(FINAL/APPROVED 06/12/2007)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 29, 2007
Fifth Floor
Conference Room 2

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

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:15 a.m.

PRESIDING: John O. Beckner, Chairman

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

MEMBERS ABSENT:
Bobby Ison
Diane Langhorst

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Tiffany N. Mallory, Administrative Assistant
Elizabeth Revere, Administrative Assistant
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Emily Wingfield, Chief Deputy Director, DHP

QUORUM: With eight members of the Board present, a quorum was established.

Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2.

APPROVAL OF AGENDA: Mr. Beckner announced the following additions to the agenda: Sandra Ryals, DHP Director, will be addressing the Board to provide an update on several items. A possible amendment to Guidance Document 110-19 relating to continuing education and pharmacy technicians will be reviewed. Additionally, a summary suspension will be considered at the beginning of the meeting. Mr. Ross moved and the Board voted unanimously to adopt the agenda as amended.

REPORT OF DHP DIRECTOR, SANDRA W. RYALS

Ms. Ryals presented and provided handouts to the Board with updates on several initiatives of the administration to include the Governor's Health Reform Commission, Virginia Performs and the agency's new performance measures. Ms. Ryals also updated the Board on the department move. She informed the Board that the agency would be moving from its current location to the former Circuit City headquarters in Henrico County in mid-August. She further advised that the Department will have to be out of the current location by August 31, 2007. The agency will be co-locating with several other state agencies in a negotiated lease expected to provide significant savings.

SUMMARY SUSPENSION:

Closed session:

Mr. Ross moved, and the Board voted unanimously, to convene a closed meeting pursuant to Section 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, Elizabeth Revere, Caroline Juran, Howard Casway, Anne Joseph, Tiffany Mallory, James Schliessmann and Amanda Mitchell attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

MICHELLE WHORTON
Pharmacy Technician
Registration Number: 0230-009375

James Schliessmann, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Amanda E. Mitchell, DHP Adjudication Specialist, was also present. Additionally, Tiffany Mallory and Elizabeth M. Revere were present as Board staff.

Reconvene:

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

APPROVAL OF MINUTES:

The minutes of the January 31, 2007, Board Meeting were

approved as presented.

The minutes of the January 31, 2007, Examination Committee Meeting were approved as presented

The minutes of the March 7, 2007, Ad Hoc Regulation Review Committee Meeting were approved as presented.

PUBLIC COMMENTS:

Becky Snead, Executive Director for the Virginia Pharmacist Association (VPhA), advised the Board that the 20/20 program scheduled to be broadcast on Friday, March 30, 2007, at 10:00 p.m will be on the topic of medication errors. The segment will focus primarily on three areas, including pharmacist workload, pharmacy technicians and the lack of pharmacy counseling.

GUIDANCE DOCUMENT 110-19; CONTINUING PHARMACY EDUCATION REQUIREMENTS VIOLATIONS:

Ms. Russell provided draft amendments to Guidance Document 110-19 and Ms. Yeatts advised that the suggested new language “licensee” in the last paragraph would not work since pharmacy technicians are not licensed, so the draft was changed again to reflect "pharmacist or pharmacy technician" instead. Mr. Ross moved and the Board voted unanimously to amend Guidance Document 110-19 with the aforementioned changes.

LEGISLATIVE UPDATE:

Ms. Yeatts reviewed legislative actions of the 2007 General Assembly that the Department of Health Professions had been tracking.

UPDATE ON REGULATIONS IN PROCESS:

Ms. Yeatts presented the board with an overview of all ongoing regulation processes.

ADOPTION OF PROPOSED AMENDMENTS TO PPG REGULATIONS, 18VAC110-10-10, ET SEQ.:

Ms. Yeatts stated that the Board will need to adopt the proposed regulations on the public participation guidelines as a fast track action. The regulations will then go to the Secretary's and Governor’s offices for approval. Once the regulations have been approved, there will be a 60-day public comment period. She added that once the public comment period is over, the regulations will take effect immediately and the Board will not need to adopt final regulations. Mr. Ross moved and the Board voted unanimously to adopt proposed amendments to the public participation guidelines regulations as a fast track action.

EXEMPT ACTION ON 18VAC110-20-285:

Ms. Yeatts advised that 18VAC110-20-285(A) of the regulations needed to be amended to correct the code site by changing the subsection from “D” to “C”. Mr. Ross moved and the Board voted unanimously to adopt the amendment to 18VAC110-20-285(A) as presented to read as follows: “Unless otherwise prohibited by law, prescriptions may be transmitted by electronic means from the

prescriber of an authorized agent as defined in § 54.1-3408.01 C of the Code of Virginia for transmission of oral prescriptions directly to the dispensing pharmacy. For electronic transmission of Schedule II-V prescriptions, transmissions shall comply with any security or other requirements of federal law. All electronic transmissions shall also comply with all security requirements of state law related to privacy of protected health information."

AMENDMENT OF GUIDANCE DOCUMENT 110-35 TO ADD CHART ORDER USE IN OUTPATIENT PHARMACIES:

In follow-up from the January 31, 2007 meeting, Ms. Russell reviewed draft Guidance Document 110-35, as included in the agenda, with amendments to provide direction related to chart orders being filled by community pharmacies for outpatient or discharge medications. Ms. Yeatts was concerned about placement of the new language and suggested to make a separate section concerning chart orders instead of keeping them in a bullet mark under written prescriptions, which could have the potential to cause confusion. It was agreed that this information should be in a second bullet. Additionally, there was discussion that the use of the term "enough" that was used to modify "information" and "direction" in the second and third bullets of the new language was subjective, therefore, it would be changed to "all information necessary to constitute a valid prescription" in the second bullet and just "direction" in the second bullet. Ms. Abernathy moved and the Board voted unanimously to adopt amendments to Guidance Document 110-35 as presented in the agenda and amended as described above.

DRAFT GUIDANCE DOCUMENT RELATED TO NON-RESIDENT ENTITIES INVOLED IN THE MANUFACTURING AND DISTRIBUTION OF A PRESCRIPTIO DRUG, BUT THAT DO NOT PHYSICALLY POSSESS OR DISTRIBUTE INTO VIRGINIA:

Ms. Russell reviewed a draft guidance document included in the agenda concerning non-resident wholesale distributor inquiries regarding registration with the Board as a non-resident wholesale distributor. Ms. Russell stated that Board staff has received numerous requests to write individual letters to various out-of-state entities advising that if they do not physically possess or distribute any prescription drugs into Virginia, they do not have to be registered with the Board. Ms. Russell advised the Board that these questions may have to do with the Florida pedigree requirements, but the Board staff does not have the time to respond to these individual requests. Further, staff is uncomfortable writing such a response because these entities are not registered with the Board, and staff is relying on a few statements presented by representatives from that particular entity to write a letter telling them they do not have to be licensed. In many cases, staff will receive two separate requests, one from the manufacturer or wholesaler and the second from their legal representative. Ms. Russell advised the Board that the draft guidance document could be scanned on the agency letterhead and posted to the Board of Pharmacy website. Staff would then refer the entities to the website upon receiving requests. Ms. Russell

advised that the draft guidance document may need to be amended in the future pending different scenarios. Mr. Brown moved and the Board voted unanimously to adopt the new guidance document.

REQUEST BY JOE LEMING, M.D., FOR GUIDANCE DOCUMENT THAT ADDRESSES SUBSTITUTION OF ALBUTEROL CFC INAHLERS WITH HFA INHALERS:

Ms. Russell reviewed the draft guidance document included in the agenda regarding HFA inhalers being substituted for albuterol CFC inhalers. The guidance document was a result of a request from Joe Leming, M.D., for the Board to allow pharmacists to substitute the HFA formulation on prescriptions where the CFC formulation had been previously dispensed but was no longer available. The Board agreed that if the prescription was not specifically written for albuterol and not albuterol "CFC", then substitution would not be prohibited. Mr. Stredler moved and the Board voted unanimously to adopt the new guidance document on this subject. There was a question about the accuracy of a deadline date contained within the guidance document. Staff agreed to check the date and amend it if needed before posting the document.

EXCPT EXAM; REQUEST TO BE A BOARD APPROVED EXAMINATION FOR PHARMACY TECHNICIAN REGISTRATION

Ms. Russell discussed the background and history of Ken Shafermeyer's request to have the ExCPT examination be another Board approved examination for pharmacy technicians. At their January 31, 2007, meeting, the examination committee reviewed documents presented by Ken Schafermeyer. The minutes of that meeting reflect that there was still some concern by the committee as to whether the examination met the American Psychological Association (APA) standards for testing, which is required in the Board regulations. Ms. Russell presented an audit letter from Dana P. Hammer, Director of Bracken Pharmaceutical Care Learning Center and Teaching Certificate Program in Pharmacy Education, that was intended to be an analysis of the ExCPT examination, but was actually an analysis of the Virginia exam. Ms. Hammer stated that the ExCPT exam uses the National Commission for Certifying Agencies (NCCA) standards as a guide. Ms. Russell explained that NCCA standards incorporate APA standards and would meet the requirements in the regulations; however, the ExCPT has not been accredited by NCCA. Mr. Schafermeyer stated that they are taking steps in that direction, but that a certification program cannot receive accreditation until it has been in existence for at least two years. Several Board members expressed concern about having a second Board-approved examination in that it may cause confusion since the ExCPT exam was developed by and is offered by the same person who has the contract for the Virginia Exam. There was also a concern that pharmacy technicians may get confused and take the ExCPT exam and pay more money than they need to pay to be registered. The Virginia Exam is a one hour exam costing

$65 versus the ExCPT exam, which is a two hour exam costing $95. Further, Ms. Russell stated that for the exam to be approved as an alternative to The Pharmacy Technician Certification Board (PTCB) there would have to be a change in the statue. Ms. Abernathy continued to express concern as to whether ExCPT was a psychometrically sound exam. There was some concern about whether Dana P. Hammer's credentials qualified her as a psychometrician. Ms. Russell stated that she would contact Washington state to determine their requirements for being qualified as a psychometrician. After further discussions, Ms. Abernathy moved and the Board voted unanimously that it would consider approval of a second examination for pharmacy technicians, but would only reconsider the ExCPT exam upon receipt of supporting documentation and evidence that the test is psychometrically sound and that it meets APA standards.

REQUEST FROM MERCK NOT TO PROVIDE SOCIAL SECURITY NUMBERS FOR OWNERS:

Ms. Russell explained to the Board that Merck has applied for a registration as a non-resident wholesale distributor and submitted a recent letter expressing concerns with the requirement to provide social security numbers for the corporate officers and directors. The letter asked that the Board consider this request. Ms. Russell advised that staff members have communicated to Merck that social security numbers are required by statute, § 54.1-116 as well as Board regulation 18 VAC 100-50-70 and that application information is not subject to the provisions of FOIA. Mr. Casway advised the Board that it did not have the authority to waive the requirement. Mr. Stredler moved and the Board voted unanimously to inform Merck by letter that the Board has no authority to waive the requirements of statutes or of its regulations.

REQUEST FROM ROBERT M. WOLIN, ATTORNEY FOR DAVITA RX, NON-RESIDENT PHARMACIES TO DIPENSE TO DIALYSIS PATIENTS IN VIRGINIA:

Ms Russell provided a handout and gave some background concerning a request by Robert M. Wolin, attorney for Davita Rx, regarding a chain of dialysis centers being an alternate deliver site. There is a non-resident pharmacy associated with approximately 53 dialysis centers located in Virginia, and Davita Rx would like to offer the dialysis patients seen at these centers the option of having dialysis supplies and all prescription medications dispensed by Davita Rx and delivered to the dialysis center for pickup. Davita Rx would not want to limit this service to only those drugs used or administered in conjunction with the dialysis process. Davita Rx argues that this is a fragile population, that transportation to pharmacies is frequently an issue, and that it is more convenient for the patients to receive the medications at the dialysis centers because they already have transportation there three times a week. Further, this entity claims that because this particular population primarily consists of low income patients, the security and integrity of the drugs are compromised by mailing

prescription medications directly to the patients' homes. Ms. Russell advised that, in the past, the Board had not approved entities to be alternate delivery sites unless the second location was a pharmacy, had a physician on site during operating hours, or was either a government agency or was receiving prescription drugs from a government entity and there was a compelling patient safety reason for not delivering the drugs directly to the patient address. Mr. Kozera inquired how this request is different from the community services boards ("CSB"). Ms. Russell explained that the mental health patients are a fragile population due to the fact that many patients do not have a permanent address of record and they are not competent enough to self administer medications. The Board had allowed the "Aftercare Pharmacy" to deliver drugs to the patients at the community service boards for about 10 years before the law actually changed to allow this via a controlled substance registration certificate because of compelling patient safety reasons. Additionally, the majority of the prescription drugs for the CSB patient populations are dispensed by a government agency pharmacy and the CSBs are closely tied to local government with oversight by DMHMRSAS. The concern with delivery to any alternate location is that of diversion with a large quantity of drugs going to one location, as well as the risk of error in the wrong patient being handed the incorrect medication. After further discussion, Mr. Stredler moved and the Board voted unanimously to deny DaVita Rx's request to be allowed to deliver prescriptions for dialysis patients in Virginia to the dialysis centers as alternate delivery locations.

NEW PHARMACIES AND HOW FAR IN ADVANCE OF OPENING SHOULD THE BOARD INSPECT AND ISSUE THE PERMIT:

Ms. Russell provided a background summary regarding inspections and anticipated opening dates for new pharmacies. The Board office has received new applications requesting opening inspection dates ranging from six weeks to two months prior to the anticipated opening date. These requests are usually from pharmacies that are located in a grocery store and their reasons include delays in obtaining the Drug Enforcement Agency (DEA)'s registration and Schedule II order forms, delays in obtaining the NCPDP (a/k/a NABP) number for processing claims, or delays in entering into insurance contracts. Ms. Russell commented that staff is not sure if the reasons given by the pharmacies are valid for obtaining a permit so far in advance of the actual opening of the pharmacy. Ms. Russell explained that most pharmacies have already had the paperwork submitted to DEA and NCPDP and only need to provide documentation that the pharmacy permit has been issued. Staff members have had several conversations with DEA about this and they indicate that they can usually issue the registration within several days. There was some discussion of what would be a reasonable time frame to allow a Board inspection prior to the expected opening date. After further

discussion, Mr. Yi moved and the Board voted unanimously to draft a guidance document with the following language, in concept, to allow as follows: The Board will not issue a permit more than three weeks prior to the designated opening date. Once issued, prescription drugs will be stored no more than two weeks prior to the opening date. When drugs are stored, a pharmacist must be present during the expected normal hours of operation. The pharmacist in charge must be present on a regular basis. If there is a change in the expected opening date, the pharmacy will notify the Board office and the pharmacist will continue to be on-site during regular business hours.

PHARMACY SUPERVISOR FOR PHARMACY INTERNS VERIFICATION FORM:

Ms. Russell informed the Board that staff continues to have difficulties related to applications for pharmacy intern registrations from graduates of foreign colleges of pharmacy. These applicants are trying to obtain the intern registration in order to be eligible for an H1B visa. Last year, the Board revised the application form to require the applicant to state the name of the pharmacy and supervising pharmacist where they plan to work. However, when staff attempted to verify the information provided on one application, the pharmacist named knew nothing about the pending employment and was very upset that her name and license number had been provided as the supervising pharmacist. Ms. Russell commented that staff was not sure whether the prospective employer had given out her information, or if the applicant had simply gotten it from the website. Ms. Russell reviewed a form included in the agenda, titled "Preceptor Verification Form" that would be sent to the pharmacist named on the application for that pharmacist to sign and agree to supervise the applicant. Ms. Edwards moved and the Board voted unanimously to approve the form.

DR. DISAMODHA'S REQUEST TO MAKE REQUIREMENT FOR PHARMACIES TO HAVE CALLER ID ON PHONES AND REQUIRE CHECKING OF PHOTO ID FOR PATIENTS WHEN PICKING UP PRESCRIPTIONS:

Ms. Russell provided a summary of Dr. Amarasinghe's request to require pharmacies to have caller ID on their telephones and to verify with a photo ID that the pharmacy is dispensing controlled drugs to the correct person. Dr. Amarasinghe is concerned that pharmacies are not readily catching forgeries because they are not required to have caller ID from which oral prescriptions are transmitted, and because a photo ID is not required to pick up a prescription. Ms. Russell stated that the process for petitioning for rulemaking was explained to Dr. Amarasinghe, and in a series of subsequent emails, he requested that staff submit the petition on his behalf. Ms. Russell advised the Board that she declined to submit the formal petition, but agreed to place his request on the Board agenda. The Board discussed that photo IDs may not be useful as patients do not always pick up their own prescriptions. Additionally, caller ID may not be of assistance due to complex phone systems that frequently do not show the actual number from

which the call is placed, and also because prescribers may call from a number of phones, including home, cell, or any phone. After discussion, Mr. Stredler moved and the Board voted unanimously to deny Dr. Amarasinghe's request because the Board considered the requirements to be overly burdensome on pharmacies with very little benefit in many cases.

REPORTS:

- **REPORT ON BOARD OF HEALTH PROFESSIONS:** The minutes and a summary from the January 18, 2007 Board of Health Professions meeting was included in the agenda.

- **REPORT ON DISCIPLINARY PROGRAM-FAYE LEMON, DIRECTOR, ENFORCEMENT DIVISION:** Ms. Russell stated that, due to time constraints, this report will be postponed and presented at the next board meeting.

- **REPORT ON THE DISCIPLINARY PROGRAM** Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that as of March 28, 2007, 260 cases were at the enforcement level, 93 cases were at the probable cause level, 20 cases were at the APD level, 46 cases were at the Board level, one case was at the Attorney General Office level, eight cases are at the informal conference level and two cases are at the formal hearing level.

- **REPORT ON LICENSING, INSPECTIONS, NEWSLETTERS AND THE WEBSITE:** Ms. Juran provided an update on licensure statistics stating that approximately 450 additional licenses had been issued since the January meeting. This figure included 38 new licenses and permits issued to entities to dispense controlled substances, pharmacies, and physician selling drugs. Licenses were issued to 35 pharmacists and registrations to 256 pharmacy technicians. Additionally, the inspectors inspected 155 facilities since the January meeting. Ms. Juran also stated that a meeting was recently held with the pharmacist inspectors to promote understanding of the laws, regulations, and consistency within the inspection program. Ms. Juran reminded the Board that the next e-newsletter is scheduled to be posted on the Board's website on May 1, 2007.

- **REPORT ON THE PRESCRIPTION MONITORING PROGRAM:** Ms. Russell provided statistical information on the prescription monitoring program and gave an update on program activities.

SUMMARY OF RETREAT: Betty Jolly presented the Board with a summary of discussion and

action items from the previous day's retreat. Mr. Kozera moved and the Board voted unanimously to adopt the summary and outcomes. (Attachment 1)

ADJOURN: With all business concluded, the meeting adjourned at 2:49 p.m.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Board Chair

Date

CONVERTING CORE VALUES INTO PERFORMANCE STANDARDS
Outcome: Committee formed to review and make any needed modifications to Sanction Reference tool for consideration at next Board meeting.

Discussion by Board for Committee Use:

- Key performance measure of 90% of patient care cases closed in 250 days is a goal to be addressed immediately and with collaborative, dedicated, goal oriented action between Board and staff;
- Data may need scrubbing regarding what is "patient care" in order to determine baseline;
- One tool that has proven useful to other Boards in decreasing days to closure is sanction reference;
- Sanction Reference Point study was discussed as a system to determine appropriate sanctioning for professional misconduct, with no negative actions resulting from its use and the positive result of increasing the potential of respondents acceptance of sanction;
- Board resolved to address key performance measures.

The Board of Pharmacy recognizes high-quality service efforts expected of the Department through Governor Kaine's "Virginia Performs" and encourages effective performance on all three measures, and will begin that focus by examining systems to achieve the 250 day closure on patient care mandate.

TOPIC 1: BOARD FACILITATED DRUG DISPOSAL COLLECTION
Outcome: exploratory committee appointed

- Board Discussion for Committee Use:

  Beginning exploration will be internal, without the immediate input of DEQ or law enforcement;
  Exploration will research what is applicable in Virginia law and regulations for disposal at the present time;
  Exploration will conclude next step of Board action: advisory issues, guidance document developed or regulations sought immediately.

- Expert available for consultation: Lynn Rubinstein, Executive Director, Northeast Recycling Council

TOPIC 2: MANDATE SPECIFIC CONTINUING EDUCATION TOPICS
Outcome: Legislative proposal to be reviewed by Board at next meeting

- Board Discussion for Committee Use:

  Mandate concept applies to pharmacist as well as technicians;

  Mandated course for professionals could include patient safety curriculum, state laws update, or any current core competency;

  Flexibility in mandate would include the choice of no mandate for that year;

Notification could be included with renewals, with compliance audit on completion of mandated course.

TOPIC 3: DISPENSING ERRORS AND PROMOTING PATIENT SAFETY
Outcome: CQI committee appointed

- Board Discussion for Committee Use:
  - The need for the Board is to be proactive in continuous quality care (CQI) for patient safety; and should be presented to pharmacies as risk management;
  - Develop a guidance document for pharmacy sites on patient safety approaches to avoiding dispensing errors;
  - Triage factors most likely to lead to dispensing errors;
  - Triage infractions by importance and limit the number to top 3/top 10 rather a menu of every shortcoming; making inspections more substantive and routinized;
  - Approach quality control as ongoing;
  - Examine legislation in other states, directives from other state Boards; JCHC guidelines'; IOM documents;
  - Involve pharmacist input thorough survey or focus group.
- Partner with national expert organization for national data and trends and methods: ISMP Donna Horn
- Draft language to amend 54.1-2400.6 to expand requirement for reporting to include retail (all) pharmacies will be presented at next Board meeting.
- Draft language for anonymous reporting of medication errors will be presented at next Board meeting.

TOPIC 4: AT THE POINT OF INSPECTION FINES
Outcome: Draft legislation to be reviewed by Board at next meeting

- Legislation needed to allow for immediate fines when on site inspection identifies an infraction
- Ticket issued on site and mailed in later
- Fine goes against the pharmacy permit, not PIC
- Payment responsibility left to the business not the Board

TOPIC 5: LICENSE RENEWAL PROCESS REVIEW
Outcome: Group decision: stagger by license type but retain annual renewal

- Pharmacists' and technicians' licenses in state would continue to be due December 31, annually;
- "Outliers" such as non-residents, due same date, TBD, but not 12/31;

Facility licenses, due same date, TBD, but not 12/31.