

Maryland Board of Pharmacy
Public Minutes
March 21, 2007

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

Commissioners Present: Margie Anne Bonnett, David Chason, Joseph DeMino, Harry Finke, Jr., Mayer Handelman, Rodney Taylor, and Michael Souranis

Absent Commissioner: Cynthia Anderson and Alland Leandre

Board Staff: LaVerne Naesea, Executive Director; Patricia Gaither, Administrative and Public Support Manager; Shirley Costley, Licensing Manager; Anna Jeffers, Legislation and Regulations Manager; Tamarra Banks, MIS Manager; Bonnie Rosiak, Compliance Officer; Colin Eversley, Compliance Investigator; Vanessa Thomas-Gray, Compliance Secretary.

Board Counsel: Linda Bethman

Guests: Ron Nicholson, VetCentric; Hammad Shah, VetCentric; Chris Wilburn, Walgreens; Roger Jones, VetCentric; Georgette Zoltani, Division of Drug Control; Dot Doan, Target; Howard Schiff, MPhA; and Tony Tommasello, PEAC.

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 February 21, 2007

Page 2 – Change - The Board also voted..... to a Motion – Motion: Jeanne Furman moved to mail information about the Board’s upcoming vacancies to all licensed Maryland pharmacists. Harry Finke, Jr. 2nd the Motion.

Page 3 – Under Budget Hearings, 1st paragraph, sentence 9 - *strike out* “if future scheduled meetings” replace with “in the future if meetings must be canceled.

Page 4 – Under Legislation, 2nd sentence – *strike out* “that were for hearings before February 15th, *replace with* “prepared for scheduled hearing before February 15.” Change uppercase “H” in the word “Hearings” Change to lower case “h” hearings. sentence 9 – “The Bill prohibits prescription transfers except in certain situations” replace with “The Bill would prohibit transfers accept in certain situations.” Sentence 10 – “The amendments she is suggesting would bring the Bill’s actions into compliance with the Board’s Act” *change to* “The amendments she was going to suggest would bring the Act

into compliance with the current Maryland Pharmacy Act.” Sentence 11 – “(i.e. pharmacists are allowed prescription transfers otherwise authorized by the.....) *change to* (i.e. which allows the transfer of prescriptions between pharmacies.....”)

Page 5 – Under HB 820 Health Occupation Boards...strike – would exclude the Secretary for DHMH... *change to* – would exclude the Secretary of DHMH.....

Page 6 – Under Division of Drug Control – *insert numbers for closing inspections* – “closing inspections – 4”

Page 7 – 2nd paragraph, 2nd sentence – strike “by the end of Board meeting week....” *replace with* “by the end of the week, February 23, 2007.

Page 11 – Under Online Comments – suggested that instead of comments listed should state “comments were made.”

Jeanne Furman asked whether the template that Cindy Anderson developed for the Practice Committee could be utilized for Public Meeting minutes. Donald Taylor stated that he would need to review the format. It was suggested to include a section for action items in order to facilitate tracking and follow-up on the progress of Board issues.

Motion: Jeanne Furman moved that the minutes be continued to be written, and that beginning in April, a new section documenting the Board’s actions, the responsible party(ies), and the due dates for follow-up reports should be attached as an addendum to all Public Meeting minutes. Dave Chason seconded the motion.

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

III. President/Executive Committee Report – Mark Levi

Mark Levi asked the guests in the audience to introduce themselves. LaVerne Naesea introduced Rebecca Castner and Kimberly Wu from the School of Pharmacy, who were in attendance during their one day rotations at the Board. Mr. Levi welcomed Bonnie Rosiak, the newly hired Pharmacist Compliance Officer.

Mr. Levi announced that mailing of Board packets should not be delayed because materials have not been submitted and/or printed in time for inclusion in the Commissioners’ Board packets. Effective immediately, if materials for the Board packets are not ready for submission by the dates due, then revised agendas and any materials submitted and/or printed after the Board packet mailings will be distributed at the Board’s meetings as an addendum packet.

Mr. Levi reported on the meeting with the Division of Drug Control regarding the upcoming transition of inspection responsibilities to the Board of Pharmacy. Dave Chason and Cindy Anderson have revised the items to be included on the Hospital Inspection form. The Division of Drug Control wanted legal citations for most of the

items listed on the inspection form. The language for the contract with PEAC has been finalized after a meeting between representatives of the Board and PEAC.

IV. Executive Director's Report – LaVerne Naesea

HB 736 – Salary Setting/Classifications Bill

Ms. Naesea briefed the Board on her testimony given to support HB 736, Job Classifications and Grades for Staff bill. Four other Boards provided Letters of Support for the Bill indicating that they recognized the Board of Pharmacy's unique set of personnel concerns. Delegate Elliott testified as the bill sponsor and noted the difficulty the Board has been having with recruiting and retaining a Compliance Officer and other key positions. An opposing position paper is going to be submitted by the Department of Budget and Management because a Summer study is planned to look at all "at-will" positions throughout the State. At-will positions are assigned outside of the usual State personnel system and allow employers greater flexibility in terminating employees without following the usual progressive disciplinary procedures. A cross-filed bill has also been filed in the Senate.

NABP Conference Delegate/Alternate

Jeanne Furman is the assigned Board Delegate attending the NABP conference in Portland and Joe DeMino is the Alternate. Ms. Naesea will be attending the conference as well. Bonnie Rosiak, Compliance Officer, will be attending the American Society of Consultant Pharmacists' national conference.

Ms. Naesea announced that the National NABP meeting will be held in Baltimore in May 2008. The Board will be expected to play a role in coordinating the meeting.

V. Legislation and Regulation Manager Report – Anna Jeffers

Regulation Updates

Ms. Jeffers reported that the Pharmacist Administration of Influenza Vaccine regulations will be published Friday, March 30th.

Ms. Jeffers asked the Board to approve revisions to Regulation .11 Reciprocity of the Pharmacy Technicians Regulations. The revisions were made on the advice of Board Counsel so that the regulations would comply with the statutes. Those revisions included 1) Evidence of being in good standing in the state or states of current registration **or** 2) Evidence of having worked as a pharmacy technician in another state; and to add **for at least 6 months**. The change was made to be consistent with the statutory language.

Motion: Mike Souranis moved to accept the editing of .11 Reciprocity of the Pharmacy Technician regulation to comply with State law. Harry Finke, Jr. seconded the motion.

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

Ms. Jeffers also reported that work on the draft language for the Long Term Care regulations is on-going. An assigned Task Force will be assigned to write the Wholesale Prescription Drug or Device Distributors regulations if the bill is passed.

Six official comments were received and responded to regarding the Sterile Pharmaceutical Compounding regulations. Ms. Jeffers requested the Board's approval for changes made to the proposed regulations following receipt of the comments. The regulations will need to be repropose because of the changes. Ms. Jeffers was asked to e-mail Board members an updated version of the bill with the changes indicated in red. Ms. Jeffers will present the amended regulations to be repropose at the April 18th Board meeting.

Legislation

Ms. Jeffers referred Board members to the Board's position papers included in the Board packets. She also gave an update on the Wholesale Distributor legislation. Ms. Furman and Ms. Jeffers testified at the March 1st hearing on the Wholesale Distributor legislation. After discussions with stakeholders through several meetings chaired by Delegate Montgomery and/or Morhaim, the House voted on an amended version of the bill that reflected changes made during those meetings. The Senate version of the cross-filed bill was heard the afternoon of the Board meeting (March 21st). According to Ms. Jeffers, the proposed legislation will likely be amended in the Senate so that it reflects the amendments made to the House version.

The dextromorphan bill has been amended, and Ms. Jeffers stated that she is waiting to review the final amendments. As currently proposed, the Department will be required to prepare regulations and to notify pharmacies and retail stores of requirements.

VI. Administration and Public Support – Patricia Gaither

Personnel Update

Ms. Gaither reported that interviews for the Health Occupational Investigator position were conducted. The Coordinator for Special Programs and the Regulations Officer positions were also in the recruitment phase until the State hiring freeze was implemented. The Board has since submitted hiring freeze waiver requests for all three positions. .

Public Information Officer Report – Summar Goodman

1. Cultural Competency Conference - Registration information about the two-day Conference to be held on Monday, April 23rd and Tuesday, April 24th from 8:00 am until 4:00 pm. was disseminated to Board members and the other guests at the Public Meeting. Ms. Goodman will register those who are interested in attending the Conference, and also

will attend the Conference as the Board's representative. Information about the Conference will also be posted on the Board's website.

2. Prescription Drug Repository Program postcards - Postcards regarding the new Program were mailed to all Maryland pharmacies on February 28th.

The Board has not received any applications from pharmacies requesting to be repositories or drop-off sites. It was suggested that the Board send a letter to Delegate Rudolph to recommend that the State create incentives to encourage permit holders to volunteer as repositories or drop-off sites.

3. Board membership nominations – Postcards announcing the upcoming Board membership openings were mailed February 23rd to all registered Maryland pharmacists.

4. Newsletter - Ms. Goodman is working on the Spring Newsletter. She asked the Board members for specific topics to be addressed in the Spring issue. Articles regarding pharmacy technicians registration updates and the Prescription Drug Repository Program were suggested.

5. Flower Mart - The Board will be participating in the 90th Annual Flower Mart, Friday, May 4th from 11:00 am until 5:00 pm. The Board will be working with the Pharmacy Coalition and the School of Pharmacy and needs volunteers to work at the Board's booth. The colors for this year's Flower Mart are lime green and black. This year's theme is "Ninety Years and Still Blooming."

6. Best Buy Drugs Information – The Board has been requested to support the *Consumer Reports Best Buy Drugs* public education project to help educate the public about drugs before they visit their pharmacists by publishing Best Buy reports. The reports are based on available scientific evidence. Although the consumer site does not list prices for the various drugs reviewed, medical professionals can access *Best Buy* summary reports that compare drugs on effectiveness, safety, and price through personal digital assistants (PDAs).

Best Buy Drugs would like the Board to help inform pharmacists and consumers about the website (www.CRBestBuyDrugs.org), to disseminate their brochure at consumer events (e.g., Flower Mart), and to provide a mailing list of pharmacists and pharmacies. They have also asked the Board to consider featuring an article about them in the Board's Newsletter. Board members asked that the website address for the project be e-mailed to each member for review prior to voting at the April meeting whether it will become a partner with this project.

VII. Management Information Services – Tamarra Banks

Board members asked that the Board's website be updated with current information about the Commissioners and their respective committees. Ms. Banks reported the statistics for the month of February. She also noted that the contractors for the Board's database

project require additional funding to complete the project. The additional money relates to additional responsibilities that the Board has requested since the original contract was written (i.e., pharmacy technicians, DDC inspections, pharmacists rehabilitation, etc.). Ms. Naesea noted that she has requested that the Department's Director of Information Technology, Phil Hamlet, conduct an independent audit. The project is expected to be completed by the end of the Summer. The staff was asked to provide the Board members with the exact increase in amount once it is determined.

Motion: Jeanne Furman moved to accept the increase in Towson's MOU of approximately \$70,000 (including \$9,000 for help desk staff support for related Board projects). Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the project's increase.

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

Dr. Tommasello reported that PEAC's caseload consists of 12 cases, of which 2 are pharmacy students. PEAC has received 60 urine results with no positives, discharged one client, and has 5 Board pharmacists being mentored by PEAC. Dr. Tommasello informed the Board that a pharmacy had failed to follow the Duty to Report requirements. He did not disclose the name of the pharmacy; however he briefed the Board about his concerns about the supervising pharmacist's failure to report under the "Duty" requirement. An article about the "Duty to Report" will be included in the next Board's newsletter.

IX. Committee Reports

A. Practice Committee – Dave Chason

1. Constituent Questions and Responses

Steve Yang of Adventist Rehab Hospital of Maryland contacted the Board concerning whether he needs to purchase a Barrier Isolator type hood even though he rarely mixes IVs. Mr. Yang is required to meet equipment requirements for any volume of sterile compounding performed. He was referred to recently published proposed regulations (COMAR 10.34.19.01 – 16) accessible from the front page of the website (www.mdbop.org) under *What's New* for the Legislation/Regulation Section.

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

Board Action: The Board voted unanimously to approve the Practice Committee's letter to Steve Yang.

Jennifer Thomas and Shirley Geize, R.Ph. of Johns Hopkins Hospital contacted the Board concerning the dispensing and storage of controlled dangerous substances, specifically methadone, in a disaster/emergency. In the event that the Governor declares a state of emergency, current laws may be relaxed.

Motion: Dave Chason moved to accept the Practice Committee's letter as amended to replace the phrase 'catastrophic emergency' with 'state of emergency'. Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the letter to Jennifer Thomas and Shirley Geize, R.Ph.

Daniel R. Radvansky Regulatory Compliance Project Support for Office Team – Administrative Staffing contacted the Board concerning Maryland's regulatory requirements for wholesale distributors of prescription drugs or devices. He asked several questions related to wholesale distribution and controlled dangerous substances laws in Maryland. He was referred to the current wholesale distribution laws under HO 12-602 E and the proposed wholesale distribution bills (HB 1030 and SB 759) that are accessible through the state web site (www.mlis.state.md.us). He was also referred to the Division of Drug Control (www.dhmh.state.md.us/drugcont/) and DEA www.dea.gov for requirements regarding CDS.

Amendments were made to the second and third responses, noting that the Wholesale Distributor bills were currently under consideration so the law may change, and referring the inquirer to the MD Board of Physicians for requirements regarding physician assistants, respectively.

Motion: Jeanne Furman moved to accept the Practice Committee's letter as amended. Harry Finke, Jr. seconded the motion.

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

Dan Luce, Manager of Pharmacy Affairs, Walgreens contacted the Board concerning Walgreens request to proceed with their central prescription processing. Although the Board does not endorse specific products, the Board advised Mr. Luce that any pharmacy participating in central prescription processing is required to be a licensed pharmacy or non-resident pharmacy in Maryland. Further, any pharmacist participating in central prescription processing at a location that is not a licensed pharmacy is required to be licensed in Maryland.

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

Board Action: The Board voted unanimously to approve the letter to Daniel F. Luce.

Dave Sellis, RPh, Director Automation Services of MedTimes contacted the Board concerning whether the MedTimes product complies with Maryland laws and regulations. He was advised that under current law, any system described as his would

not meet regulatory requirements because it does not limit simultaneous access to multiple drugs and doses. He was referred to COMAR 10.34.28.04B and to the Office of Health Care Quality's web site (www.dhmh.state.md.us/ohcq/). Since the Board does not endorse specific products, the letter was amended to generally address any system that is similar to the one described in the letter.

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 letter to MedTimes.

Long Term Care Task Force – Mayer Handelman

Mr. Handelman reported that the Long Term Care Task Force members are currently reviewing the draft LTC Inspection form and will bring their comments to the next Task Force meeting. Mr. Handelman informed the Board about the issue of patients who leave facilities on home visits (loa's). He said that the regulation states that a family member cannot take medications back into a facility (i.e. nursing home after a home visit). Mr. Handelman stated that the Task Force will be reviewing the regulation to consider whether it should be amended.

An inquiry received from Richard Mazinger was deferred to the next Task Force meeting since a representative from the Office of Health Care quality was not available at the March meeting.

B. Licensing Committee – Michael N. Souranis

February Statistics

Mr. Souranis reviewed the February statistics. The Licensing Committee asked if distributors that indicate *no controlled substances* on their distributor application would be acceptable if an out of state distributor shipped controlled drugs in other states, but not into Maryland. Shirley Costley indicated that when her staff asks for clarification regarding shipping any control substances, the distributors sometimes change their answer from yes to no in order to avoid having to acquire a MD CDS license.

Motion: Michael Souranis moved that distributor must obtain a Maryland CDS license if it has a license to distribute controlled substances in other state. Harry Finke, Jr. seconded the motion.

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

Mr. Souranis questioned whether waived pharmacies should be required to indicate their actual hours of operation. It was decided that the hours of operation should be required in the waived pharmacies' applications.

Influenza Vaccination

Mr. Souranis reported that no new pharmacists were certified in March and four (4) certificates were renewed. A total of 127 certificates have been issued to date. Board members asked that the Licensing Unit send a letter to all certified pharmacists to ask how many vaccines they administered during the past influenza season.

Pharmacy Technician Application

The revisions related to the *Grandfathering* provision of the regulations will be reflected in the three draft applications that were disseminated. Pharmacy technician application cover letters are being drafted to include information on where applicant can have criminal background checks conducted. Once the emergency regulations are promulgated, pharmacy technicians, and *Examination and Training Program* applicants can obtain applications from the website along with instructions on how to obtain their criminal background checks. *Background check* application forms along with the technician applications to permit holders after the emergency regulations are promulgated. Pharmacy technicians and students may submit applications after the emergency regulations are published, but they will not be required to register until after the non-emergency proposed regulations are passed. The Board will notify the permit holders when technician and student registration becomes mandatory.

Technicians are required to have a GED or high school diploma and to be at least age 17. Training can be completed while technicians are working on the job.

Motion: Michael Souranis moved to approve the three Pharmacy Technician Program applications as amended (regular technician application, grandfathered technician application and student application). Harry Finke, Jr. seconded the motion.

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

D. Disciplinary Committee – Mayer Handelman/Bonnie Rosiak

Ms. Rosiak reported on the Division of Drug Control's inspections for the month February. There were 66 Pharmacy Inspections; 13 Opening Inspections; 4 Closing Inspections; 0 Board/DEA/DDC Special Investigations. Ms. Rosiak stated that the Compliance Unit is currently working with DDC to try to resolve that issue of illegible handwriting of inspectors. Members also discussed concerns regarding the length of time inspectors spend inspecting pharmacies. One pharmacy reported that it took approximately seven hours for the inspection of its retail pharmacy to be completed.

X. Other Business – Donald Taylor thanked the Board and staff for the basket sent to he and his wife following their recent hospitalizations.

The Board adjourned the Public Meeting at 11:58 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.

BOARD ACTION ITEMS

Action Topic	Discussion	Follow Up Activities	Responsible Person(s)	Board Update Due Date	Completion Date*
1. Sterile Pharmaceutical Compounding regulations. (3/20)	Comments received regarding proposed regulations	E-mail Board members copy of proposed regulation changes based on comments. Indicated changes in red font	Anna Jeffers	Present draft repropoed regulations at April Board meeting for approval.	April 18, 2007 (projected)
2. Prescription Drug Repository (3/20)	Ask Delegate Rudolph to recommend that the State create incentives to encourage permit holders to volunteer as repositories or drop-off sites.	E-mail and follow-up phone call will be made to Del. Rudolph in early June.	Anna Jeffers	June Board Meeting	June 20, 2007 (projected)
3. Spring Newsletter Articles (3/20)	Prepare articles regarding update for Pharmacy Technician registration and the Drug Repository Program.	Pharmacy Tech (LaVerne), Drug Repository (Anna), Newsletter entry (Summar)	Summar, Anna and LaVerne	April Board meeting	April 18, 2007 (projected)
4. <i>Consumer Reports Best Buy Drugs</i> public educational project (3/20)	Board was concerned that prices would be included and that patients would request drug based on cost rather than prescriber determined need.	E-mail web-site address of the project to Board members for consideration prior to the April meeting.	Summar Goodman	Board to revisit at the April 2007 meeting.	April 18, 2007 (projected)
5. Web site updating (3/20)	Board members asked that the website be updated with current information about members' and committees they serve.	Update the Board Administration section of the web site. Summar will review and update info, Duane will physically make changes on web pages, and LaVerne will review and approve changes.	Duane Truesdale & Summar Goodman LaVerne Naesea	Update will be provided at the April 2007 meeting.	April 18, 2007 (projected)
6. Towson University Database Project (3/20)	Request the Department's Director of Information Technology to conduct an independent audit of the project upon completion.	Secure exact amount for increase in project cost and request an independent audit when project is completed.	Tamarra Banks, Pat Gaither and LaVerne Naesea	Update will be provided at the April 2007 meeting	August (projected)
7. Duty to Report (3/20)	Dr. Tommasello expressed concern that pharmacists were not meeting their legal duty to report pharmacists who are impaired by alcohol or drug abuse.	An article about the "Duty to Report" will be put in the April Board newsletter.	Summar Goodman	Update will be provided at the April 2007 meeting	May 16, 2007 (projected)
8. Administration of Influenza Vaccine (3/20)	Board members asked that the Licensing Unit send a letter to all certified pharmacists to ask how many vaccines they administered during the past Influenza season. .	Compose and send letter to all certified pharmacist.	Shirley Costley	Update will be provided at the April 2007 meeting	May 16, 2007
9. Pharmacy Technician Application (3/20)	a. The application cover letters are being drafted to include where applicants can have	a. Draft letter for review by the Board. b. Post applications on web	Licensing Committee/ Shirley	a., b., c. All updates will be provided in	a. April 2007 (projected) b. April 2007

Action Topic	Discussion	Follow Up Activities	Responsible Person(s)	Board Update Due Date	Completion Date*
	criminal background checks conducted. b. Post applications on web site after Emergency regulations are promulgated. c. Mail applications and criminal background check cards upon request	site. c. Mail applications and criminal background check cards	Costley	April 2007 meeting	c. June 2007

*Item to be removed from chart following date when action item is determined completed by the Board.