

**Maryland Board of Pharmacy  
Public Meeting Minutes**

**Attendance:**

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

**Commissioners Present:** John Balch, Donald Yee, Mayer Handleman, Ramona McCarthy-Hawkins, Donald Taylor, Christiaan Blake and Margie Bonnett

**Commissioners Absent:** Mark Levi, and Joseph DeMino

**Staff Present:** LaVerne Naesea, Executive Director; Shirley Costley, Licensing Unit Manager; Patricia Gaither, Administrative Services Manager; Christina Harvin, Regulations Manager; Chandra Mouli, Pharmacist Compliance Officer; Aiyana Waldron, Board Secretary, Adrienne Hanstein, Staff Intern

**Board Counsel:** Paul Ballard, Assistant Attorney General (Interim)

**Guests:** Sushant Sidh, Life Span; Pamela Kumar, NADONA; Jacqueline Vance, NADONA; Ann Marie Barnett, NADONA; Darlene Young, NADONA; Norma Schullz, Life Span, Agnes L. Giannini, NADONA; Stephen Handelman, Woodhaven Health Services; Richard Mainzer, Woodhaven Health Services; John McGrath, PEAC; Heather Heiler, NADONA; Howard Schiff, MPHA; Arnold Clayman, MD-ASCP; Eric Johnson, MD-ASCP; Joe Hill, ASCP; Faith B. Terren, NADONA; Steve Riggan, CVS Pharmacy; Pat Howard, Stella Maris; Sheila Mackerticel, HFAM; Hoai An Truong, Pharmacy Student; Clifton Porter, Manor Care; Joseph Fine, DHMH

**1. Record of conflict of interest**

President Melvin Rubin called the Public Board Meeting to order at 9:00 a.m. and asked Board Members if there were any conflicts of interest concerning the January 19, 2005 Public Meeting. There were no conflicts of interest.

**2. Corrections to the Minutes- 12/15/04**

**Page 1**

- Under Executive Director's Report, 1<sup>st</sup> sentence, change word "on" to "about"
- Under Executive Director's Report, 2<sup>nd</sup> sentence, change capital "A" to lowercase "a"

**Page 2**

- Under Executive Director's Report, 2<sup>nd</sup> paragraph, 3<sup>rd</sup> sentence, omit the words "a letter be written to NABP regarding a resolution for NABP testing" and replace with "the Board sponsor a resolution regarding NABP testing."
- Under Regulations/ Legislative Officer Report, Board Action, 1<sup>st</sup> sentence, add words "pending reformatting" to the end of the sentence

### **Page 3**

- Under Long Term Care, 2<sup>nd</sup> sentence, change word “offices” to “officers”
- Under USP 797 Task Force, 3<sup>rd</sup> sentence, change word “pharmacies” to “pharmacists”
- Under USP 797 Task Force, 4<sup>th</sup> sentence, add words “is enforced” to the end of the sentence
- Under USP 797 Task Force, 5<sup>th</sup> sentence, omit the words “expressed a possibility of less expensive alternatives to USP 797” and replace with the words “noted that the Board may wish to focus on outcomes and allow facilities to explore less expensive alternatives.”
- Change Title “Suspended Pharmacist Allowances” to “Suspended Pharmacist Employment”

### **Page 4**

- 1<sup>st</sup> paragraph, 1<sup>st</sup> sentence, add the word “are” between the words “prescription contained”
- 1<sup>st</sup> paragraph, 2<sup>nd</sup> sentence, change word “record” to “requirements”
- Under Anticipatory Compounding, 1<sup>st</sup> sentence, change word “have “ to “has”
- Under Anticipatory Compounding, 2<sup>nd</sup> Paragraph, omit the entire paragraph. Move paragraph to public relations portion of the minutes.

**Board Action** - The Board voted to approve the revisions to December 15, 2005 minutes

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

President Rubin expressed his gratitude to all those who showed their sympathy toward him during the time of his mother’s death.

#### **New Staff Welcome**

President Rubin welcomed Anna Jeffers, Regulations and Legislative officer and Adrienne Hanstein, Staff Intern.

#### **Council of Boards Report**

President Rubin reviewed a questionnaire on “Evaluating Your Licensing Boards Disciplinary Program.” He explained that the purpose of the questionnaire was to ensure that consumers are being informed of their rights in regards to filing complaints and that the State Board’s Disciplinary Program was fulfilling it’s obligations. He then stated that the Maryland Board of Pharmacy has met the standards of the questionnaire. The Disciplinary Committee will further review the questionnaire.

President Rubin then welcomed all the guests in attendance and allowed them to introduce themselves to the Board and Staff.

#### **4. Executive Directors Report- LaVerne Naesea**

Annual Report - Ms. Naesea reviewed the 2004 Annual Summary Report included in the member's packets. She noted the 5-year goals and suggested that members review them in concert with the summaries of the Administration, Licensing Unit, Compliance Unit, Legislation/ Regulatory Unit and the Management Information Services Unit activities during FY 2004.

University of Maryland School of Pharmacy Meeting - LaVerne Naesea noted that John Balch, Raymond Love and Joseph DeMino and she met with Dean Knapp. She stated that the meetings were originally planned quarterly, however, this was the first meeting held in a year. The issues discussed included the progress of the Drug Therapy Management program, Long Term Care regulations, and how to better equip pharmacy students by making them more cognizant of how to avoid medication errors and providing more emphasis on customer service training.

Raymond Love also discussed providing students feedback on their area(s) of weakness when they do not pass the NAPLEX or the Law exam (MPJE). He then said that the Board would be exploring how to encourage discussion of the issue at future NABP meetings along with initiatives being taken by the AACP (pharmacy schools' national organization).

Staff Family Loss - Ms. Naesea informed the Board of the death of Pharmacist Compliance Officer, Chandra Mouli's, father.

#### **5. Guest Presenters- Joe Fine, Medicaid**

Mr. Joe Fine, Director of Pharmacy Services for Medicaid, spoke on Narrow Therapeutic Index Drugs. Medicaid wants certain drugs that have generic substitutes removed from the Narrow Therapeutic Index (NTI) list so generic substitutions may be made if appropriate. He noted that the idea of changing the NTI began in 1999 with the Board's support but was not carried out because of political opposition. Mr. Fine asked the Board to continue to support the change. Raymond Love noted that the Board continues to support the initiative and suggested that the Board write a letter to DHMH Secretary, Anthony McCann on their position regarding the Narrow Therapeutic Drug Index. Jeanne Furman suggested that the Board of Pharmacy and Medicaid both send a letter to the Secretary. Melvin Rubin recommended that the Board also inform the Board of Physicians of the issue.

Board Action - John Balch moved to work with Maryland Medicaid on composing a letter. The Board approved the motion.

#### **6. PEAC (Pharmacist Education and Assistance Committee)- John McGrath**

Statistics - John McGrath reviewed the PEAC statistics for the month of December, stating that 13 Board referred cases were under contract with PEAC of which 10 are in

good standing. He noted that there were two positive urinalysis collected out of the 32 screenings performed.

Mr. McGrath next briefed members on the recent PEAC monitor training and thanked Jeanne Furman for participating. Jeanne Furman commented that she explained the Boards expectations on Board referred cases. The monitors in attendance had a lot of questions on reporting infractions. She then stated that any infraction (minor or major) must be reported to the Board on any Board referred case.

Raymond Love led a discussion regarding pharmacists on probation who fail to inform their employers of their probationary status, thus committing a contract infraction. Dr. Love mentioned that the Board had discussed putting a subtle notation on the probationary pharmacist's license so the employer would be made aware of their probationary status. Mayer Handelman and Jeanne Furman supported the idea as well as did John McGrath. A guest participant suggested that the pharmacist's employers should be solely responsible for verifying the status of their employees. Dr. Love responded that it is also the Board's responsibility to ensure protection of the public. Melvin Rubin stated that this issue would be forwarded to the licensing committee for further examination and recommendation.

The next PEAC meeting will take place on February 17<sup>th</sup> at 8:00 a.m.

**Board Action** - Raymond Love moved that the Licensing Committee discuss methods of indicating probationary status on the license of pharmacists and report back to the Board. Jeanne Furman seconded and the Board approved the motion.

## **7. Regulations/ Legislative Officer Report- Christina Harvin**

### **Legislation Update**

**Pharmacy Technician Bill** - Christina Harvin summarized the status of obtaining sponsors for the Pharmacy Technician Bill. She and Donald Taylor had recently met with Delegate Rudolph who subsequently agreed to be the lead sponsor of the Pharmacist Technician bill. Delegates Elliott and Bozman will co-sponsor the bill. Delegates Goldwater and Sophocles have also expressed interest in co-sponsoring the bill. Delegate Rudolph expressed concerns regarding the minimum age requirement, noting that the minimum age of 16 years may hinder the approval of this bill. John Balch noted that the original age requirement was 18 years and older in the previous draft legislation. Ms. Harvin asked the Board if it want to consider changing the minimum age requirement to 18 if necessary. Donald Taylor expressed that he did not want to see the bill stalled over a 1 or 2-year difference in the minimum age requirement. Jeanne Furman expressed the same concern, but suggested receiving input from MPHA and NACDS on the age debate. A guest suggested a 17 years old minimum as a possible compromise.

**Other bills under consideration by Delegate Rudolph** - Delegate Rudolph gave Christina Harvin and Donald Taylor a list of proposed bills, including one on Mail Order

Pharmacies and equal access to all patients. Mr. Rudolph has asked for technical advice from the Board in drafting a bill. The Board agreed to assist Del. Rudolph. Other issues for proposed bills included: Re-importation, Regulating PBM's and Medicare Part D issues. Raymond Love recommended that the legislative committee further communicate with and educate Delegate Rudolph with information concerning the bills being considered for proposal.

Wholesale Prescription Drugs and Device Distribution and Licensing Act - Ms. Harvin received a letter from Delegate Stern regarding wholesale prescription drugs and device distribution and licensing act. She mentioned that she had just received the related proposed legislation and would provide the licensing committee with a copy of the legislation in the near future.

Senate Bill 24 -Health Occupations Practicing Without at License - Ms. Harvin explained that Senate Bill 24 was brought to the Board in 2004 and the Board agreed to support it. Senate Bill 24 makes performing certain occupations with out a license a felony. Currently, performing without a license is a misdemeanor. Ms. Harvin and Anna Jeffers developed a position paper on the issue based on comments received from Board members and will distribute it to the Board for review in the near future.

House Bill 14-Prenatal Dietary Supplement Distribution - Christina Harvin noted that this was another bill that will be reviewed in detail on a later date. She then passed out documents to the Board for review. Ms. Harvin informed the Board of a position paper due on this subject.

House Bill 433- Prescription Drug Safety Act - Christina Harvin informed the Board of a change in the deadline. The deadline for the interim report was originally on March 15. Delegate Mandel moved the deadline up to February 1<sup>st</sup>. Ms. Harvin stated that the Committee would be able to meet the new deadline date.

## **Regulation Update**

Christina Harvin updated the Board on regulations including: 10.34.02- Examination for Licensure Professional Experience Programs, Licensing of Wholesale Prescription Drug Distributors, Pharmaceutical Services for residents in Long Term Care Facilities and 10.34.32- Pharmacist Administration of Influenza Vaccinations.

Administration of Influenza Vaccinations - Raymond Love recommended that staff meet with the Board of Nursing to discuss the legislation and proposed regulations regarding Administration of Influenza Vaccinations along with a joint letter from the Board of Pharmacy and the Board of Physicians, explaining their position on the regulations, specifically dealing with administration of emergency medications as part of the protocols.

Long Term Care – President Rubin allowed three guest attendees to present their organizations' views on the proposed Long Term Care regulations. The first presenter,

Ms. Jackie Vance of NADONA (nursing organization) listed several reasons why she felt the repackaging portion of the Long Term Care regulation puts patients at risk. Specifically: (1) Lack of storage space in Long Term Care Facilities (2) Infrequent Shipments (3) Inability to replace a small number of pills immediately, if necessary, (4) Inability to change specific patient medications at anytime, which would lead to frequent unnecessary shipments and (5) Lack of knowledge of medication origin. Ms. Vance argued that all of the problems she outlined could place patients in danger and indicated that repackaging may not be cost effective.

Clifton Porter of Manor Care (nursing home) also expressed his concern regarding the Lack of space in Long Term Care facilities. He also stated that he agreed with all the points Ms. Vance brought up prior to his presentation.

The last presenter, Mr. Sushant Sidh of Life Span (non-profit nursing home/assisted living providers), expressed the similar concerns as those presented by Ms. Vance and Mr. Porter.

Ms. Jackie Vance informed the board of NADONA's desire to attend any meetings regarding Long Term Care.

Raymond Love on behalf of the Practice Committee reminded the public of the fact that repackaging was only an option, not an order, and provided a historical summary of the development of the Long Term regulations. He reminded participants that all stakeholders were invited to the Task Force meetings and that there was an opportunity for public comment following the proposal of the Long Term regulations in the Maryland Register. He indicated that after the closing date for receipt of public comments, the Practice Committee considered the concerns expressed on the proposed regulations by Mayer Handelman. Dr. Love stated that the Practice Committee recommends that Board consider amending the regulations to specifically address the repackaging issue and then re-propose the regulations within the timeframe allowed.

**Board Action** - Raymond Love moved for the Board to accept the Practice Committee's recommendation to consider adding patient safety and quality assurance language to the repackaging portion of the Long Term Care regulations and to subsequently re-propose the regulations. Jeanne Furman seconded the motion, which was approved by the full Board.

## **8. Administration and Public Support- Patricia Gaither**

**Staffing** - Patricia Gaither summarized the staffing status sheet that was included in the member's packets. She specifically noted that regarding the Compliance Unit's vacancies, an offer had been made to a Compliance Investigator candidate and that the recruitment of the Compliance Specialist was underway.

Newsletter – Ms. Gaither mentioned that despite the vacancy caused by the leaving of the former Public Information and Education Officer, Joan Lawrence, the January newsletter is completed and expected to be printed and mailed out by the end of January.

Flower Mart - Ms. Gaither informed members that the rental and leasing of equipment for the Flower Mart had been completed and a list of donors, volunteers and a schedule will be developed. The Public Board meeting date was changed to Tuesday, May 17<sup>th</sup> so the Board members can participate in the Flower Mart.

## **9. Management Information Services**

The Board reviewed the Internet statistics included with the Board Packets.

## **10. Pharmacy Practice Committee**

Post Inspection Survey - John Balch reviewed the Post Inspection Survey. The survey was formed to improve the pharmacy inspection process.

**Board Action** - Raymond Love moved to accept the Post Inspection Survey. Jeanne Furman seconded and the motion was carried by the full Board.

Long Term Care Task Force Report - John Balch explained that a draft joint communiqué by the Board and Office of Health Care Quality (OHCQ) had been prepared concerning the numerous errors that occur when patients are transferred from a hospital to a Long Term Care facility. Problems also occur when patients transfer from Long Term Care facilities to hospitals. Mr. Balch explained that ultimately, the goal would be to have a licensed pharmacist review all discharge summaries and orders of patients leaving their facility for accurateness and completeness of the medication profile. The Board and OHCQ would like all facilities to be aware of any change in the discharge/transfer of patients between LTC and Acute Care, so they will not be overwhelming when instituted. Margie Bonnett suggested that the letter inform the facilities of what actions expected to be taken in response to the concerns expressed in the letter. Mr. Balch noted that the communiqué is not yet complete. OHCQ will add a final paragraph with a possible goal statement.

### Questions for the Board

1. Is it acceptable for inspector to enter the pharmacy area of a building?

The Practice Committee recommends that the position of the Board is that it is acceptable for a building inspector to enter a pharmacy area of a building only if a licensed pharmacist is present.

2. Can a certified technician take a verbal order?

The Practice Committee agreed that the answer should be “No”.

**Board Action:** The Board voted to accept the recommended responses to the questions.

## **USP 797**

Donald Yee informed the Board that Maryland State is supposed to be following USP standards. The USP 797 committee is currently refocusing on an inspection of what Maryland State wants minimally for our pharmacies.

## **11. Licensing Committee- Shirley Costley**

### **Licensing Unit Statistics**

The Board reviewed the Licensing Unit Statistics individually in order to conserve time.

### **Application for Distributor Permit from Canada**

Shirley Costley briefed the Board on a recent application that was submitted from a distributor located in Canada. Some members of the Board were not aware that the Board gave permits to distributors located outside of the United States. Jeanne Furman suggested that the Board contact the FDA on this issue. The Board decided that the Licensing Committee should review this subject further and that the FDA be contacted.

### **Virginia's Licensing System**

LaVerne Naesea informed the board of a plan to use Virginia's licensing system as a benchmark for Maryland State. She mentioned that their process seems to be more efficient and less time consuming compared to our current system. LaVerne Naesea and Shirley Costley will be taking a trip to Virginia to gather information in the near future.

## **12. Disciplinary Committee- Jeanne Furman**

Steven Marcalus - Melvin Rubin briefed the Board on the case of Steven Marcalus. Mr. Marcalus' license was revoked in 1987 for Medicare insurance fraud. Mr. Marcalus has requested that the Board reinstate his license. The Disciplinary Committee recommended that the Board reinstate Mr. Marcalus' license because he fulfilled all the requirements of his order.

**Board Action** - Donald Yee moved to reinstate Mr. Marcalus. The Board accepted the motion.

**The meeting was adjourned at 11:51 a.m.**