(FINAL/APPROVED 09/12/2007)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 12, 2007
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

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

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
Bobby Ison
David C. Kozera
Diane Langhorst
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Elaine J. Yeatts, Senior Regulatory Analyst
Ishneila Moore, Assistant Attorney General
Tiffany N. Mallory, Administrative Assistant
Sandra W. Ryals, Director, Department of Health Professions
Emily Wingfield, Chief Deputy Director, Department of Health Professions

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

APPROVAL OF AGENDA: Additions to the agenda included consideration of whether to allow a pharmacist licensed in another state to become licensed by examination in Virginia rather than reciprocity and the presentation of a possible summary suspension were added to new business. Hearing no other changes to the agenda, the agenda was approved as amended.

APPROVAL OF MINUTES: Hearing no changes to the minutes of March 28, 2006 and March 29, 2007, the minutes were approved as provided in the agenda package.

PUBLIC COMMENTS: Mr. Beckner called for public comment. There was no public comment.

REPORT OF DIRECTOR, DHP, SANDRA W. RYALS

Ms. Ryals provided an update on strategic planning by the Department in order to meet agency performance standards. Ms. Ryals reported that the agency has three key performance measures and that it was already meeting two of the three measures related to customer satisfaction with the licensing processes and issuance of licenses within 30 days of receipt of a completed application. Ms. Ryals went on to report on plans to meet the third and most difficult measure of completing patient care cases within the 250 day timeline. She provided statistical information to the Board of its caseload as well as the caseload for the other larger volume boards. The Board of Pharmacy has the fourth largest case volume of boards within the department behind nursing, medicine, and dentistry. She reported on historic trends as well as a snapshot of the Board's caseload as of May 2007. Historically, the Board's best performance was 350 days in 2000, but in 2006 with increased caseload, it increased case resolution time to 514 days. Currently the Board has most of its open cases either at the investigations stage or probable cause stage.

In order to meet this goal the Department is looking at a number of different things. In some cases this means hiring additional personnel, but also reviewing processes for opportunities to streamline and become more efficient. This means taking advantage of opportunities already available in law such as increased use of agency subordinates and delegation to staff where appropriate. Ms. Ryals acknowledged that this Board has delegated a number of things to staff such as probable cause determination when appropriate, issuance of pre-hearing consent orders and CCAs where there is guidance, but that it could in certain cases delegate closure of cases. She stated that she is aware that the Board is planning to set a date for the sanction reference committee who will review the use of the sanction reference guidelines, and also will review the use of agency subordinates. She is also very interested in the inspection process and the development of the "speeding" ticket approach to inspection deficiencies using the authority currently available for pre-hearing consent orders.

LEGISLATIVE UPDATE:

- **SPECIFIC TOPIC CONTINUING EDUCATION**

The Board reviewed draft legislation to allow the Board to require up to two hours of specific topic continuing education each year by notifying its pharmacists of the specific requirement prior to January 1 of the year in which the continuing education will be required. Mr. Ross moved, and the Board voted unanimously, to approve the draft legislation and submit it to the Director for inclusion in the agency's legislative submissions.

- **SCHEDULING BILL**

The Board reviewed draft legislation to add lisdexamfetamine, a newly approved drug to treat attention deficit disorder, to Schedule

II in conformity with DEA scheduling action. Mr. Yi moved, and the Board voted unanimously, to approve the draft legislation and submit it to the Director for inclusion in the agency's legislative submissions.

- **RENEWAL DATES**

The Board reviewed draft legislation that would remove language from the Code that assigns specific expiration dates to a number of different types of licenses issued by the Board. This will allow the Board to shift some of its license expirations dates to dates other than December 31 annually. Currently the 20,000-plus licenses issued by the Board expire on December 31 of each year which makes workload during that time period too heavy. The Board had agreed that pharmacists, pharmacy technicians, and possibly pharmacies should continue to renew at that time, but that other types of facilities could be shifted to alternate dates. Mr. Ross moved, and the Board voted unanimously, to approve the draft legislation and submit it to the Director for inclusion in the agency's legislative submissions.

- **MANDATORY REPORTING**

The Board reviewed draft legislation for a new section of law that would require two different types of mandatory reporting. The first type of reporting, in paragraph A of the new section, would somewhat mirror the mandatory reporting requirements of §54.1-2400.6 and require certain persons to report knowledge of either mental or physical conditions, or knowledge of actions on the part of another pharmacist or pharmacy technician that may either make that person's practice a danger to the public or that constitutes a violation of law for which the Board could take action. After some discussion, the Board reached agreement that the requirement for reporting should be made for every pharmacy owner, pharmacist, or pharmacy technician, with language included in the legislation to not obligate reporting if one of these persons knows that someone else has already reported it.

The second type of reporting, in paragraph B of the new section, would require reporting of every dispensing error with all identifiers of both the patient and the dispenser redacted. This would allow the Board to collect information and collaborate with USP, FDA and ISMP concerning types of errors for analysis of cause, and subsequently facilitate improvements to products and systems to reduce the possibility of the same error occurring again. Ms. Russell stated that if the Board would consider approving this portion of the proposal in concept, she would research other states, and the CQI committee would meet and wordsmith this part before it is released for comment from interested parties. She stated that there would need to be a definition of "dispensing error" or similar term to ensure that the Board gets the type of information that will be helpful. After much discussion, the Board agreed to allow the CQI committee to research and wordsmith the proposal with the

understanding that the full Board would review the language in September. Ms. Yeatts explained that we had not received the 2008 legislative proposals instructions and deadline dates, but if it follows previous years, there would be an opportunity for "placeholder" legislation if the deadline for submission to the Secretary is prior to the September 12 Board meeting, so the Board will be able to review and approve the final draft. Mr. Stredler moved, and the Board voted unanimously to approve the draft legislation in paragraphs A, C, and D and approve B in concept with final approval of that exact language at the September Board meeting, and submit it to the Director for inclusion in the agency's legislative submissions.

REGULATION UPDATE:

- **COLLABORATIVE PRACTICE-FINAL**

Ms. Yeatts gave a brief update of current regulation processes. The Board reviewed a summary of public comment on the amendments to the collaborative practice regulations, 18 VAC 110-20-40 et seq. The comments were all positive, commending the Board for easing some of barriers to being able to participate in collaborative practice agreements. Kaiser made one comment requesting clarification of what the Board meant by the phrase related to alternates being at a "location where patients receive services" because they were thinking of centralizing their clinical pharmacy services to a location where patients were not routinely seen. Representatives from Kaiser were present at the meeting, and responded to some questions from Board members as to whether clinical pharmacists could talk to patients by telephone. It was determined that this phrase in the regulations did not mean that some of the contact could not be conducted by use of the telephone. Mr. Kozera moved, and the Board voted unanimously, to adopt the summary of public comment as presented and to respond to the commenters that the Board appreciates their participation in the process and that based on the comments received, the Board will make no changes to the proposed regulations. Mr. Yi moved, and the Board voted unanimously, to adopt the proposed regulations as published as final regulations.

- **NOIRA FROM PERIODIC REVIEW OF REGULATION 18 VAC 110-20-ET SEQ.**

The Board reviewed a draft NOIRA of issues or problems identified with this set of regulations during the periodic review recently concluded. Mr. Yi moved, and the Board voted unanimously to approve the draft NOIRA as presented.

- **PUBLIC HEARING ON PEDIGREE REGULATIONS, 18 VAC 110-50 ET SEQ.**

The Board held a public hearing on the proposed regulation for establishment of a pedigree system. Anne Leigh Kerr, Esquire, Troutman Sanders, provided comment on behalf of PhRMA that there may need to be clarification of 18 VAC 110-50-180 (A) to clarify that a manufacturer or wholesale distributor would not be required to provide information for the authentication of a pedigree for any transaction other than one in which that manufacturer or

wholesale distributor participated. She stated that one member company had concerns that the current language could be construed to require a manufacturer to provide information concerning transactions that were conducted by another party. There were no other commenters during this hearing. Mr. Beckner informed the public that written comments would be received until August 10, 2007.

REPORTS:

- **NABP ANNUAL MEETING REPORT, MAY 19-23, 2007**

Ms. Russell reported on the NABP annual meeting. Ms. Russell and Mr. Beckner attended the meeting on behalf of the Board. Ms. Edwards and Mr. Ross also attended the meeting.

- Ms. Russell stated that she had been successful in her election to the Executive Committee as District II's representative for a three year term, and acknowledged and thanked the Board members who had worked very hard to get her elected. Mr. Beckner also acknowledged the efforts of former board member Mike Ayotte in the campaign. Larry Mokhiber rotated to Committee Chair after serving as President, and Rich Palombo was elected President-Elect which gives District II three members on the Executive Committee.
- Continuing education presentations included sessions on pedigree requirements of Nevada and California, pseudoephedrine sales tracking, regulating for patient safety, and a regulatory update on issues affecting boards of pharmacy.

- **REPORT ON THE DISCIPLINARY PROGRAM**

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that as of June 8, 2007, 253 cases were at the enforcement level, 93 cases were at the probable cause level, 9 cases were at the informal conference level, 31 cases were at the APD level, 10 cases were had Confidential Consent Agreements pending, 5 cases had pre-hearing Consent Orders pending for a total of 401 cases. Further, there were 236 cases at the Compliance Tracking level.

- **REPORT ON LICENSING, INSPECTIONS, NEWSLETTERS AND THE WEBSITE**

Ms. Juran reported that 275 inspections had been performed between March 1, 2007 and June 1, 2007. The majority of the inspections consisted of 182 routine inspections, 28 remodel inspections, 36 new inspections and 20 change of location inspections. Additionally, she reported that 599 licenses had been issued between March 30, 2007 and June 11, 2007. Of significance, 348 pharmacy technician registrations were issued and 125 pharmacy intern licenses were issued. Lastly, Ms. Juran reported that there had been a few changes to the Board's website including new pictures and the Board Powerpoint presentations to the section formerly designated solely to newsletters. Ms. Juran

stated that the Board continuously monitors the website in an effort to provide current and helpful information to its licensees.

- **REPORT ON THE PRESCRIPTION MONITORING PROGRAM ("PMP"):**

Mr. Orr reported some highlights of the annual National DEA conference he attended the previous week:

- DEA plans to release a Methadone training module this summer after their Methadone Mortality Conference in July. Continuing Medical Education credit will be available for completion of the module.
- A more efficient electronic DEA106 is coming soon. It enables the person to edit and provides a greater drop down selection of drugs.
- The CII multiple prescription regulation has been sent to the Department of Justice and will then be sent to OMB. It is anticipated that the final regulation printed in the fall of 2007.
- The electronic prescription regulations are not ready for publication, however, discussions between DEA and HHS are continuing.
- Sometime in June, DEA registrants will be able to update name, address, etc online.

Mr. Orr reported that PMP now holds over 13 million records with about 1 million records being added each month. The number of non-reporting dispensers continues to decrease to less than 1% on the current non-reporting list. He stated that the number of registered users of PMP and noted that to date in 2007, PMP has processed 7881 requests for information compared to 6333 in the 2006 year. Mr. Orr stated that, while the workload is increasing, response time still averages less than 30 minutes and advised that the program hired a new part-time administrative assistant, Debbie Carter. Mr. Orr informed the Board of a new project with Virginia Commonwealth University's School of Medicine to develop a web-based module training program on pain management practices, laws and regulations and the role of PMP. The project should be complete in late September 2007. Mr. Orr advised the effect the recent Purdue Pharma settlement will have on PMP in that, if by the presiding Judge, PMP will receive $20 million that will be placed into a trust for PMP. Only a certain amount of money may be removed from this fund on an annual basis and should fund the program for the foreseeable future. This new funding will enable the program to enhance its marketing and education functions as well as provide stability to the budget. The program forecast had been that in fiscal year 2009, the program would need to use licensing fees for its operation. Mr. Orr invited the Board members to attend the next meeting of the PMP Advisory Committee that is scheduled for July 25, 2007.

NEW BUSINESS:

- **ELECTION OF OFFICERS, BOARD OF PHARMACY, PERIOD JULY 1, 2007-JUNE 30, 2008**

Mr. Kozera nominated, and the Board voted unanimously to elect, Bobby Ison for the office of Chairman. Mr. Stredler nominated, and the Board voted unanimously to elect, Dave Kozera for the office of Vice-Chairman.

- **2008 CALENDAR FOR FULL BOARD MEETINGS**

Dates for the 2008 full Board meetings were determined and are as follows: March 12, 2008, June 11, 2008, September 10, 2008 and December 10, 2008.

- **LICENSURE BY EXAMINATION FOR PHARMACIST IN ANOTHER STATE**

Ms. Russell explained that she recently received an inquiry from a pharmacist initially licensed by examination in Tennessee, and by reciprocity in Maryland where she is currently living and working. Ms. Russell stated that because of a steep professional tax in TN, this pharmacist no longer wanted to keep her TN license, but was afraid to give it up because TN is her base state, and not all states allow reciprocity from a reciprocal state, even though NABP allows and facilitates this now. She requested that MD allow her to re-take the NAPLEX and be licensed there by examination, but MD told her that because she is already licensed by reciprocity, she cannot do that. She then called Virginia to see if we would allow her to become licensed here by retaking the NAPLEX. Ms. Russell stated that she has received similar requests from pharmacists who have had their licensed suspended or revoked in other states and because of the difficulty in getting the license back in the other state, want to start all over again in VA. She stated that NABP states that they can perform a clearinghouse check for VA about an applicant for licensure by exam who has already passed the NAPLEX and been licensed by another state. Ms. Moore advised the Board that unless it had a specific prohibition against allowing a person to be licensed by examination if they were already licensed in another state, and provided there were not disciplinary grounds to deny a license, that the Board would have to allow this. Ms. Russell stated that there was nothing that specifically prohibited it. Based on advice of counsel, the Board took no action, and staff will inform the requestor that she can apply.

COMMITTEE MEETING DATES

Mr. Beckner accepted volunteers for the "Inspection Committee" to work on revamping the inspection process. Ms. Russell stated that she will be contacting the members of the various committees to set dates in June or July as follows:

- **CQI committee**

Ms. Abernathy, Mr. Stredler, Mr. Beckner, and Ms. Edwards with Sammy Johnson and Vicki Garrison

- **Sanction Reference Committee**

Mr. Ison, Mr. Ross, Mr. Kozera and Mr. Yi

- **Drug Disposal Committee**

Mr. Beckner, Mr. Yi, Ms. Edwards, Mr. Kozera, with Becky Snead and Lynn Rubenstein as consultants if needed

- **Inspection Committee**

Mr. Ross, Mr. Ison, Mr. Yi, and Mr. Stredler with Sammy Johnson

and Vicki Garrison

SUMMARY SUSPENSION:

Closed session: Mr. Ison moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Tiffany Mallory, Caroline Juran, Ishneila Moore, Tiffany Mallory, James Schliessmann and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

KEISHA M. HAZELWOOD
Pharmacy Technician
Registration Number:
0230-009019

James Schliessmann, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension.

Reconvene: Mr. Ison moved, and 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 closed meeting were heard, discussed or considered during the closed meeting.

Decision: Mr. Ross moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Keisha Hazelwood poses a substantial danger to the public; and therefore, the registration of Keisha Hazelwood to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. Hazelwood for the indefinite suspension of her registration in lieu of a hearing.

CONSENT ORDER PRESENTATION:

Closed Meeting: Mr. Ison moved, and the Board voted unanimously, to enter into closed session pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Tiffany Mallory, Caroline Juran and Ishneila Moore attend the closed meeting.

Reconvene: Mr. Ison moved, and 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 closed session were heard, discussed or

considered during the closed meeting.

Mr. Ross moved, and the Board voted unanimously, to accept the consent order signed by Ronald Clark.

ADJOURN: With all business concluded, the meeting adjourned at 1:15 p.m.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Chairman

9-12-07
Date