

**Maryland Board of Pharmacy
Public Board Meeting
February 19, 2003**

NOTE: Due to inclement weather several unit and committee reports were not provided.

Mr. Stanton Ades, President called the Public Board Meeting to order at 9:30 a.m.

Attendance

Commissioners Present: Stanton G. Ades, W. Irving Lottier, Jr., John Balch; Melvin Rubin; Raymond Love; Jeanne Furman; Wayne Dyke; and Donald Yee

Absent: Rev. William Johnson, Ramona McCarthy-Hawkins, and Linda Bethman

Board Counsel: Paul Ballard, Assistant Attorney General

Board Staff: Catherine Putz, Compliance Officer, James Slade, Latonya Dickerson, Board Secretary, LaVerne Naesea, Executive Director, (via conference call)

Guests: Tony Tommasello, UM-OSAS & PEAC, Jack Freedman, Division of Drug Control; Kathryn Lavriha, Barr Labs; and H.F. Van Horn

Corrections and Approval of Minutes (1/15/03)

Page 3, third paragraph, last sentence should read, “ The Center for Substance Abuse Treatment (CSAT) has taken over the process of certifying the physicians and all qualified physicians **are** urged to place their new DEA number on the prescription.”

Page 3, first paragraph, should read, “**Buprenorphine** is a sublingual tablet under the tongue and the first **two dosages** are taken in the physicians’ office.”

Page 3, first line (website: www.buprenorphinesamhsa.gov)

Page 3, middle of the page, last sentence, strike the sentence, “Another initiative noted by Dr. Tommasello involves locating the primary care doctor who manages the patient at the pharmacy where the patient picks up the methadone treatment.

Page 3, middle of the page, The National Narcotic Act should read “**The Harrison Narcotic Act (1914).**”

Under the PEAC section, first paragraph, third line, “He reported that PEAC is purchasing new computers in order to move up to a faster pace” should read “He reported that PEAC **purchased a new computer** in order to move up to a faster pace”

Board Action

Dr. Love made a motion to accept the January 15, 2003, public-meeting minutes with the corrections listed above. Mr. Melvin Rubin seconded the motion. Motion passed.

President/Executive Committee Report – Stanton Ades

NABP 99th Annual Meeting

NABP's 99th Annual Meeting will be hosted May 3-7, 2003, in Philadelphia, Pennsylvania. The Board will be sending Jeanne Furman as its voting delegate. President Ades asked that a member volunteer to attend as an alternate delegate. Members agreed that either Don Yee or Melvin Rubin would attend as an alternate.

Bioterrorism Task Force Update

The Bioterrorism Task Force held a meeting on Friday, February 14, 2003. Participants reviewed a number of issues including the fifth Phase I Training, which was slated to be held in Montgomery County on the evening of March 5, 2003. Ms. Naesea drafted a letter to the Governor to request a meeting with his staff to apprise them of Task Force activities. No response had been received to date. Ms. Gail Wowk, of DHMH asked the Board of Pharmacy to change the Task Force name to the Bioterrorism and Emergency Preparedness Task Force to allow them to address natural and chemical disasters in addition to bioterrorism. The Board accepted the recommendation of Ms. Gail Wowk to change the Task Force name to Bioterrorism and Emergency Preparedness.

Change to Mission Statement.

President Ades noted that the Board no longer regulates manufacturers and suggested that the Board remove the word 'manufacturers' from its mission statement

Board Action

Ms. McCarthy-Hawkins moved that the term manufacturers be taken out of the Board's mission statement. Dr. Love seconded and the motion passed.

Executive Director's Report

Staffing Updates

Ms. Naesea introduced Latonya Dickerson as the new secretary for the Board of Pharmacy. Ms. Dickerson began employment with the Board on February 5, 2003. Ms. Dickerson will be supporting the Board and Disciplinary and Practice committees, and will work directly with Ms. Naesea, Mr. Slade, and Ms. Catherine Putz.

Mrs. Catherine Putz, the new Compliance Officer, was also introduced. Ms. Putz, was most recently an inspector with the Division of Drug Control. She will be supervising Mrs. Deitra Gale. Mrs. Putz will support the Disciplinary committee and the Practice committee, as needed. After the backlog for the Compliance Unit has been significantly lessened, Mrs. Putz may also be assigned to the Bioterrorism Committee.

Office Renovations

Ms. Naesea stated that Ms. Banks, Ms. Gale, and Ms. James' offices have been relocated, noting that Ms. Gale is now able to lock the complaints and disciplinary records in her office.

Ms. Naesea reported that effective March 15, 2003 the a new telephone system will be placed in the building for usage by all of the occupants. She said the change is related to the leasing to several new agency occupants who had a new phone system included in their lease contracts. New staff telephone numbers will be placed on the website as well as on answering machines for callers. There is no immediate cost to the Board of Pharmacy for the new telephone system

House Budget Hearing

Ms. Naesea informed the Board that due to inclement weather she was not able to attend the hearing scheduled in Annapolis on February 18, 2003. Ms. Naesea will check to see if the hearing was canceled due to the State of Emergency issued by the Governor.

Drug Importation FDA Conference Call

On February 12, 2003 at 1:00 p.m., a conference call took place regarding the importation of drugs. LaVerne Naesea, Catherine Putz, Deitra Gale, Joan Lawrence and Jack Freedman participated in the conference call. There were FDA Participants that took part in the conference call. Ms. Naesea made the following recommendations to the Board:

- (1) Issue a transmittal to permit holders regarding the issue
- (2) Publicize the FDA letter on our website and through other means (newsletter)
- (3) Reproduce the FDA consumer brochure on the subject
- (4) Ask the Board to encourage consumer reporting by providing some type of 'amnesty' for those who do report adverse events related to drugs they have purchased from other countries.

Mr. Ades stated that we can put this information on the website.

DDC Test Laptop Inspection

Ms. Naesea and Mr. Konstantinov accompanied inspectors from the Division of Drug Control to test the use of laptops to perform inspections. Mr. Vladimir will be providing on hands training for the Inspectors and staff. Ms. Naesea stated that the Division of Drug Control made an offer to the Board of Pharmacy to split the cost to purchase five (5) printers. The cost would be \$750.00 for DDS and the Board each. The shared cost is outlined in the proposed MOU between the Maryland Board of Pharmacy and the Maryland Division of Drug Control.

Board Action

Dr. Love moved that the Board appropriate \$750.00 for 50% of the cost of purchasing the printers. Melvin Rubin seconded the motion. Motion passed.

Memorandum of Understanding (MOU)

Ms. Naesea recommended that Mr. Stanton Ades sign the MOU (which was included in the November 2002 Public Board Packet).

Board Action

Dr. Love made a motion that the Board empowers the Executive committee to review the MOU and approve it if found acceptable. . Mr. Balch seconded the motion. Motion passed

Board of Pharmacy – Newsletter

Ms. Naesea informed the Board that the January 2003 Maryland Board of Pharmacy Newsletter went out in the mail last week. The newsletter included the process for selecting new Board Members to fill At-Large Pharmacist, Chain Pharmacist, and Acute Care Hospital Pharmacist seats. Ms. Naesea noted that all of the associations have been contacted and have begun to process potential candidates; even though the public notice of the selection process was only recently issued through the newsletter.

BPQA Bioterrorism Preparedness Training

Ms. Naesea attended the BPQA training and stated that it was very well attended. BPQA Coordinators anticipated about 80 to 100 physicians. The training had about an additional 100 walk-in physician participants who had not pre-registered. The training focused on diagnosing various Bio related illnesses and viruses related to terrorism more so then on treatment antidotes. Dr. Alcorta, of the Maryland Emergency Management Program was a presenter at the training. Ms. Naesea suggested that the Board may want to consider using him for Phase II Training. She said that Dr. Alcorta put into context the roles that volunteer practitioners might play. Dr. Alcorta said that police authorities, MEMA, and Federal authorities would be making security and logistical decisions and that practitioners should instead concentrate on being team leaders and emergency practitioners in terms of treatment. He said a few may be used in some of the triage activities, in terms of quick examination of patients directing them to specific treatment lines. Mr. Alcorta gave a greater perspective of the big picture.

Ms. Naesea noted that Joey Scalletta, from DHMH's Epidemiology Unit did not present and that Dr. Julie Cassini presented for Ms. Arlene Stephenson.

Emergency Preparedness Meeting

There was a DHMH Emergency Preparedness committee meeting on the same day as the Board's Task Force meeting on February 14, 2003. The most significant discussion was

with David Morgan, Attorney General who spoke on three different questions regarding volunteer liability that have repeatedly come up. One question related to practitioner liability, which has been addressed by Board Counsel, Paul Ballard. A second question related to when a practitioner becomes ill with the virus he has treated and the availability of State medical protection. Mr. Ballard stated that currently Legislators are proposing bills regarding Practitioners becoming ill with the virus. Mr. Ballard stated that there is a Bill in legislation to grant workers compensation to any volunteers that are injured. The third question regarded whether pharmacists working for a pharmacy who are then called as volunteers would be given the same pay as if they were in the Army Reserve and on leave from their jobs to work with the National Guard etc. Presently, the State can not force employers to provide volunteers with compensation because they are off doing volunteer work. This is an arrangement that Employer and Employee would need to individually work out.

The Emergency Preparedness committee will be notified when the two latter issues are addressed. Ms. Naesea stated that Board staff will receive training March 27, 2003 on internal procedures to follow during a catastrophic emergency. Staff responsibilities have not been coordinated with Board, task force and volunteer responsibilities. The importance of employees not losing their identification badges was noted.

Regulations/Legislative Officer Report

BOP Regulations Status Report

Mr. Slade directed the Board's attention to the Board of Pharmacy Regulations Status report, contained in the Board packet. Regulations noted were 10.34.02 Examination for Licensure and Professional Experience Programs (Effective 2/17/03), 10.34.09 Fees. (Reciprocity fee), 10.34.11 – Monetary Penalties (Effective January 20, 2003), 10.34.13 – Reinstatement (Effective February 17, 2003), 10.34.22 Licensing of Wholesale Prescription Drug Distributors, 10.34.26 Patient Safety Improvement; and 10.34.29 Drug Therapy Management.

Dr. Love asked if it was possible to list new regulations that are not in the most recent edition of the law book on the Board's website so that people will know which laws have changed since the publication of the book. Mr. Slade indicated that he would talk to Ms. Banks, but that it could probably be done.

Senate Bill 48 – Controlled Dangerous Substance – Dispensing Monitoring Program The bill is dead.

House Bill 134 – Commercial Law – Consumer Protection – The Social Security Number Protection Act does not have a grandfather clause. The Board noted that this is not their issue.

Senate Bill 283 – Consumer Protection – Maryland Consumer Protection Act, the Board decided not to take a position on this bill. The hearing is February 26, 2003.

Senate Bill 354 – Public Health – Licensed Pharmacists – Dispensing Emergency Contraception hearing will be held on March 13, 2003. Mr. Slade proposed that we do a letter of support concept. Mr. Slade stated that this bill is not written well and that certain groups are against it (MedChi, BPQA, possibly the Local Health Officers, and Family Health Administration).

Board Action

Dr. Love made a motion for the Board to support the concept of Senate Bill 354. Melvin Rubin seconded the motion. Motion passed.

House Bill 410 – Health Insurance – Private Review Agents – Examination of Pharmacy Benefit Managers essentially says that the Maryland Insurance Administration has to examine PBM every three years or in compliance with another status. Mr. Slade noted that he received an audit that the Maryland Insurance Administration did on Blue Cross/Blue Shield.

Senate Bill 537 – Health Occupations - Gifts from Pharmaceutical Manufacturers or Pharmaceuticals Marketers Prohibited – This Bill prohibit a gift of \$50.00 or more from pharmaceuticals manufacturers and pharmaceuticals marketers.

Board Action

Dr. Love made a motion for Mr. Slade to prepare a letter of concern, Jeanne Furman seconded the motion, motion passed. Mr. Slade stated that the hearing is on 2/27/03 and he will draft a letter and email it to Board Members.

Senate Bill 656 – Tax Compliance Act of 2003 - Mr. Slade will do a fiscal impact on this bill.

Board Action

The Board decided to do a letter of concern, check with other interested parties, to see what they are doing.

Senate Bill 684 – Pharmacists & Pharmacies – Practice – Advice of Generic Drug Option – This Bill requires the pharmacists or employee of the pharmacists to tell consumers about generically equivalent drugs that might be cheaper.

Board Action

The Board will recommend supporting the bill with amendment(s). The hearing is February 27, 2003. Mr. Stanton Ades will testify.

House Bill 725 - Senior Citizen Prescription Medicine Relief Act – The bill places the Senior Citizen Prescription Medicine Act into the Boards statute but never mentions the Board and its role. The bill talks about the Department and Medical Assistance.

Board Action

The Board will do a letter of concern stating that the bill places the law in the wrong part of the law. It should be in the Medical Assistance law.

Senate Bill 677 - Maryland Health Care Commission Fees Health Care Practitioners – taking nurses out of having to pay the HCC fees. Pharmacists still have to pay. The Board will join the other boards provided they agree not to support the bill.

Mr. Slade noted that he sent out HB 647, which is the task force on the study of regulations of long-term care providers; Mid Atlantic Health Span is on it.

SB 511- Establishes a Managing for Results Committee - the hearing is March 6, 2003.

PEAC (Pharmacists Education and Assistance Committee) – Update

Dr. Tommasello reported on the Rehab Committee and Pharmacists Education and Assistance Committee. The Conference planned on October 16th or 23rd is moving ahead. The Committee is looking at a site in Columbia for the program. PEAC is negotiating with the Anna Leonhardt group to perform the administrative tasks related to conducting the program so that deadlines on CE requirements can be met. The topics will be broader, to attract a broader audience, including non-pharmacist.

PEAC looking at a mechanism for providing a broader report to the Board in the future. PEAC wants the Board to gain greater knowledge about cases that are not Board referred while the individuals retain their anonymity. Only names associated with people that are Board referred and under Board orders are shared with the Board. The other cases would be on the spreadsheet but no names would be associated with the statistical information. PEAC now have twenty-six cases active in the program of which thirteen are Board referred. Mr. Tommasello noted that PEAC caseload is exactly at 50% Board referred and 50% self or employee referred cases. To do marketing Mr. Tommasello said PEAC has CEU programs, brochures, and speakers give talks at the pharmacist school every year. Dr. Tommasello stated that he is disappointed that pharmacists in trouble inform PEAC that they did not know about the program.

COMMITTEE REPORTS

Pharmacy Practice Committee

Drug Therapy Management Regulations

President Ades and Mr. Slade met with MedChi to discuss MedChi's comments. Certain changes were made based on the discussion; none of which were in conflict with the intent of the drafters of the regulations. MedChi indicated that it thought that the draft regulations were in line with the statute. BPQA would be holding a hearing on the draft regulations on February 26, 2003, at which President Ades and Mr. Slade would present

the draft regulations. Mr. Slade indicated Dr. Rodriguez de Bittner would be present as well to address any educational concerns.

Board's Action

The Board voted to publish the January 27, 2003 version of the drug therapy management regulations.

Questions received by the Practice Committee 2/5/03

- The Maryland Board of Pharmacy received an email from Thomas Bolton, RPh, Taneytown Pharmacy/Carroll drugs.com, asking for clarification on whether he would need two pharmacy permits to operate Taneytown Pharmacy and Carrolldrugs.com.

The Committee appointed Ms. Putz to respond to Mr. Bolton by letter stating that Mr. Bolton is not required to obtain another permit if the brick and mortar pharmacy and internet pharmacy have the same name, otherwise he will need two permits one for each name.

- Ms. Furman brought Larry Siegel's question, seeking clarification on automated cabinets with step out drawers, which would allow access to more than one strength of medication at a time. The Committee will have Ms. Furman send Mr. Siegel a letter stating that only one drug, and one strength of the drug should be able to be accessed at a given time.
- Catherine Putz received a question from William Popomaronis in the form of an email. Mr. Popomaronis wants to know if pharmacists are qualified providers for Therapeutic Shoes. The Board's response is that it is their opinion that these shoes qualify as devices under State law and therefore are legal for pharmacist to dispense. The reimbursement issue is not an issue for the Board.
- John Balch reported to the Committee that Assisted Living residents are receiving unmarked medication that is forwarded from a physician, who obtained it from a manufacturer. Workers are creating their own labels for the medication in the Assistant Living Facility. The products are more than samples of medication. Office of Health Care Quality (OHCQ) is not aware that this is occurring. In other cases, they are using the Maryland Med Bank. The Med Bank will mail boxes of medication with improperly labeled medication enclosed.

The committee will recommend to the Board to have BPQA send out reminders to physicians about complying with the dispensing regulations. The Committee will ask the Board to send out letters to drug manufacturers to include a notice to physicians that they may need to

comply with state regulations regarding dispensing. In this letter to the manufacturers, it would request that manufacturers consider coupon programs rather than introducing unlabeled supplies of medication into the system, which increases the potential for medication errors and diversion. The Committee will recommend that the Board formally request NABP to become involved in this issue. This committee will ask the Board to formally notify OHCQ that unlabeled medications are regularly showing up in assisting living facilities.

- The Board discussed dispensing medication outside of pharmacies and will require the pharmacists to submit rationale for this particular service and how they intend to comply with the rules and regulations of the Law.
- Dr. Love reported to the Board that Karen Nishi, Cardinal Health, wants to come to a Board Meeting to show us how her new Cardinal Assist Automated Logistical Process System works. The Committee asked Ms. Furman to relate to Ms. Nishi that we cannot entertain vendors during a public meeting unless there is a specific issue that we have with the product.

Licensing Committee

Mr. Wayne Dyke introduced H.F. Van Horn, Pharmacy/MBA Program from the Shenandoah Pharmacy School.

Mr. Dyke noted that his report would be brief because the Licensing committee meeting was scheduled for the previous day, but cancelled due to the inclement weather.

Mr. Dyke reported that the last Wet Lab session was conducted on January 21, 2003, and he thanked everyone that assisted in its administration. Thirty-six candidates were present and took the test and thirty-six positive results were posted on the website by candidate number.

Mr. Dyke referred to the licensing statistics enclosed in the Board Packets. He discussed the first part of the report titled renewals and non-renewals that covered November, December 2002 and January 2003. During the month of January 2003 the Committee received 12 reciprocity applications. Esther Frey, Peggy Kraus, Clarence Todd, William Wentzel, Maureen Logue, Abena Milner, Donna Grimm, and Danielle Sine, are pharmacists that have met the Board requirements for reciprocity.

Ms. Tamarra Banks sent a letter to NAPB regarding the FPGEE scores, TSE, Tofel, and whether or not foreign candidates had been cleared for certification. Mr. Dyke presented four individuals' files as being prepared for action by the Board.

Board Action

Melvin Rubin made a motion that the Board accept the four candidates who have met all requirements, but are simply lacking a certificate from NABP. Dr. Love seconded the motion and the motion passed. The candidates will be informed of the Board decision.

Mr. Slade noted that the Licensing Committee has been working on adding Device Distributors to regulations because they are required by statute. In the draft, the Licensing committee removed the purpose paragraph. Mr. Slade included the definition of “health care entity” created from the Federal Regulations. Mr. Slade reported that one provision concerning what is not wholesale distribution in the federal law conflicts with Maryland law. Mr. Ballard said that he would provide an advice of counsel on the issue. Dr. Love indicated that he would not vote to revise the regulations unless some sort of language was drafted to allow pharmacies to buy in groups and divide the bulk purchase between the pharmacies.

Board Action

The Board decided to table this issue and look at it more thoroughly at the Board meeting scheduled for March 2003.

Disciplinary Committee

Ms. Jeanne Furman reported that the Patient Safety Coalition final report was issued and also presented to the General Assembly. It can be found on the Maryland Health Practitioner Website; www.mhcc.state.md.us. The site contains the Executive Summary, Final Report, and Appendices. Part of the Patient Safety Coalition recommendations include (1) a mandatory reporting system for serious events, and (2) establishment of a Patient Safety Center.

The Disciplinary Committee met, and decided that since Melvin Rubin is the Board’s representative on the PEAC Committee, he should work with the Compliance Unit to obtain a list of all pharmacists under Board’s orders and the requirements of their consent order. When Mr. Rubin meets with PEAC, he should use the list to assist with this review and provide report to the Disciplinary Committee at the next available meeting.

The Committee was concerned about how to handle voluntary surrenders. The Committee will make the language clearer in future voluntary surrenders. The Committee is looking for more aid in guiding the pharmacist back into reinstatement. In the future when the Board has someone reinstated, they will be invited to appear before the Board.

Ms. Furman stated that the Committee decided that when a Consent Order is signed, a new PEAC contract will need to be developed, even if the pharmacist had a previous PEAC contract through self-referral. The Board-required term for the pharmacist to be under contract with PEAC will begin with the signing of the new contract.

The current PEAC vendor contract will be extended until June 30, 2003. LaVerne Naesea and Jeanne Furman reviewed the current Request for Proposal (RFP) and made many changes on it. Ms. Furman stated that she is not sure of the status of the RFP. PEAC is not living up fully to requirements of the current contract. One of the contract requirements is for PEAC to give the Board a full report twice a year July and January on the disposition of all their cases. The report should include who the pharmacists are, the kinds of substance abuse they have, the kinds of contracts they have, where they are in their contract, and if they have relapsed, how it was handled. In the contract it also states that PEAC is suppose to aid the pharmacist through the process of reinstatement.

Ms. Furman noted that some pharmacists come before the Board unprepared. that PEAC uses the competency assessment to return the dispensing for only non-board cases and that PEAC should report all infractions to the Board.

The Committee did review disciplinary cases at its last meeting. Out of 20 medication error data collections, question forms mailed out, eight were returned. Ms. Furman commented that the forms are very useful and make things easier. Those who did not return the forms will receive a warning letter indicating that the Board will take further action if the forms are not submitted.

Technology and Automation Report

No Report

Public Relations Report

No Report

HIPPA Update

Mr. Mel Rubin will provide information at next months meeting.

Council of Boards Report

No Report

Correspondence

None

Informational

Information regarding Drug Importation Websites dated October 25, 2002 was included in the Board Packets.

ANNOUNCEMENTS

Buying Prescription Medicines Online: A consumer Safety Guide provided information on the potential risks of purchasing medicines online. This data, which can be found at www.fda.gov/cder/drug/consuemr/buyonline/guide.htm , also provided information on basic do's and don'ts to purchase medicines online safely and securely.

Toxtdbits (the Maryland Poison Center's monthly newsletter) provided information on RICIN Poisoning stating that if orally ingested, Ricin usually produces gastrointestinal symptoms in about six hours. If Ricin is inhaled by or injected into victims of warfare, death may occur within 36-72 hours. Initial symptoms of inhaled Ricin include fever, cough, and respiratory distress, leading to pulmonary edema and hypoxia. Victims of injected Ricin also experience fever and an elevated white blood cell count, which may lead to shock. No antidote for Ricin poisoning currently exists. Treatment consists of activated charcoal for decontamination in oral exposures, and aggressive fluid and electrolyte replacement along with appropriate supportive care for symptomatic patients.

Mr. Ades adjourned the Public Session at 1:30 p.m.