

Maryland Board of Pharmacy

Public Board Meeting

September 18, 2002

President Ades called the Public Session of the September 18, 2002 Board meeting to order at 9:15 a.m.

Attendance:

Commissioners Present: Stanton Ades, President; John Balch; Melvin Rubin; Ramona McCarthy-Hawkins; Raymond Love; W. Irving Lottier, Jr.; Jeanne Furman; Wayne Dyke; Rev. William Johnson; Barbara Faltz-Jackson and Donald Yee

Absent: None

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

Board Staff: LaVerne Naesea, Executive Director; James Slade, Legislative/Regulations Officer; Shirley Costley, Fiscal/Personnel Officer; Joan Lawrence, Public Education Officer; Deitra Gale, Compliance Specialist; and Sandra Hines, Secretary

Guests: Thomas Cargiulo (PEAC); Howard Schiff (MPhA); Kathryn Lavriha (Barr Labs); Kim Fisher (MPhA); Matthew Garhey (Purdue Pharmacy); Phil Cogan (MPhA); Lynette Bradley-Parker (CVS Pharmacy); Nathan Gruz (MPhA); Jack Freedman (DDC)

Introduction

President Ades 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 (08/21/02)

Page 2, under New Law Books, 3rd line from the bottom should read, "Mr. Phil Cogan said that the commentary plus the statutes and regulations combined in the MPhA project."

Page 2, under 2nd Board Action, should read, "Pres. Ades reported that the Board decided to exercise its right to amend the state contract with Lexis and not issue the contract for the bid."

Page 2, under 2nd Board Action, Dr. Love commented that he did not make that particular motion.

Page 3, under Staffing Update, the word panelist should be changed to "panelists."

Page 5, under Drug Therapy Management, last sentence of the page should read, "According to BPQA's current interpretation of their declaratory ruling and the related statute, local health department nurses will be able to dispense based on nurse practitioner experience."

Page 9, 1st sentence, insurance cost should be, "insurance costs."

Board Action

Ms. McCarthy-Hawkins moved for acceptance of the August 21, 2002, public meeting minutes with amendments. The motion was seconded by Ms. Faltz-Jackson and passed by the Board.

President/Executive Committee Report

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Pres. Ades announced a welcome back to Barbara Faltz-Jackson.

Bio-Terrorism Task Force

Pres. Ades reported that the Bio-Terrorism Task Force will meet following the public session to review the two training presentations that were conducted on the previous Saturday, at the University of Maryland. He indicated that approximately 240 pharmacists attended the program, which also offered CE credits. Bruce Anderson, Director, Maryland Poison Center, discussed Biologic Agents; Joey Scaletta, DHMH, discussed the National Pharmaceutical Stockpile; Board member Melvin Rubin presented a summary of the Board's Deployment Plan; Paul Ballard, Board Counsel, presented information related to liability issues and illustrated key points about when the state will provide legal representation through a juggling performance. The entire program was well received. Ms. Lawrence stated that she is awaiting the result of the program evaluation survey. The next training is scheduled on October 5th, in Ocean City, Maryland.

Board Member Appointment – Update

Pres. Ades reported that Mr. Charles White, newly selected Consumer member, has not contacted the Board and the Board is not aware of his actually having been officially appointed. Based on a brief discussion, he had with the State Appointments Secretary, Mr. Ades said the process for selecting a new consumer member will likely need to begin again.

Pres. Ades announced that replacing recently resigned Board member Laura Schneider, will probably be made after the new Governor is appointed (January 20, 2003).

Executive Director's Report

Staffing Update

Ms. Naesea reported that she and James Slade conducted interviews for the Secretary III position. A tentative candidate has been selected and references are being checked. Ms. Naesea said she wanted the selected individual to begin working in time to attend the Board meeting in October. If not, Ms. Sandra Hines has agreed to fill-in until a new Secretary can be selected. The Licensing Secretary II position has been filled and that individual is scheduled to start on October 9th.

Ms. Naesea reported that the Compliance Officer's position has been difficult to fill. The Board has been working with DHMH in an attempt to recruit a qualified candidate. Two of the three candidates were found not qualified. The State has a strict definition of what a clinical pharmacist is. The Board is requesting a reevaluation of the position requirements, however, the clinical pharmacist position has been used in the past because it is the highest State salary position for a pharmacist. Ms. Naesea reported that the third candidate was an attorney/pharmacist with hospital experience. However, due to delayed notice from state personnel for an interview, the candidate took another job. The Board will re-advertise and highlight more benefits as an incentive to attract more candidates.

Ms. Naesea announced that the Board received approval to re-fill the temporary contractual position for the Data Entry position.

Board Staff Retreat

Ms. Naesea announced that the Board staff is planning a retreat in November or December. The retreat will run for one-and-one-half days, and will take place on a Friday and Saturday. The Board members will be informed as soon as plans are completed.

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Shortage of Pharmacists – Update

Ms. Naesea reported that she had not received the survey results from the University of Maryland, on the Pharmacists perceptions related to the shortage. She indicated that they should be presented at the Shortage of Pharmacist meeting, scheduled at 5 p.m. on the same day as the public session. A full report will be given at the next Board meeting

Legislative/Regulations Report

BoP Regulations Status Report

The BoP regulations status report was included in the Board packet. Mr. Slade discussed revisions pertaining to the addition of an “ongoing full quality assurance” to the Unlicensed Personnel regulations. The regulations have been published and the Board is awaiting comments.

PEAC (Pharmacists Education and Assistance Committee) – Update

Mr. Thomas Cargiulo reported on behalf of PEAC that they have 34 active cases; of which 6 were Board referred. The Annual Conference/Seminar hosted by PEAC will be held on October 26th at the Maritime Institute.

Board Member Participation at PEAC Meetings

Mr. Rubin reported a concern regarding the fact that his attendance at PEAC meetings was not beneficial to the Board because he is not allowed to hear pertinent information on referred cases. He said that not receiving this kind of information can hinder the Board’s ability to make a fair decision with Board referred cases. Ms. Furman noted that a PEAC representative regularly attends Disciplinary Committee meetings where there is an opportunity to ask specific information about Board pharmacists under contract with PEAC. After careful discussion, it was decided that Mr. Rubin should participate in discussions of Board referred cases at the PEAC meetings and report information back to the Disciplinary Committee.

Committee Reports

Pharmacy Practice Committee

Dr. Love reported that the Committee met on September 4th. Dr. Love stated that the Committee continued to review and refine the Drug Therapy Management Regulations and the Pharmacy Technician Regulations based upon the preliminary comments received from interested parties. Also, the Pharmacy Technician draft statute was further reviewed based upon the preliminary input received. Dr. Love reported that the Committee would review the ‘Pharmacist-In-Charge’ issue. The Committee decided to contact other States for feedback, to find out what pharmacist-in-charge provisions were in various States. Dr. Love further stated that the issue of pharmacist-in-charge arose when it was asked to whom the technicians would report and be responsible, and who would be responsible for providing the supervision

Dr. Love reported that the Committee received an inquiry regarding re-dispensing samples for use in Long-Term Care Facility. Board Counsel stated that he checked with the FDA and received clarification that an off-site pharmacy (contracted pharmacy) for a Long Term Care Facility would be viewed by the FDA in the same manner as an on-site pharmacy and that the pharmacy could re-package and dispense samples for a long-term care facility. However, the FDA notes that the pharmacy may not charge for that re-packaging.

The Practice Committee felt that if the sample was legitimately obtained and given to the pharmacy for repackaging, the pharmacy or pharmacist could charge for services related to repackaging the samples. Dr.

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Love stated that the FDA does not have the authority to regulate what Pharmacist may or may not charge regarding the provision of pharmacy services within a particular state. Dr. Love stated that the Committee's final interpretation was to convey the opinion of the FDA to the inquirer along the Board's position regarding whether one can charge for repackaging. It is noted however, that anyone who charges needs to be aware that they may be required to defend their actions to the FDA.

Long Term Care

Mr. Balch reported that the Committee met on September 17th and are getting answers and understand what regulations are needed to ensure safety to long-term care pharmacy patients (Nursing Homes, Assisted Living Facilities, Correctional Facilities and DDA patients). Mr. Adam Kane, Director of Public Policy, Mid-Atlantic LifeSpan attended the last meeting and will be attending the Task Force as LifeSpan's representative to provide information regarding Assisted Living issues. Mr. Balch mentioned that currently there is limited medication management and pharmacy overview in the Assisted Living system.

The Committee will spend the next few months talking to the Office of Health Care Quality. Mr. Balch stated that Mr. Mayer Handelman, NeighborCare, recommended a speaker from that state unit to attend the next Committee meeting.

Nurse Dispensing Task Force

Donald Yee reported that the Committee met on September 10th to review the exam written by consultant, Bobbi Brown, to test and train nurses that will be provided authority to dispense. Mr. Yee reported that the Committee was in full support of this exam and is satisfied with the process. Each nurse in local health departments will have to pass the exam before being authorized to dispense.

Mr. Slade announced that he and Mr. Ades will represent the Board on September 25th at BPQA's meeting where Drug Therapy Management will be one of the discussion topics.

Licensing Committee

Reciprocity – List of Candidates

Mr. Dyke reported Reciprocity meeting was held on September 17, 2002. He presented the names of candidates for licensure by reciprocity in Maryland. Thirty-one (31) candidates took the examination; nine (9) applicants: Kenyatta Byrd; Nichodemus Elebeke; Jack Fogelsonger; Kikelola Gbadamosi; Shetaye Gulelat; Creighton Moorehead; Jill Twehues; Marybeth Verbos and Konjit Worku are pending passage of the oral competency exam.

Candidates – Passed

Wuraola Adamolekun	Carinda Field	Gregory Malat	Hemlata Patel	Michelle Weisburgh
Omar Badawi	Amy Hatfield	Michelle McLean	Jennifer Sheehan	Helen Xanthakye
Sharon Barnes	Vaughn Hilburn	Anna Memoli	William Vanderpool	
Pamela Bowman	Andrew Kennedy, III	Jeff Mouakket	Ruth Woung	
Trupti Desai	Julia Keune	Lilian Parisotta	Michael Weisburgh	

Board Action

Ms. Faltz-Jackson moved to license the twenty-two (22) candidates who passed the exam and to approve the nine (9) candidates pending their meeting oral competency requirements. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

NAPLEX/MPJE – Fee Increase

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Mr. Dyke reported NABP announced that Chauncey International, NABP's testing vendor, will be increasing sitting fees for the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). Effective January 1, 2002, NAPLEX candidates will pay a base fee of \$300 and a \$130 vendor administrative fee for a total registration fee of \$430. Those registering for the MPJE will pay a \$110 base fee and a \$60 vendor administrative fee for a total of \$170.

Mr. Dyke presented a memo from NABP that a US Company is offering access to Canadian medications. The Kansas State Board of Pharmacy recently notified NABP that its Board received correspondence regarding CARE, a Texas-based company that appears to offer its employees access to Canadian medications dispensed by Cross Border Pharmacy in Alberta, Canada. Mr. Ballard said it would not be feasible for the Board to approach the issue from a state local level. He suggested that the FDA should address this since it is a Federal issue regarding distribution from a foreign company. It was recommended for the Board to refer this type of matter to the FDA.

Wet Lab Exam - Update

Mr. Dyke reported that the Wet Lab Exam will be given on Tuesday, October 1, 2002. Eighty-one (81) candidates are eligible to take the exam. There will be two scheduled sessions for the exam. Mr. Dyke has asked for enough volunteer proctors to run the two laboratory rooms.

Mr. Dyke reported that the Licensing Committee meeting was held on September 10, 2002. The Committee discussed reducing the current one hundred dollar lab fee by half to a fifty-dollar fee, once the Wet Lab is eliminated for the exam. However, the decision is not final yet.

Canadian Pharmacies/Distributors

Mr. Slade reported that the Licensing Committee also discussed writing regulations for the distributors' use of devices, such as contact lenses and gases. Once the Committee has determined the scope of what the regulations are being prepared by the Board of Optometry, it will determine how pharmacy regulations may need to be amended for drug distributors (or whether the Board will have to add a new chapter).

The next Licensing Committee meeting is scheduled for Tuesday, October 15, 2002 at 10 a.m.

Disciplinary Committee

Updated Inspection Forms – Mel Rubin

Mr. Rubin reported that Board database specialist Mr. Konstantinov, has worked on the inspection forms using the old format so that the Division of Drug Control can start using laptops to enter data. Mr. Rubin will be working with Mr. Freedman, over the next few weeks to develop new questions on a revised form. The Committee is gathering a list of questions for the inspection. There will be a pre-inspection form mailed two to six weeks prior to inspection. The pharmacies will have to complete the forms and send them back to the Division of Drug Control prior to inspection.

Technology and Automation Report

On-Line Renewal System

Ms. Naesea reported that the on-line renewal system is in its final stages and is anticipated to be ready for testing in October.

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Network Administrators Meeting

GroupWise

Ms. Banks submitted a summary of items discussed at the meeting held on August 28, 2002. The summary stated that any virus that gets through the firewall into GroupWise should be reported to the help desk and that thus far the state has been successful in keeping viruses out of the DHMH networks. DHMH is looking into agencies with non-Group Wise email accounts; yahoo, Erols, and AOL. Use of other email accounts also raises questions about security and the protection of State correspondence.

GroupWise should be upgraded to version 6 by the end of the year. The new server and software and software upgrade was delayed because the new computer room construction cannot be completed since it was recently discovered that the 201 Preston Street building has reached its maximum power limitation.

Internet

The attempt to turn "Scripting Off" to stop pop-up ads will cause the termination of all pop-ups, including the legitimate ones.

Security

The Department of Budget and Management in Annapolis announced that agencies should allocate for an additional 15% in FY 2004 budgets for security. The DHMH Intranet contains new IT Security Policies that authorize IT Security persons to report and monitor all hardware and software systems, including State email systems. Everyone who has access to State computers must sign the newly revised security policies. DBM will be auditing agencies to determine if they are in compliance.

All IT Security personnel will be expected to participate in the annual security training to be held over the next three months, starting September 5, 2002.

HIPPA

Secretary Benjamin is currently working on HIPPA standard policies for all IT Systems.

Web Site Statistics

Ms. Banks reported Web Site statistics for Fiscal Year 2003. The statistics shows categories of data from visitors -- busiest day weekday pages; education requests -- government, organization and commercial and foreign county request -- popular pages and email. All three of the web site categories were visited by someone(s) in Belize (formerly British Honduras) in August. Belize ranked #1 in foreign county visitors for the .COM and .ORG sites.

Public Relations Report – Joan Lawrence

Board's 100th Year Celebration – Updates

Mr. Lawrence reported that the Board decided to issue a press release for their 100th Year Celebration. A draft press release statement was sent by email and also distributed to Board members for a review and comments that were due the day of the public meeting.

Council of Boards Report

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Ms. Faltz-Jackson reported that the Council of Boards discussed the new lease for the building. The Attorney General's office is requesting that all Boards raise all fines to accommodate legal processes required to access penalties at the circuit court level. The Attorney General's Office wants to extend the statutes of limitations to three years for all Board Health Professions, under a uniform statute, because an illegal practice may not have to be discovered until a year later or more. Currently, the statute of limitations is three years only for persons practicing medicine. The statute of limitations is one year for other Boards. If the fines are increased, the Attorney General's office would have three years from the time of unauthorized practice to perform an investigation and prosecute for unauthorized practice at the circuit court level, if necessary.

Ms. Faltz-Jackson reported the Council of Boards will be meeting with Secretary Benjamin to discuss concerns about surplus funds that were taken from some Board's special funded accounts to meet a state budget deficit. The Boards' funds are supposed to be exempt from use by the state except for administrative functions related to the Boards.

Question(s) for the Board

Dr. Love presented a question to Mr. Ballard about the Attorney General opinion that involves collaborative practice in hospitals. Ms. Naesea will place the Attorney General's opinion in the packet for the next Practice Committee meeting.

Pres. Ades asked for a motion to close the public session to discuss issues pertaining to the recently administered Wet Lab Examination.

Board Action

Ms. McCarthy-Hawkins moved that the Board close the public session to discuss the alleged misconduct during Wet Lab Examination on June 13, 2002. The motion was seconded by Dr. Love and passed by the Board.

After much discussion and review, Dr. Love moved to notify the three candidates in question by writing, of the Board's investigation regarding their behaviors during the examination and questions raised regarding their character, and to inform them that if they desired to continue to pursue a license in Maryland, they must request a personal appearance to discuss the matter before the Board. The motion was seconded by Mr. Balch and passed by the Board.

Pres. Ades adjourned the Public Session at 11:40 a.m.