

**Maryland Board of Pharmacy
Public Board Meeting Minutes
May 17, 2006**

Attendance:

Officers: John Balch, President, Mark Levi, Treasurer, and Donald Taylor, Secretary

Commissioners: David Chason, Joseph DeMino, Jeanne Furman, Mayer Handelman, Rodney Taylor, Michael Souranis, and Don Yee

Absent Commissioner: Margie Ann Bonnett

Board Staff: LaVerne Naesea, Executive Director; Colin Eversley, Compliance Investigator; Anna Jeffers, Legislative Officer; and Alicia Carter, Executive Secretary

Board Counsel: Linda Bethman

Guests: Gil Cohen, PEAC; Kim McCollough; Chandra Mouli, Division of Drug Control; Mel Rubin; Mike Swarner, Target; and Howard Schiff, Maryland Pharmacist's Association

I. Call to Order/Record of Conflict of Interest

President Balch called the Public Meeting to order at 9:00 am. There were no conflict of interest declarations. Guest attendees were asked to introduce themselves. President Balch welcomed Donald Taylor as the newly elected Board Secretary and thanked Jeanne Furman for her service as the former Board Secretary.

II. Corrections to Minutes April 19, 2006

Page 1

- Under Commissioners add Mayer Handelman's name to the list

Page 2

- Under NABP, 6th line – “ Ms. Naesea reported that the FDA invited all Boards to begin a partnership in providing a better....” change to “Ms. Naesea reported that the FDA invited all Boards to begin a partnership in providing better.....”

Page 3

- Under Joe DeMino's Report, 7th line – “Mr. Schafenmeyer administers the exam for pharmacy technicians” change to “Mr. Schafenmeyer administers an exam for the pharmacy technicians”.

-Under Joe DeMino's Report, 9th line – “Warren Peacock” change to “Oren Peacock”.

Page 4

- Under Old Business – 4th line – “In addition, PEAC’s is transitioning” change to “In addition, PEAC is transitioning....”
- Under New Business – 3rd line – “PEAC contracts should be reported to (if Board referred) the Board.” delete “(if Board referred)”
- Under New Business – 3rd line – “John Balch inquired about who monitor’s the reporting.... “ delete apostrophe “John Balch inquired about who monitors the reporting....”
- Under New Business – 4th line – “process and if quality assurance is done annually/semi-annually?” delete question mark “process and if quality assurance is done annually/semi-annually.”

Page 8

- Under E, 5th line – “document in on the prescription?” change to “document on the prescription?”

Page 10

- Under B. Long Term Care Task Force – “The request to have the system approved...” change to “The request to approve the use of the system....”

Page 11

- Under C. Licensing Committee – 7th line – “hours have been performed before reciprocating To Whom It May Concern” change to “hours have been performed before reciprocating to Maryland.”

Motion: Joesph DeMino moved to accept the minutes with corrections.

Board Action: The Board voted unanimously to accept the motion.

III. Motion: John Balch asked for a motion to close the public session. Don Taylor moved to close the public session at 9:15 am and to open the closed meeting for the Kim McCullough reinstatement hearing. Jeanne Furman seconded the motion.

Board Action: The Board voted unanimously to accept the motion.

Board Action: The Board voted to reinstate Ms. McCullough under certain conditions. A letter will be prepared and mailed from the Board Counsel.

Board Action: The Board voted unanimously to close the reinstatement hearing for Kim McCullough and to reopen the public session at 10:35 am.

IV. President/Executive Committee Report – John Balch

Mr. Balch thanked Rodney Taylor for participating in the School of Pharmacy’s ACPE accreditation process.

Mr. Balch informed the Board that he plans to review and complete Board member committee assignments by the June meeting. He noted that notification of new Board member appointments had not been issued as of the date of the public meeting.

V. Executive Director's Report – LaVerne Naesea

A. Board Relocation:

Ms. Naesea reported that the Board office telephone system would be down Thursday, May 18th, through Monday, May 22nd. Messages can be left for staff on voice mail or by email. The office is scheduled to be moved to the first floor during the same period.

B. Meeting with Division of Drug Control:

Ms. Naesea reported that she and Tamarra Banks met with representatives of the Division of Control (DDC) regarding their new MIS system for collecting and inputting inspection report data. Drug Control requested what type of information and items the Board would want to have included from the inspection reports. Following that meeting, Ms. Naesea communicated to Ms. Zoltani, Chief for Drug Control, that she was not comfortable with DDC's decision to move forward with the new data collecting system before receiving a response to the Board's request to reorganize the manner in which pharmacy and distributor inspections are performed in Maryland. A copy of the memo to Ms. Zolanti was forwarded to Lisa Ellis at the Department of Health and Mental Hygiene. Ms. Ellis responded to Ms. Naesea that the pending issue would soon be addressed.

Mr. Balch noted to the DDC representative, Chandra Mouli, concerns about pharmacy errors and asked that DDC provide monthly reports on aggregate data about inspections performed on behalf of the Board. Mr. Mouli agreed to provide the requested reports. In addition, Mr. Balch requested that DDC provide a detailed written monthly report (e.g., problems at specific pharmacies) to the disciplinary committee. Mr. Mouli was concerned that DDC inspectors are unaware of pharmacy errors when they inspect a pharmacy, are not asked to collect information on pharmacy drug errors during inspections and are not involved in disciplinary proceedings. Ms. Naesea stated that Mike Souranis and the Licensing Committee are reviewing and updating all inspection forms. Written recommendations received from DDC have been provided to Mr. Souranis. Once the inspection forms are updated, the Board of Pharmacy will train DDC inspectors. Howard Schiff asked whether inspectors check to ensure that patient safety regulations are being followed by pharmacies, specifically related to the requirement of on-going quality assurance programs that include staff education and maintenance of a quality assurance manual. The pre-inspection survey addresses that requirement, and inspectors should verify the information provided in the surveys when they inspect pharmacies.

Ms. Naesea further indicated that she and Colin Eversley are developing a template letter for permit holders that will identify key problem areas as indicated on inspection reports and require that corrective action be taken within a certain time period as determined by

the Disciplinary Committee. DDC will be copied with each letter sent and asked to re-inspect cited pharmacies to insure that the appropriate actions have been taken.

VI. PEAC – Tony Tommassello

Mr. Tommassello updated the Board on PEAC's poster campaign. The poster will be the focal point of a CE presentation to be presented at the Maryland Pharmacists Association meeting in Ocean City. The campaign is intended to make pharmacists aware of the reporting laws and the assistance available through PEAC. Since most PEAC referrals are from chain drug stores, the posters will be specifically disseminated to that venue. Mr. Balch asked Mr. Tommassello about the client update report. Mr. Tommassello responded that he had forwarded the report to Colin Eversley.

VII. Legislation and Regulation Manager Report – Anna Jeffers

John Balch announced that Anna Jeffers would address the Senior Pharmacists at noon today at Howard University. Ms. Jeffers reported on the following:

A. Legislation – Bill signings

1. Prescription Drug Repository Program – signed May 2, 2006
Some Board Commissioners/staff attended the photograph ceremony.
2. Registration of Pharmacy Technicians
There may be a specially scheduled photograph ceremony in a few weeks.
The governor's office will reschedule. The regulation has not been signed but will become law unless vetoed by the Governor.

B. Regulations – status report

1. Prescription Drug Repository Program – The Task Force will submit draft regulations to the Practice Committee and the Board in the near future. .
2. Registration of Pharmacy Technicians – Prepared draft regulations will be reviewed by the Practice Committee at its June meeting.
3. Reinstatement of Certain Revoked Licenses – Regulations are being drafted to complement HB 1569/CR 5702 passed this year regarding the ability for pharmacists to be reinstated after their licenses have been revoked due to certain federal violations.
4. Long Term Care – Work on these regulations will begin in June.
5. Influenza Administration – A change to address fees will be submitted to the Practice Committee in June.
6. USP 797 draft regulations will go before the Practice Committee in July.

VIII. Committee Reports

Wholesale Distributors

Mr. Mark Levi reported that many of the items in the Wholesale Distributors Law could be implemented through regulation. A letter will be sent to Delegate Stern to inform her the committee would like to move forward on promulgating regulations with her approval and to request that her Aide, Ethan Moore, be assigned to participate in the workgroup that will draft the Wholesale Distributors regulations.

Pseudoephedrine

Mr. Mark Levi reported that the Practice committee recommends the proposed regulations be withdrawn because related federally enacted requirements supercede the regulations proposed by the State.

Motion: Jeanne Furman moved to accept the recommendation to withdraw the pseudoephedrine regulations from AELR.

Board Action: The Board voted unanimously to accept the motion.

Negative Formulary

Mr. Mark Levi reported that the Board Counsel, Linda Bethman, has advised the Board of Pharmacy to prepare language to repeal the September 21, 1995 negative formulary policy issued by former Secretary Adele Wilzack. Medicaid would be responsible for issuing the notice through the Maryland Register. The repeal process should be completed by the end of the summer. Mark Levi stated that the Board will publish information about the policy being repealed in the Board's newsletter and on its website.

Motion: Jeanne Furman moved to have the Board of Pharmacy forward the notice to repeal the negative formulary policy of September 21, 1995 to Medicaid.

Board Action: The Board voted to unanimously to accept the motion.

Drug Repository Program

The Practice Committee plans to review the proposed regulations and present them before the full Board at its June meeting. In light of the fact that MedBank will lose its state funding beginning in FY 2007, John Balch asked if voluntary pharmacies could participate in the program. Pharmacies will not be mandated to participate. The question

was raised whether MedBank is considered a worthwhile program. Mr. Balch stated that many people in Western Maryland have benefited from the MedBank program.

Long Term Care Task Force - John Balch

John Balch reported that the Task Force had received a request from the Office of Health Care Quality (OHCQ) which involved Medicaid's (MA) interest in improving hospital discharge summaries. Mr. Balch noted that the Long Term Care Task Force would have input in MA's planned forum to address discharge summaries. OHCQ also requested that the Task Force develop a list of medications that could readily be dispensed in bulk to patients in Long Term Care facilities. Mr. Balch stated that the request to develop the list is being reviewed by the Task Force and they will advise OHCQ next month on this issue. Mr. Balch stated the Task Force also plans to revisit the regulations on re-packaging.

Licensing Committee – Joe DeMino

Joe DeMino reported on statistics for the month of April. A reciprocity candidate will be discussed during the closed session. Chandra Mouli asked whether a pharmacy would need to be re-inspected after it remodels the pharmacy area. Mr. DeMino stated that pharmacies should be re-inspected only after major remodeling is done or when they move to another location.

Matthews Book Company

Mr. Chason stated that the Practice Committee was concerned that the distributor's trade name does not reflect what the company actually does. Mr. DeMino stated that the Licensing Committee was also concerned because the company's name indicates it is a book company. Mr. Balch asked if the Licensing Committee was otherwise recommending approval of the Matthew Book Company distributor's permit. Mr. DeMino indicated that the company is eligible for approval, but that the trade name is misleading. After some discussion, it was concluded that the trade name was acceptable.

Motion: Mark Levi moved to approve issuance of a distributor permit to the Matthews Book Company.

Board Action: The Board voted unanimously to accept the motion.

IX. Constituent Response Letters

a. Phyllis Mahon – Medi-Scripts

Phyllis Mahon wrote to the Board regarding *Generic Substitution* language being included on the bottom of pre-printed prescription blanks, and she asked about any other applicable changes to Maryland requirements regarding initials and dates on pre-printed prescription pads.

Motion: Dave Chason moved to accept the Practice Committee's response which indicated that check-off boxes do not meet the spirit of Health Occupations Article 12-504c(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 many reimbursement sources or Medicaid requirements.

Board Action: The Board voted to unanimously accept the motion.

b. Catherine Woods - ExcelleRx

Catherine Woods asked the Board whether the stocking of CII medications in an automated medication system in a hospice inpatient facility for dispensing to terminally ill patients is allowable under COMAR 10.19.03.08A(4), and also if Maryland law allows for terminally ill hospice patients in IPU to receive appropriate CII medications when necessary through the use of the emergency situation clause in COMAR 10.19.03.08A(4).

Motion: Dave Chason moved to accept the Practice Committee's response to Catherine Woods as amended by Jeanne Furman.

Board Action: The Board voted unanimously to accept the motion.

c. Syed Hussain – Automated pharmacy admixture system

Syed Hussain wrote to the Board concerning the Board's requirements for installing an automatic pharmacy admixture system in a hospital pharmacy.

Board Action: The Board voted unanimously to table the response letter until the Practice Committee developed a recommended response based on discussions held at the meeting.

d. Jim Green – SureScripts

Jim Green wrote the Board concerning requirements for installing an automated pharmacy admixture system in a hospital pharmacy.

The Board agreed with the Practice Committee's response that both Maryland's Confidentiality of Medical Records Act and HIPAA generally permit the disclosure of medical information between health care providers for treatment purposes. However, the letter also advised the inquirer to consult with his private counsel to ascertain the extent to which those exemptions cover the specifics of his situation. It was recommended that the citation for the Maryland Medical Records Confidential Act be included in the letter.

Motion: Dave Chason moved to approve the Practice Committee's letter as amended.

Board Action: The Board voted unanimously to accept the motion.

X. Administration and Public Support – LaVerne Naesea for Patricia Gaither

A. Personnel

Ms. Naesea provided a personnel update for Patricia Gaither, who was not available due to the Board's office move. There is only one candidate eligible for the Compliance Officer position who will be interviewed during the following week by an interview panel comprised of Donald Taylor, Mayer Handelman and LaVerne Naesea.

The temporary receptionist, Donna Watson, had to be dismissed because her contract with the State had expired. (The State requires that temporary employees stay on staff no longer than 6 months.) An emergency contractual employee will be recruited to take Ms. Watson's position. Six candidates are being considered for the Licensing Secretary position. Preparations to recruit for the Database Specialist position are in process. The position description for the Compliance Specialist position is being changed to a Mental Health service position. The Board is reorganizing its system for monitoring pharmacists under Board orders. The restructured position would require experience/education in counseling and mental health services.

The Board hired Matthew Smith, Data Support Assistant, through the State sponsored Quest Program. The Quest Program assists disabled persons with securing employment in state agencies. Mr. Smith possesses a degree in mathematics and recently earned an A+ in network certification. He will perform database, help desk, troubleshooting and other related functions at the Board.

B. Public Information Officer Report – LaVerne Naesea for Summar Goodman

Flower Mart

Ms. Naesea reported that most of the Board staff participated in the very successful event. 243 patient screenings for diabetes and 140 blood pressure screenings were recorded. The School of Pharmacy provided 36 student pharmacists to perform blood pressure screenings and for assistance with decorating the booth. Pharmacist-faculty members also participated in providing counseling services and supervising students. Board members Mark Levi and Jeanne Furman supported the event by answering patient questions regarding their prescriptions. Ms. Naesea thanked Mayer Handelman for referring potential give-a-way donors to the Pharmacist Coalition.

Newsletter

There was discussion on an article concerning customer service from pharmacists. Ms. Naesea stated that the intent of the article was to make pharmacists aware of how to avoid complaints about customer service. Jeanne Furman stated that she had made edits to the article on the Technician bill. Edits will be completed and sent to Donald Taylor for final editing. Ms. Naesea informed the Board that the Newsletter is anticipated to be mailed in June. Summar Goodman has asked for ideas for articles from Board members for the summer issue so that staff can begin developing articles. Ms. Furman stated that she has some ideas and feels that it is the responsibility of Board members to write articles that are pertinent to pharmacists. Ms. Furman commented on her concern about the timeline for publishing the newsletter. Ms. Naesea noted that the newsletter is edited by Board members following internal review and then forwarded to Board Counsel for legal considerations. Ms. Furman suggested that the Board could borrow articles from the NABP newsletter. Ms. Naesea agreed with Ms. Furman's suggestion, and commented that permission from NABP to use articles has been granted and that she has submitted articles from the national group's newsletter on several occasions.

District I & II Meeting

Ms. Naesea reported that Anna Leonhardt, consultant with the Maryland School of Pharmacy, had e-mailed the Board office to request information regarding the District I & II meeting. Ms. Naesea referred Ms. Leonhardt to her contracting agency (the Maryland School of Pharmacy). Ms. Naesea also asked the School to communicate with Ms. Leonhardt regarding the information she requested. Jeanne Furman raised concerns about funding, CE's, and speakers. Ms. Naesea informed Ms. Furman that the School of Pharmacy is responsible for those project areas, and that she was also concerned regarding delays in carrying out agreed upon plans. Mr. Balch stated that he would contact Ms. Leonhardt.

XI. Management Information Services – LaVerne Naesea for Tamarra Banks

The MIS contract with Towson will be renewed. Ms. Banks has developed two draft letters to be used for potential volunteers taking the new on-line Emergency Preparedness course. The link will be accessible to all Maryland licensees. The approved minutes for 2005-2006 have been posted on the Board's website. Photos of the Flower Mart event are also posted on the website. The recent drug recall for sterile vials has been posted on the website. Mark Levi suggested that it would easier to refer people to the FDA. Ms. Banks is currently updating the consumer section of the website.

XII. Nurse Dispensing Formulary

The Garrett County Health Department requested the addition of NuvaRing (birth control drug/device) to the Nurse Dispensing Formulary.

Motion: Don Yee moved that the Board accept the inclusion of the NuvaRing (birth control drug/device) to the formulary.

Board Action: The Board voted to accept the motion.

XIII. Drug Therapy Management (DTM) Committee

Mr. Don Yee reported that the University of Maryland Hospital has submitted applications with protocols for Metabolic Syndrome and Tobacco Use and Dependence. Don Yee informed the Board that the DTM Committee has sent a letter requiring minor changes to the protocols before approval by the Board of Pharmacy and Board of Physicians could be recommended. The application may be presented at the June Board meeting, pending receipt of a response to the Committee's letter.

XIV. Informational

Wisconsin Pharmacy Examining Board Request – Joe DeMino

Mr. DeMino introduced a letter from Carmen Catizone, NABP, regarding the Wisconsin Pharmacy Board's new rule that a pharmacy in another state may not ship, mail, or deliver a prescribed drug or device to patients in Wisconsin unless the pharmacy is licensed in Wisconsin.

Canadian Pharmacies – Donald Taylor

Donald Taylor informed the Board about recent legislation enacted in the state of Nevada to license Canadian pharmacies. NABP emailed the Boards expressing their concern that the licensing of Canadian pharmacies condones and fosters violations of federal law and may jeopardize patients in Nevada that may use the services of these pharmacies. NABP is also concerned that the licensure of Canadian pharmacies will create a double standard for pharmacies, wholesale distributors, and pharmacists licensed by other Boards.

Motion: The Board voted to end the public session at 11:35 pm