

**Maryland Board Of Pharmacy
Public Meeting Minutes
October 20, 2004**

Attendance

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

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

Staff: LaVerne G. Naesea, Executive Director; Shirley Costley, Licensing Unit Manager; Joan Lawrence, Public Information Officer, Patricia Gaither, Administrative Services Manager, Christina Harvin, Regulations Officer; Linda Bethman, Staff Attorney; Sharon Gordon, Board Secretary; and Teisha Taylor, University of Maryland School of Pharmacy Student Intern

Absent: Tamarra Banks, Management Information Services

Guests: Howard Schiff, Maryland Pharmacists Association, Stephen Riggin, CVS, Chandra Mouli, Lawrence Onyekweri, CIANEL

Melvin Rubin called the Public Board Meeting to order at 9:15 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 October Public Meeting Agenda.
2. Corrections to the Minutes- (09/15/04)

Page 3–1st paragraph, last sentence, the year “004” should be changed to “2004.”

Under Public Relations, last paragraph, 2nd sentence, “8 untrained Liaisons, and 8 are trained” should be “and 8 liaisons are trained.”

2nd paragraph, 1st sentence, “approved of and” should be “approved and entered into a MOU”.

Page 4– 2nd paragraph, under Board Action, last sentence “This is an area of increasing “important”, should be “importance.”

Page 4 - Long Term Care, 1st sentence “the Departments” should be “Departments””, 3rd sentence, “she indicated such a dual system potentially compromises the health care delivery system and cause a breakdown”” should be “could cause a breakdown in coordination of health care services”. 2nd sentence,

Board Action

Raymond Love moved acceptance of the September 15, 2004 minutes as corrected. Ramona McCarthy Hawkins seconded the motion. The Board members unanimously supported the motion.

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3. President/Executive Committee Report – Melvin Rubin

A. Formulary

Mr. Rubin noted his understanding that the Board of Pharmacy is responsible for holding hearings for possible changes in the State Formulary of Generic equivalents. Maryland Medicaid has expressed interest in deleting the items excluded from pharmacist substitution. Delegate Elliott had objected to this change in the past, but Mr. Rubin said there is indication that he may be willing to accept changes now. One issue is that Coumadin 2 mg, 2.5 mg, and 5 mg are on the ‘negative’ formulary, but other strengths are not. Medicaid reimburses based on generic price of all the other strengths unless the physician obtains preauthorization for the brand named drug. Dr Love questioned whether the Board is responsible for hosting hearing to review the issue and suggested that the statute be changed to eliminate the committee and accept only the FDA Orange Book listings as justification for legal substitution. Mr. Rubin said that he preferred that the Board conduct hearings since it has shown in the past that it could make changes faster than FDA when needed. He reminded the Board of the furosemide problem, which the State handled well, years ago. As to whether the Board is responsible for hearings, it was suggested that since the regulation states “the Department” that we leave it to Medicaid to take the lead.

B. DDC Pre-Inspection Booklet

Melvin Rubin explained that advance copies of the pre-inspection booklet had been mailed to most of the major pharmacy chains. Mark Levi asked when the final booklet would be mailed out. LaVerne Naesea stated that the Board recently signed a contract for the printing the booklet. Don Taylor asked if there would be a lead-time for inspections so that pharmacies could prepare for the new process. He was told that the Board would be sending a copy to describe the system well before inspections under the new process begins.

The mailing will include an explanation of the process. Mr. Rubin stated that an advance copy will be mailed to every pharmacy before January 2005 and that a second copy of the booklet will be sent out shortly before each pharmacy’s regular inspection. He said that filling out the booklet is not mandatory, but it will help expedite the on-site inspection process if voluntarily used. The booklet is a guide for the permit holder when the Division of Drug Control conducts inspections. Mark Levi asked if the booklet would be posted on the website. LaVerne Naesea stated that the information will be discussed in the upcoming newsletter and link to the article could be put on the web site. Don Taylor suggested that we update the website and noted that the announcement for upcoming Board meetings was outdated.

IV. Executive Director's Report – LaVerne Naesea

A. Staffing Updates

LaVerne Naesea announced James Slade’s resignation to assume a new position with the Office of Governmental Affairs. Christina Harvin will assume supervision of the Legislative/Regulations Unit and a request has been submitted to hire a person to fill Mr. Slade’s PIN. Patricia Gaither stated that a hiring freeze exemption has been requested. An exemption was also submitted to hire a temporary office clerk to replace Ms. Lakeya Davis who is on extended maternity leave. The Board concluded interviews for the position of Investigator for the Compliance Unit and is in the final process of hiring

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the Pharmacist Compliance Officer. Mr. Chandra Mouli, the selected candidate was present as a visitor at the October meeting.

B. Office Space Issues

Ms. Naesea requested the Board's approval to explore moving the Board offices to a larger location to accommodate the anticipated need for additional staff to handle registration of pharmacy technicians. She stated that the 1st floor of building or moving across the street as two possible options. Possibly moving part of the office is also a consideration, but Mr. Rubin strongly recommended that the staff stay together in one location instead of splitting the staff in the current building. Mayer Handelman supported Mr. Rubin's concerns.

Board Action: Jeanne Furman moved that the Board approve Ms. Naesea explore all options for relocating its offices and to provide a report when completed. Ramona Hawkins seconded and Board voted to approve.

C. Conference Attendance

LaVerne Naesea, Melvin Rubin and Jeanne Furman are going to attend the NABP District II Meetings in West Virginia.

V. PEAC (Pharmacists Education and Assistance Committee) –

John McGrath, Executive Director, updated the Board on PEAC activities and invited Board members to attend the seminar to be held on the following day. The Board reviewed the annual report that PEAC presented and had no questions.

VI. 2004 Regulations/Legislative Officer Report – Christina Harvin

A. Pharmacy Technician Workgroup Update

Christina Harvin reported on House Bill 998 – Registration of Pharmacy Technicians. The bill authorizes the Board of Pharmacy to regulate technicians and individuals participating in technician training programs. Ms. Harvin informed the Board that the Pharmacy Technician Work Group met on September 24, 2004 and made non-substantive changes to the bill. Christina Harvin explained the Work Group's changes, obtained feedback from Board members and subsequently agreed to place sections regarding regulations for pharmacy students, examinations, training and work experience in a separate part of the bill. Board Counsel stated that placing those sections in a different area would allow the provisions to have an early effective date. This modification will allow the Board to promulgate regulations (in advance) so that Technicians can begin the registration process.

Below the sections of the bill were revised by Board members:

Page 30 I and II: These provisions were deleted from the bill after last week's meeting with Linda.

Page 30 #2: The new change to #2 is shown below...This was Don Taylor's comment at the Board Meeting.

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(2) AN INDIVIDUAL WHILE ENGAGING IN A BOARD APPROVED PHARMACY TECHNICIAN TRAINING PROGRAM UNDER THE DIRECT SUPERVISION OF A LICENSED PHARMACIST OR A REGISTERED PHARMACY TECHNICIAN PROVIDED THE INDIVIDUAL DOES NOT PERFORM DELEGATED PHARMACY ACTS BEYOND A SIX MONTH TIME PERIOD.

Page 32 I, II and 5: A portion of these provisions were deleted to reflect new language.

Page 33 I: A portion of this provision was also deleted to read as follows: IN THE PRESCRIPTION AREA OF A PHARMACY THAT POSSESSES A VALID PHARMACY PERMIT WITHIN A SIX MONTH PERIOD.

Page 35 #5: Pay the application fees set by the Board was deleted based on discussions at the October 20th Board Meeting.

Page 47 Section 4: This section of the bill was deleted. The new section 4 will read as follows: AND BE IT FURTHER ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, THAT The Laws of Maryland read as follows:

Page 47 12-6B-01A: Linda decided to add this section to cross-reference it with the remaining 12-6B. The new provision reads as follows: THE BOARD SHALL ADOPT REGULATIONS THAT ESTABLISH THE REQUIREMENTS THAT SHALL BE MET BY PHARMACY STUDENTS IN ORDER TO PERFORM DELEGATED PHARMACY ACTS.

Page 47 12-6B-02A: This new provision will read as follows:

A) THE BOARD SHALL ADOPT REGULATIONS ESTABLISHING THE REQUIREMENTS TO OBTAIN BOARD APPROVAL OF AN EXAMINATION UNDER THIS SUBTITLE.

(B) THE BOARD SHALL ADOPT REGULATIONS ESTABLISHING THE REQUIREMENTS TO OBTAIN BOARD APPROVAL OF A TECHNICIAN TRAINING PROGRAM UNDER THIS SUBTITLE.

(C) THE BOARD SHALL ADOPT REGULATIONS ESTABLISHING REQUIREMENTS REGARDING WORK EXPERIENCE UNDER THIS SUBTITLE.

Page 47 12-6B-03A: THE BOARD SHALL SET FEES TO BE PAID BY APPLICANTS APPLYING TO BE REGISTERED PHARMACY TECHNICIANS.

(This provision was decided upon at the October 20, 2004 Board Meeting.)

Page 48 Section 5: AND BE IT FURTHER ENACTED, That Section 4 of this Act shall take effect **October 1, 2005**. (This was changed from July 1, 2005 back to October 1, 2005 to allow the Board time to write the regulations.)

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Page 48 Section 4-6: SECTION 4- 6. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take effect on the taking effect of the termination provision specified in Section 5 of Chapter 249 of the Acts of the General Assembly of 2002. If that termination provision takes effect, Section 1 of this Act shall be abrogated and of no further force and effect. This Act may not be interpreted to have any effect on that termination provision. (This language was incorporated per Linda's suggestion.)

Board Action

Mark Levi motioned that we accept all sections except section 12-707. Ray Love seconded.

VII. Public Relations – Joan Lawrence

A. Health Department Training Seminar

Joan Lawrence reported that the Board would be participating at the Governor's Conference on Vital Aging on November 5 at College Park.

B. Emergency Preparedness Liaison/Team Leader Training

She noted that 107 persons attended the most recent Emergency Preparedness training for liaisons and team leaders in attendance. At October 2, 2004 training, it became evident that the team leaders and liaisons did not completely understand the decision-making hierarchy regarding deployment of volunteers. Donald Taylor stated that the "ground rules" keep changing from a medical model to a non-medical model and that the latter model would eliminate real patient interaction, monitoring of patients and monitoring of dispensed medications. The Secretary is responsible for implementing a process. Joan Lawrence stated that she helped to develop a 4-page newsletter for issuance to all boards and dissemination to their volunteers on a quarterly basis. She indicated that the newsletter might be used as a tool to clarify and provide information. The Committee plans to prepare a letter to the participants thanking them for attending and enclosing informational documents that would include the names of local Health Department contacts.

C. HRSA/JHU Hospital Emergency Preparedness Project

Ms. Lawrence informed members that LaVerne Naesea and she had attended a 2 hour meeting on September 30 with representatives from Johns Hopkins and Baltimore City Health Department to discuss the HRSA hospital emergency planning and inventory assessment project that will determine the availability of medications to hospital patients and how they will be transported before receipt of the National Pharmaceutical Stockpile; as well as systems for dispensing medications.

VIII. Management Information Services – LaVerne Naesea

LaVerne Naesea stated that a little more than one quarter of licensees have registered/renewed on line. John Balch suggested a marketing effort to reward licensees who renew early. Ms. Naesea indicated that she and staff were reviewing alternative methods to increase on-line renewals.

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IX. Committee Reports

A. Pharmacy Practice Committee – Ray Love

Nurse Midwives Formulary

The Practice Committee meeting on October 1, 2004 was attended by a Board of Nursing representative to discuss the nurse midwives formulary. Emmaline Woodson of the Board of Nursing attended. The Committee expressed the following concerns:

- The formulary is not a formulary; it is a list of drug classes
- Some of the drug classes contain agents of considerable toxicity, which are generally prescribed by physician specialists. The Committee is concerned about the safety of nurse midwives prescribing drugs in these classes.
- There does not appear to be consistency with regards to which drugs are in the “independent prescribing” versus “co-management” categories. Anticoagulants for instance are in the “independent” category while Ms. Woodson indicated that they are only co-managed.

The Board of Nursing representative, Ms. Woodson, made a list of concerns to take back to the nurse midwives with regard to the formulary. The Practice Committee offered to work with the nurse midwives in coming up with a formulary of specific agents.

Letter to the Practice Committee

The Committee received a letter from Diane Darvey concerning suggested changes to the Pharmacy Practice Act regarding pharmacist rehabilitation committees. The Committee decided to table action until a discussion of a general “Practice Act Revision Bill.”

Influenza Administration Statute

The Committee discussed who would be meeting with the Board of Physician’s Practice of Medicine Committee concerning the regulations regarding influenza vaccine administration. Christina Harvin will attend. The Committee also asked Cherokee Lason Wolf to attend and she consented.

2. Long Term Care Task Force

The Committee discussed when an order (as opposed to a prescription) is acceptable. Prescriptions have limits on refills; orders may continue to be filled if properly reviewed and renewed. An order is only acceptable when:

- The facility has a controlled medication delivery system through a single provider.
- The pharmacy provider conducts regular chart review of all clients.

The Committee considered a draft letter regarding the matter of prescriptions vs. orders instructing pharmacists to cease operating on orders except in the cases noted above. However, the Committee decided that this could result in patients not receiving medication. The Committee recommended that this letter be tabled until such time as the LTC regulations are in effect. The reason is that the implementation of the letter would require further regulatory action. In the meantime, the Board interprets current law as follows:

- There is a difference between an order and a prescription written in a traditional manner.

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- A traditional prescription cannot be interpreted to be an order as there are limitations on refilling a traditional prescription.

The Board accepted these recommendations.

Comments to Long Term Care Regulations

The Committee reviewed responses received after the publication of the long term care regulations. Most of the responses dealt with repackaging issues. The Committee asked Christina Harvin to craft a response that stated that the repackaging regulations:

- Allow access in a manner that generates considerable savings for consumers so long as the medication is not adulterated or counterfeit.
- Do not force any pharmacist to engage in repackaging.
- Allow consumers who could not otherwise afford medication to access medication.
- Reduce the potential medication errors that could result from employing multiple distribution systems from multiple pharmacies in a single facility.
- Preserve the concept of freedom of choice of pharmacy for residents of facilities.
- Provide for a secondary review of dispensed drugs before they are redispensed, thus putting in effect a double check by two pharmacists system that should further reduce errors.

Upper Chesapeake Anticoagulation Clinic

The Committee reviewed several policies from this clinic. Patients serviced by the clinic are patients of the hospital receiving laboratory services of the hospital. The protocol included dosage adjustments as called for by the AG opinion on hospital drug therapy management. Therefore, the pharmacist can operate under the protocol. The pharmacist cannot write a prescription to be filled outside the hospital. The pharmacist can convey a prescription to another pharmacist as an agent of an authorized prescriber. The Committee would advise that any pharmacist calling in an order to another pharmacist identifies both him/herself and the authorized prescriber on whose behalf they are calling. The Board asked the Executive Committee to approve final language for this letter.

Legibility of Prescription Work Group

Christina Harvin reported on the current status of this group. An update was given by the workgroup, which is to study prescription legibility. A letter will be sent to the legislature asking for an extension of the time needed to report to them. The workgroup will send a letter to all stakeholders asking them to work with the group. This will include the Board of Physicians, Dental Board, Board of Nursing, Maryland Association of Chain Drugstores, long term care facility representatives and the Office of Health Care Quality. The group needs a contact for the Podiatry Board. Further meetings are being planned.

Drug Therapy Management

The Committee approved changes in the pharmacist information form for applications for drug therapy management. Considerable discussion regarding implementation took place. The Joint Committee seemed happy with the process and forms development.

Letters Approved

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The Committee approved responses to Bob Feroli regarding emergency dispensing and Mayer Handelman regarding maintaining prescription records via imaging software. The Board approved these letters.

Inquiries

The Committee asked Christina Harvin to draft letters responding to the following inquiries:

- Can a technician check another technician without a pharmacist being involved when dispensing anesthesia trays? The Committee responded that we do not allow technicians to check technicians in this state.
- Can a central company transmit prescriptions for physicians? The Committee responded that any such system would have to be HIPPA compliant, that the pharmacist must be confident that the prescription was not changed by an intermediary, that the system must be approved by the Board of Pharmacy and the system must comply with the freedom of choice statute and therefore any fees charged pharmacies for this system might be problematic.
- What is required to open a pharmacy? The Committee replied with a citation for appropriate regulations and statutes.

Board Action:

Ray Love moved that Board members empower the Executive Committee to approve final letters and then send to Christina Harvin. Don Yee seconded the motion.

B. Licensing Committee – Joseph DeMino

Mr. DeMino summarized a situation where a permit holder who opened his pharmacy in September questioned whether he would be required to pay another renewal fee in December because it was so close to the fee he paid for initial opening. The permit holder was in attendance at the meeting and explained his position. Mr. Rubin responded that state statute will only allow the Board to issue a permit for a maximum of 12 months and that legislation would need to be passed in order to waive his fee. Mr. Rubin told the permit holder that it would be possible for anyone to request a legislator to sponsor such a bill.

Joseph DeMino stated that in September 292 pharmacist renewal applications were mailed, and 60 pharmacists did not renew or the applications were pending additional information of which 3 specified they did not want to renew and 1 was deceased.

The Committee submitted recommendations for two candidates licenses. The first, Aziz Ud-din Nasir, wanted to transfer his MD pharmacist license to Maine, New York, and Pennsylvania through NABP's Electronic Licensure Transfer Program (ELTP). NABP would not recognize Mr. Nasir as having a valid MD license because the scores were improperly transferred to MD in October 2001, without going through NABP's Clearinghouse. The Board should not have accepted the scores transfer directly from Mr. Nasir in 2001. However, having done so he is a valid MD licensee. The Committee recommended that the Board send a letter of good standing to NABP, Maine, New York and Pennsylvania. The Board accepted the recommendation.

The second candidate, Betty Abera, had requested an exemption from having to receive FPGEC certification in order to reciprocate to Maryland, because she had been validly licensed by the New

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York Pharmacy Board, which did not require candidates to receive FPGEC certification at the time she was licensed.

Board Action: Joe DeMino moved that the Board approve the waiver of FPGEC certification. Jeanne seconded the motion that was approved by the full Board.

C. Disciplinary Committee – Jeanne Furman

Jeanne Furman stated that two reciprocity candidates that had been referred to the Disciplinary Committee. George Cawthorne was referred because he was on probation for a CE violation in another state. He has since met state CE requirements that caused the probationary status. The Board granted permission to approve his reciprocation to Maryland. The second candidate, Trisha Lim was referred because she was involved in a dispensing error. The Board reviewed the issue and approved her to reciprocate to Maryland.

D. Council of Boards Report - Melvin Rubin

Mr. Rubin stated that the new board member training session was well attended. Mayer Handelman, Margie Bonnett, Donald Taylor and Christina Harvin attended from the Board of Pharmacy.

The Public Board session adjourned at 12:10 p.m.

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