medical/mental health records contained in an accommodation request that are excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations. (motion by Kozera, second by Dabney).

Motion to certify the purpose of the closed meeting:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for

executive meeting were heard, discussed, or considered during the closed session just concluded. (motion by Kozera, second by Dabney).

Motions:

The Board voted to approve the examination accommodation request from Abiy Tekle allowing him twice the normally allotted amount of time for completing the Virginia Federal and State Drug Law Examination and a private room with a proctor appropriately monitoring his testing experience. (motion by Kozera, second by Dabney; opposed by Adams and Stelly).

Mr. Casway departed the meeting at 2:00 p.m. and Rachel Baer, Assistant Attorney General, served as board counsel for the remainder of the board meeting.

FORMAL HEARINGS:

BRIAN P. MUSGROVE
Pharmacist Reinstatement Applicant
License # 0202-009540

Mr. Musgrove appeared to discuss his application to reinstate his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the August 5, 2011, Notice.

Corie E. Tillman Wolf, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Ms. Allen did not participate in this hearing.

Cecile Custer, DHP Senior Investigator, testified on behalf of the Commonwealth.

Brian P. Musgrove testified on his own behalf.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the board voted 8-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Brian P. Musgrove. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day and Rachel Baer attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the board re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Kozera and duly seconded by Mr.

Dabney, the board voted 8-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Wolf and amended by the board and read by Ms. Baer.

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the board voted 8-0 that Mr. Musgrove's application to reinstate his license to practice as a pharmacist be approved contingent upon certain terms and conditions.

PHILIP D. RICHARD
Pharmacist Reinstatement Applicant
License # 0202-004237

Mr. Richard appeared to discuss his application to reinstate his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the August 30, 2011, Notice.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Darren Buss, Pharmacy District Manager, Rite Aid Pharmacy and Nan Dunaway, DHP Pharmacy Inspector, testified on behalf of the Commonwealth.

Philip D. Richard testified on his own behalf.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the board voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Philip D. Richard. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day and Rachel Baer attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the board re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the board voted 9-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the board and read by Ms. Baer.

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the board voted 9-0 that Mr. Richard's application to reinstate his pharmacist license be denied and his license be continued on indefinite suspension for a period of not less than one year.

Adjourn:

With all business concluded, the meeting adjourned at 6:40 p.m.

Gill Abernathy, Board Chairman

12/14/11
Date

Caroline D. Juran, Executive Director

12/14/11
Date