

**Maryland Board of Pharmacy
Public Board Meeting Minutes
April 19, 2006**

Attendance:

Officers: John Balch, President, and Mark Levi, Treasurer

Commissioners: Margie Ann Bonnett, David Chason, Joseph DeMino, Donald Taylor, Rodney Taylor, Michael Souranis, Don Yee, and Mayer Handelman

Absent Commissioners: Jeanne Furman, Secretary

Board Staff: Colin Eversley, Compliance Investigator; Shirley Costley, Licensing Manager; Summar Goodman, Public Information and Education Officer; Patricia Gaither, Personnel Officer; and Alicia Carter, Executive Secretary

Board Counsel: Linda Bethman, Staff Attorney

Guests: Mike Swarner, Target Pharmacy; Kathleen Kline, Pharmacy Technician Certification Board; Todd Philbrick, Pharmacy Technician Certification Board; Howard Schiff, Maryland Pharmacist's Association; Stephen Riggan, CVS Pharmacy; Cathy Putz, PEAC; Tony Tommasello, PEAC; Melvin Rubin

I. Call to Order/Record of Conflict of Interest

President Balch called the Public Meeting to order at 9:15 am. There were no conflict of interest declarations. Guest attendees were asked to introduce themselves.

II. Corrections of Minutes 3/15/06

Page 3

- #1, 1st line, end of the page, capitalize the letter "L" and capitalize the letter "S".

Page 4

- Under Staffing Issues, 1st line – add an "s" to the word Addiction.

- Under Staffing Issues, 2nd line – change "who" to "whose".

- Under Educational information on non-Board referred cases, 8th line, "Mr. Handelman has offered office space..." change to "Mr. Handelman has **suggested** a location to use for the PEAC office space".

Page 5

- Under Task Force Reports- USP 797, 2nd paragraph, take last line out.

Page 6

- Under #7, Committee Reports – A. Drug Therapy Management – 2nd line, add "a" after the word raised.

- Under Plantex USA - 2nd line, change the word “licensed” to “license”.

Motion: David Chason moved to accept the minutes with corrections.

Board Action: The Board voted unanimously to accept the minutes with corrections.

III. President/Executive Committee Report – John Balch

John Balch stated that the re-vote for the office of Treasurer would take place prior to the Board Executive session. Mr. Balch plans to re-evaluate committees. Mr. Balch announced that Mark Levi was re-elected Treasurer for the Board.

IV. Executive Director’s Report – LaVerne Naesea

NABP National Meeting

LaVerne Naesea reported on the NABP National Meeting that was attended by John Balch, Joe DeMino, Jeanne Furman and herself. Ms. Naesea gave highlights on presentations at the conference. Tommy Thompson, former Secretary for the Department of Health and Human Services, spoke about the future of Medicare, Medical Insurance, Medicare Part B, and the Medicare Modernization Act. In addition, Ms. Naesea reported that the FDA invited all Boards to begin a partnership in providing better oversight for medical gases. Ms. Naesea stated that there was discussion on <USP 797> in terms of approaches to inspecting pharmacy sites. Revisions in language will be made to existing <USP 797> regulations.

Workshops are planned with different entities to provide updated information and training on <USP 797>. Wal-Mart founded a program entitled “Effective Communication Delivery of Board Policy and Public Meeting with the Media.” The program educates Board directors on how to present positions and policies as related to their perspective Boards. The program also teaches the Board directors how to maintain focus on subject messages that they would like to have developed. There was a report from Louisiana on natural disaster planning and emergency preparedness. The District I and II Meeting was mentioned at the conference. Lawrence MoKhiber, Director to the New York Board of Pharmacy, has been elected as the new President of NABP. Information was shared about the existing Model Rules and new legislation pertaining to Sterile Compounding was recommended. Ms. Naesea will provide that information to the Maryland Board of Pharmacy Sterile Compounding Committee.

John Balch stated that he would like the Board to become more involved with NABP. Mr. Balch asked Don Taylor to write NABP indicating his experience with emergency preparedness and request to be assigned to the new task force that NABP plans to start.

Joe DeMino's Report

Mr. DeMino also provided a report about the NABP conference. Mr. DeMino stated that Tommy Thompson is described as a “champion to pharmacists”. Some topics Mr. Thompson spoke about were banning smoking, health issues in America and why people should walk more. There was discussion on ways to correct prescription errors, emergency preparedness, and about certification for pharmacy technicians. Mr. DeMino met with Kenneth Schafenmeyer to discuss pharmacy technicians. Mr. Schafenmeyer administers an exam for pharmacy technicians. Mr. DeMino stated that Mr. Schafenmeyer was excited to learn that Maryland’s pharmacy technician bill passed. Mr. DeMino informed the Board that Oren Peacock of Texas was elected as NABP President-Elect.

Sessions of the conference can be viewed on the NABP website. Ms. Naesea informed everyone that Joe DeMino’s father received an award for Community Service.

Financial Disclosure Reports

Ms. Naesea reminded the Board Commissioners to complete the financial disclosure statement due May 1, 2006. A recommendation to consolidate some of the smaller Boards was made. However, the Board of Pharmacy, the Board of Dental Examiners, and the Board of Social Work Examiners were not included in that recommendation.

Board Relocation

The relocation of the Board office should take place in May. Work has not been finished at the new location. Ms. Naesea is hoping that the move will take place by the end of May.

Remarks

Ms. Naesea mentioned that the Maryland Board of Pharmacy law book will need to be revised. Ms. Naesea requested to have a Board Commissioner and involvement from the Practice Committee to assist with revisions to the law book. Ms. Naesea announced that she plans to discuss the revisions with Lexis.

She also thanked everyone for the cards she received during her time of bereavement.

V. PEAC - Tony Tommasello

Old Business

Mr. Tommasello stated that the PEAC poster is scheduled for mailing this Friday. Mr. Tommasello has received some responses for the Addictions Counselor position that was posted on the Alcohol and Drug Abuse Administration website. PEAC is still seeking office space. In addition, PEAC is transitioning their e-mail account from Direct-way to Hughes-net. It is hoped that the current problems with their e-mail system will be resolved soon. Mr. Tommasello invited Board members to attend PEAC's meeting May 1st to discuss upcoming changes. The meeting is scheduled for 11:00 a.m. until 2 p.m. at the School of Pharmacy, 4th Floor. Finally, PEAC has contracted with the Hayberman Group to coordinate their fundraising activities.

New Business

Mr. Tommasello gave an overview of a handout describing how PEAC cases are reported to the Board. Pharmacists that violate their PEAC contracts should be reported to the Board. John Balch asked who monitors the reporting process and if quality assurance is done annually/semi-annually. Mr. Tommasello responded that cases are reviewed on a case-by-case basis. Additionally, Mr. Tommasello stated that PEAC would like to review all cases that have been reported to the Board. According to Mr. Tommasello, PEAC has a committee that meets by phone on a regular basis to review each case. Mr. Tommasello stated that, during their May 1st meeting, the committee would review the decision process to ensure that everyone is following the procedure.

Questions were raised about consent order violations and pharmacists who are considered a danger to the public. Mr. Tommasello responded to both questions. 1) Pharmacists that violate their consent order should be reported to the Board immediately. 2) PEAC, as a committee, makes the determination if a pharmacist is considered a danger to the public. Mr. Tommasello is currently serving as the Executive Director for PEAC. Mr. Tommasello was reminded of his scheduled meeting with John Balch and LaVerne Neasea after the executive meeting today.

VI. Legislation and Regulation Manager Report – Anna Jeffers

John Balch and Board members applauded Anna for her outstanding job of tracking bills during the legislative session. Anna Jeffers provided the Board with an updated chart of bills. Ms. Jeffers gave an overview of bills that passed/failed. The Wholesaler Distributor bill did not leave the House Committee. Ms. Jeffers stated that there are 7 sets of regulations that will need to be promulgated soon:

1. Pharmacy Technician
2. Reinstatement Regulation
3. Long Term Care
4. Drug Repository

5. USP 797
6. Pseudoephedrine (2)
7. Negative Formulary

Mel Rubin informed the Board that Larry Klein could be contacted concerning questions pertaining to the pharmacy technician's law exam. Todd Philbrick, Associate Director for the Pharmacy Technician Certification Board, offered to distribute information to the Board about certification for pharmacy technicians. John Balch explained to Mr. Philbrick that presentations should be made before the Practice committee. John Balch expressed the Board's disappointment that the Wholesaler Distributor regulations did not pass. It was suggested that the Board communicate changes to improve the regulations with Delegate Stern. Ms. Naesea asked who from the Board of Pharmacy would staff the Advisory Board of Prescription Drug Monitoring (task force). Howard Schiff expressed an interest to have someone from the Board of Pharmacy represented on the 21 member Board. Mr. Balch stated that it would be problematic, at this time, for the Board to provide staffing for the task force.

VII. Administration and Public Support – Patricia Gaither

Personnel

Board members were reminded to fill out their expense forms completely. Start and finish times and an explanation of the meeting should be provided on the form. The state General Accounting Department prepares calculations. Itemized receipts should be submitted after making charges with credit cards. Travel reservations must be made through the Department of Health and Mental Hygiene. Every effort to obtain desired flights is made by the Department.

Ms. Gaither reported that recruitment for the program manager, office secretary and the office service clerk positions is in progress. The closing date for the program manager position was April 13th. The office secretary position closed April 18th and the office service clerk position had no posting (candidate names were taken from a list). After the Department (DHMH) screens resumes, interviewing will begin. Ms. Gaither announced the resignation of Vlad Konstantinov, database officer. Ms. Naesea mentioned the accomplishments of Vlad Konstantinov while working at the Board and how much he would be missed.

PIO Report – Summar Goodman

District I & II Meeting

Ms. Goodman reported that 276 "Save the Date" cards were mailed to Board members in District I & II, deans, chairpersons, and NABP. An online e-mail link will be established to enable participants to make hotel reservations for the conference. Ms. Goodman will inform Board members when the system is ready to be utilized. Camden yards has been

reserved for the Board's event from 8 a.m. until 12 p.m. The cocktail reception will be held at Sports Legends at Camden Yards from 6 p.m. until 8 p.m. Ms. Goodman stated that she is currently working on acquiring speakers and special guests to come to the event that evening. Participants attending the conference are expected to be approximately 150-200. LaVerne Naesea stated that program sessions would be finalized after meeting with Dean Knapp on May 3rd.

Flower Mart

Summar Goodman invited Board members to participate in the Flower Mart events. The Board of Pharmacy and students from the School of Pharmacy will man the booth on Friday, May 5th. Games, health tips, and blood pressure screenings are some of the activities being featured at this year's event. John Balch stated he could make available a bone density machine. A question about who would finger stick patients for diabetes testing was asked. John Balch stated that patients should finger stick themselves if blood glucose testing is provided.

Newsletter

Ms. Goodman distributed three templates of the newsletter for the approval of the Board. Rodney Taylor asked if the phrase "inside the issue" could be moved from template #2 and be incorporated into template #1 on page 1. Everyone agreed to have the graphics removed from the top portion of page 1, move everything up, and include the phrase "inside the issue" on the first page. The new layout will be used for the next issue of the newsletter.

Motion: Rodney Taylor moved to accept template number one with changes to be used for the next issue of the newsletter.

Board Action: The Board voted unanimously to accept template number one with changes.

IX. Committee Reports

A. Practice Committee Items

1. Constituent Response Letters

A. BD Medical – Jeff Salzman

Jeff Salzman wrote the Board regarding whether Maryland law permits a pharmacist to unilaterally substitute a product sold over-the-counter, i.e. substitute BD insulin syringes with another brand when the prescribing healthcare provider specifies "BD" or "Dispense as Written" on the original prescription?

Committee Recommendation: No, a pharmacist may not unilaterally substitute a product sold over-the-counter if the health care provider writes “brand medically necessary” or dispense as written”.

Motion: Don Taylor moved to accept the Practice Committee’s letter to Jeff Salzman.

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

B. Neighbor Care – BarCode Technology for Final Check

Rosanne Barto, R.Ph. wrote the Board concerning whether the June 24, 2004 letter from former Board President Mel Rubin allowing technicians to complete the final check (drug to label) using bar code technology is still valid.

Committee Recommendation: Yes, provided that the provisions noted in former Board President Mel Rubin’s letter from June 24, 2004 are met, the final check (drug to label) can be completed by a technician using bar code technology

Motion: Don Taylor moved to accept the Practice Committee’s letter to Rosanne Barto, R.Ph.

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

C. PharMerica – Dispensing Meds in Original Container – Zakia Corria, Chief Pharmacist

Zakia Corria wrote the Board concerning whether the pharmacist is required to indicate the expiration date on the label if the dispensing date also appears on the original container from the manufacturer.

Committee Recommendation: Yes, the pharmacist is required to indicate the expiration date on the label.

Motion: Don Taylor moved to accept the Practice Committee’s letter to Zakia Corria.

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

D. McKesson – Survey – Tina Massengale

Tina Massengale wrote requesting the Board to complete a survey to assist with determining the proper licensure their company could accept from two types of customers. The first set of questions pertain to teaching institutions that do not have a medical director/physician on staff or a pharmacy license but wish to purchase legend items to support their curriculum.

1) Does the Maryland Board of Pharmacy allow teaching institutions to purchase:

Committee Recommendation: Needles (yes), Syringes (yes), IV Solutions (no).

- 2) If you have answered yes to any of the above types of legend product, what type of documentation may we accept as proof that the teaching institution may purchase the product (i.e. a letter explaining what they intend to use the product for)?

Committee Recommendation: none required in Maryland.

- 3) Is there anything you would like to add about teaching institutions that will further help us to comply with your regulations?

Committee Recommendation: The Maryland Board of Pharmacy regulations do not address this issue.

- 4) **Board Comment:** Please be advised that the distributor should be able to determine that the product was received, and that tracking mechanisms are in place for needles, syringes and IV solutions.

The second set of questions pertain to the sale of flu and pneumonia vaccines to nursing homes, home health agencies, or nurses that provide vaccinations as a public service to community.

- 1) Assuming that a nursing home does not have a medical director/physician on staff nor pharmacy, what type of license may we accept in order to sell flu and pneumonia vaccine

Committee Recommendation: Nurse Practitioner (yes) Registered Nurse (no) Physician's Assistant (yes) Other (no) please specify – as long as for immediate administration.

- 2) What type of license may we accept from a nurses' association or home health agency that does not have a pharmacy or medical director/physician on staff?

Committee Recommendation: Nurse Practitioner, yes; Registered Nurse, no; and Other no.

- 3) Is there anything you would like to add about the sale of flu or pneumonia vaccine?

Committee Recommendation: Please see attached Health Occupations Article, §12-508 Annotated Code of Maryland regarding administration of influenza vaccinations.

Motion: Dave Chason moved to accept the Practice Committee's responses to the McKesson Medical-Surgical Inc. survey.

Board Action: The Board voted unanimously to approve the Committee's responses.

E. Rakesh Patel, Pharm.D. – Methadone Rx

Rakesh Patel wrote to the Board concerning questions regarding methadone prescription dispensing procedures.

- 1) Does a methadone prescription require a written diagnosis on the script, such as chronic pain, before it may be dispensed, or may the pharmacist call the physician to verify the purpose of methadone use and document on the prescription?

Committee Recommendation: No, a methadone prescription does not require a written diagnosis on the script. Please be advised, however, that if the prescription is suspect the pharmacist should verify it with the prescriber.

- 2) Does a prescriber require a specific DEA number for prescriptions for suboxone and subutex?

Committee Recommendation: Yes, a physician is granted a valid waiver to prescribe suboxone, and is given a special DEA number that always starts with an "X". It is required on all suboxone prescriptions.

Motion: Don Taylor moved to accept the Practice Committee's letter to Rakesh Patel.

Board Action: The Board voted unanimously to approve the committee's responses to the questions.

F. Dennis Reaver – Repackaging

Dennis Reaver wrote to the Board concerning whether a pharmacist should remove prescription medications from the manufacturer's blister pack and repackage in a child-proof prescription vial to be in compliant with current regulations.

Committee Recommendation: The Maryland Board of Pharmacy laws and regulations do not address specific packaging. Please be advised to contact the manufacturer in writing regarding whether the blister packs are considered child-resistant packaging.

Motion: Michael Souranis moved to accept the Practice Committee's letter to Dennis Reaver.

Board Action: The Board voted unanimously to approve the Committee's response.

G. Jerome Fine – Labeling Requirements for Multi-pack Rx

Jerome Fine wrote the Board regarding whether there are specific labeling requirements for multi-pack prescriptions. Would the label be in compliance if it contains all of the items listed in COMAR with directions for each of the drug items?

Committee Recommendation: Yes, the label would be in compliance as long as it contains all items with directions.

Motion: Joe DeMino moved to accept the Practice Committee's letter to Jerome Fine.

Board Action: The Board voted unanimously to approve the Committee's response.

H. Jane Malphrus – Washington County Health Department – Blister pack

Ms. Malphrus wrote the Board concerning whether a school nurse may cut out around a blister pack without removing the pill, place it in a field trip envelope and send with the teacher to be given to the student.

Committee Recommendation: Prescription medications are required to be labeled with directions for use in Maryland. Please refer to the State of Maryland Department of Education guidelines regarding administering prescription medications on field trips.

Motion: Don Taylor moved to accept the Practice Committee's letter to Ms. Jane Malphrus.

Board Action: The Board voted unanimously to approve the Committee's response.

I. Barbara Rosvold – Pre-positioning prophylactic antibiotics for First Responders

Barbara Rosvold wrote to the Board concerning the content of a protocol for pre-screening and pre-positioning medications at First Responder sites.

Committee Recommendation: The Maryland Board of Pharmacy reserves a definite response until the complete protocol has been submitted.

Motion: Don Taylor moved accept the Practice Committee's letter to Barbara Rosvold.

Board Action: The Board voted unanimously to support the committee recommendation.

J. Fariborz Zarfeshan – USP 797 guidelines

Fariborz Zarfeshan wrote the Board concerning whether the Board has any mandates regarding the new USP <797> guidelines for clean rooms, particularly in the home care setting.

Committee Recommendation: Yes, you must comply with USP <797> guidelines if you do sterile compounding

Motion: Don Taylor moved to accept the Practice Committee's letter Fariborz Zarfeshan.

Board Action: The Board voted unanimously to approve the Committee's response.

K. Sandra Zieve, MD – FYI – Thank you letter to the Board for it's input to Patient First advising not to pre-print a check-off box indicating "brand medically necessary" on either computer-generated or paper prescriptions.

L. Aki K'Singam – Technician to Certify a Pharmacist on USP 797

Aki K'Singam wrote to the Board requesting copies of the Board's Practice Committee Meeting minutes from March 2006. Ms. Singam first wrote to the Board

concerning whether Maryland law allows a technician to certify a pharmacist on USP <797> matters such as aseptic techniques.

Motion: The Board voted to refer back to the Practice Committee.

M. Phyllis Mahon – Medi-Scripts

Phyllis Mahon, Director, Medi-Scripts wrote the Board requesting approval for pre-printed prescription pads.

Motion: The Board voted to table a vote until the May meeting.

B. Long Term Care Task Force – John Balch

Mr. Balch reported on Frederick Memorial's request to have the Board approve their automated dispensing system. The request to approve the use of the system was sent first to QHCQ. OHCQ was unfamiliar with the system and requested that the Task Force look at the system. The Long Term Care Task Force approved the system and is awaiting approval from the Practice Committee. Inadvertently, the approval of the dispensing system was left off of April's Practice Committee agenda. Mr. Balch asked that that Frederick Memorial's automated dispensing system approval be placed on May's Practice Committee agenda.

The Task Force discussed researching a standardized discharge summary. The Task Force would like to have allergies and diagnosis indicated on discharge summaries so that pharmacists would have more information on the patient.

C. Licensing Committee – Joe DeMino

Joe DeMino reported on the March stats. Mr. DeMino stated that Shirley Costley, supervisor for the Licensing unit, has received numerous student requests for reciprocating from New York to Maryland. New York foreign students must register as an intern with the New York Board of Pharmacy if they want to have their hours worked verified by the New York Board. LaVerne stated that the Maryland policy has been revised so that all students must meet the requirements in the state where their hours have been performed before reciprocating to Maryland.

The public meeting was adjourned at 12:15 pm.

