

**Maryland Board of Pharmacy  
Public Board Meeting – Draft  
December 18, 2002**

Mr. Irving Lottier called the Public Session of the **December 18, 2002**, Board meeting to order at **9:15** a.m.

**Attendance**

**Commissioners Present:** W. Irving Lottier, Jr., Secretary; John Balch; Melvin Rubin; Raymond Love; Jeanne Furman; Wayne Dyke; Donald Yee; and Ramona McCarthy-Hawkins

**Absent:** Stanton Ades, President; Rev. William Johnson;

**Board Counsel:** Paul Ballard, Assistant Attorney General and Linda Bethman, Staff Attorney

**Board Staff:** LaVerne Naesea, Executive Director; James Slade, Legislative Officer; Joan Lawrence, Public Education Officer; Bobbi Small, Board Secretary

**Guests:** Lynette Bradley-Baker, CVS/Pharmacy; Jack Freeman, Division of Drug Control; Gil Genn, MACDS; Howard Schiff, MPHA; Kathryn Lavriha, Barr Labs; Gil Cohen, PEAC; Nathan Gruz, MPHA

**Introductions**

Mr. Lottier asked each guest to introduce him or herself.

**Recusals**

There were no recusals of members due to conflicts of interest.

**Corrections and Approval of Minutes (11/20/02)**

Page 2, under Regulations/Legislation Officer Report – Add *Slade* after James.

Page 3, under LTC Task Force, change 2<sup>nd</sup> line to read, Balch reported that *he and President Ades will be meeting with representatives of the Office of Health Care Quality* to discuss Medication Care...

Page 3, under Reciprocity, 2<sup>nd</sup> paragraph, third line, change “XYZ” to “Freedman”

Page 4, delete heading “board action” and the 1<sup>st</sup> paragraph under Board action

Page 4, under Wet Lab Exam, following 1<sup>st</sup> line, add new section entitled, “**FPGE Suspension by NABP**”, second paragraph should follow the new section delete the words “In addition, the examination suspension” and begin with, “Mr. Dyke indicated that NABP’s suspension of the FPGE exam, effective...seeking licensure in Maryland.”

Page 4, under second Board Action, 2<sup>nd</sup> line, change FGBE to *FPGE*

Page 4, under Licensing Statistics, 4<sup>th</sup> line, change XYZ to “Mr. Dyke”, last line should read, “...applying.” “He noted that more than the usual number of candidates took the last in-state exam and that the overall annual statistics will show a more accurate monthly average.”

### **Board Action**

Ms. Furman moved for acceptance of the November 20, 2002, public meeting minutes with corrections. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

### **President/Executive Committee Report – Irving Lottier**

Mr. Irving Lottier, Board Secretary, reported in the absence of President Stanton Ades he would preside at the meeting.

### **Executive Director’s Report**

#### **Staffing Updates**

Ms. Naesea reported that a candidate for the Compliance Officer position would be interviewed this week. In addition, reference checks are currently being performed for the Secretary III candidates. Ms. Naesea anticipates both positions to be filled by the next scheduled Board Meeting.

#### **Proposed Fiscal Restructuring Report**

Ms. Naesea directed the Board’s attention to the draft Commission on Maryland’s Fiscal Structure, 2002 Interim Report contained in the Board packets. The Report outlines recommendations the new governor will consider in addressing the budget deficit. Ms. Naesea noted the section on regulatory Boards that mentioned the lack of attention given to regulatory boards in the past. Specifically mentioned were health boards such as Office of Health Care Quality. Ms. Naesea stated the Board of Pharmacy might be able to reference the report to support some positions that the Board may need to take.

#### **Bio-Terrorism Task Force**

Dr. Love reported that in terms of overall numbers, the Board of Pharmacy has recruited a much higher percentage of volunteers than any other professional board, but there is a lack of volunteer pharmacists from the Montgomery and Prince Georges County areas. He stated that the committee is planning to host another training session in Montgomery County. In addition, perhaps an evening weeknight session may be offered to accommodate those that cannot attend on Saturday.

A discussion was held by the committee concerning the change in administration and the effect on the Bio-Terrorism Task Force, the staff was asked to put together a summary of what the Bio-Terrorism Task Force has accomplished thus far. Dr. Love stated the summary would consist of Bio-Terrorism objectives and unanswered issues that should be presented to the new administration upon taking office. Also an update on the role of the Bio-Terrorism Task Force and issues awaiting action will be presented.

Dr. Love discussed how the smallpox inoculations process would occur and whether pharmacist should be involved in the initial inoculation. The committee's position is that if pharmacists are needed to dilute the vaccine the Board would be happy to provide them with volunteer resources to the extent the Board could provide oversight.

Dr. Love stated there is concern that Team Leaders are not well represented in the D.C. suburbs. The Bio-Terrorism Task Force was favorably impressed with the criteria Mr. Mel Rubin set up for the leaders selection process.

A letter composed by Counsel Ballard about volunteers and their liability was discussed. It was noted Johns Hopkins had concerns about the previous version of the letter. The Task Force recommended that the draft letter be sent to them for comment.

In addition, the media attention received regarding the previous training session was discussed. Ms. Joan Lawrence noted that seven media sources published reports. They included, the Baltimore Business Journal, The Daily Record, Washington Post, Fox 45, Capital News Service, Maryland Independent and University of Maryland TV Channel concerning training.

#### Shortage of Pharmacist

Ms. Naesea reported she was working with Mr. Slade, Legislative Officer, to prepare a draft report, which maybe delayed due to the legislative session. The Shortage of Pharmacist Task Force will meet in January to review portions of the draft.

#### Pharmacist Survey Results

### **Board Counsel Report**

#### **Guest Presenters**

Mr. Howard Schiff, MPHA requested permission to read a letter submitted by his Board of Trustees concerning drug therapy management. The letter indicated concern regarding the length of time it has taken to prepare the regulations and the time that would remain to test the new process. It further recommended that Ms. Magaly Rodriquez de Bittner of the University of Maryland School of pharmacy assist the Board in explaining concepts related to the regulations during discussions with the Board of Physicians Quality Assurance. In response, Mr. Slade pointed out it has been less than six months since the Governor signed the bill, which went into effect October 1. He also responded that the bill required regulations to be develop six months from the effective date (i.e., April at

the earliest). Mr. Schiff responded that MPhA knew it would be difficult to develop regulations. He indicated that MPhA is trying to offer any kind of assistance or aid that is out there to expedite the process. Ms. Magaly Rodriguez de Bittner, University of Maryland is currently one of the foremost practitioners in the state of Maryland, in the field of Drug Therapy Management. Dr. Love recommended that Ms. Rodriguez de Bittner be invited as a resource to some of the discussions with BPQA. Mr. Slade agreed to contact Ms. Rodriguez de Bittner

## **Regulations/Legislative Officer Report**

### *BOP Regulations Status Report*

Mr. Slade directed the Board's attention to page 2 of the *December 9, 2002, Board of Pharmacy Regulations Status Report*, noting that every year during session the moratorium on filing regulations is usually just a couple of weeks. As a consequence of the election year, it has been extended from December 20, 2002 to February 7, 2003. Mr. Slade mentioned that regardless, the Board needs to continue working on the regulations with which it has been involved.

### *COMAR 10.34.21 Standard of Practice from Unlicensed Personnel*

Mr. Slade informed the Board that the phrase "On Going" was added to comply with the new statute

### *COMAR 10.34.02 & 10.34.13 Notice of Proposed Actions*

Mr. Slade informed the Board that comments regarding these regulations could be sent until January 2, 2003 during the comment period.

### *COMAR 10.09.03 Pharmacy Services – Notice of Emergency Action*

Mr. Slade stated that this proposal was included for informational purposes because it involved reimbursements for pharmacy services.

### *COMAR 10.07.02 Comp. Care Facilities and Extended Care Facilities – Notice of Proposed*

Mr. Slade stated this proposal was included for informational purposes for members who work in the field of Long Term Care.

### *PBM Model Regulation Act*

Mr. Slade reported the *PBM Model Regulation Act* that Delegate Goldwater asked the Board to comment on by January 2, 2003, appears to essentially be the same as last years. He will prepare a response and submit the draft to the Executive Committee before the January 2, 2003 deadline.

Mr. Mel Rubin commented on the frequent reference to the term “to the Commissioner”. Mr. Slade stated during last year’s hearing, the Maryland Insurance Administration stated they were suppose to regulate PBM’s because they fall under the Private Review Agent Act, but that after several PBM’s testified, the Maryland Insurance Administration stated there were no any PBM’s registered. The Maryland Insurance Administration is conducting a survey, the Board has requested a copy of the results, the Maryland Insurance Administration does not classify this as a study, but it will make specific requests to specific companies. Therefore the Board will be enabled to extrapolate any information it needed.

### **PEAC (Pharmacists Education and Assistance Committee) – Update**

Mr. Melvin Rubin stated that the report would be included in the executive session because specific cases would be discussed.

## **COMMITTEE REPORTS**

### **Pharmacy Practice Committee**

Dr. Love reported at its December 4, 2002 meeting, the Practice Committee addressed the issues of Drug Therapy Management and Unlicensed Personnel. The committee is charged with reviewing the statute so the Board would have regulatory authority of unlicensed personnel. In addition, regarding the issue of Pharmacist in Charge, Dr. Love noted that many states have legal provisions, which delegate that titled individual as the responsible party for all pharmacy activity. Mr. Rubin suggested that the Pharmacy Practice Committee present model actions to the Board

### **Board Action**

Mr. Yee moved for the Board to instruct the Pharmacy Practice committee to construct draft provisions and submit them to the Board. The motion was seconded by Mr. Balch and passed by the Board.

### **Drug Therapy Management**

Mr. Slade reported that Pres. Ades, Ms. Rodriquez de Bittner, and he plan to meet with the Practice Committee of BPQA to discuss the draft regulations. He said that the Board had made some amendments based on the meeting with the BPQA in November 2002. Yesterday he received comments from MEDCHI, which requested a definition for the

term Technical Modifications. It was noted that Ms. Rodriguez de Bittner would be very helpful in clarifying the definition. Mr. Slade mentioned that the Board does not want to send every slight change back thru the process.

### **LTC Task Force**

Mr. Balch stated that the mismanagement of medication is a huge problem at assisted living facilities. He said that the Task Force's focus is to identify problems and present them to the Office of Health Care Quality and other groups such as Lifespan. The Board's long term care regulations, which are for patients in nursing homes, sub-acute hospitals or transitional care are superseded by the Skilled Nursing Facilities (SNF) regulations. He noted that this is a problem because what currently exists are rules that apply only to the pharmacy that is serving a Long Term Care facility that operates under different rules. Ms. Naesea recommended drafting a letter to the State Nursing Home Ombudsman to invite them to the next LTC.

### **Licensing Committee**

#### **Reciprocity**

**Mr. Dyke reported that in November 2002, twelve applications for reciprocity were received, 7 individuals satisfied the requirements. Bobbi - GET LIST OF Reciprocity PERSONS FROM DORIS AND USE SAME FORMAT USED IN PREVIOUS MINUTES**

#### **Wet Lab Exam**

Mr. Dyke reported the next Wet Lab is scheduled on January 21, 2003. Forty candidates are slated for testing at the University of Maryland. He directed the Board's attention to the registration form for Board member volunteer proctors. This is anticipated to be the last exam since the regulations will be amended around March 1, 2003. Future candidates will be informed when there will no longer be a wet lab exam.

#### **FPGE Exam Suspension**

Mr. Dyke mentioned that there could be a problem with foreign graduates whose test score are only valid for one year, if they are unable to take the FPGE within a year of having taken other required examinations.

### **BOARD ACTION**

Dr. Love moved to extend the validation period for persons who are slated to take the FPGE for one year. The motion was seconded by Mr. Yee and passed by the Board.

#### **Monthly Licensing Statistical Report**

Mr. Dyke directed members to the Licensing Statistics contained in the packets and indicated that the new report would provide useful information monthly.

He asked Ms. Rupal Amin to report on the oral competency project she was assigned through her internship with the Board. Ms. Rupal reported that Maryland is the only state that administers its own oral competency exam. In addition, she said that no one has ever failed the Maryland oral exam. Mr. Dyke added that the Test of Speech (TSE) & Test of Foreign Language exams (TOFL), administered by NABP are much more difficult. He said that the Maryland oral competency exam is a cumbersome step in the reciprocity process. Mr. Dyke mentioned that Mr. Slade indicated that statutory language required a state oral examination and that the Committee would like to have more flexibility under a regulation. He said this would allow the current and future Board members to add component if necessary or change it more easily as it currently exists. Mr. Dyke specified the candidate must demonstrate a competency in the English language by passing a Board approved standardized test. Dr. Love agreed with the statement unless they graduated from an ACPE accredited institution, they would be exempt from testing.

## **BOARD ACTION**

Dr. Love moved to instruct Mr. James Slade, Legislative Officer to craft language that revises the provision regarding oral competency testing in order to omit the requirement for graduates of ACPE accredited schools of pharmacy. The motion was seconded by Ms. Ramona McCarthy-Hawkins and passed by the Board.

### *On-line Pharmacies*

Mr. Dyke stated that Internet pharmacies were discussed during the committee meeting. He said that on-line pharmacies that are authorized and licensed to operate in Maryland would be placed on the Board web site. There was some concern as to which ones were authorized to ship in the state. Mr. Rubin asked whether that would include the Canadian pharmacy, Mepapharm. His understanding was that the FDA does not allow any foreign pharmacies to distribute into the United States. Ms. Furman specified there are some exceptions. Mr. Ballard indicated that there are certain items that can be shipped legally.

Mr. Dyke distributed a draft license format for review by the Board. He indicated that since forms are in the process of being updated to change add the new Secretary's name, Board members may want to make suggest information to be included or deleted. Ms. Naesea informed the Board that the back of the current license does not list all of the change information candidates are required to report such as change of address or phone number. She also noted that Ms. Arlene Stephenson has been appointed Acting Secretary for the Department of Health and Mental Hygiene.

### *Multi-permits at Single Pharmacy Site*

Mr. Rubin commented that he had received an inquiry from a permit holder who wanted to set up two types of pharmacies at one location. His specific question was whether two separate pharmacists would need to be hired if one of the permits were for a specialty pharmacist that does not serve the general public. Mr. Rubin indicated that a pharmacist would be on-site but not present at all times while technicians operated the specialty pharmacy.

Dr. Love recommended that the Practice Committee develop a method to deal with multi-permits at a single location to avoid ad hoc discussions concerning this recurrent issue.

### **Disciplinary Committee**

Ms. Furman reported that the Disciplinary Committee did not meet in December. However, the student interns had assisted with resolving the complaint backlog. Ms. Furman expressed concern about the fact that a pharmacist is not present at the Board office to routinely respond to inquiries.

In addition, Ms. Furman reported that the PEAC contract is scheduled to expire in April 2003. The contract's scope of services needs to be reviewed and revised by the Disciplinary Committee before a new RFP is issued. Ms. Furman indicated that this would not be possible prior to the contract expiration. Ms. Naesea noted that according to Ms. Costley, the Board might be able to extend the current contract with PEAC through to October 2003 so that the RFP can be revised as necessary. Ms. Furman said that she wanted to include a couple of minor changes in the extended contract with PEAC. Ms. Naesea indicated that she would check with Ms. Costley, to determine if changes could be made in the scope if the Department approves the request for a contract extension.

### **Board Action**

The Board approved staff to request a six-month extension of the current PEAC contract in order to provide the Disciplinary Committee with sufficient time to complete the review of the current scope of services and issue a new RFP.

### **Inspection Forms Update**

Mr. Mel Rubin reported that he had made some revisions to the Pre-Inspection Form, noting the items on the form that are required by law. He pointed out that he had annotated the legal requirements as references on the form. Mr. Rubin questioned the possibility of separating the form into two parts, for mandatory and voluntary responses. In addition, to the requiring responses to questions 6, 12, 32, & 64, Dr. Love recommended separating the form into two sections, one for questions that would always be asked and the other for areas of Board focus for a particular pharmacy. For the time being the Board would not use the focus section however, if a pharmacy has issues the focus section would be implemented to gain more information. Dr. Love said that since questions 6, 12, 32, & 64 are more informational, they could be placed in the area of

focus section. Mr. Rubin suggested using asterisks to indicate questions that do not require responses.

Ms. Naesea informed the Board that the original pre-inspection form, with changes, had been formatted for on-line access by the Division of Drug Control and the Board of Pharmacy. However, implementation is a concern, because the Division of Drug Control does not have the ability to leave a completed inspection form on site because they do not have printers. She reminded members that it was decided at the November 2002 meeting that DDC would only leave with the pharmacy written information on items requiring corrective action at the conclusion of an inspection. Upon returning to the office, they would enter the information that would automatically go to the Board and submit a full report to the pharmacist in charge. Ms. Naesea reported the MOU was drafted to curtail any delays in completing the project and insure that DDC and the Board understand all expectations. Ms. Naesea pointed out that there are some issues involved with automating the process, such as the Division of Drug Control's concern about allowing sufficient time to train personnel.

### **BOARD ACTION**

Dr. Love moved that the decision to provide hard copies, to the pharmacies under inspection, be delegated to the executive committee for final choice of method. The motion was seconded by Ms. Ramona McCarthy-Hawkins and passed by the Board.

### Disciplinary Proceedings

Mr. John Balch responded to the Disciplinary Proceedings regulations assigned at the November 2002 Board meeting. He directed the Board's attention to the Order Summary Section, which he read verbatim. Dr. Love initiated a discussion on the Notice of Intent clause. Mr. Ballard clarified the intent by reciting the regulation on page 12, .12 (D). It was decided if certified mail was issued to an individual that would serve as Notice of Intent.

### **BOARD ACTION**

Ms. Furman moved to approve the Disciplinary Proceedings draft regulations. The motion was seconded by Mr. Balch and passed by the Board.

### **Technology and Automation Report**

#### On-line Renewals

Ms. Naesea reported for Ms. Banks that the on-line pharmacy renewal testing was up and has been tested by two chains, one distributor, three non-resident waiver pharmacies, and one independent pharmacy. There were only minor glitches therefore, Ms. Banks was confident that the system will be ready for pharmacies to renew on-line by 2003.

### Computer Generated Inspection Forms

Two DDC Inspectors had received training on on-line inspection form system. There are currently three additional inspectors awaiting training. Ms. Naesea informed the Board of Ms. Banks additional duties as the Licensing Supervisor and the excellent job she has been doing.

### **Public Relations Report**

Ms. Joan Lawrence reported that due to weather conditions and staff illnesses the annual report will not be published until mid-February. Photographs for the Annual Report will be taken in January. The Board will publish the January newsletter with four pages instead of eight pages.

### **Council of Boards Report**

Mr. Mel Rubin reported as the alternate, he attended the meeting. The Council is forming a group to discuss the department's intention to centralize some of the Board's functions and consolidate some guidelines and policies. The Council wants individuals as representatives on the group.

The Board's building lease has been extended at the present location for 10 years. The new rental agreement includes a reduction of monthly rent payments and benefits. However, additional new contract expenses keep the total rental fees about the same.

On January 29, 2002, the Council of Boards will host a Reception for the Legislature in Annapolis, Maryland. They requested the all Board members to provide their legislative districts to be used as greater incentive for legislators to participate. In addition, they requested all Boards to supply any materials that they want distributed at the reception.

Dr. Benjamin's name is to be replaced with Ms. Arlene Stephenson's name on Official stationary until a new Secretary is appointed.

There was a discussion regarding more consumers' participation and activity on Boards to provide greater consumer perspective.

### **BOARD ACTION**

Dr. Love moved to recommend Mr. Melvin Rubin as the BOP Representative on the group that will review centralizing of some departmental functions. The motion was seconded by Ms. Furman and passed by the Board.

### **Correspondence**

*NACDS "Letter of Request" – RE: Canadian Pharmacists*

Ms. Naesea read an excerpt and summarized the letter that was distributed by the NACDS. The letter clarified that Canadian pharmacist graduates do meet the statutory requirements that the Board currently utilizes for licensure in the state of Maryland. Following a discussion, it was determined the letter provided all the statutory components necessary for the Board's acceptance.

Ms. Furman initiated a discussion concerning the Illinois, Board of Pharmacy now reciprocating pharmacists from Canada. Mr. Rubin mentioned that as a next step the Board might want to consider reciprocating students, if they have graduated from an ACE school. The Licensing Committee will review the feasibility.

### **ANNOUNCEMENTS**

Ms. Naesea congratulated Mr. Melvin Rubin for his reappointment as a Member of the Maryland Board of Pharmacy.

Mr. Lottier, Secretary, announced that donations would be accepted to acknowledge Rev. Johnson's recent hospitalization. The funds will be utilized to purchase a get-well gift for both he and Ms. Deitra Gale, who had be absent for family medical leave.

**Mr. Lottier adjourned the Public Session at 12:00 p.m.**