

**Maryland Board of Pharmacy  
Public Board Meeting  
January 21, 2004**

President Ades called the Public Board Meeting to order at 9:10 a.m.

**Attendance**

**Commissioners Present:** Stanton G. Ades, President, Melvin Rubin, Secretary, Jeanne Furman, Treasurer, John Balch, Raymond Love, Wayne Dyke, Ramona McCarthy-Hawkins, Christiaan Blake, Rev. William Johnson, Sr., Donald Yee, Joseph DeMino and Mark Levi

**Board Counsel:** Linda Bethman, Staff Attorney

**Board Staff:** LaVerne G. Naesea, Executive Director; James Slade, Legislative Officer; Catherine S. Putz, Compliance Officer; Shirley Costley, Fiscal/Personnel; Joan Lawrence, Public Relations; Tamarra Banks, Information and Technology; Deitra Gale; Compliance Specialist

**Guests** Tony Tommasello, PEAC, Howard Schiff, MPhA, Kathryn Lavriha, Barr Labs, Gil Cohen, PEAC, Gary Wirth, Giant, Marhl Flowers, Safeway/MPhA, Huseyin Tunc, Safeway, Jeff Maltese, Shoppers, Jack Freedman, DDC, Scott Staso, CVS, Sandip Patel, Pharmacy Student, Deborah MacCubbin, Pharmacy Student, Diane Darvey, NACDS, Gil Genn, MACDS, and Sherrise Cumberlandler, Walgreens, Corey Johnson, Healthcare Consulting and Logistics

**Recusals**

Stanton G. Ades asked Board members to indicate if there were any conflicts of interest with agenda items. No members responded.

**Approval of Minutes (11/19/03)**

Page 3, heading NABP District II Meeting, add “Catherine Putz” after LaVerne Naesea at the beginning of the first line.

Page 4, heading Dinner for Former Board/Staff Members, delete the word “former”.

Ray Love moved to accept the November 19, 2003 meeting minutes with corrections. Jeanne Furman seconded the motion. The Board passed the motion.

**Approval of Minutes (12/17/03)**

Page 1, heading Commissioners Present, delete “and Joseph DeMino”.

Page 3, heading Summit with Chains, add “and agenda items of mutual concern”, at the end of the last sentence.

Page 9, heading Johns Hopkins Pharmacy, delete the last sentence “In order to do so a waiver permit would need to be held”.

Mark Levi moved to accept the December 17, 2003 meeting minutes with corrections. Ramona McCarthy-Hawkins seconded the motion. The Board passed the motion.

### **Guest Speaker(s)**

Gil Genn, representing the Maryland Association of Chain Drug Stores (MACDS) thanked the Board for the opportunity to discuss how the chains may be able to enter into a dialog to improve Quality Assurance (QA) programs, so that the Board will understand the chains' internal operations, in terms of peer review and the QA programs at different pharmacies. He stated the Chains would like to engage in further dialog concerning the data reporting form, and investigating pharmacies and pharmacists, through the Board meeting forum, and other mechanisms.

Mr. Genn suggested that there are serious legal questions of due process and equal protection with the Board investigative process. He stated that it is very difficult to examine the law by having a Board or an entity as the investigator and the arbitrator because the same person(s) making the decisions regarding the investigation would be the same person(s) voting regarding the guilt or innocence of the permit holders. He stated that MACDS wants to raise the issue of conflicts of interest. He said these conflicts are not found in other professional organizations -- medical organizations, or lawyers. Mr. Genn described how other professions have an independent investigator to investigate the facts, and report back to the Board or the Commission unlike the Board of Pharmacy which reviews the facts and renders a decision. Further he said that MACDS has a very serious question as to the fairness of the procedures that may be imposed by this Board.

Finally, in light of what the Board decides in terms of investigations, he said that MACDS would like to know the Board's fiscal note, in order to address the causes for Board's backlog. He asked if more investigators had been requested and how the Board plans to streamline and improve the investigative process. Mr. Genn stated that clearly there might be areas, which MACDS can help assist the Board in the Budget process.

Diane Darvey, National Association of Chain Drug Stores (NACDS), addressed streamlining the investigation process, noting that the peer review process needs to be handled by an entity different and separate from the disciplinary body. Ms. Darvey commended the Board for the excellent job with the Quality Assurance process. She suggested to the Board that it should allow the QA process to work and allow an investigative body separate from the Board handle the investigation, but not mix the two.

Huseyin Tunc, of Safeway reemphasized some facts mentioned by Mr. Genn and Ms. Darvey. He expressed a need to increase direct communication between the Board and chain representatives. Secondly, he mentioned that letters from the Board seem to already assume that an error has occurred and sometimes the incidents may have occurred a year to six months earlier. When this is the case many of the complaints have already been resolved through a chain's review process.

Gary Wirth, Giant Pharmacy, thanked the Board for the opportunity to speak to the Board. He stated that Giant implemented a systems approach to their pharmacy operation and quality assurance a year ago and that it is working well. Currently, Giant is revising the internal QA process to meet the Board's new requirements. Mr. Wirth commended the Board on its Consumer Education efforts. He asked the Board to direct any questions to the Director of Operations at Giant in order to insure that it receives the information needed to resolve consumer issues.

Jeff Maltese, Director of Pharmacies at Shoppers, is responsible for the entire pharmacy operation. Jeff Maltese explained Shoppers' internal process dealing with dispensing errors and consumer complaints.

Shoppers has a mandatory form to be completed when an incident report whenever there is a dispensing error. The pharmacist involved in an incident is required to complete the form and submit it to the Director of Pharmacies immediately. The pharmacist is subject to disciplinary action or termination if this procedure is not followed. The Operations Team and the Director execute the proper courses of action. The Operations Team reviews the forms every Monday.

Sherrise Cumberlander of Walgreens, described their quality assurance program noting that it had recently hired a Pharmacy Supervisor for each district that is responsible for making sure there is a follow-up regarding errors.

Scott Staso, CVS, explained that they have their own external process. CVS introduced a Quality Assurance Program five years ago that was proactive and reactive in nature, including a review process for pharmacists that have repeated errors. CVS would like to continue to work with the Board, as in the past, to correct any issues or errors. CVS also has an online reporting process similar to Walgreens.

Melvin Rubin noted that when a consumer makes a complaint to the Board of Pharmacy, the Board is required to investigate the complaint. He said that the Board needs a way to gather enough information, to determine if an error occurred. However, when the Board doesn't receive a response then it cannot complete its investigation.

Stanton Ades stated that there seems to be a discrepancy between what the Board is asking for and the response the Board receives. He said that the proper information helps the Board to determine whether an error occurred.

Ray Love noted that several of the presenters mentioned that something about the Board's process was problematic. He stated that somehow there is a need to investigate sufficiently to decide whether the Board wants to take action. He noted that the Board has recognized that it did not have the proper resources to meet all investigative needs and has talked about whether more investigative resources are needed and acknowledged that it needs to be discussed further.

Howard Schiff, MPhA, stated that the Board had asked him several months ago whether MPhA supported private or public hearing proceedings for pharmacists with error problems. He said that at that time he had not read the regulations enough to know how to properly answer the question. Mr. Schiff said his response at that time was MPhA supports its attorney's position. Since that time Mr. Schiff had reviewed the regulations and noted that in C.O.M.A.R. 10.34.01 a pre-hearing conference is described in which members of the Board are able to review and possibly settle the complaint with a pharmacist or permit holder without going through a formal hearing process. If the respondent does not agree with the resolution then it goes to the full Board for a hearing and possible disciplinary action. Mr. Schiff said he believes that the regulation allows same participants on the pre-hearing conference to then be part of the full Board hearing; making it appear that the prosecutor becomes the jury. He said that this is not a fair process that is part of the law.

### **President/Executive Committee Report – Stanton Ades**

#### **NABP 100<sup>th</sup> Annual Meeting**

The National Association of Boards of Pharmacy's (NABP) and NABP's Centennial Celebration, will be held on April 24-27, 2004 at the Fairmont Chicago, Chicago, IL. The Board traditionally sends two Board members. Joseph DeMino will represent the Board as a Delegate and Jeanne Furman will represent the Board as an alternate. Melvin Rubin will also be attending. The Board will provide financial support for Ms Furman and Mr. Rubin. Mr. DeMino will provide his own financial support.

Ray Love brought to the Board's attention the Board action to sponsor a resolution for the next meeting of NABP that requires NABP to re-evaluate its post examination procedures for FPGEC to accelerate the certification process and notification to Boards of candidates' eligibility. Jeanne Furman noted that the proposed resolutions must be received at NABP Headquarters by March 15, 2004.

#### Follow-Up Chart

LaVerne Naesea reviewed the new 'Follow-up Chart' which indicates action items which are still in progress. Melvin Rubin stated that he would like for the format for the follow-up chart to be also be used for the Executive Session.

#### **Board Action**

The Board passed a motion that a follow-up chart be developed and used to keep track of the status of complaints and medication errors.

#### Board Members

Stanton Ades reported that 2004 marks the end of terms for Rev. Johnson, Wayne Dyke, and himself. Nominations for a consumer member, chain member, and a long-term-care pharmacy member are in process.

#### Election of New Officers

Terms usually run from July 1 – June 30<sup>th</sup>. In March 2004 the Board will hold elections of new officers for the positions of President, Secretary, and Treasurer. LaVerne Naesea will send out a copy of duties of officers to Board members.

#### **Executive Director Report - LaVerne Naesea**

#### Staff Updates

The Compliance Investigator was hired but withdrew his interest due to personal issues. The Board will review the others interviewed to select an appropriate candidate. If necessary the Board may need to begin the process over again. The Personnel Officer position was offered to Maryann Pinder who accepted and will begin in mid-March 2004. The Board renovations will begin February 2004 thru March 2004 to accommodate office space for new staff.

LaVerne Naesea developed a survey to mail to interested parties to arrange a convenient date and time to schedule the summit. A draft of the survey was included in the Board packet for discussion.

#### Summit with Chains

Joe DeMino, Jeanne Furman, and Ray Love will have a meeting to develop agenda items for the summit. The request for agenda items will remain on the summit survey to be mailed to pharmacy permit holders operating retail establishments. The Board has committed to two agenda items, one being medication error reporting and the other getting the chains to respond to PEAC more.

#### **Board Action**

The Board passed a motion to limit the choice of dates to host the summit to March 1 or March 11, 2004.

### **Board Action**

Ray Love moved that the Board continue current policy for pursuing and investigating patient complaints and medication errors up to and including if necessary subpoenas until such time that the Board develops a revision of the policies. John Balch seconded the motion. The Board passed the motion.

Mel Rubin suggested to notify each person that attended the public session today of the Board's action. Ray Love suggested placing the summary statistics for disciplinary cases and complaints in the public minutes.

### **Board of Nursing**

LaVerne Naesea reported on the letter written to Donna Dorsey, Executive Director for the Board of Nursing. Ray Love asked that we not specify only inoculations. When the meeting takes place the Board will make this clear. Barbara Neuman responded on Donna Dorsey's behalf with a date, which many of the Board members could not make. The Board responded to Barbara Neuman offering alternative dates. Barbara Newman informed the Board that she received the new dates and will get back to the Board.

### **Travel Information**

The New and updated travel information was included in the packet. Items that apply to the Board are in bold. Please contact Shirley Costley or LaVerne Naesea if you have a question.

The Board has a new copier in the office that scans documents and can send to the computer network. A trial run was performed by sending the Board packet to members, but the members' systems rejected the document because it was too large. Staff will attempt to develop a private website that will give Board members a link so that they can go online to view and download the material. The hard copies will still be mailed. Testing various methods will be done. Ray Love suggested e-mailing the minutes separate from the packet, eliminating section dividers in the packets, and sending Board members communication items weekly.

### **PEAC**

Tony Tommasello, PEAC reported that they are handling 26 cases of which eleven were Board referred. PEAC had one case discharged and one new client referred by the Board. Mr. Tommasello reported that PEAC's CE program is on the calendar for October 21, 2004. The speakers have already committed to the program. The topic is on "Prescription Drug Use: Overcoming Abuse of Addiction".

PEAC is recruiting for a Director's position. There are two candidates in the running for this position.

PEAC is considering using saliva testing as a method in addition to urine testing for monitoring impaired pharmacists. Saliva testing is used by other drug treatment programs and has been found to be useful, accurate and easier. It will give PEAC the ability to do on the spot drug testing with clients. PEAC will schedule a presentation regarding saliva testing to the Disciplinary Committee.

### **Regulations/Legislative Officer Report – James Slade**

James Slade reported that the Legislative Session began last week. He sent some bills to the Board and received a few comments on: SB 87 – authorizing any person to file with a circuit court that has venue a

petition alleging violation of specified provisions of the Open Meetings Act if a public body fails to comply with these provisions, etc. and HB 114 – prohibiting the sale, distribution, prescription, or dispensing of dietary supplement products containing ephedrine group alkaloids; providing for exceptions to the prohibition; establishing penalties for violation of the prohibition; and defining a term.

#### Regulations Status Report

The report will be included in February's packet.

#### Chapter 23 Pharmaceutical Services to Residents in Long-Term Care Facilities

James Slade presented the Board with final changes to the regulations from the Pharmacy Practice Committee.

#### **Board Action**

Jeane Furman moved to publish for comment the Chapter 23 Pharmaceutical Services to Residents in Long Term Care Facilities, with amendments recommended by the Pharmacy Practice Committee. Ray Love seconded the motion. The Board passed the motion.

#### Pharmacy Equipment COMAR 10.34.07

James Slade presented a memorandum dated January 7, 2003 to the Pharmacy Practice Committee regarding pharmacy equipment. The Committee received a question about prescription balances.

The Committee recommended a change in regulations. The Committee is proposing to change the regulations to state that a pharmacy shall have the following equipment to carry out the practice of pharmacy in Maryland: "A Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity to a Class A prescription balance".

#### **Board Action**

Joseph DeMino moved that the Board approve an amendment to COMAR 10.34.07.01. John Balch seconded the motion. The Board passed the motion.

#### *Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit*

No comments were received during the comment period that ended January 12, 2004. The regulation will become effective as proposed. Mr. Slade will put a copy of the final action in the Board packet when it is published in the Maryland Register.

#### *Licensing of Wholesale Prescription Drug or Device Distributors*

The comment period will end January 26, 2004. The Board will not receive the comments until the end of the January. The Licensing Committee will review the comments.

#### *Drug Therapy Management Joint Committee*

The Board sent a letter to the Maryland Board of Physicians regarding the Drug Therapy Management Joint Committee to notify them that Joe DeMino, Ray Love, and Don Yee were appointed to represent the

Maryland Board of Pharmacy. The Board also asked the Maryland Board of Physicians to quickly name their appointees to the committee.

## **Public Relations**

### *2003 Annual Report*

Joan Lawrence presented the 2001 and 2002 Annual Report to show the color scheme used. Ms. Lawrence presented the choices for a color scheme for 2003. Member selected the theme for the 2004 report.

## **Board Action**

### *Upcoming Events*

On January 13, 2004, Langley Park held a health fair on blood pressure screening. On January 17, 2004, there was a Vietnamese Health Fair. The Board worked with Dr. Boyle in the student section of the Maryland Public Health Association and provided give-away items. A Hispanic health fair is planned on February 28, 2004. Ms. Lawrence indicated that those interested in the mentioned could contact her.

### *Newsletter*

Joan Lawrence passed out copies of the newsletter for those did not receive them. LaVerne Naesea commented the contents of the recent newsletter were very substantive and reflective of current pharmacy practice issues. Ms. Lawrence stated that all articles for the next issue should be submitted by March 1, 2004. Committee chairs are expected to submit articles.

### *Maryland Pharmacy Coalition*

Ms. Lawrence noted that she is waiting for information regarding the 2004 Flower Mart.

### *Pharmacist Legislation*

Howard Schiff announced that notices will be mailed soon for Legislation Day sponsored by the Pharmacy Coalition, scheduled on February 19, 2004.

## **Pharmacy Practice Committee- Dr. Ray Love**

The Pharmacy Practice Committee met on January 7, 2004. The Committee worked on issues in Long Term Care Regulations related to pharmacy equipment. Mr. Slade reported on specific language being considered during his earlier report.

### *Maryland Pharmacists Association*

The Committee approved letters to be mailed to Howard Schiff of the Maryland Pharmacists Association, regarding the "Do Not Substitute" line in the fact that they are valid. The Committee also responded to the question concerning faxed prescriptions. The Committee believes that faxed prescriptions may be reduced in size and do not have to be retained on an 8 ½ x 11 piece of paper as long as all of the prescription information is included.

### PBM Bill

The Committee previously reviewed and provided written comments on the PBM bill. James Slade orally presented revision to the bill with the Committee. Ray Love noted that legislators involved are interested in having a PBM bill go forward this year.

### Practice Committee Questions

The Committee considered two additional questions. The Board was asked whether it permits automated drug distribution systems in transitional care units and hospitals. The Board does permit automated drug distribution systems for use in transitional care units. The Committee will write a letter the Division of Drug Control to make sure that they understand. In the past there has been a problem with Division of Drug Control interpretation of the Board allowing this.

The other question addressed by the Committee was who can dispense medication in a free clinic. If a free clinic has a pharmacy license, the pharmacist can dispense in accordance with the regulations. Also an authorized prescriber can dispense medication.

### Waiver Permits

Waiver permits were discussed. The Committee questioned whether the current waiver permits do everything that is needed to ensure good pharmacy practice. Presently, the waiver permits only indicate what practice areas the pharmacy in which the pharmacy may participate. The Committee discussed whether specialty permits are needed for pharmacies that specialize in cancer chemotherapy, infusion, compounding sterile products, and areas of that nature. There seemed to be a consensus that there were certain activities that should require added oversight when they deal primarily with narrow therapeutic patients and drugs issues and areas. The Committee will continue discussion and develop more direction along with the Licensing Committee concerning possible additional permit waiver standards.

### **Licensing Committee- Wayne Dyke**

The next Licensing Committee meeting is scheduled for January 29, 2004.

### Licensing Unit Statistics

The Licensing Unit Statistics FY 2003 for December 8, 2003 were included in the Public Board packet for review. Wayne Dyke reported that in December 2003, eight (8) people were licensed by reciprocity. They were: Cynthia Bloss, Sabrina Mozawalla, Gregory McClanahan, Mojgan Rahemjadeh, Vicky Chan, Tiffenee Jones, Roopa Chokshi, and Shideh Hafezi.

### License Renewals

The Licensing Committee will develop procedures to communicate with pharmacists who did not respond to the notification to renew their license.

### **Disciplinary Committee – Jeanne Furman**

The next Disciplinary Committee meeting is scheduled for January 29, 2004.



Deitra Gale reported the Board received a call from Bill Vanderpool, M.S. R.Ph., Director of Pharmaceutical Services seeking clarification regarding whether a rubber stamp signature would be permissible for any written prescription. While pharmacies are not required to have a follow-up signature for any verbal prescription that is communicated, the CMS statement seems to be exclusive to a home health nursing, therapy, etc. role. Mr. Vanderpool was not sure whether the State law supercedes the requirement or whether he can refer to Medicare. Medicare now permits the use of a rubber stamp on verbal orders. Deitra Gale sent Mr. Vanderpool a copy of Health General 21-258(b)(14) for clarification.

#### *MEDIA ALERT*

The Board received a press release from the North Carolina Board of Pharmacy stating that they issued cease and desist orders against six locations which advertised that they would arrange for prescriptions to be filled in Canada and sent to North Carolina consumers.

LaVerne Naesea reported that Board members indicated by e-mail that there is a need for similar dialog and actions by the Maryland Board. It was noted that the Board had previously voted to send cease and desist letters and the Compliance Unit was directed at the meeting to immediately initiate sending letters out.

#### *Disciplinary Complaints*

On December 4, 2003, the Disciplinary Committee reviewed twenty-eight (28) complaints.

#### **Emergency Preparedness Committee – Ray Love**

The Emergency Preparedness Committee met January 16, 2004. The Committee reviewed a CD presentation by Arlene Stephenson and Paul Ballard that was developed to present at Health Professional Trainings when they are unable to attend. The Committee talked about using the CD for individualized Phase I Training. The Committee also reviewed proposed revisions to the Board's website regarding emergency preparedness. Local Health Liaison planning was discussed at the meeting.

The Committee has made several attempts to meet with representatives from the chains in Maryland to discuss what the Board is doing regarding emergency preparedness in trying to understand what chains are doing regarding the same issue. The Board has had no success in scheduling the meeting. The Committee will attempt to schedule a meeting.

The Committee recommended to the Board to enter into a Memorandum of Agreement with the Maryland Poison Center to develop a Phase I CD or DVD that would be used to train individuals. LaVerne Naesea reported that the Committee reviewed a sample CD prepared by Bruce Anderson to get an idea of what the finished product would look like. The training would be divided into modules and be used for offsite and onsite training. The logistics are still being developed.

#### **Board Action**

The Board passed the motion to award funds for MOU with the Poison Control Center to develop and reproduce a CD modular for Phase I Training. Ray Love recused from the discussion.

The Committee is considering April 17, 2004 for Phase I Training in the morning and the Liaison training in the afternoon. Ms. Lawrence reported that the Board has a trained volunteer (with an ID Badge) who has pleaded guilty to 8 counts of Insurance/Medicaid fraud. She said based on his plea its likely that the Board will take action after the federal government completes its action, however, it may take up to 12 months for Medicaid to send the Board its final decision. The volunteer may have no knowledge that the Board is aware of his guilty plea to fraud. Ms. Lawrence asked if the Board wanted to terminate the

pharmacist's volunteer status and retrieve his ID Badge, to temporarily suspend his volunteer status and ID Badge, to request a voluntary surrender of the ID Badge, take no action until the Board's final decision, or to not take action until the Board takes final action. Melvin Rubin stated that the Committee felt that the Board should decide, however the consensus was that the Board should not set a precedence by penalizing volunteers who have been accused, but who have not gone through due process and had a decision rendered by the Board. Ms. Naesea added that it was not practical since the volunteers would be allowed to retain his license and still practice during non-emergency periods.

### **Board Action**

The Board agreed to take no action because the volunteer continues to be licensed to practice pharmacy in Maryland.

### **Technology and Automation Committee**

#### *Illegal Importation of Prescription Drugs and Devices from Foreign Countries*

The position paper on the Illegal Importation of Prescription Drugs and Devices from Foreign Countries was distributed for Board Members to review. A notice will be sent to Board members who should comment by February 4, 2004. The Executive Committee will then decide whether to approve the final draft being forwarded to DHMH.

#### *Web Statistics*

The Maryland Board of Pharmacy Web Statistics for period July 1, 2003 – December 31, 2003 was included in the public Board packet.

### **Council of Boards Report**

Melvin Rubin reported that Adele Hammerman, Consumer Member, is developing a consumer pamphlet for each Board. Ms. Hammerman requested three items that are of most importance for the Boards in protecting the public. Melvin Rubin and Joan Lawrence prepared a Board of Pharmacy statement.

### **Correspondence**

LaVerne Naesea reported that James Slade received a letter of commendation from the Board of Social Work Examiners for his expertise, dedication, and hard work during the past few years. He no longer is under the Board of Social Work's administration.

### **Informational**

#### *New NABP Headquarters*

NABP will relocate its headquarters to Mount Prospect by the end of 2004.

#### *FDA to Ban Sale of Dietary Supplements Containing Ephedra*

The Food and Drug Administration (FDA) will issue a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra). FDA issued letters to manufacturers who market ephedra-containing supplements, informing them that such supplements present an unreasonable risk of illness or injury and are, therefore, adulterated under the Federal Food, Drug, and Cosmetic Act, In addition, FDA urged consumers to stop using ephedra-containing supplements immediately.

The final rule is expected to be published in the coming weeks and will be enforceable 60 days after its issue date.

The Public Board session was adjourned at 1:15 p.m.