

Maryland Board Of Pharmacy Public Minutes- August 18, 2004

Attendance

Officers: Melvin Rubin, President; Raymond Love, Treasurer, Jeanne G. Furman, Secretary

Commissioners: John Balch, Christiaan Blake, Mark Levi, Mayer Handelman, Donald Taylor, Donald Yee, Margie Bonnett and Joseph DeMino

Absent: Ramona McCarthy-Hawkins and Jeanne G. Furman

Staff: LaVerne G. Naesea, Executive Director; Linda Bethman, Staff Attorney; James Slade, Regulatory Compliance Unit Manager; Shirley Costley, Licensing Unit Manager; Tamarra Banks, Management Information Services Manager; Joan Lawrence, Public Information Officer, Patricia Gaither, Administrative Services Manager, Christina Harvin, Regulations Officer; Sharon Gordon, Board Secretary and Aiyana Neal, Temp. Secretary

Guests: Colleen Bonedonna, Solvay Pharmaceuticals; Howard Schiff, MPHA; Tony Tommasello, PEAC Coordinator; John McGrath, PEAC Executive Director

Melvin Rubin called the Public Board Meeting to order at 9:02 a.m.

- 1. Record of Conflict of Interest:** Melvin Rubin began the first order of business by asking if Board members had any conflicts of interest with any meeting agenda item. There were no conflicts of interest pertaining to the August Public Agenda.
- 2. Corrections to the Minutes- (07/21/04)**

Page 2 - Under 5, 1st sentence, change the name "Boedonna" to "Bonedonna"

Page 3 - Under 9A:Committee Proposed Correspondence, 1st Board Action add Taylor after the name 'Don'.

Page 3-4 change last sentence to "the pharmacists who knowingly fill a questionable prescription should be aware that they are violating the pharmacists code of conduct".

Page 4 - Under Immunization Workgroup-1st sentence, change "specific drugs in case of emergency" to "Influenza vaccines"; under Licensing Committee Minutes, 2nd sentence change "commitment" to "contributions"; under Proposed Regulations Change, 1st sentence, change "confirming that individual will graduate" to "confirming that individual is on schedule to graduate"; 2nd sentence change "recognized" to "verified"

Page 5 - under End of Year Drug Control Inspection Report, 1st sentence, replace "and there should be" with "for reviewing inspection reports".

Board Action

Don Taylor moved acceptance of the July 21, 2004 minutes as corrected. Mark Levi seconded the motion. The Board members unanimously supported the motion.

- 3. President/Executive Committee Report – Melvin Rubin**

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Melvin Rubin asked LaVerne Naesea to introduce new staff members. LaVerne proceeded to introduce Christina Harvin Regulations Officer, Patricia Gaither, Fiscal /Personnel Manager and Sharon Gordon, Board Secretary.

Melvin Rubin reviewed the revision made to the cover letter to the pre-inspection form provided in the public packet.

Board Action: Mark Levi moved to accept letter and Don Taylor seconded the motion.

4. Executive Director's Report – LaVerne Naesea

LaVerne Naesea mentioned that the budget report was still in draft form and would be reported on at next Board meeting on September 15, 2004. She then updated the Board on the status of staff recruitments; specifically, that the Board had advertised and received several applications for the Pharmacist Compliance Officer position, and would be soon advertising for the Compliance Specialist and Compliance Investigator positions. Ms. Naesea also indicated that the Board staff was in the process of reorganization, and that Regulations Officer James Slade had been promoted to Manager of the new Regulatory Compliance Unit. The new Unit will house staff of the former Compliance Unit and former Regulations/Legislative Unit. Ms. Naesea indicated that the change was precipitated to insure more integration of the two functions and for better management oversight. She assured the Board that the Pharmacist Compliance Officer would still function independently regarding clinical and pharmacy practice decisions; as well as provide direct supervision of the compliance staff.

Ms. Naesea next informed members that Johns Hopkins University had received a sub-grant from HRSA through DHMH to assess existing regional pharmaceutical supplies and develop guidelines for creating, maintaining, and distributing a pharmaceutical cache for Maryland hospital pharmacies in preparation for possible catastrophic events. JHU will provide approximately \$14,000 of its grant funds to the Board of Pharmacy to assist with the project. The funds will be applied towards involved staff and Board members salary and per diems (respectively).

Guest Presenter(s): None

PEAC (Pharmacists Education and Assistance Committee) – Tony Tommasello, Director

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Tony Tommasello introduced the new PEAC Executive Director, John McGrath—Mr. McGrath presented his resume and gave a brief synopsis of PEAC’s new direction and goals. Mr. Tommasello discussed the positive outcome of the recent PEAC retreat, and thanked Ms. Naesea and Ms. Harvin for representing the Board at the retreat. He indicated that PEAC will work with the Board to develop several ideas for expanding outreach and identifying impaired pharmacists which were discussed during the retreat. Mr. Tommasello noted that two new volunteer monitors were trained at the retreat. He distributed a brochure describing the October 21, 2004 CE program entitled: ***Prescription Drug Use Overcoming Abuse of Addiction***. He noted that the brochure included phone numbers and other contact information for pharmacists. Finally, Mr. Grath indicated that PEAC has 10 active monitors following 26 cases. He said that PEAC is considering requesting the State Department of Budget and Management for funding for new personnel to handle complaints/inquiries, once outreach efforts take effect. Mr. Grath noted that currently volunteers make up most of PEAC’s staff.

7. 2004 Regulations/Legislative Officer Report – James Slade

Advisory Council on Pain Management

James Slade began by noting that the State Advisory Council on Pain Management had completed a draft final report that was included in the Board packets. He asked that members review the document and provide comments before the August 25th comment period deadline. Melvin Rubin stated that he was surprised by the lack of involvement by pharmacy concerning this issue. Mark Levi noted that the Board should be involved in the Prescription Monitoring Program under recommendation 30. Ray Love pointed out that the only sections that seem to specifically address involvement by health occupation boards were recommendations 27, 28, 29, and 30.

Board Action: Ray Love moved that the Board send a letter recommending that any electronic reporting system should not overburden the pharmacy dispensing system, and to refer the Council to the existence of pharmacy based collaborative practice models to emphasize the valuable role of the pharmacist in coordination of care among multiple providers and to point out the need for pharmacists to be able to participate in electronic medical records. John Balch seconded the motion that was endorsed by the membership.

Long Term Care

Mr. Slade discussed DHMH’s long-term care proposal to restructure the Medicaid program,” that was included in the Board packet and asked for Board members comments. Dr. Ray Love commented that the mental health drugs are listed separately from other drugs.

Board Action: Dr. Love motioned to send a letter to DHMH to note that the division of pharmacy benefits into mental health and non-mental health drugs could have a negative impact on the valuable coordination of care roles played by pharmacists. Joe DeMino seconded the motion, to which the Board voted approval.

James Slade referred the Board to the Long Term Care Regulations Subtitle 34, 10.34.23 in the Board packets, citing the minimum care language. Board members agreed that Managed Care Organizations should be involved to ensure care of individuals to help manage costs of prescription drugs.

8. Public Relations – Joan Lawrence

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Joan Lawrence referred the Board to the FY 2005 Public Education Events Calendar in the Board packet. Board members noted additions that should be made to calendar. Mayer Handelman and Joe DeMino suggested the Board of Pharmacy participate in the Vital Aging Conference on November 5, 2004. The Board determined that it would participate in the event, pending availability of personnel resources. Ms. Lawrence also noted that the National Academy of Managed Care Pharmacy meeting will be hosted in Baltimore on October 13 & 16. Ms. Naesaa recommended that Ms. Lawrence include a listing of all pharmacy-related events that would allow the Board to select which activities in which to participate.

9. Committee Reports

A. Pharmacy Practice Committee – Raymond Love

Dr. Love began his report by summarizing the minutes of the August Practice Committee meeting of pharmacy students and techs that are enrolled in training programs. He told the Board that the committee had worked on defining the term “direct supervision”, of pharmacy students and techs that are enrolled in training programs. He also stated that the minimum age of registered pharmacy techs had been proposed at 18 years old and that the committee decided to change the age to 16 years and enrolled in high school, or to possess a diploma or GED. Dr. Love cited Virginia Law as an example of a possible option. The next meeting for the Technician Workgroup is scheduled for Sept 2nd.

Dr. Love next mentioned that the Committee reviewed the revisions of the Practice Act which included proposing that Consumer Board members could be elected as Board Officers.

Inspection of Hospital Pharmacies

Dr. Love indicated that a committee had been appointed to work on the revisions of the hospital inspection form.

USP 797

Mr. Rubin recommended that a subcommittee be established under the Practice Committee to research and recommend whether the Board should develop regulation based on the sterile compounding standards recommended under USP 797. Don Yee mentioned that he had begun to compare manufacturers standards to hospital standards, and said that the difference seemed to amount to practicality versus good practice standards. Mr. Rubin recommended that the Board form a subcommittee headed by Don Yee to review regulations before coming to a decision. Mr. Yee accepted the assignment.

Committee Proposed Responses to Correspondence

Dr. Love stated that the committee reviewed several practice questions submitted to the Board.

- Regarding whether the Board would allow a pharmacy to retain a prescription in an electronic format vs. a hard copy, the committee recommended that retention in an electronic format be acceptable for all prescriptions except for schedule C-II prescription. C-IIs are not allowed because the federal laws are prohibitive. The Board agreed with the recommendation and discussed how to implement changes in the requirement. It was decided that Medical Assistance

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should participate in the process. Mr. Rubin suggested that the Board seek the opinion of DDC concerning this issue before the Board makes a final decision on this issue.

Board Action: Mark Levi moved that the Board consult with Medicaid and the DDC before moving forward with implementing its decision. Joseph DeMino seconded the motion and the Board voted to support the motion.

Board Action: The Board supported the following proposed responses submitted by the Practice Committee:

- Regarding whether the Board had special requirements for Drive-thru windows at licensed pharmacies, the committee recommended that as long as all state and federal requirements were met for pharmacy operations, there were no other special requirements. The Board concurred with the response.
- The committee proposed responses to questions related to involvement in manufacturing. First, the Board does not address any differentiation between clinical research and clinical treatment and diagnosis; second, it provided the definition of compounding under the MD Pharmacy Act regarding compounding vs. manufacturing; and finally it referred the inquirer to policy guidance from the FDA (Sec. 460.22 Pharmacy Compounding). The Committee felt that the inquiry represented compounding.
- Regarding under what condition(s) a distributor permit would be required,, the inquirer was referred to COMAR 10.34.22 and to the FDA's 21 USC 360 and 21 CFR 207.3.
- Regarding requirements for dispensing prescription medication to clients/patients (pets) without a veterinarian having a prior patient relationship, the inquirer was referred to COMAR 15.14.01.03 that defines the veterinarian/client relationship and to 21 CFR §1306.04 to a veterinarian. The Committee stated that veterinarian may not dispense for an animal unless the animal is cared for by the veterinarian.

B. Licensing Committee – Joseph DeMino

Committee Minutes: Joe DeMino reviewed the Licensing Committee Minutes and statistics included in the Board Packets from the committee's July meeting.

Pre- inspections – Mr. Rubin reported that the pre-inspection booklets were in final preparation for mailing. Related activities will need to be coordinated with the Division of Drug Control

Proposed Regulations Change – 10.34.22

Mr. DeMino discussed drug returns by retail pharmacies under 10.34.22.02 and noted that the committee is considering revisions to the regulation.

End of Year Online Renewal Report

Mr. DeMino noted that a copy of the Licensing Unit's On-line Statistics was included in the Board packet for review.

C. Disciplinary Committee – Jeanne Furman

There was no disciplinary committee report.

D. Emergency Preparedness Committee – Melvin Rubin

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Mr. Rubin referred to the \$14K grant discussed during the Executive Director's report. He noted that the committee will be determining staff and committee member assignments to the project.

E. Technology and Automation Committee – Tamarra Banks

Tamarra Banks presented the FY 2005 Internet Statistics to the Board. She also gave an update concerning on-line renewals and discussed PC maintenance.

F. Council of Boards Report - Melvin Rubin

Mel Rubin mentioned that the Board Member Training had been rescheduled to 10/15/04.

10. Informational

- A. The NABP District II meeting will be held in W. Virginia on October 22, 2004.
- B. ASHP Fed Legislative Affairs seeking Executive Director
- C. Pharmacy Compounding Accreditation Program-Call for Surveyors
- D. California License Transfer
- E. Florida Store Fronts

The Public Board session adjourned at 12:00 p.m.

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