

FINAL/ARRPROVED

**VIRGINIA BOARD OF PHARMACY
DRAFT/ MINUTES OF BOARD MEETING**

December 14, 2011
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:22 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
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
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

INTRODUCTION OF NEW BOARD MEMBER: Ms. Abernathy welcomed Dinny Li, new citizen member, to the Board of Pharmacy.

APPROVAL OF AGENDA: An amended agenda was distributed to the Board members that corrected the page numbering and added under the miscellaneous section "Consider amending Guidance Document 110-41". Additionally, staff requested for approval the inclusion of minutes from the Special Conference Committee and Informal Conference Committee meeting held on December 6, 2011. With these changes, the agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 20, 2011 (Board Meeting); September 27, 2011 (Special Conference Committee and Informal Conference Committee); October 6, 2011 (Telephone Conference Call); October 13, 2011 (Telephone Conference Call), October 19, 2011 (Special Conference Committee and Informal Conference Committee), November 22, 2011 (Special Conference Committee and Informal Conference Committee), and November 29, 2011, (Regulation Committee for Automated Counting Devices,

Automated Dispensing Devices, and Definition of “Low Volume”). Ms. Abernathy recommended adding a statement in the November 29, 2011 Regulation Committee minutes to explain the purpose of the meeting.

MOTION:

The Board voted unanimously to approve the minutes as amended. (motion by Kozera, second by Stelly)

PUBLIC COMMENTS:

Ms. Abernathy called for public comment. Alan Friedman, Kaiser Permanente, stated he would be taking on additional responsibilities. Mr. Friedman introduced Dr. Soumi Saha as the new Government Relations and Government Affairs Officer for Kaiser. Mr. Friedman extended appreciation to Board staff for past assistance and the expeditious manner in which it is generally provided.

DHP DIRECTOR’S REPORT:

Dr. Cane reported the agency continues its work with agency efficiency measures and that the interoperability of the Prescription Monitoring Program (PMP) to Indiana and Ohio has been extended to all registered users of the PMP. The Virginia Health Workforce Development Authority held a meeting in November and has hired a new executive director who will begin January 15, 2012. Dr. Cane also reported that the legislative proposal approved by the Board of Pharmacy to place tramadol and carisoprodol into Schedule IV was submitted to the Secretary’s Office, but was not included in the Governor’s package. However, she did comment that the DEA is federally placing carisoprodol into Schedule IV effective January 11, 2012. Dr. Cane also spoke on the Agency Head Summit she attended here in Richmond where Jim Collins, author of “Good to Great” was the keynote speaker. She summarized some of the key points that Mr. Collins believes is characteristic of a good leader.

REGULATIONS:

Ms. Yeatts provided a status update of the Board’s current regulatory packages. The public comment period for the proposed regulations for the community service boards, behavioral health authorities, and crisis stabilization units ends January 20, 2012. The CQI emergency regulations were signed by the Secretary on December 14th and have been forwarded to the Governor’s office for review. The proposed rules for administrative fees are at the Secretary’s Office. The regulation eliminating an alarm system in emergency services under specific circumstances will become effective December 22, 2011. Additionally, she reported that the public comment period for automated dispensing devices will end on December 21, 2011. She also indicated that there may be legislative proposal regarding the Prescription Monitoring Program that would require a method of payment data field and expand access authority to a federal entity such as the FBI.

AUTOMATED COUNTING DEVICES:

Ms. Abernathy indicated that the Regulation Committee met on November 29, 2011 to consider Delegate Chris Jones’ request to make the run dry requirement in Regulation 18 VAC 110-20-355 less burdensome. The Committee recommended that the full board consider adopting a Notice of Intended Regulatory Action (NOIRA) to amend Regulation 18 VAC 110-20-355 regarding automated counting devices.

Specifically, the committee recommended striking the “run dry” requirement and including the statement, “In the event of a drug recall involving one of multiple lots placed in a cell of an automated counting device in the last four months, all drug shall be removed from the cell and not used for patient care.” The full board received public comment from Alan Friedman, Kaiser Permanente. He indicated that the run dry requirement should be eliminated based on data that he has collected from the vendor, Innovation. Mr. Friedman stated that he is still currently gathering information, however, 3 months may be more reasonable than the 4 month requirement recommended by the Regulation Committee. His concerns with the Committees’ recommendation included: the possibility of unnecessary wasting of drugs; not taking into consideration if a run dry happened to have been performed within the last four months; and lack of exemption if the pharmacy could prove that the recalled drug no longer remains in the cell. He recommended the Board consider broader language and receive public comment. Staff stated that the Board may wish to consider a requirement for routinely cleaning the device per manufacturer’s recommendations to ensure a potential buildup of drug residue does not have negative implications or affect the accuracy of the counting device.

MOTION:

The Board voted unanimously to adopt a NOIRA to amend 18 VAC 110-20-355 regarding automated counting devices to ensure the regulation appropriately addresses public safety concerns, to include the possible dispensing of recalled or expired drugs, and the routine cleaning of the device to prevent drug contamination and ensure counting accuracy. (motion by Allen, second by Yi)

REMOVAL OF “LOW VOLUME” FROM GUIDANCE DOCUMENT 110-9

Ms. Abernathy reported that the Regulation Committee also considered on November 29, 2011 the received request to expand the Board’s definition of “low volume” in Guidance Document 110-9. The term is referenced in USP Chapter 797 regarding allowances for performing sterile compounding of hazardous drugs in an area not physically separated from other preparation areas. Ms. Juran indicated that Board counsel recently advised that the Board may not define the term in guidance since USP standards are simply adopted by reference in statute. It could, however, define the term in regulation after convening an expert panel to determine an appropriate number of hazardous drugs which may be compounded. Additionally, Ms. Juran stated that the USP expert panel previously convened to revise Chapter 797 could not agree on an appropriate number, but that she was informed by USP staff that a newly formed expert panel intends to revisit this issue. The Regulation Committee recommended to the full board to not define “low volume” since USP has indicated its newly formed expert panel will revisit this issue.

MOTION:

The Board voted unanimously to remove the definition of “low volume” from Major Deficiency 24 found in Guidance Document 110-9 and take no further action at this time. (motion by Kozera, second by Allen)

PETITION FOR
RULEMAKING TO PLACE
TETRAHYDROCANNIBOL
INTO SCHEDULE II:

The Board discussed a petition for rulemaking requesting the rescheduling of tetrahydrocannabinol from Schedule I into Schedule II for medical use. Ms. Yeatts indicated that the Board had received two public comments in opposition of the petition and that the DEA had denied a petition for rulemaking in June 2011 to reschedule marijuana federally. Ms. Juran explained that technically tetrahydrocannabinol is not currently scheduled in the Drug Control Act, but is placed in Schedule I federally. Mr. Casway explained that even if tetrahydrocannabinol was placed into Schedule II, the federal rule is more restrictive and practitioners must comply with the more restrictive rule. Alan Friedman, Kaiser Permanente, commented that the federal and state governments are not on the same page and there has been a lot of debate and resistance between the two. Ms. Abernathy stated that she also questioned the efficacy of tetrahydrocannabinol for treating bipolar disorder and was not aware of information to support the claim.

MOTION:

The Board voted unanimously to deny the petition for rulemaking to reschedule tetrahydrocannabinol from a Schedule I drug to a Schedule II drug based on concerns expressed by DEA for why it should not be rescheduled federally. (motion by Munden, second by Rhodes)

REQUEST FOR ONE-TIME
MANDATORY CE ON
EMERGENCY AND
DISASTER PREPAREDNESS:

Karen Mulharen, pharmacist with INOVA Systems, addressed the Board to support her request for the Board to mandate pharmacists obtaining two hours of continuing education, as permitted in § 54.1-3314.1 J, in the subject area of emergency and disaster preparedness. Ms. Mulharen stated that pharmacists in Virginia could benefit from the CE since Virginians have experienced several recent environmental disasters, the state has several military installations, and massive distribution of drugs requires additional training beyond a pharmacist's educational training. Ms. Munden noticed that Ms. Mulharen recommended participation in the Medical Reserve Corp, but that the training is not considered formal CE. Discussion ensued regarding the need to encourage pharmacists to participate in the Medical Reserve Corp and Ms. Mulharen had hoped a mandatory CE requirement may lead to increased participation. Ms. Allen recommended the Board could increase awareness by including an article in the next e-newsletter. Additionally, Mr. Owens recommended that a member or staff could contact the Virginia Department of Health, Office of Emergency Preparedness, to learn of its needs regarding the Medical Reserve Corp and how the Board could raise awareness of the program. Mr. Rhodes moved that the Board deny the request to mandate CE on disaster and emergency preparedness, but instructed the Board to review other subject areas needing mandatory CE and to increase awareness of the Medical Reserve Corp. Ms. Munden seconded the motion, but the motion was subsequently withdrawn by Ms. Rhodes and Ms. Munden.

MOTION:

In a second motion, the Board voted unanimously to deny the request for a one-time mandatory CE requirement in the subject area of emergency and disaster preparedness, but to direct staff to contact the Virginia Department of Health to assess its needs for educating pharmacists and pharmacy technicians to the Medical Reserve Corp and take appropriate actions to increase awareness.

(motion by Stelly, second by Yi)

APPROVAL OF
DISCIPLINARY MINUTES:

The Board's attention was brought to handouts of the minutes from the November 30, 2011 meeting (Panel of the Board, Formal Hearing) and December 6, 2011 meeting (Special Conference Committee and Informal Conference Committee).

MOTION:

The Board voted unanimously to approve the minutes of the November 30, 2011 meeting (Panel of the Board, Formal Hearing) and December 6, 2011 meeting (Special Conference Committee and Informal Conference Committee) as presented. (motion by Kozera, second by Rhodes)

REQUEST TO DISCUSS
CONCERN REGARDING
DIVERSIONS OF
HYDROCODONE DRUG
PRODUCTS:

Mr. Adams brought to the Board's attention his concerns regarding the diversion of hydrocodone drug products from pharmacies within the recent years. Based on his research, he stated that hydrocodone is the most diverted drug and believed that every state shared concerns on how best to prevent diversion.

MOTION:

A motion was made to reschedule hydrocodone containing drug products from a Schedule III to a Schedule II. (motion by Adams, second by Shinaberry)

DISCUSSION:

Mr. Rhodes stated that placing hydrocodone containing drug products into Schedule II may deny nursing home patients legitimate use of the drug based on the more stringent requirements associated with the issuance of a Schedule II prescription. Mr. Rhodes suggested that pharmacists should voluntarily monitor the inventory of hydrocodone containing drug products as good practice.

MOTION WITHDRAWN:

The motion made to reschedule hydrocodone containing drug products from a Schedule III to a Schedule II was withdrawn. (withdrew by Adams, second by Shinaberry)

MOTION:

A new motion was made requiring a pharmacy to inventory 1/3 of the hydrocodone containing drug products on-hand every 30 days such that all hydrocodone containing drug products are inventoried within 90 days. (motion died for a lack of a second)

Mr. Yi stated that the Board needed to discuss the prevention of diversion in general, not just hydrocodone containing drug products. Mr. Kozera stated that monthly inventories of hydrocodone containing drug products would be too onerous given the volume of hydrocodone containing drug products. Mr. Rhodes suggested the pharmacist-in-charge could be required to sign and date invoices of drugs being received as a means of increasing awareness of drug movement. Ms. Stelly stated that the Board could consider increasing disciplinary action against the pharmacist-in-charge, when diversions occur, for not properly securing drug inventory. Vicki Garrison, Pharmacy Inspector, informed the Board that the number of cases received may be a result of effective loss prevention efforts. The Board decided after further discussion to

take no action on the subject at this time.

PHARMACIST TO
PHARMACY TECHNICIAN
RATIO:

Mr. Kozera explained that the § 54.1-3320 was amended in 2010 to remove the 4:1 pharmacy technician to pharmacist ratio and require pharmacists to supervise no more pharmacy technicians than allowed by Board regulation. He requested the Board consider eliminating the 4:1 ratio in Board regulation and allow a pharmacist to exercise professional judgment as to how many pharmacy technicians he may safely supervise at any given time. Ms. Juran explained that the Board attempted to remove the ratio from regulation in 2007 during the periodic review of regulations, but realized that it was also required in statute and would require an amendment of the statute. She clarified that the Board was not responsible for the 2010 legislative proposal for amending the statute. Concern was expressed that a corporation may attempt to decide the number of pharmacy technicians which may be supervised by a pharmacist.

**MOTION/
ACTION ITEM:**

The Board voted unanimously to refer the topic of amending the pharmacist to pharmacy technician ratio in Regulation 110-20-270 to the Regulation Committee for further review. (motion by Kozera, second by Yi)

REQUEST TO EXTEND
DELEGATION OF
AUTHORITY FOR
DISCIPLINARY MATTERS:

Ms. Juran requested that the Board consider extending the delegation of authority to the executive director for the handling of certain disciplinary matters as outlined in guidance document 110-15. She explained that staff was able to resolve approximately 15 cases during the last 6 months using this delegation which improved the efficiency of handling disciplinary matters.

MOTION:

The Board voted unanimously to extend the delegation of authority to the executive director for the handling of certain disciplinary matters as outlined in guidance document 110-15. (motion by Rhodes, second by Adams)

GUIDANCE DOCUMENT 110-
41: "CHANGES A
PHARMACIST MAY MAKE
TO A SCHEDULE II
PRESCRIPTION"

Ms. Juran explained that in correspondence received by the National Association of Boards of Pharmacy on August 24, 2011 from DEA, DEA clarified that pharmacists should use their professional judgment and knowledge of state and federal laws and policies when deciding if it's appropriate to make changes to a prescription such as adding the practitioner's DEA number to a Schedule II prescription or correcting the patient's name or address since this may vary on a case-by-case basis depending on the facts present. Therefore, Ms. Juran requested that the Board consider amending Guidance Document 110-41 to include an allowance to correct the patient's name and address upon verification, or add the prescriber's DEA registration number to the Schedule II prescription.

MOTION:

The Board voted unanimously to amend Guidance Document 110-41 to include an allowance to correct the patient's name and address upon verification, or add the prescriber's DEA registration number

to a Schedule II prescription. (motion by Ms. Munden, second by Ms. Allen)

REVIEW AGENCY'S
CONSIDERATION OF
PAPERLESS LICENSING:

Ms. Juran reported that the agency is considering moving toward a paperless licensing system, with current focus on individuals not facilities, wherein an initial paper license would continue to be issued, but no expiration date would be printed on the license. Additionally, an annual paper license would not be provided upon renewal of the license. Because there have been cases of individuals fraudulently manipulating their paper licenses and the information contained on a paper license really only reflects licensing information at the time it was printed, other states have moved toward encouraging verifications through primary source verification. Ms. Munden stated that North Carolina has implemented a paperless licensing system and is not aware of problems associated with it. Additionally, Ms. Juran stated that Board counsel agreed that the posting requirement in §§ 54.1-3314 and 54.1-3430 could potentially be met by posting the initial license. She reminded members that this issue is still under review by the agency, but that she will report any decisions made on the subject in the future.

REPORT ON BOARD OF
HEALTH PROFESSIONS:

Mr. Rhodes stated that currently the Board of Health Professions is still forming committees and intends to continue its review of scope of practice issues for nurse practitioners. He reported that they were still in the process of placing new members on the Board of Health Professions. Ms. Juran indicated that the executive director for the Board of Health Professions informed her that a review of pharmacists' scope of practice may begin in February 2012.

REPORT ON LICENSURE
PROGRAM:

Mr. Johnson reported that the Board issued 933 licenses and registrations for the period of September 1, 2011 through November 30, 2011, including 130 pharmacists, 305 pharmacy interns, and 377 pharmacy technicians. Inspectors performed 266 facility inspections including 134 routine inspections of pharmacies. Thirty-two resulted in no deficiency, 35 with deficiencies, and 67 with deficiencies and a pre-hearing consent order. No new pilot programs were approved. Key Performance Measures for the quarter ending September 30, 2011, identified a 96% customer satisfaction rating and that 100% of applicants were licensed within 30 days of the Board receiving a complete application.

ACTION ITEM:

The Board requested staff to include, somewhat regularly, information regarding common deficiencies in future e-newsletters.

ACTION ITEM:

The Board requested staff to send a blast e-mail in the near future regarding the need to inventory carisoprodol prior to January 11, 2012 as a result of it being placed into Schedule IV federally.

REPORT ON DISCIPLINARY
PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between September 19, 2011, and December 12, 2011. Current open cases are 51 at the investigation stage; 79 at the probable cause stage; 16 at the administrative proceedings

division stage; eight at the informal stage; five at the formal stage; and 157 at the pending closure stage.

Further, Ms. Reiniers-Day reviewed the department's Quarterly Performance Report for the first quarter (July 1, 2011 through September 30, 2011) that indicates a clearance rate of 124%, pending caseload greater than 250 business days of 6% and a 93% closure rate of patient care cases within 250 business days.

EXECUTIVE DIRECTOR'S
REPORT:

Ms. Juran updated the Board on two bills referred to study by the Joint Commission for Healthcare, HB 1966 and HB 1961. The Joint Commission recommended no action at this time. Additionally, she reported that SB 878 that was referred to study by JCHC resulted in a recommendation to introduce legislation requiring the National Precursor Log Exchange for the sale of ephedrine and pseudoephedrine and a recommendation that the Crime Commission review several other options involving amendments to criminal law.

Ms. Juran reported that Ralph Orr, Program Director, Prescription Monitoring Program, reports that PMP has 2600 new registered users which include 550 new pharmacists. There has been a 27% growth in registered user in the past year and 21% growth in prescribers. PMP will be processing 600,000 requests this year compared to 433,000 last year. Statewide access for interoperability will be accessible this week for Indiana and Ohio, and will soon be implementing Michigan, West Virginia and Connecticut. In the summer of 2012, North Carolina and Tennessee are anticipated in participating in the interoperability.

Ms. Juran stated that the US Census report indicated a 13% population growth between 2000 and 2010. Specifically, those individuals age 65 and older increased by 23.3% and age 85 and older increased by 40.3%. This was a higher relative increase than that for the US overall. Ms. Juran requested that the Board take this into consideration when promulgating regulations.

There will be several staffing vacancies in the near future for the Board. Gloria Williams, Licensing Specialist, will retire December 31, 2011. Additionally, Susan Beasecker, Compliance Case Manager, will assume another agency role outside of the Board of Pharmacy as of December 27, 2011. Also, the Board intends to hire a new part-time employee to assist with certain inspection and continuing education matters. Recruitment is ongoing for filling these three positions.

Ms. Juran informed the Board that she was invited to participate as a NABP taskforce member to review and recommend revisions to the Controlled Substance Act. The taskforce will convene January 24-25, 2012 at the NABP Headquarters in Mount Prospect, IL. Expenses are being covered by NABP.

Ms. Juran reported that she is still currently serving as Chairman for the Board of Forensic Science. Staff for the Department of Forensic Science has been providing technical assistance on possible upcoming legislation

regarding bath salts and synthetic cannabinoids.

Ms. Juran stated that she continues to serve on the Rx Partnership Board as an ex-officio member. Additionally, she provided a presentation to the Virginia Association of Free Clinics in Staunton, Virginia last month and provided a webinar to the affiliate clinics who are members of Rx Partnership. She reminded the members that Rx Partnership provides free patient assistance medications to indigent patients using free clinic pharmacies that are primarily staffed with volunteer pharmacists.

Ms. Juran also reported that after the last full board meeting, she attended the NABP Executive Director Interactive Forum which was extremely informative. Panel discussions were held to share information and debate appropriate strategies for addressing difficult topics being confronted by all the boards currently. Additionally, she was invited to participate as a panel member in the discussion regarding the licensing of physicians to dispense drugs. Expenses were paid by NABP.

In October, Ms. Juran attended the Joint AACP/NABP District I and II meeting in Boston, MA. Leo Ross (former Board member), Crady Adams, Empsy Munden, Jody Allen, and Ellen Shinaberry also attended the meeting. The presentations were informative and relevant to current practice issues. Two resolutions were voted on and approved by District I and II to be submitted to NABP for consideration at its annual meeting in May where Ms. Juran will be representing District I and II on the NABP Resolutions Committee. No expenses were paid by the Board.

NEW BUSINESS:

There was no new business at this time.

CONSIDERATION OF
CONSENT ORDER:

**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 a consent order that is 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 Munden).

**MOTION TO CERTIFY THE
PURPOSE OF THE CLOSED
MEETING:**

The Board voted unanimously that only public business matters lawfully exempt 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 Rhodes).

MOTION:

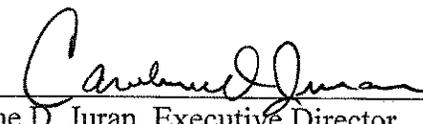
The Board voted unanimously to accept the consent order with amendments for Meredith Disney, pharmacy technician. (Motion by Kozera, 2nd by Allen)

ADJOURN:

With all business concluded, the meeting adjourned at 2:10pm.


Gill Abernathy, Board Chairman

3/13/12
Date


Caroline D. Juran, Executive Director

March 13, 2012
Date