

Maryland Board of Pharmacy
Public Minutes
April 18, 2007

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

Commission Present: Cindy Anderson, Margie Anne Bonnett, David Chason, Joseph DeMino, Harry Finke, Jr., Alland Leander, and Rodney Taylor

Absent Commissioners: Mayer Handelman and Michael Souranis

Board Counsel: Linda Bethman

Board Staff: Howard Schiff, MPhA; Ron Nicholson, VetCentric, Mike Swarner, Target; Gary Wirth, Giant; Georgette P. Zoltani, Division of Drug Control; Chandra Mouli, Division of Drug Control; Tony Tommasello, PEAC; Chris Wilburn, Walgreens; Gil Genn, MACDS; Steven Riggan, CVS; Michelle Andoll, MPhA; Sue Anderson, HBABCS; Rhiannon Fitzsimmons, John Hopkins; Tyrone Buldock, HCL and Senator Paula Hollinger

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 March 21, 2007

Page 3 – under V – Legislation and Regulation Manager Report, 3rd paragraph – add “s” to the word “regulation” – “regulations”.

Page 3 – under V – Legislation and Regulation Manager Report, 3rd paragraph – add “s” to the word “statue” – “statues”

Page 3 – under Motion – 2nd line – insert the word “to” after the word regulation.

Page 4 – 1st paragraph – 2nd sentence – insert “will be assigned to” after the word Force.

Page 6 – under PEAC (Pharmacist Education and Assistance Committee) 3rd sentence change “5 pharmacists under Board disciplinary orders” change to “5 Board pharmacists being mentored by PEAC.”

Page 9 – under “Pharmacy Technician Application” – 3rd sentence – delete “s” from the word “applicant”

Page 9 – under “Pharmacy Technician Application” – 11 sentence – delete the word “public” and insert the word “permit holders.”

III. President/Executive Committee Report – Mark Levi

Mr. Levi asked members of the Board, staff and guests to introduce themselves. A moment of silence was held for those who lost their lives at Virginia Tech, Monday, April 16th. Board Commissioners were asked to complete the nomination forms in their packets and return to LaVerne or Alicia.

Mr. Levi reported on the meeting with the Division of Drug Control regarding the progression of the upcoming transition of inspection responsibilities to the Board of Pharmacy. The Board has approved the Hospital Inspection form. A report on the Retail Inspection form will be forthcoming for approval by the Board. Inspectors will be able to electronically enter their data into the new inspections forms. The Board will conduct pharmacy opening inspections. The Division of Drug Control will perform follow-up inspections after approximately three months to review the controlled drug inventory. The Board will conduct all annual pharmacy inspections. The Division of Drug Control will perform closing pharmacy inspections - Board inspectors may elect to participate. The Board and DDC will ensure that copies of all inspection reports are provided to each unit.

IV. Executive Director’s Report – LaVerne Naesea

Ms. Naesea directed attention to the Board’s Action Items report in the Board’s and public’s packets. She noted that each action item would be reported on as part of each Manager’s presentation during the Public Meeting. Ms. Naesea acknowledged Senator Hollinger’s attendance at the meeting, and stated that she would be meeting with her the following week to discuss the Board’s efforts and issues. Members of the Board were reminded to submit their 2006 State Financial Disclosure Statements to the State Ethics Commission by April 30, 2007. The form and instructions may be accessed through the State Ethics Commission’s website: <http://ethics.gov.state.md.us>.

Consumer Reports Best Buy Drugs – Sue Anderson

Ms. Anderson provided an overview of Consumer Report’s Best Buy Drugs initiative in follow-up to the March Public Board meeting. The web based initiative is intended to help consumers make better decisions about their prescription medications. The project is privately funded through a New York Foundation, National Institute of Health and a National Library of Medicine Grant. Ms. Anderson’s company, Health Benefit’s ABC’s, is responsible for providing outreach to consumers through linking with various organizations to disseminate information about the initiative. The website address is: www.CRBestBuyDrugs.org. It provides reports comparing different classes of drugs in terms of *effectiveness, safety and costs*. Patients can print the summaries in order to discuss with their prescribers. The reports can also be acquired by consumers through the Senior Reader Van and libraries located in Maryland. Ms. Anderson asked the Board

of Pharmacy to assist Best Buy Drugs with outreach about the project. It was suggested that a representative of Best Buy should attend the upcoming Flower Mart and also to link the project's web site to the Board's website.

Motion: Cindy Anderson moved that the Board of Pharmacy partner in promoting the initiative to consumers and linking the Consumer Report's Best Buy Drugs website to the Board's website. Alland Leandre seconded the motion.

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

V. Legislation and Regulations Manager Report – Anna Jeffers

A. Legislation

Ms. Naesea asked Board members to join her in congratulating Ms. Jeffers for her outstanding tracking of bills during the legislative session. Ms. Jeffers provided the Board with an updated chart of bills that passed and failed. The Wholesale Distributor bill passed after four years. Ms. Jeffers announced that the bill signing dates are tentatively scheduled on April 24th, May 8th and May 17th.

B. Regulation Updates

Pharmacist Administration of Influenza Vaccination

Ms. Jeffers reported that the proposed revised regulations were published March 30, 2007. Fees charged for the administration of influenza vaccine should not exceed the Medicare reimbursement rate.

Pharmacy Technicians and Amended Reinstatement Regulations

The anticipated publication date for the proposed emergency regulations is May 11, 2007. Ms. Jeffers suggested to the Board that they consider extending the anticipated enforcement date of July 1, 2007. The extension date listed on the website will be changed.

Pharmaceutical Services to Residents in Long-Term Care Facilities

The Long-Term Care Task Force will work on revising the Long-Term Care regulations throughout the next fiscal year.

Licensing of Wholesale Prescription Drug or Device Distributors

Regulations must be promulgated for the recently passed Wholesale Prescription and Drug Device bill. Ms. Jeffers ask the Board to begin considering participants for the regulations' workgroup, including assignment of Board member participants and a chair.

Sterile Pharmaceutical Compounding

The proposed Sterile Compounding regulations were published in January 19, 2007. Six official comments were received to which responses were prepared to which responses were prepared the Practice Committee. According to Ms. Jeffers, the regulations will have to be re-proposed if the Board approves the revisions that resulted from the comments. Ms. Jeffers reviewed the draft revisions and requested the Board to accept the changes and the draft response letters.

Motion: Dave Chason moved to accept the revisions made to the proposed regulations and draft response letters as amended. Rodney Taylor seconded the motion.

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

VI. Administration and Public Support – Patricia Gaither

A. Personnel Update

Ms. Gaither reported that the Pharmacist Compliance Officer has resigned. Two previously interviewed candidates are being contacted to determine their continued interest in the position. Interviews are in progress for the Coordinator of Special Programs Health Services within the Compliance Unit. A selection for that position should be made by the next Board meeting. The contractual position for the Health Occupation Investigator is frozen by the State. Ms. Gaither anticipates that the State will approve a freeze exemption request for that position in the near future. The six month contract for the temporary Helpdesk/Webmaster position expired in March, 2007. The Towson University contractors agreed to hire staff to perform those functions for the Board through April 25, 2007. Ms. Gaither stated that the Department is seeking a vendor contract for the Help Desk position.

B. Public Information Officer Report – Summar Goodman

Newsletter (Action Item Completed)

Summar Goodman reported that update articles regarding the Pharmacy Technician registration, Drug Repository Program and pharmacist rehabilitation issues were included in the Spring Newsletter, as noted in the Board Action Items report for March. The Newsletter should go to print as soon as review by the Editorial Committee is complete.

Flower Mart

Ms. Goodman reported that the Board would participate in the Flower Mart on Friday, May 4, 2007 from 11:00 am - 5:00 pm. Staff continues to work on the project with the Maryland School of Pharmacy and the Maryland Pharmacy Coalition. The booth set-up will begin at 7:00 a.m. Judging of booths will commence at 10:00 am. Volunteer

students from the School of Pharmacy are expected to participate. The theme for this year's Flower Mart is "Ninety Years and Still Blooming" and the colors are yellow and black. Board members and other volunteer pharmacists are needed to support the project and should contact Ms. Goodman for more information.

VII. Management Information Services – Tamarra Banks

Tamarra Banks informed the Board that the licensing statistical report has been moved to the Licensing Unit. She noted that Michelle Xu, Database Specialist, is creating a report that will allow anyone to obtain statistical information from STATE2000.

Database – In-house Database Implementation

Ms. Banks disseminated a chart that explained the outstanding tasks to be completed through the Towson contract. A demonstration of various components of the new database system was provided to all Board department managers on March 29, 2007. Ms. Banks reported that the project cost minus Board add-on items (database and helpdesk support during staff vacancies) is \$307,000. The projected cost, including Board added items, is projected not to exceed \$370,000. The anticipated delivery date is July 1, 2007.

HIPDB

The HIPDB database information was sent to NABP April 4th, and the first follow-up was done April 11, 2007. NABP reported that they had not prepared all of the Board's updates yet. Ms. Banks plans to check with NABP on the support they are to provide to the Board this afternoon. She also stated that the Board Office may need to submit the report itself should there be a problem with NABP updating the information in the HIPDB database on the Board's behalf.

MS Access

The Board's budget database has been revised. The revision to the database includes a mechanism for tracking expenditure and balances. The revised database will provide additional features, such as historical tracking from the previous fiscal year's budget submission, so that reports are more comprehensive.

Other Information

Ms. Banks provided information on various *searchable databases* that could be utilized by other units such as the disciplinary unit.

An update of the website revisions as reported by Ms. Banks included:

- a. Pharmacy Technician update posted April 4th (License)
- b. Prescription Drug Repository update March 14th (Legislation & License)

- c. Board Membership updated April 4th (About the Board)
- d. Consumer – Senior Information page updated April 12th (Consumer)
- e. PEAC description revised

New staff PCs were purchased by the Fiscal Unit and installed. Laptops in the possession of former Board members still need to be returned to the Board. Over the past three weeks, DHMH agencies have been experiencing difficulties sending email to certain Internet Service Provider customers (e.g., Comcast). The problem was reported by the Board of Physicians and MHCC. Another systems' virus was also detected on March 29th. MIS staff was able to clear the virus, perform the updates and restore connectivity to the other networks.

A demonstration of a new on-line banking product by Cyber Source is scheduled for Fiscal and MIS staff members on Thursday, April 26, 2007 at the Dental Board. The product works with the Bank of America to provide such services as telephone-banking options in addition to the current on-line banking options. The current system, RPO, works fine, and has been working almost 1 year with few problems. A meeting is scheduled in May with Bank of America to discuss adding an online payment procedure for the 2007 Establishment Online renewal season.

Finally, Ms. Banks reported that Microsoft has announced that it would no longer support Windows XP effective January 31, 2008. Many computer manufacturers are concerned because Vista, the new operating system proposed to replace XP, is reportedly having several problems, and has not been configured to accept all software yet.

VIII. PEAC (Pharmacist Education and Assistance Committee) - Dr. Tony Tommasello

Dr. Tommasello reported that PEAC's caseload consists of 10 cases, of which two are pharmacy students. PEAC has received 31 urine results with no positives; two cases are under assessment; and one patient has been discharged. Dr. Tommasello announced that the October 18, 2007 CE program, "*The Bottom Line in Addiction*", will be held in Calverton, Maryland. There will be presentations on "Best Practices" in dealing with impaired health professionals and on the "Duty to Report". A "save the date" postcard was mailed about the upcoming Program. Detailed information about the entire Program will be mailed.

IX. Committee Reports

A. Practice Committee – Dave Chason

1. Constituent Questions and Responses

- a. *Gary Wirth, RPh, MBA, Ahold USA Pharmacy Department*, asked the Board whether prevention of transmission of disease is an acceptable indication of need

for the sale of needles and syringes. He was referred to (COMAR) 10.13.08.01 Sale of Needles and Syringes or Other Paraphernalia.

Motion: Jeanne Furman moved to accept the Practice Committee's letter as written. Margie Anne Bonnett seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's response that prevention of transmission of disease is an acceptable indication of need for the sale of needles and syringes.

b. *Laura Carpenter, RPh, JD, Quarles & Brady LLP*, contacted the Board concerning requirements for implementation of a refill reminder program. Maryland laws and regulations do not contain more stringent requirements. The Practice Committee recommended referring Ms. Carpenter to the U.S. Department of Health and Human Services (HHS) Privacy FAQ website: (<http://www.hhs.gov/hipaafaq/use/285.html>) and providing information about the content of the website. It was recommended that a general referral to the U.S. Department of Health and Human Services (HHS) Privacy website be made without including specific discussion of the content on the site.

Motion: Donald Taylor moved to amend the letter that the Practice Committee's as written. Alland Leandre seconded the motion.

Board Action: The Board voted unanimously to approve the letter as amended.

c. *Alissa K. Smith, Attorney at Law, Dorsey & Whitney LLP*, contacted the Board concerning whether a contract between a pharmacy and a third party data management company that identifies patients who take certain medications with regular refills would comply with Maryland law and regulations. Ms. Smith was referred to the U.S. Department of Health and Human Services (HHS) Privacy website: <http://www.hhs.gov/hipaafaq/use/285.html> which appears to address this question. It was recommended that a response similar to that provided to Ms. Carpenter (above) be provided to this inquirer also.

Motion: Rodney Taylor moved to accept the change to Practice Committee's letter as amended. Jeanne Furman seconded the motion.

Board Action: The Board voted unanimously to approve the letter as amended.

d. *Rich Dyroff, President, Sarakem Corporation*, contacted the Board to ask whether Maryland has laws and regulations that govern the operation of a small Maryland warehouse which accepts used and outdated drugs for disposal, including controlled dangerous substances, from a national mail back program. The Practice Committee determined that the operation described would require the company to obtain a distribution permit from the Board. The company would be considered a reverse distributor in Maryland because it would accept prescription medication returns for disposal.

Motion: Donald Taylor moved to accept the Practice Committee's letter as written. Cindy Anderson seconded the motion.

Board Action: The Board voted unanimously to approve the response to Rich Dyroff indicating that a distribution permit from the Board of Pharmacy would be required.

e. *Mel Rubin* contacted the Board concerning whether a prescription, presented to a pharmacist either in writing or by phone from the prescriber which needs additional information or clarification (such as adding the MD DEA number), satisfies Maryland law by adding that information into the computer only, without having to also write the information on the paper copy. The Practice Committee determined that additional prescription information, obtained by an additional contact or verification with the prescriber, must be written on the paper copy of the prescription. If the computer will generate a label or document containing all elements required to be on a prescription and can be attached to the hard copy prescription, then it complies with the Maryland Pharmacy Act.

Motion: Harry Finke, Jr. moved to accept the Practice Committee's letter as written. Joe DeMino seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter to Mel Rubin.

f. *Susan DelMonico, RPh, JD, CVS*, contacted the Board of Pharmacy concerning whether a licensed pharmacist employed by a closed pharmacy must be present when prescription drugs and patient prescription files are transferred to another pharmacy. The Practice Committee determined that a licensed pharmacist is required to be present on the premises during the transfer of prescription drugs and patient prescription files. The licensed pharmacist may be employed by, or contracted with, either the buyer or the seller.

Motion: Donald Taylor moved to accept the Practice Committee's letter as written. Margie Anne Bonnett seconded the motion.

Board Action: The Board voted unanimously to approve the response that a licensed pharmacist must be present, but may be employed by, or contracted with, either the buyer or the seller.

g. *Chandra Mouli, Deputy Chief, DDC*, contacted the Maryland Board of Pharmacy concerning whether a pharmacy may advertise the name of practitioners on pharmacy store's bags. The Practice Committee determined that a pharmacist may advertise the name of practitioners on their pharmacy store bags so long as the ads on their store bags were not printed in exchange for referrals to the pharmacist or pharmacy for a product or service to be provided by that pharmacist or pharmacy.

Motion: Jeanne Furman moved to accept the Practice Committee’s letter as written. Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the Committee’s recommendation.

h. Ilene Verovsky, MD Psychiatric Research Center, contacted the Board of Pharmacy concerning the role of a pharmacist employed by a pharmacy that has changed licensure status from a waiver pharmacy (dispensing psychotropic medications to a certain population), to a research pharmacy only. Specifically, (Q) What are the boundaries for the research pharmacist? Is the role of the research pharmacist limited to only things related to the clinical research studies? (A.) The research pharmacist must work within his/her competency which may include counseling patients at a clinic. See the Code of Maryland Regulations (COMAR) 10.34.10.04 Pharmacist Code of Conduct – Competence; (Q) May the research pharmacist give out the non-research medications filled by the other pharmacy to patients? (A) The pharmacist may give out the medication but the Board suggests, however, that there should be a written agreement between the retail pharmacy and the counseling pharmacist delineating the responsibilities of each party; (Q) If the research pharmacist is not interacting with the clinic patients, what is the responsibility of the outside retail pharmacy in terms of patient counseling? (A) Practicing pharmacy includes providing information, explanation, or recommendations to patients about the safe and effective use of prescription drugs. See Health Occupations Article, 12-101(s), Annotated Code of Maryland; (Q) May the research pharmacist communicate with the retail pharmacy to resolve the questions for the patient? (A) Yes, the research pharmacist may communicate with the retail pharmacy to resolve the questions for the patient; and (Q) May the research pharmacist still answer the patient questions regarding the medication that has been dispensed by the retail pharmacy? (A) Yes and you may access the Health Occupations Article of the Annotated Code of Maryland and the Code of Maryland Regulations (COMAR) on the Board’s website at: www.mdbop.org. Click on Laws, Regulations, Legislation and Reports.

Motion: Jeanne Furman moved to accept the Practice Committee’s letter as written. Donald Taylor seconded the motion.

Board Action: The voted unanimously to approve the responses as submitted by the Practice Committee.

B. Long Term Care Task Force – Mayer Handelman - The Task Force did not meet in March, and therefore, did not submit a report.

C. Licensing Committee – Shirley Costley

Statistics

Ms. Costley reported the statistics for the month of March. She noted that pharmacist Robert A Low, Jr. should be removed from the non-renewed pharmacists' list because he renewed his license after the list was generated. The number of pharmacists due to renew in April was 341 compared to 297 April last year; the total renewed to date 313 (244 renewed online), compared to 264 last year (117 online); the non-renewed total was 28 compared to 33 last year.

Under new establishments there were:

Distributor –in-State- (3) – out-of-State – (2)

Resident Pharmacy – 1 New - 15 Non-Resident – 1

Pharmacy w/Waiver –1

Closed:

Distributor – In State 0, compared to 5 last month; Distributor-Out-of-State – 0, compared to 0 last month; Pharmacy – 1, compared to 2 last month; Non-Resident Pharmacy – 2 compared to 0 last month; Pharmacy w/Waiver – 1; compared to 0 last month.

Drug Therapy Management

One new application was received for Metabolic Syndrome. Ms. Costley stated that the application would need approval, but that the protocol has been approved. She informed the Board that the agreement portion of the application has to be approved. Pharmacists on the DTM Committee approved the agreement and are presently awaiting approval from the Physician's Board.

Ms. Costley asked whether non-resident pharmacies that have a CDS license in another state should be required to obtain a CDS license should they want to do business in Maryland.

Action Item: The question was referred to the Division of Drug Control (DDC). The Licensing Committee was asked to write a letter to DDC and to request a citation to law with their response.

Pharmacist Influenza Vaccine Certified

Shirley Costley requested approval from the Board for a draft letter to certified pharmacists that administer the flu vaccine that requests the number of vaccinations they administered during the 2007-year flu season.

Motion: Jeanne Furman moved to approve the letter as drafted. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the letter to certified pharmacists.

Pharmacy Technicians

Ms. Costley also asked that the Board approve the Pharmacy Technician training programs checklist.

Motion: Rodney Taylor moved to accept the Pharmacy Technician training checklist with the amendment to number 3b that the Board will define the term “Nationally Certified.”

Board Action: The Board voted unanimously to approve the Pharmacy Technician training checklist as amended.

Training Programs

Training program applications to pharmacies will not be mailed until after the official comment period. The instructions and cover letter will be posted on the Board’s website after they have both been approved following the May 11, 2007 publication of the emergency regulations.

Action Items: Training program applications will be reviewed by the Licensing Committee for approval. A certificate will be designed for technicians. Work on setting up the database is being completed.

The Board adjourned the Public Meeting at 12:00 pm, and immediately thereafter convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administration Session.