Maryland Board of Pharmacy Public Board Meeting

February 16, 2005

Attendance:

Officers: Melvin Rubin, President; Jeanne Furman, Secretary

Commissioners: Joseph DeMino, Donald Yee, Donald Taylor, John Balch, Mark Levi, Ramona McCarthy-Hawkins, Margie Bonnett

Absent: Raymond Love, Treasurer; Mayer Handelman

Staff: LaVerne Naesea, Executive Director; Shirley Costley, Licensing Unit Manager; Patricia Gaither, Administrative Services Manager; Christina Harvin, Regulations Manager; Chandra Mouli, Pharmacist Compliance Officer; Tamarra Banks, Management Information Services; Colin Eversley, Compliance Investigator; Aiyana Waldron, Executive Secretary

Guests: Howard Schiff, MPHA; Dawn Sobiera, UM School of Pharmacy; John McGrath, PEAC; Susan Shern, Pharmacist; Tom Shern, Pharmacist; Stephen Riggin, CVS

1. Record of conflict of interest

President Melvin Rubin called the Public Board Meeting to order at 9:10 a.m. and asked Board Members if there were any conflicts of interest concerning the February 16th, 2005 Meeting. There were no conflicts of interest.

2. Corrections to the Minutes- 01-19-05

Page 1

- Under Guests- 3rd line change NANDONA to NADONA
- Under record of conflict of interest- change December 15th, 2004 to January 19th, 2005

Page 3

• Third paragraph-1st sentence- strike out "noted the discussion related to" and replace with "discussed"

Page 4

- Under Board Action- strike out "Disciplinary committee examine the probationary pharmacist issue further" and replace with "Licensing committee discuss methods of indicating probationary status on the license of pharmacists and report back to the board".
- Under Pharmacy Technician Bill- 4th sentence-change "Sophocles" to "Sophocleus"

Page 6

• 5th Paragraph-1st sentence- add "on behalf of the practice committee" between the words "Love" and "reminded"

Page 7

• Under Long Term Care Task Force-4th sentence-strike out the whole sentence

Board Action

Donald Taylor moved to accept the minutes as amended

3. President/ Executive Committee Report

Melvin Rubin had the audience introduce themselves. He also reminded all in attendance to remain silent while others speak because otherwise, the recording system picks up all background noises making transcribing difficult.

4. Executive Director's Report

New Staff Welcome

LaVerne Naesea welcomed Mr. Colin Eversley, the new Compliance Investigator.

New Space for the Board of Pharmacy

Ms. Naesea reported the possibility of new space for the Board of Pharmacy. If approved, the Board of Pharmacy will be able to move into a much bigger space in the near future. Board Members noted that the Board should also continue looking at other spaces in the meantime.

Board Action

Upon motion by John Balch the Board approved staff to investigate all possible new spaces for the Board of Pharmacy.

Meeting with Delegate Hurson

John Balch and LaVerne Naesea briefed the Board on the recent meeting with Delegate Hurson. Also in attendance were President Rubin and Mark Levi. Discussion included a review of the pharmacy technician proposal, the need for additional office space and exploring the possibility of Board acquiring special appointment status for staff members. Both Mr. Balch and Ms. Naesea mentioned that the meeting went very well. Mr. Balch hopes that meeting with Delegate Hurson will become an annual thing.

Nomination Ballots

John Balch was nominated uncontested as President and Jeanne Furman was nominated uncontested as Secretary. Joseph DeMino and Mark Levi were nominated for the Treasurer position.

Board Action

On motion by Donald Taylor the Board voted to approve the collection of all ballots submitted on February 16, 2005 and obtain the ballots of absent members by phone, mail or email before the next board meeting.

The results of the votes collected on February 16, 2005 and the votes collected after by email and phone are as follows:

John Balch- President (unanimous) Jeanne Furman- Secretary (8 votes) Mark Levi- (6votes)

Staffing Issues

LaVerne Naesea noted that the Board had submitted a request for approval of three new positions and 3 contractual conversions in the state budget proposal. The department and the Governor's office approved all of the positions for inclusion in their budget requests. However, the legislative analyst only recommended approval of the three contractual conversions. Ms. Naesea indicated that the three conversions would possibly be approved by the legislature, but that she will be testifying in Annapolis before the Senate Budget Sub-committee in support of the three new positions which are needed, particularly if the Pharmacy Technician bill is passed during the 2005 session.

4. PEAC

John McGrath supplied the Board with a printed progress report on Board referred and non-Board referred cases for the month of January. Mr. McGrath explained a need for more PEAC monitors.

Board Members requested a more detailed report that will present aggregate information about non-Board referred cases and Board referred cases. The current report does not

provide specifics that will enable the Board to understand the public risk in light of the treatment efforts made by the Board and PEAC. Mr. McGrath was concerned about a more accurate report providing confidential patient information on Non-Board referred cases. He stated that he could not make any decisions concerning the PEAC report until he speaks to his associates at PEAC. Melvin Rubin suggested that the Board meet with John McGrath in the near future to discuss PEAC report specifics.

John Balch asked Mr. McGrath about a permanent office location for PEAC. Mr. McGrath explained that PEAC Maryland does not have an office yet.

5. Regulations/ Legislative Manager Report

Pharmacy Technician Bill

Christina Harvin explained the current issue concerning unapproved changes the bill drafter made to the Pharmacy Technician Bill. She explained that Delegate Rudolph was disturbed by the changes and noted that Melvin Rubin, Raymond Love and Anna Jeffers discussed ramifications the changes made. They proposed 19 amendments to the bill to reflect the intent of the Pharmacy Technician Workgroup. Ms. Harvin summarized the amendments to the Board. Mark Levi, Don Taylor and Ms. Harvin will meet with Delegate Rudolph on February 18, 2005 to discuss the amendments. Ms. Harvin has informed stakeholders that the Board of Pharmacy did not make the changes to the bill and that the changes are being dealt with.

Profile Action Items

Ms. Harvin updated the Board on numerous bills and the Board's position on these bills.

- SB 24 Health Occupations Practicing w/o a License (Letter of Support w/ amendments)
- **HB 431**-Health Occupations- Practicing w/o a License (Letter of Support w/ amendments)
- **HB 54** Clinical Trials Data Bank (**No Position**)
- **HB 65** Prescription Drugs-Canadian Mail Order Plan (Letter of Concern)
- **HB 113** Health Care Malpractice-Emergency Medical Care-Good Samaritan Immunity (Letter of Support w/ amendments)
- **HB 114**-Evidence-Health Care Malpractice-Certain Statements and Conduct (Letter of Support w/ amendments)
- **HB 115**-Health Care Malpractice Claims- Division of Lawyers' Fees- Prohibition (Letter of Support w/ amendments)
- **HB 176**-Prescription Drugs-Senior Citizens-Purchasing Outside the State (**No Position**)
- **HB 203** Income Tax Credit for Services Donated by Health Care Professionals (Letter of Support w/ amendments)
- HB 231-Prescription Drugs-Canadian Mail Order Plan- (Letter of Concern)
- SB 742-Prescription Drugs- Canadian Mail Order Plan- (Legislative Committee will have a position in the near future)

- **HB 233** Public Health- Legibility of Prescriptions Workgroup- Reports (Ms. Harvin will supply the Board with more information in the near future)
- SB 251- Task Force to Study Electronic Health Records- (Letter of Support)
- **HB 277** Health Care Malpractice Actions- Attesting Experts- Qualifications (**No Position**)
- **HB 295** Open Meetings Act- Executive Function- Study (**No Position**)
- **HB 317** Prescription Drug Repository Program (Letter of Opposition)
- SB 372- Crimes- Pseudoephedrine- Prohibitions (Letter of Education)
- **HB 618** State Board of Pharmacy- Registration of Pharmacy Technicians (**Previously updated**)
- **HB 835** Wholesale Prescription Drug and Device Distribution Protection and Licensing Act of 2005 (Concerned with Fiscal Burden)

Board Action

Upon motion by John Balch the Board accepted all the recommendations of the Legislative Committee.

HB 233- Legibility of Prescriptions

Ms. Harvin stated that she spoke with Delegates Mandel and Boutin and that Delegate Mandel suggested changes to make to the interim report. Ms. Harvin informed the Board that the final report submission date was moved from August to July 2005. Jeanne Furman summarized the changes made to the interim report. She also expressed concern in regards to Delegate Mandel wanting the final report in July instead of August. Research is still required and the HB 233 committee needs all time allowed to do such research to ensure a satisfactory final report. Ms. Furman suggested that the Board meet with Delegate Mandel regarding certain specifics regarding the goal of this bill. Mark Levi noted that doctors that have written records are not going to be able to immediately change all their documents over to electronic documents. He feels there should be a period of time that will give all doctors enough time to change over all medical documents to electronic form. Jeanne Furman stated that electronic prescribing could be done without changing all medical records over to electronic form.

6. Practice Committee

Letter from the Office of Health Care Quality (OHCQ) regarding Discharge Orders

John Balch updated the Board on the letter written by OHCQ in regards to taking precautionary measures to ensure patient protection when changing healthcare providers by checking Discharge Orders more accurately. He informed the Board that the letter was almost complete. He stated that he submitted an additional paragraph to the letter to clarify the intent of the letter. The completed letter should be ready in time for the Practice Committee to approve it on March 2nd.

Long Term Care Regulations (Repackaging)

The Practice Committee recommended that assisted living facilities be regulated separately from nursing facilities when it comes to repackaging so that assisted living facilities could utilize the benefits of repackaging. Nursing homes could then also be protected from the problems that could occur from repackaging in nursing homes. John Balch informed the Board of his contact with all the representatives of long term care facilities that recently made presentations concerning the long term care regulations. He mentioned that he extended a formal invitation to all those who were interested in attending the Long Term Task Force meeting in February and noted that none had attended.

Drug Therapy Management

Ms. Harvin informed the Board that Marie Savage is no longer with the Board of Physicians. She is now the Assistant Director of Governmental Affairs. Karen Wulff has taken her place. Ms. Harvin will be meeting with Ms. Wulff in the near future to apprise her of what is going on with drug therapy management.

Influenza Vaccine

Christina Harvin will be meeting with Linda Bethman to discuss the issue with the Epipen. She explained that there have been some difficulties with getting the Board of Nursing to support the concept of Pharmacist's administering emergency medications when needed following the administration of the Influenza Vaccine.

USP 797

Anna Jeffers informed the Board that the USP 797 task force would meet on February 24, 2005. Stakeholders will be in attendance to this meeting, with the agenda of discussing what other states have done (are doing) to address the new sterile compounding standards. Donald Yee mentioned that Chandra Mouli has noted that compounding pharmacies are already complying with USP 797 standards by state regulations. Mark Levi suggested that a representative from the Independent Pharmacy Community should participate on the Task Force.

Questions to the Board

- **Q** How are sample medications, supplied to a physician by a pharmaceutical company, to be dispensed to the end user?
- **A-** The Board defers to the FDA rules on samples.
- **Q** Does a check-off block meet the spirit of HO 12.504. (c.) (1) if the authorized prescriber does not state EXPRESSLY prescription is to be dispensed only as directed?

- **A-** Check-off boxes on a prescription form are problematic because a non-authorized person could check them, including a patient seeking refills. The check-off boxes also do not meet the spirit of Health Occupations Article, § 12-504©(1), Annotated Code of Maryland, since the authorized prescriber does not state EXPRESSLY that the prescription is to be dispensed only as directed. Additionally, this format does not meet Medicaid requirements.
- **Q** What does Maryland regulations say regarding security of the pharmacy?

Do your regulations require the pharmacy to be enclosed with floor to ceiling walls or barriers?

Is anyone allowed to be in the pharmacy when a pharmacist is not on duty?

Are there any restrictions on who may have access to the keys to a pharmacy?

- **A-** COMAR 10.34.05 addresses all security questions
- **Q** Where are the regulations on sample distribution by a third party distributor for pharmaceutical manufacturers located?
- A- The Maryland Code of Regulations (COMAR) relates to the Licensing of Wholesale Prescription Drug Distributors and excludes the distribution of drug samples from triggering the requirement of a license, COMAR 10.34.22.03B(8)(b)(vii). A license, however, would be needed for most other prescription drugs distributed.
- **Q-** What is the validity of a prescription written by a dermatologist to treat hypertension and diabetes in a pregnant employee of that dermatologist?
- **A-** Under Maryland law, physicians must prescribe CDS within their scope of practice. In addition a pharmacist has discretion whether or not to fill any prescription based on professional judgment. Health Occupations Article, §12-501, Annotated Code of Maryland. A pharmacist may notify the prescriber's licensing board of the pharmacist's position regarding the prescription.
- **Q-** For one particular patient, legally, how many different prescriptions can be written on one prescription?
- A- As long as the prescriptions are legible and contain the necessary information for dispensing and labeling, there is no law or regulation that dictates how many prescriptions may be included on one prescription. Keep in mind, however, that more than one prescription on a form increases the possibility of error. Controlled dangerous substances must be on separate prescription forms. Health General Article, §21-220(b)(3), Annotated Code of Maryland.

- **Q-** Is it necessary for the doctor's license number to be on each prescription that he/she writes?
- **A-** A doctor's license number by law, does not have to be on a prescription. Maryland Code of Regulations addresses the content of prescriptions for Dangerous Devices and Substances in COMAR 10.19.03.07.
- **Q-** Is there a recommended method of disposal of Schedule II fentanyl patches in medically supervised settings advocated or mandated by the Board?
- **A-** The patch should be considered medical waste and disposed of accordingly.
- **Q-** A significant amount of fentanyl remains in the patch even after the patient has used the patch for the prescribed amount of time. If the used patch must be returned to the pharmacy, or the disposal must be documented by the nurse removing the patch, does the Board require that the unused amount in the patch be accounted for as a wasted dose? If so, how is the waste amount determined?
- **A-** The Board does not require that the amount of waste be determined.
- **Q-** Is the Board aware of any specific environmental issue that may affect the safe disposal of this product in the state of Maryland?
- **A-** The safe disposal is to consider it a medical waste and dispose of it accordingly.

Board Action

On motion by Mark Levi the Board voted to approve the responses the questions for the Board as amended.

7. Administration and Public Support

Staffing

Patricia Gaither updated the Board on staffing.

Newsletter

LaVerne Naesea commended Ms. Patricia Gaither for a job well done on the Newsletter during the period of the Public Information and Education Officer vacancy. The Board was reminded to submit their entries in a timely fashion.

Flower Mart

Ms Gaither reminded the Board of the Flower Mart on May 18th, 2005. The Public Board Meeting date is changed to May 19th, 2005.

8. Emergency Preparedness

The Board is having a simulated mock drill on March 19, 2005. Monitors from UMBC will be have been contracted by the Department to evaluate all Health Occupation Boards' drills. The Board will be sending letters to all liaisons and team leaders to inform them of the date and notify that further information will be sent. They will not be told where to go or what time to go until the day before the drill. They will be told the scenario the day before along with the location and time. They will receive a short training session for about an hour and then everything else will be hands on. There will be station areas with team leaders assigned. Some pharmacists will be doing repackaging and others will be sent to do triage. Additionally, other pharmacists will be asked to make calls to ask the availability of other volunteers for a tabletop exercise to test the Board's deployment response system. Mr. Rubin noted that this is an ambitious goal but he has confidence in the drill. The initial notice will be sent out by February 17, 2005.

9. Licensing Committee

Joseph DeMino noted that there was no Licensing Committee Meeting for the month of February. Joseph DeMino recommended reciprocity candidates from the licensing unit statistics. The candidates are:

Bosede Oppong	Elena Chiru	Valerie Riege	John Chakan
Jennifer Bonner	Glenn Anderson Jr.	Meredith Summers	Jennifer Zammiello
Brielle Watters			

Board Action

Upon motion by Don Yee the Board approved the nine candidates listed for reciprocity for licensure.

Joseph DeMino summarized the January licensing statistics document that was provided in the Board packet.

ACPE

Mr. DeMino briefed the board on ACPE's Professional Degree Program Accredidation Standards: Release of First Draft of Revised Standards and Invitation to Comment.

10. Management Information Services

Shirley Costley noted that there was a significant drop in on-line applicants for the month of January. Melvin Rubin stated that there would continue to be a lack of on-line applications due to the fact that the applicants still have to type in the titles and other information regarding all CE credits taken.

11. Allowing Pharmacists to Practice in Maryland, Washington D.C. and Virginia

Currently, if a nurse gets licensed with the state of Maryland, they are automatically allowed to practice in the states of Washington D.C. and Virginia. This policy was recently adopted by the Board of Nursing. Donald Yee presented this idea to the Board of Pharmacy. This will help with the shortage of pharmacists in the state of Maryland. Donald Yee volunteered to call Washington D.C. and Virginia to learn more about how the compact between the states works. Jeanne Furman suggested that there be a Task Force to explore this idea. She mentioned that there is potential for problems because the State of Maryland does things differently from the other two states. LaVerne Naesea noted that the Task Force should be under the Licensing Committee.

12. Thomas C. Shern Hearing

Board Action

Don Yee Moved to close the open portion of the public meeting in order to hold the hearing for Mr. Thomas C. Shern based on State Government Article § 10-508 (a) (13)

Board Action

The Board reopened and upon motion of Mark Levi the Board voted to reinstate Mr. Shern with a probation of 2 years.

The meeting was adjourned at 12:00 p.m.