

**Maryland Board of Pharmacy
Public Minutes**

November 15, 2006

Officers Present: Mark Levi, President; Donald Taylor, Secretary;
and Jeanne Furman, Treasurer

Commissioners Present: Cynthia Anderson, Margie Anne Bonnett, David Chason,
Joseph DeMino, Harry Finke, Jr., Mayer Handelman, Alland Leandre, and Michael
Souranis

Commissioners Absent: Rodney Taylor

Board Staff Present: LaVerne Naesea, Executive Director; Patricia Gaither,
Administrative and Public Support Manager; Shirley Costley, Licensing Manager; Anna
Jeffers, Legislation and Regulations Manager; Colin Eversley, Compliance Investigator;
Vanessa Thomas-Gray, Compliance Secretary; Alicia Carter, Secretary; and Soumi Saha,
MBOP Intern

Board Counsel: Linda Bethman

Guests: Mike Swarner, Target; Howard Schiff, MPhA; Georgette P. Zoltani, Division of
Drug Control; Teresa McCoy, UMMC-Department of Pharmacy; Tony Tommasello,
PEAC; Jim Polek, Division of Drug Control; Ron Nicholson, VetCentric; Hammad Shah
VetCentric; Gil Genn, NACDS

I. Introduction/Recusals- Members of the Board with a conflict of interest relating
to any item on the agenda were asked to notify the Board at this time. There were
no recusals.

II. Approval of Minutes October 20, 2006

Page 1 – Apostrophe after Vanessa Thomas-Gray’s name

Page 3 – Change “Joe Demino” spell correctly “Joseph DeMino”

Page 3 - Fourth sentence – last paragraph, delete “increasing the salary requirements”
insert “recruitment of”, insert a coma after the word “Officer”, and delete the word
“position.”

Page 4 – Under V. – last sentence, insert “PEAC”, incorrect last name “Sugarman”
change to “Summerfield”

Page 4 – Second sentence delete “Six” change to “25-30”.

Page 5 – Third paragraph – 3rd sentence delete “that” change to “which”

Page 5 – Under VI, #1 – delete “Pharmacies reviewed quarterly” change to “Medication
Chart Review”

Page 6 – Third paragraph – 2nd sentence, add the word “medications”

Page 6 – Third paragraph – 7th sentence, delete “It was explained that the Board could not justify the separation of”

Page 6 – Third paragraph – 8th sentence, delete “operational personnel and pharmacy technicians.”

Page 7 – First paragraph – 5th sentence, delete “?” after the word technician, add “s” to the word “technician”

Page 7 – Third paragraph – 8th sentence, delete “required students to pay only a \$45 per two year” change to “did not register students working as technician”

Page 8 – Move section “B” under Regulations

Page 8 – Under “Legislation” – Second sentence change “September 20, 2006” change to “September 29, 2006”

Page 8 – Under “Legislation” – Third sentence insert “October 13, 2006”

Page 9 – Insert response to Dorcus Taylor letter – “The Board will not place any additional restrictions on Plan B in Maryland.”

Page 9 – Last paragraph – First sentence, change “drafter” change to “draft”

Page 10 – Under First paragraph - #4, change “From” change to “from”

Page 10 – Move “The motion was seconded by Mr. Chason” move from “Board Action” to “Motion”

Page 10 – Move “The motion was seconded by Mr. Chason” move from “Board Action” to “Motion”

Page 10 – Last paragraph – First sentence, delete “The” change to “Division of Drug Control”, insert “associated” add “s” to the word “cost”, insert “with impoundment”.

Page 10- Last paragraph – Fourth sentence delete “Drugs” change to “drugs”

Motion: Mayer Handelman moved to accept the minutes with corrections. The motion was seconded by Donald Taylor.

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

III. President/Executive Committee Report – Mark Levi

Mr. Levi reviewed upcoming meetings that are being planned for the near future, including: a meeting with the Board of Physicians to discuss the increasing problems related to out of state physicians prescribing meds over the internet without prescriber/patient relationships; a meeting with the Board of Nursing to continue the dialogue initiated by former Board President Balch; a meeting with PEAC to discuss the renewal option for the PEAC contract with the Board; and a meeting between Delegate Hammen and the Executive Committee to discuss upcoming legislative issues related to pharmacy in Maryland.

Mr. Levi also reported that the Board will host an Open House of its new offices following the Board meeting on January 17, 2007 from 3 pm until 6 pm.

Mr. Levi congratulated Mike Souranis on the birth of his new son and presented him with a gift from the Board and staff.

IV. Executive Director's Report – LaVerne Naesea

Ms. Naesea attended a legislative audit hearing on November 11th. She reported that the Board of Pharmacy, along with 15 of the 17 total Boards, was cited for not having an independent reconciliation of cash receipts and licenses issued. The Boards disagreed with that audit finding, because not all licenses are issued within a month of receipt of the fees. Applicants have up to a year to meet state requirement exams, submitting documentation, etc.) after their applications and fees have been submitted. The Board was also cited for an employee (the licensing unit manager) having the ability to both approve applications and print licenses. The Board has corrected that audit deficiency by removing that employee's printing privileges.

In response to the auditors' citations, Secretaries Van Mitchell and McCann stated that the Department has limited control of financial oversight and verification of the various Boards because each of the Health Occupations Boards' laws are written differently. They recommended that there be a legislative review of each Board's statutes. Ms. Naesea stated that she has suggested that the Boards consider jointly paying an independent auditor in order to insure that the all of the Boards' procedures are uniform and in compliance with State requirements. This issue will be discussed during the next Council of Boards meeting.

Motion: Donald Taylor moved that LaVerne Naesea should advocate on behalf of the Board in the development of independent auditing procedures by all the Boards and Commissions. Mike Souranis seconded the motion.

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

Division of Drug Control Report

Ms. Naesea gave the Inspection Report for October 2006 submitted from the Division of Drug Control: 40 Pharmacy Inspections; 11 Opening Inspections; 5 Closing Inspections; and 2 Board/DEA/DDC Special Investigations.

Ms. Naesea spoke with Ms. Zoltani, Chief of Drug Control, about the Board of Pharmacy's proposal to perform its own pharmacy inspections that included a timeline beginning in January 2007 with the actual inspections by the Board's inspectors starting in October 2007. Ms. Zoltani reported that she had received an assurance from her supervisor, Mr. Wadja, that a response to the proposal will be provided to the Board before Thanksgiving.

IV. PEAC (Pharmacist Education and Assistance Committee) Client Update – Dr. Tommasello

Dr. Tommasello reported the PEAC statistics for the month of October to the Board: 11 self-referred pharmacists and 17 Board-referred pharmacists, for a total of 28 cases.

Dr. Tommasello disseminated information about the "Bridge to Safety" program being offered by PEAC to Hospital Pharmacies with plans to market the program to Chains. The program is presented by approved PEAC presenters and is designed to educate the

entire pharmacy staff about the “Duty To Report” law regarding substance abuse (COMAR 34.10.05). Discussion about PEAC’s contract with the Board ensued. Ms. Naesea stated that the Board’s contract option with PEAC will end on December 31st.

VI. Legislation and Regulation Manager Report – Anna Jeffers

Corrections to Pharmacy Technician Procedures

Pharmacy Technician Program procedures on the Pharmacy Technician Application were discussed and the following changes were made:

Changes:

- 1st sentence change, #1, under Customary “while” change to “when”
- ^d line, under Customary, add “beginning to”, change “fulfilling” change to “fulfill”, change “their” change to “the”
- 2nd bullet – 2nd line insert “160 hours”
- 4th bullet – last sentence, delete “Evidence of a request for” and delete “submitted to any local police”

Soumi Saha, MBOP Intern, provided information on the required criminal background check (See attachment I).

Motion: The Board voted to approve the Pharmacy Technician Application process with corrections. Mike Souranis seconded the motion.

Board Action: The motion carried. 8 supported, 2 opposed (Donald Taylor and Mayer Handelman).

Prescription Drug Repository Program – Published 9/20/06

The Board received a comment from NACDS that the National Association of Chain Drug Stores (NACDS) had asked for clarification in the regulations that a pharmacy’s participation in the Prescription Drug Repository Program is voluntary. The fact that this Program is voluntary is clearly set forth in Health-General Article, 15-601(c) and (e), Annotated Code of Maryland. After careful consideration of NACDS’s request, the Board of Pharmacy will not be making any revisions or amendments to the published regulations at this time, since the passed statute clearly states that the Program is voluntary.

Motion: Mr. Chason moved to approve the response to NACDS that revisions would not be made to the regulations because the statute, as passed, addresses NACDS’s concern. Jeanne Furman seconded the motion.

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

Pharmacist Administration of Influenza Vaccination

The Pharmacist Administration of Influenza Vaccination fee amendment was published October 13, 2006. The Board received comments from MPhA, NACDS, and MedImmune that stated that the Board’s amendment is beyond the scope of the statute.

However, the statute requires the Board to set fees for the administration of the influenza vaccination. It has come to the Board's attention that there are two separate reimbursement rates for the cost of the influenza vaccine and for the administration of the influenza vaccine. Therefore, the Board voted at the November 15, 2006 Public Board Meeting to revise the proposed new regulation .08 to read:

"Fees charged for the administration of influenza vaccinations may not exceed the Medicare reimbursement rates." Because this is a legally substantive change, the regulations will be repropose in the Maryland Register. MPhA, NACDS and MedImmune will receive a written response from the Board to that effect.

The Board also voted to add to the proposal that CPR Certification may only be obtained through in-person classroom instruction with hands-on learning.

Motion: Jeanne Furman moved to repropose regulations excluding the cost of the vaccine, and adding that CPR certification must be obtained via a live-course. Donald Taylor seconded the motion.

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

Ms. Jeffers reported the status of regulations in progress:

- a. USP 797 – to be submitted to the Communication on Joint Administrative Executive and Legislative Review Committee (AELR);
- b. Wholesale Distributors – still being amended;
- c. Reinstatement – to be submitted to the Communication on Joint Administrative Executive and Legislative Review Committee (AELR); and
- d. Long Term Care – still being amended

B. Legislation

Ms. Jeffers reported on the status of the following legislation:

1. Physicians and Pharmacists – Therapy Management Contracts – Sunset Extension – submitted with the Departmental package;
2. State Board of Pharmacy – Means of Notification of Renewal Revised – Delegate Elliott will sponsor;
3. State Board of Pharmacy – Pharmacist Rehabilitation Committee Membership - Delegate Rudolph will sponsor; and
4. Wholesale Distributor educational briefing to a legislative sub-committee is planned for December or January.

VII. Administration and Public Support – Patricia Gaither

Personnel Update

A permanent position has been approved by the Department of Human Resources for the Executive Secretarial position. Ms. Gaither stated that job specifications are being revised for the Regulations Officer position. Two resumes have been received for the

Compliance Officer position and have been forwarded to the Human Resources Office. The candidate selected for the Administrative Specialist position in the Licensing Unit has declined the Board's offer. Interviews for the Database Officer position are ongoing. The Compliance Secretarial position is planned to be converted from a temporary to a regular contractual position in the near future.

Motion: Michael Souranis moved to pursue the regular contractual position as a permanent position in the Compliance Unit. Jeanne Furman seconded the motion.

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

Public Information Officer Report – Summar Goodman

Ms. Goodman noted the receipt of thank you letters from NABP President Lawrence H. Mokhiber and Carmen A. Catizone, Executive Director/Secretary, for the Board's hosting of the District I and II NABP meeting.

VIII. Management Information Services – Tamarra Banks

Ms. Naesea reported the October statistics for Ms. Banks: 7877 Pharmacists, of which 5404 practice in Maryland; 106 Maryland Pharmacists are under public disciplinary orders; 1622 pharmacies, of which 1117 are located in Maryland; and 808 Distributors, of which 238 are located in Maryland.

The In-House Database Implementation

Towson was given the go ahead in mid-October to complete the Licensing component of the new in-house database. The next review is scheduled for November 20, 2006.

Joseph DeMino requested that pharmacists' license numbers should appear next to the pharmacists' names on the MBOP web site. In addition, Mr. DeMino would like to have the Technical Law Exam updated everyday on the MBOP web site.

Personnel

The Database Specialist Committee, consisting of Board members Margie Bonnett, Alland Leandre, DHMH/IRMA employee Kevin Smith, LaVerne Naesea and Tamarra Banks, have been briefed by the Department's Equal Opportunity personnel. Interviews for the Database Specialist position are scheduled to begin Thursday, November 16, 2006. There are 8 applicants for the position.

IX. Committee Reports

A. Practice Committee – Dave Chason

1. Constituent Responses

a. Dr. Gary Hollenbeck – UPM Pharmaceuticals, Inc.

May a drug development company (with a DEA number) obtain a few CDS tablets from a local pharmacy for comparative dissolution testing against commercially available prescription drug products?

Motion: Mr. Chason moved to accept the Board of Pharmacy response that Dr. Hollenbeck complete a 222 form and submit it to either a pharmacy or a distributor for the purchase of the amount of medication needed for the comparative dissolution testing. Jeanne Furman seconded the motion.

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

b. Rachel Hold-Weiss – Arent Fox PLLC

May a pharmacy that repackaged drugs the first time be permitted to repackage the drugs a second, or possibly a third time, if there is a mid-cycle discontinuation of a drug contained in the blister pack?

Motion: The Board voted to table until the next Board meeting.

c. David G. Miller – Merck

i. May a licensed hospital pharmacy in MD dispense a tri-fold pack of EMEND ® to outpatients of the hospital or its affiliated clinics or Departments?

Motion: Mr. Chason moved for the Board to accept that if the licensed Maryland hospital pharmacy has a general pharmacy permit, then the hospital pharmacy may dispense prescription medications to outpatients. Donald Taylor seconded the motion.

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

ii. If such dispensing is permitted, are there specific labeling, record-keeping or other statutes, regulations or rules of which the permit holder should be aware?

Motion: Mr. Chason moved for the Board to accept that if the hospital pharmacy has a general permit, or a waiver permit that allows dispensing to outpatients, the hospital pharmacy must comply with all labeling and documentation requirements that apply to all pharmacies in Maryland. Mike Souranis seconded the motion.

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

d. Cinda Martin – PharMerica

Are there any regulatory issues from the Board of Pharmacy's perspective regarding the release of medications upon discharge for residents in LTC and other health care facilities in Maryland?

Board Action: The Board referred the question back to the Practice Committee to be sure that the Board's response is consistent with previous responses.

e. Jim Sand – consulting pharmacist in MD

Under what conditions may a patient receive medications upon discharge from a LTC facility?

Board Action: The Board referred the question back to the Practice Committee to be sure that the Board's response is consistent with previous responses.

f. Jack McNamara – Southern Maryland Hospital

The hospital has a subacute care facility located under the same roof as the hospital that is regulated under long term care regulations. If the hospital were to add automatic dispensing systems to that unit, what additional license would the pharmacy be required to have if Class II narcotics were to be dispensed from these machines? Would the hospital have to have a separate DEA license and DEA number of state of Maryland CDS registration?

Motion: Mr. Chason moved for the Board to accept that no additional or separate license is required where a hospital pharmacy is dispensing CII narcotics from an automated dispensing system in a subacute care facility located under the same roof as the hospital. Jeanne Furman seconded the motion.

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

g. Crystal Lipp – PTCB

Is a pharmacy technician required under the new MD pharmacy technician law to maintain their national certification after passing the PTCB exam?

Motion: Mr. Chason moved for the Board to accept that under the Health Occupations Article, Subtitle 6B, Annotated Code of Maryland, there is no requirement that a pharmacy technician maintain his or her national certification after initial registration with the Maryland Board of Pharmacy. Donald Taylor seconded the motion.

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

h. Dr. Dan McDougal – WCHSYS

Examples of e-prescribing were sent to the Board for interpretation.

Motion: Mr. Chason moved that a letter be written to the Board of Physicians clarifying the various formats for prescriptions and physicians signature options. Harry Finke seconded the motion.

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

2. Long Term Care Task Force – Mayer Handelman

Mr. Handelman reported that the LTC Task Force has been working on the Repackaging issue. He stated that only 10 states allow repackaging issue. Mr. Handelman has made a listing of articles from NABP and his thoughts regarding repackaging that he plans to present at the next Board meeting.

C. Licensing Committee – Michael N. Souranis

Statistics – Mr. Souranis reviewed the October statistics. There was discussion about discontinuing having Commissioners review licensing applications for missing information and direct the Board’s staff to perform that task following written guidance from the Licensing Committee.

Motion: Mr. Souranis moved to have approvals of licensing applications reviewed by Board staff unless there are questions. Jeanne Furman seconded the motion.

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

Drug Therapy Management Update – Shirley Costley

Shirley Costley will be contacting the DTM Committee members to remind them that it has been over 60 days since the Anticoagulation Application has been submitted. It was suggested that LaVerne Naesea write the Board of Physicians to remind it of the requirements for reviews of applications that are in the Drug Therapy Management statute.

The public meeting was adjourned at 12:15 pm.

