

Maryland Board of Pharmacy
Public Minutes
(Revised)
June 20, 2007

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

Commissioners Present: Cindy Anderson, Margie Anne Bonnet, David Chason, Mayer Handelman, Alland Leander, Michael Souranis, and Rodney Taylor.

Commissioner Absent: Joseph DeMino and Harry Finke, Jr.

Board Staff: LaVerne Naesea, Executive Director; Patricia Gaither, Administrative and Public Support Manager; Anna Jeffers, Legislation and Regulations Manager; Summar Goodman, Public Information Officer; Tamarra Banks, MIS Manager; Vanessa Thomas-Gray, Compliance Investigator; Colin Eversley, Compliance Investigator; Steven Kreindler, Compliance/Health Services Coordinator, and Fannie Yorkman, Licensing Specialist.

Board Counsel: Linda Bethman

Guests: Ron Nicholson, VetCentric; Cherokee Layson-Wolf, Assistant Professor; University of Maryland, School of Pharmacy, Elizabeth Germick, Pharmacist Technician, Walmart; Roopa Pastaksa, Pharmacy Manager, Target; Dr. Tony Tommasello, PEAC; Chandra Mouli, Division of Drug Control; Chris Wilburn, Walgreens; Amaka Pharmacy Student, University of Maryland, School of Pharmacy.

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 May 16, 2007

Page 3 – under section IV, 1st paragraph, 4th sentence, insert the words “Pharmacists certified to administer vaccines”.... before the words Ms. Naesea.

Page 3 – under section IV, 9th sentence, insert “in Maryland” after the word “license”

Page 3 – under section IV, 9th sentence, insert the word “pharmacy” before the word “permit”

Page 6 – under HIPDB, 3rd sentence, insert the words “a representative of” before the acronym “NABP”

Page 8 - Change Practice Letter to Tom Lesko as follows: “The Practice Committee determined that Maryland Law does not address this issue, but the National Association

of Boards of Pharmacy and the American Society of Consultant Pharmacists have urged that this practice be discontinued due to substantial concern regarding the safety of repackaged products. The Practice Committee recommended that the practice be discouraged based on patient risk, and that the inquirer be referred to NABP and ASCP for follow-up information.”

Page 9 – Change Practice Letter-response to MedStar, question #2 as follows: “The Maryland Board of Pharmacy laws and regulations impose no restriction regarding “breaking” unit-dose boxes into smaller quantities”; Insert question and answer to #3 as follows: “Can a waiver pharmacy exist in the same location under the same management to provide patient specific medications? Yes, a waiver pharmacy may exist in the same location under the same management providing patient specific medications provided all pharmacy security regulations are followed.”

Page 10 – 2nd **Motion:** change the word “websites” to “citations”; 2nd **Board Action:** change the word “websites” to citations”

Page 13 – 1st paragraph – 5th sentence, change “the Board determined that since this is a ...on a single premises it...” to “even though this is a pharmacy on a shared premises, it...”

The PEAC (Pharmacists’ Education and Assistance Committee) report was inadvertently omitted from the minutes for May, the report was as follows:

Total PEAC Cases:	13
Pharmacists:	10
Technicians:	1
Pharmacy Students:	2
Drug Testing results:	30
Discharges:	0
New Cases:	1

Motion: Mayer Handelman moved to accept the minutes as amended. Michael Souranis seconded the motion.

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

III. President/Executive Committee Report – Mark Levi

Mr. Levi welcomed Steven Kreindler; the Board’s newly hired Compliance/Health Services Coordinator.

Mr. Levi and Dave Chason co-chaired the initial Wholesaler Distributor Workgroup meeting on June 11, 2007. The workgroup discussed draft regulations that had been prepared prior to the passage of SB 759 to determine which had been addressed in statute.

Action Item: Ms. Jeffers will prepare an amended draft for participants to review at the next meeting on July 9, 2007.

PEAC (Pharmacist Education and Assistance Committee – Dr. Tommasello

Dr. Tommasello noted that the Board Minutes for May had omitted the April 2007 PEAC report for the month of April. The self-referred caseload consisted of a total of 13 cases, of which 10 were pharmacists, one (1) was a pharmacy technician, two (2) were Pharmacy Students. He noted that PEAC had 1 New Case in April. Mr. Tommasello reported receipt of 30 urine screenings of which none were positives and that there were no case discharges for the month of April.

The total number of cases in May was 13 of which 10 were pharmacists, one (1) was a technician, and two (2) were pharmacy students. Twenty-six (26) urine results reflected no positives and there were no discharges, and no new cases for the month of May.

PEAC hosted a booth at the MPhA Annual Convention in Ocean City, Maryland on June 17, 2007. The PEAC Continuing Education Program will be held in Silver Spring, Maryland October 18, 2007 is approved for 7 CE credits.

IV. Executive Director's Report – LaVerne Naesea

Ms. Naesea introduced Steven Kreindler as the Board's new Compliance/Health Services Coordinator.

Ms. Naesea provided the Division of Drug Control Inspection report statistics for May 2007: 44 Pharmacy Inspections; 11 Opening Inspections; 8 Closing Inspections; and 11 Board/DEA/DDC Special Investigations.

Ms. Naesea stated that Donald Taylor, Summar Goodman and she hosted the Board's booth at the MPhA Annual Conference held in Ocean City, Maryland. She noted that participants at the Conference expressed concerns that Board members should attend all MPhA conferences and other meetings. Donald Taylor discussed the MPhA resolution which failed to receive majority support during the Conference. The resolution recommended that the Maryland Board of Pharmacy be officially represented at, minimally, the annually conventions of the major Maryland Pharmacy organizations. i.e. MPhA, MSHP, and MD-ASCP. A second proposed resolution would have required the Board to require pharmacists to complete 2 hours of CEs in Law. That resolution was also defeated.

Action Item: Ms. Naesea noted that she would send Board members a copy of established protocols for participating in association and other meetings.

It was suggested that Board members sponsor a booth at the MD American Society for Consulting Pharmacists (ASCP) Annual Conference.

Motion: Jeanne Furman moved that the Board purchase a booth and send a representative to the ASCP, MPhA and MSHP annual Conference.

Board Action: The Board voted unanimously to approve both motions. Also, that the Board members may purchase a display to participate on behalf of the Board at these and similar organizations' meetings.

Ms. Naesea announced that Sandra Hines, Administrative Assistant would be retiring this month. A Jazz Luncheon is scheduled in Ms. Hines' honor on June 28, 2007 at the Board office.

V. Legislation and Regulation Manager Report – Anna Jeffers

A. Legislation – DTM Departmental Package to be approved at June Practice Meeting.

Ms. Jeffers asked for approval of the draft proposal for an extension of the DTM Departmental Study. The tasks mandated under the original legislation included: 1) Establishing regulations, which the Board completed on December 23, 2003. 2) Reporting to the General Assembly on October 1, 2006 of the effect of the Act, which was submitted on time; 3) Conducting a Study to assess the outcomes achieved by the Drug Therapy Management agreement, which is on-going under a contract with the University of Maryland; and 4) Expiration of the program on May 31, 2008. That is the reason the Board is being presented today with the legislative packet to extend the program beginning June 1, 2008.

Motion: Jeanne Furman moved to approve the DTM Departmental Study as amended. Donald Taylor seconded the motion.

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

B. Regulation Updates

Pharmacist Administration of Influenza Vaccination - The Pharmacist Administration of Influenza Vaccination regulations were published March 30, 2007. The Notice of Final Action was signed May 9, 2007 and will be published in the *MD Register* on June 22, 2007.

Pharmacy Technicians and Reinstatement Regulations - The Regulations were published in the *MD Register* on May 11, 2007. Comments will be considered and responses drafted for approval at the July Board meeting.

Pharmaceutical Services to Residents in Long-Term Care Facilities - Work on these regulations by the Long Term Care Task Force is on-going.

Licensing of Wholesale Prescription Drug or Device Distributor - Mr. Levi and Mr. Chason were assigned to Co-chair the Wholesale Distributors SB 759 Workgroup that reviewed and revised earlier drafted regulations at its first meeting in June 2007.

Sterile Pharmaceutical Compounding - The amended draft regulations re-proposed in the MD Register on June 22nd.

COMAR 10.07.14 Assisted Living Programs - The Assisted Living Programs regulations were published in the MD Register on May 11, 2007.

VI. Administration and Public Support – Patricia Gaither

A. Personnel Update – Patricia Gaither

Ms. Gaither reported that a request for a freeze exemption and for a classification review of the Office Secretary III position (to be vacated by Sandra Hines) has been submitted. She is presently seeking a Temp staff for the position.

A second permanent Office Secretary III position was appropriated to the Board during the last legislative session. The Board will request that position be converted to a Health Occupation Investigator position. Two (2) candidates responded to the Pharmacist Compliance Officer position. Ms. Naesea plans to meet with Senator Paula Hollinger to discuss concerns related to difficulties in filling that position. The Board has also requested approval for creating and immediately recruiting for five contractual inspector positions, including one supervising pharmacist, to perform pharmacy and wholesale distributor inspection responsibilities beginning in October 2007.

B. Public Information Officer Report – Patricia Gaither for Summar Goodman

Newsletter - Ms. Gaither reported on Ms. Goodman's behalf. The Spring Newsletter has been published and distributed. Ms. Gaither suggested that the Board research the possibility of electronic distribution the Board's Newsletter.

Action Item: Board retained e-mail addresses will be updated and the use of electronic transmissions of newsletters will be further explored by staff.

Annual Report

The Annual Report 2006 is printed and was distributed during the MPhA Conference.

MPhA Conference

The Conference was attended by Board Commissioners Donald Taylor and Harry Finke Jr.; LaVerne Naesea, Executive Director; and Summar Goodman, Public Information Officer. The Board had a booth at the 125th Annual MPhA Conference where we took

volunteer photos, collected emails and handed out give-a-ways at the Trade Show on Sunday, June 17th.

Finally, Summar Goodman and Patricia Gaither are coordinating the retirement celebration for Sandra Hines.

VII. Management Information Services – Tamarra Banks

MIS Status Report

Database – In-House Database Implementation

Ms. Banks reported that the contract with Towson University ended April 24, 2007. A meeting was held June 19, 2007 with Leslie Pachol, Towson/RESI to discuss the final contract components at no additional cost than what has been already approved by the Board. They include: rearranging the current screens in the format agreed upon by the Board Units; the license, registration and permit printing; placement of the main server and a backup server at Maryland Archives; database disaster recovery recommendation; office and the warranty period.

HIPDB

NABP responded to questions regarding the length of time it took for the HIPDB database records submitted April 4th and returned April 30th. NABP manually corrected many of the duplicate records submitted by the Board. Corrected data entry procedures were provided and the Executive Secretary corrected the remaining duplicate records. MIS is awaiting the next submission and will monitor the response from NABP.

Online Renewal Database

MIS has received calls (over 20 since June 1st) from pharmacists who have forgotten their passwords from their last renewal period 2 years ago. MIS recommends removing the current online statement that suggests they change their password and re-programming to allow users to reset their password back to the last four digits of their SSN (not to another password that could be forgot again).

Division of Drug Control/Inspections

In FY 2002, after Sunset Review, the Board was required to perform annual inspections. DDC has been acting as the Board's agent for performing those inspections. DDC has been using an electronic inspection database created for them by the Board to make the process more expeditious, eliminate the need for retyping carbon copied forms, and for tracking compliance. The electronic process has not been working well for the past couple of years due to DDC's laptop and printer failures. Network connection problems have prevented the sharing of information. Additionally, Board staff have had to type the

carbon inspection forms into the Board's DDC Inspection database for the DDC Inspectors that do not have laptops.

As a temporary solution to the data entry issue, MIS recommends that Compliance meet with DDC to discuss using the MS Access database created by James Pollack, the DDC Inspector for tracking inspections with violations. In the near future, research into hand held devices, such as the Verizon 7130i Blackberry, or wireless Internet cards may also be considered for instant access to Inspection data that can be shared over a network.

Contracts

- a. The MOU for Archives to continue to provide hosting for the Board's Online Renewal Systems and both secured and un-secured web sites was submitted for renewal by June 30, 2007.
- b. The Help Desk vendor contract was approved the week of June 11th and is expected to begin June 25th. In addition to Help Desk duties, the position will assist in implementing all Disaster Recovery systems for a 6 month period ending December 21, 2007.
- c. The Towson University Database implementation MOU renewal is expected to be submitted in early July 2000.
- d. Agreements with OHCQ and Maryland Archives are still being discussed for alternate locations in the event of an emergency situation. A meeting was held May 31, 2007 at Archives to review their facilities and requirements. Photos were taken (see attached) of both their new and old computer rooms. The old room houses only a few tower style PC's, while the new room houses more than 50 different front end and backup servers for Boards, MVA, Lottery, etc. They recommend any new servers or storage devices be purchased to configure into the new computer room.

Emergency Preparedness

- a. The new Photo ID machine was delivered to the Board replacing the broken machine, however DHMH personnel were unable to get it functioning. DHMH personnel will return with the procedure manual.
- b. The Disaster Recovery Plan is being re-formatted to fit State guidelines. It is expected to be completed by weeks end. An email was sent to the Office of Legislative Services for clarification on the level of support they expect from the Board during an emergency.

Web Site

Number of emails for	January: 336	February: 271	March: 295
	April: 264	May: 374	

Hardware/Software

- a. Laptops – Former Board member Don Yee returned the Board laptop and it was re- issued to Donald Taylor 6/7/07.
- b. All other hardware and software issues will be addressed when the new Help Desk vendor contract is initiated.

Other New/Events

- a. Establishment Online Payment: A draft letter will be sent to the Licensing Unit for review to obtain information regarding payment methods currently in use by a variety of pharmacies. After July 1st the Bank of America will submit the projected cost for adding any additional payment features to the Online Renewal System.

VIII. Committee Reports

A. Practice Committee –Dave Chason

1. Constituent Questions and Responses

- a. Michael Swehla, St. Louis College of Pharmacy Student

Mr. Swehla contacted the Board concerning compounded medications and the state specific laws that apply to their dispensing.

1. Are compounded drug products allowed to be compounded and delivered to a physician's office for "Office Use?" If so, is there a limit on the percentage of a compounding pharmacy's prescription volume that can be used for this purpose?

Additionally, compounded drug products may be prepared pursuant to a patient specific prescription or an order for office but may not be dispensed to the patient. See the Code of Maryland Regulations (COMAR) 10.34.22.02B(11)(b)(ix).

2. Can a compounded medication be delivered to a physician's office in anticipation of receiving a patient specific prescription prior to the time that the prescription is received by the pharmacy?

No, although anticipatory compounding is permitted, however the drug product may not be dispensed (must remain in the pharmacy) until receipt of the prescription. As sated above, non-patient specific compounds may be sold to a physician for office use so long the aggregate annual quantities distributed do not exceed 5 percent of the pharmacy's annual sales.

3. Is automated dispensing, (i.e. use of Pyxis® or Diebold® type machines), allowed in physician's offices or in a medical clinic in your state? If so, can compounded

medications be placed in these machines and then administered without a pharmacist on site? A pharmacist could/would enter a prescription remotely following the physicians order.

Automated dispensing is allowed in physician's offices or in a medical clinic in Maryland. The pharmacist cannot prepare, however, a compounded prescription to be dispensed to a patient through an automated medication system in a physician's office. Maryland law does not allow remote dispensing. The physician may compound and dispense if the physician has a dispensing permit pursuant to COMAR 10.13.01.01 - .05. The physician would obtain the dispensing permit from the Maryland Board of Physicians. Please refer to their website at www.mbp.state.md.us.

a. Would a physician being registered to dispense have any bearing on question #3. See answer above.

4. If #3 or #3a is allowed, who would be responsible for stocking the machine? Could a pharmacist compound a product, either for office use (if permitted) or in anticipation of receiving a prescription, and deliver the medication to the office, where it could be stocked by a nurse or other office employee?

The physician would be responsible for stocking the machine.

5. Does your state have any standard for determining the amount of product that a compounding pharmacy can keep on hand for future use based on the anticipation of a prescription/order? Can this be correlated to historical prescription patterns or does your state have a specific way to determine what quantity can be made in advance?

The Maryland Pharmacy Act does not address standards for determining the amount of product that a compounding pharmacy can keep on hand for future use based on the anticipation of a prescription/order. The pharmacy may estimate the quantity to be compounded based on historical prescribing patterns.

Motion: Jeanne Furman moved to accept the Practice Committee's letter as amended. Michael Souranis seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter to Michael Swehla as amended.

b. Richard Mainzer, Woodhaven contacted the Board concerning compliance with Code of Maryland Regulations (COMAR)10.34.23.01 - .11, Pharmaceutical Services to Residents on Long-Term Care Facilities, by retail, community, independent and mail order pharmacies.

The Board requested that quotation marks be inserted for quoted statute text. Policies and procedures developed by the pharmaceutical services committee of a nursing home may not prohibit or restrict a resident from receiving medications from the

pharmacy of the resident's choice except that, when the costs of any medication obtained from the pharmacy selected by the resident exceeds the cost of the same or equivalent medication available through a pharmacy that the facility has contracted with to provide pharmaceutical services, the resident shall be responsible for the excess amount. See the Code of Maryland Regulations (COMAR) 10.07.0215B(3)

If a patient desires to designate a particular pharmacy to provide his drugs, he shall inform the pharmacist that he must conform with the facility's written policies concerning the provision of drugs. If the pharmacist agrees to comply with the facility's policies, the patient may request that the consenting pharmacist perform the service. If the pharmacist fails to comply with the policies, a representative of the facility shall discuss with the patient the policy infractions. If after being informed of the infractions the pharmacist then refuses to cooperate, the patient shall select another pharmacist who will agree to comply with the facility's policies. Providers of drugs and consulting pharmacists, shall have access to a copy of the written patient care policies. See COMAR 10.07.02.15D(3)

Any pharmacy chosen by a patient in a long-term care facility must fully comply with COMAR 10.34.23.01 - .11, as well. Keep in mind, however, that emergency prescriptions are excluded from this limitation.

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

Board Action: The Board voted unanimously to approve the Practice Committee's letter as amended to Richard Mainzer, P.D.

c. Alan Friedman, Kaiser Permanente contacted the Board concerning laws and regulations in Maryland in relation to prescription processing.

"I am looking at when an RX number needs to change:

a. If a doctor is on vacation and another doctor covering in that office authorizes the refill, does the Rx number have to change? Can we just put a notation that Dr. X authorizes a refill, a new prescription number is required to be issued.

If a doctor is on vacation and another doctor covering in that office authorizes a refill, a new prescription number is required to be issued.

b. If we change a drug from a brand name, to its generic counterpart upon a future refill, can the Rx number remain the same? For example, Rx is filled for Amoxil 250 mg the first time, and amoxicillin 250 mg upon refill – can we maintain the same Rx number? Does it matter if the drug is controlled?

Yes, the prescription number may remain the same if the drug is changed from a brand name to its generic counterpart upon a future refill. This would also be true for CIII –

CV controlled substances. CII controlled substances may not be refilled. **“Long as proper documentation shows which product was used for each refill.”**

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

Board Action: The Board voted unanimously to approve the Practice Committee’s letter to Alan S. Friedman as amended.

d. Chris Serio, Baltimore City Health Department contacted the Maryland Board of Pharmacy concerning your medication questions as you prepare to implement the Baltimore City Health Department’s Direct Observed Therapy Program.

Do the medications need to be bubble packed?

No, the medications do not need to be “bubble packed.”

Does the provider need a new prescription for the pharmacist each day or can the provider write a 30 day prescription that the pharmacist can fill according to the patient’s regimen for thirty days?

The provider may write a 30 day prescription that the pharmacist may fill according to the patient’s regimen for thirty days.

If we decided to take on new patients with more complicated diagnoses and treatment regimens that may include mental health meds, blood pressure etc. and these meds were assembled by a pharmacist into patient specific containers for us to take to the patients and observe them taking their meds would that be acceptable to the board? Would the meds need bubble wrapping?

Based on current law, medications assembled by a pharmacist into patient specific containers for the Direct Observed Therapy Program to take to patients and observe them taking their medications would be acceptable to the Board, so long as the pharmacist complies with all labeling requirements and the prescription is patient specific. “Bubble wrapping” would not be required.

Motion: Rodney Taylor moved to accept the Practice Committee’s letter as written. Michael Souranis seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee’s letter to Chris Serio-Chapman.

2. Practice Committee announcement regarding the release of Board responses to individual inquiries.

The Practice Committee recommended that Practice Letters would not be released to the public. Those with universal appeal will be addressed in the Board’s Newsletters. The concept and issues addressed in those letters are readily available in the Board Minutes. Letters may be requested through a Public Information Announcement request.

B. Licensing Committee – Michael N. Souranis

Statistics

Michael Souranis reported the statistics for the month of May. The number of pharmacists due to renew in May were 318 compared to 331 last May; the total renewed to date was 288 (194 renewed online compared to 127 online in May 2006); Non-Renewed 30 compared to 42 in May 2006.

New Establishments:	Compared to May 2006	
New: 15		New: 9
New-Distributor-In State	2	N/A
New-Distributor – Out of State	6	N/A
New-Resident Pharmacy	4	New: 4
New-Non-Resident Pharmacy	3	N/A
New-Pharmacy w/Waiver	-	
Total Other New Estabmts.	-	5

Closed:	4
Distributor – In State	-
Distributor – Out of State	1
Pharmacies	3
Non-Resident Pharmacies	-
Pharmacy w/Waiver	-

Survey Results from pharmacists who administer influenza vaccines included: 75 responses received from 137 pharmacists certified to administer flu vaccines. The total number of shots administered during the past flu season was 8,477.

The Licensing Committee referred the development of a Definition of National Certification Program to the Practice Committee.

Ahold USA, Inc. – Ahold USA, Inc. provided a letter of support to the Board for the ICPT application to be consider as a nationally accredited technician program.

C. Long Term Care Task Force – Mayer Handelman

Discussion ensued about the problem that nurses cannot dispense medications when patients leave a LTC facility for a short time (such as for lunch or dinner with their family) and return with medications and how to resolve the problem. It was commented

that regulations should be drafted addressing medication management and short term LOA.

Mr. Handelman provided an update on the Assisted Living regulations. Anna Jeffers has the changes to the regulations that Mayer Handelman has e-mailed to her. Mr. Handelman and Ms. Jeffers plan to meet with the Office of Health Care Quality and Barbara Newman, as well as with HFAM and Life Span to discuss the issue.

Lastly, in the event that a patient living in a nursing home may need to be evacuated a Face Sheet should accompany them that includes all relevant diagnoses and medication information.

Motion: Mayer Handelman moved that the Board indicate its support to the Office of Health Care Quality on Medication Management for the need for a face sheet to accompany all nursing home patients upon leaving the facilities for any reason. Michael Souranis seconded the motion.

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

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 Administrative Session.

Revised 7/16/07