

Maryland Board Of Pharmacy

Public Minutes- July 21, 2004

Attendance

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

Commissioners: John Balch, Ramona McCarthy-Hawkins, Christiaan Blake, Mark Levi, Mayer Handelman, Donald Taylor, Donald Yee, Margie Bonnett and Joseph De Mino

Staff: LaVerne G. Naesea, Executive Director; Linda Bethman, Staff Attorney; James Slade, Legislative Officer; Shirley Costley, Licensing Officer; Tamarra Banks, Management Information Services Officer; Meagan Dillard, Governor's Summer Intern; Tracy Stafford, Pharmacy student intern; and Aiyana Neal, Temp. Secretary

Guests: Colleen Bonedonna, Solvay Pharmaceuticals; Howard Schiff, MPHA; Huseyin C. Tunc, Safeway; Steve Riffin, CVS; Jack Freedman, Drug Control; Julia Dystant, CVS;
Melvin Rubin called the Public Board Meeting to order at 9:13 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 agenda item. There were no conflicts of interest pertaining to the June Public Agenda Items.

2. Corrections to the Minutes- (06/16/04)

Page 1- Reverse the titles for Jeanne Furman who is the Secretary and Raymond Love who is the Treasurer;

Page 2 - Under 4A, 3rd sentence, change the word "mention" to "Mentioned" and "colleague" to "consumer"

Page 3 - Under 7A: 2nd paragraph, 3rd sentence, add "and" after "Independent Pharmacy", delete "and Board of Physician representatives.", and add "be invited." after ASCP;
4th paragraph, 1st sentence, add "and the Board of Physicians." after "the Board of Nursing";
4th paragraph, 2nd sentence, add "and others" following " Ms. Emmaline Woodson"

Page 6- Under Expiration of Prescription Drugs, 2nd sentence, put a period after "practicing this"; delete "such as" and begin new sentence with "For example";

Under Expiration Date of Prescription Drugs, Board Action, change Donald Yee to Don Taylor.

Page 7 - Under C., 5th sentence, put a space between " Spanrepresentatives" to read "Span representatives"; Under C, last sentence change "ASCAP" to "ASCP"

Board Action

Raymond Love moved acceptance of the May June 16, 2004 minutes as corrected. Donald Taylor seconded the motion. The Board members unanimously supported the motion.

3. President/Executive Committee Report – Melvin Rubin

Melvin Rubin informed members that he had attended the funeral for former Consumer Member Reverend William Johnson, who had recently passed away. Board members, staff and guests were asked to hold a moment of silence in his honor. President Rubin next welcomed and introduced new Consumer member, Ms. Margie Anne Bonnett who had been recently appointed to the Board by Governor Ehrlich.

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4. Executive Director's Report – LaVerne Naesea

LaVerne Naesea discussed staffing issues. She said the Board is very close to hiring new staff. The Department approved changing the requirements for Pharmacist Compliance Officer position from that of a Clinical Pharmacist to a Program Manager, Pharmacist. This will allow the Board more flexibility in finding staff for this position that has administrative capabilities. The Board was also approved to interview for the vacant Investigator position. Ms. Patricia Gaither has been selected to fill the Personnel/Fiscal position, pending final approval by the Department and candidates are being interviewed for the Secretary III position.

Ms. Naesea noted that the Board submitted a request to the Department of Budget and Management to convert the three Board contractual positions, Public Information Officer, Personnel/Fiscal Officer and Compliance Investigator, to permanent positions.

5. Guest Presenter(s): Colleen Bonedonna

Ms. Bonedonna of Solvay Pharmaceuticals addressed the board regarding her company's having become aware of certain commercial entities that are engaged in the distribution of a product called Syntest as a "generic" alternative to their product ESTATEST (Esterified Estrogens and Methyltestosterone) tablets. To Solvay Pharmaceuticals' knowledge, the manufacturer of Syntest has never submitted information to the Food & Drug administration (FDA) requesting a determination Solvay Pharmaceuticals believes that providing Syntest to patients as a generic to ESTATEST is misleading to consumers and may be a potential basis of liability to the pharmacists in the state of Maryland. Solvay Pharmaceuticals requested the Board to inform all pharmacists, pharmacy retail managers and managed care organizations licensed in the state, that ESTATEST should not be substituted with a non-AB rated product, and should be filled as written by the healthcare provider. Also, that there is no AB rated product for the digestive enzyme Creon, for which pharmacists cannot legally substitute without obtaining prescriber permission each time. She indicated that a change in the product may cause problems for cystic fibrosis patients.

6. PEAC (Pharmacists Education and Assistance Committee) - A representative was not in attendance; therefore a report was not provided.

7. 2004 Regulations/Legislative Officer Report – James Slade

A. Mr. Slade referred members to the Interim Legislative Schedule that was enclosed in Board packet

B. Proposed Bill-HB-433-Prescription Drug Safety act

Mr. Slade ask members who would be assigned to the workgroup assigned under proposed HB 433 – Prescription Drug Safety Act. Jeanne Furman was appointed to work on the report due on November 1, 2004 concerning this bill.

C. Practitioner Monitoring of Schedule II, II, IV Drugs (HR 3015)

Mr. Slade discussed H.R. 3015, which is proposed to amend the Public Health Service Act and to establish an electronic system for practitioner monitoring for the dispensing of any schedule II, III, IV controlled substance, and for other purposes.

D. Mail Order Pharmacy Issue

Mr. Slade disseminated an e-mail article discussing a Nebraskan law that was passed to reduce the number of U.S. mail order pharmacies allowed to sell medications to Nebraskans. He asked members

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how they wanted to deal with this issue. The board concluded that they did not have enough information and referred the issue to Board member Mark Levi for additional review.

E. Regulations Status Report

Mr. Slade noted the regulations profile included in the Board Packets. A drug therapy management meeting is scheduled at the end of August. He indicated that the outcome of the meeting should result in the development of an application and an explanatory document. The board decided to include information regarding drug therapy management on the website and in the October newsletter.

F. Governmental Affairs – FYI

James Slade noted the articles in the Governmental affairs section of the board packet.

8. Public Relations

Ms. Megan Dillard, Governor's Intern distributed the July 2004 newsletter in the absence of Ms. Lawrence who was on vacation.

9. Committee Reports

A. Pharmacy Practice Committee – Raymond Love

Technician Task Force

Raymond Love said that the Committee discussed the concept of *grandfathering* technicians that have been in place for 3 years or more vs. new technicians that would be expected to take a national exam. Those who are already technicians and have not taken the national exam would only be allowed to work where employed at the time of their certification and if they want to become transferable they would be required to take the national exam at that time. Dr. Love noted that the process would make the licensing process more uniform. He further noted that the committee discussed providing some types of exemption for high school students who were interested in a career in pharmacy.

Committee Proposed Correspondence

Regarding whether prior to filling a prescription a pharmacist must call a prescriber to verify its authenticity when it has been electronically sent with a digitally stored signatures, a proposed letter referenced COMAR 10.34.20 and 10.19.03.07, specify requirements that must be met in order to authenticate prescriptions. Mel suggested that the issue be posted on the Board of Pharmacy website.

Board Action: The Board endorsed sending the letter. Also, Raymond motioned and Don Taylor seconded sending out the response on the Internet

The Committee proposed sending a letter to the Board of Nursing requesting a meeting to discuss the Nurse Mid-wife Formulary.

Board Action: the Board supported sending the letter following a motion by Ray Love that was seconded by John Balch.

Pertaining to the question of whether physicians can prescribe for themselves or their family members, the Committee recommended referring the question to the Boards of Physicians, Nursing, Dental Examiners and Podiatric Examiners. The members felt that there should be a crackdown not only on the physicians themselves but also on the pharmacists who knowingly fill a questionable

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prescription and proceed to fill anyway should be aware that they are violating pharmacists code of conduct. In past years, pharmacists have not been held accountable for questionable prescriptions and the Board hopes to change this.

Board Action: The Board endorsed referring the question to the proposed entities, following a motion by Dr. Love that was seconded by Ms. Ramona Hawkins.

Regarding a request from the Maryland Commission for Higher Education that asked the Board to review a pharmacy technician curriculum that is in development, the Committee noted that presently the Board of Pharmacy does not have the authority to regulate pharmacy technicians. The Board has regulations that hold the pharmacist and pharmacy permit holder responsible for the acts of the pharmacy technicians, which may provide some guidance. The applicable regulations are COMAR 10.34.21, Standards of Practice for Unlicensed Personnel. A letter was presented to the Board for approval.

Board Action: Raymond Love moved and Christiaan Blake seconded to send the proposed response and the motion was carried by the membership.

Immunization Workgroup

Jeanne Furman informed the Board that she attended the Immunization Workgroup meeting with the Board of Nursing noting that the Nursing Board agreed to student pharmacists being allowed to administer influenza vaccines if they are certified and under a licensed pharmacists' supervision. Technicians would still not be allowed to administer drugs at any time. Melvin Rubin stated that the board would have to discuss how pharmacists may handle acute reactions to vaccines since the law does not currently allow pharmacists to administer any drug other than the vaccines themselves.

Automation - Jeanne mentioned that the automation regulations will need to be updated to address final checks as well as other issues. .

Long Term Task Force Care - John Balch discussed the need for pharmacist oversight in assisted living homes.

B. Licensing Committee – Joseph DeMino

Committee Minutes

Joseph DeMino mentioned that the May 2004 minutes were included in the Board Packets. He noted that he was the new Chair for the Committee and recognized the contributions of his predecessor Wayne Dyke.

Pre- inspections

The board reviewed and approved the pre-inspection forms and cover letter that will be sent to pharmacies in advance of the DDC on-site inspections.

Board Action

Ramona moved to send out the letter and pre-inspection document with minor revisions and Don Yee seconded. The Board carried the motion.

Proposed Regulations Change – 10.34.02.03 Licensure Examinations

The Committee recommended that pharmacist students be allowed to take the licensure examination prior to graduation if documentation is received from the pharmacy program confirming that the

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individual is on schedule to graduate. No license will be distributed to anyone without a verified degree.

Board Action: The Board endorsed the recommendation.

The Committee recommended that a person must have a Social Security Number in order to be licensed.

Board Action: The Board endorsed the recommendation.

The Committee agreed on a five day cut-off for pharmacists wishing to renew their licenses on-line, because the submission may not otherwise be processed in time for the license to be issued.

Board Action: The Board endorsed the recommendation.

The Committee also discussed whether or not the state of Maryland should accept reciprocity from California licenses. It then was determined by the Board that the state of Maryland would accept reciprocity from the state of California regardless of when they were licensed. The update will be posted on the website.

Board Action: Donald Yee motioned to accept reciprocity from California and Don Taylor seconded the motion. The entire board accepted as well.

End of Year Online Renewal Report - enclosed in the public board meeting packet.

C. Disciplinary Committee – Jeanne Furman

End of Year Drug Control Inspection Report

Melvin Rubin informed the board that there is not a formal system in place for reviewing inspection reports and there should be. Ms. Naesea recommended that the report submitted with the Board Packets be withdrawn for revisions.

Board Action: Following extensive discussion, Jeanne Furman moved and Joe DeMino seconded withdrawing report until it is reviewed and revised between the Licensing Committee and Division of Drug Control.

Importation Enforcement Workshop (NABP)

The Importation Enforcement Workshop (NABP) will address public safety and legal analysis. It also will address Cease and Desist letters and other unmentioned topics.

DEA Notice on Controlled Substances from Canada

The DEA published a warning notice because increasing numbers of Internet web sites and “brick and mortar” businesses have been claiming to assist individual consumers to purchase controlled substances from Canada and other foreign countries since 2001.

D. Emergency Preparedness Committee – Melvin Rubin

There will be a meeting with the DHMH Volunteer Corp group in the near future. The Bern Model was summarized at the last Emergency Preparedness meeting hosted by the Department of Health and Mental Hygiene. This model uses a formula to determine the number of volunteer practitioners required based on the size and type of emergency. Mr. Rubin indicated that he did not think the model was realistic in the numbers of volunteers required. He also reported that the DHMH meeting discussed reporting and other protocols that should be followed by state and local jurisdictions during emergencies.

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E. Technology and Automation Committee – Tamarra Banks

The End of Year Internet Statistics were included in the public board meeting packet.

F. Council of Boards Report - Melvin Rubin

Board Member Training has been rescheduled to October 15, 2004. The training is a refresher course on ethics for anyone who wants to attend.

- 10. Informational** - The ASHP Fed Legislative Affairs Issue Summary and the Schedule of Free State-sponsored Pharmacy In-Services were included in the public board packet.

- 11. Announcement** - The NABP District II meeting will be held in W. Virginia on October 22, 2004.

The Public Board session adjourned at 12:03 p.m.

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