

**Maryland Board of Pharmacy
Public Board Meeting
December 17, 2003**

Secretary Melvin Rubin called the Public Board Meeting to order at 9:20 a.m. in lieu of President Ades who was scheduled to arrive later.

Attendance

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

Commissioners Absent: Joseph DeMino, 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 and Latonya Dickerson, Board Secretary

Guests Howard Schiff, MPhA, Jack Freedman, DDC, Robert Chang, Drug Control, Diane Darvey, NACDS, Gil Genn, NACDS, Mathew Gainey, Huseyin C. Tunc, Safeway Inc.,

Recusals

Secretary Rubin asked Board members to indicate if they had any conflicts of interest with agenda items.

Approval of Minutes (11/17/03)

Ms. Naesea announced that the 11/17/03 Public Board minutes that had been sent in advance of the meeting were since revised. Dr. Love moved to table approval of the 11/17/ 03 minutes until the Board reviews the updated version. Mrs. Jeanne Furman seconded the motion, which was then passed by the full Board.

Executive Director Report - LaVerne Naesea

Staff Updates

- LaVerne Naesea reported that Michael LaMartina had been selected to fill the Compliance Unit Investigator position on the Board staff and will begin employment in late January or early February 2004.

- A temporary Data Entry Clerk has been hired to work with the Licensing Unit beginning the week of the December 17, 2003 Board meeting.
- The Board has selected seven (7) candidates to interview in early January 2004, to fill the Procurement/ Personnel Officer vacancy.
- Beginning February 2004, the Board office renovation plan will be instituted to accommodate space needs for new staff positions.

Pharmacist Rehabilitation and Educational Services

Ms. Naesea reported that the Board awarded the Pharmacist Rehabilitation and Educational Services contract to the Pharmacist's Education and Assistance Committee (PEAC). The contractor will provide assistance to pharmacists in need of treatment and rehabilitation from alcoholism, drug abuse, chemical dependency or physical, emotional or mental conditions. The term of the contract will begin January 1, 2004 through December 31, 2005 with the Board having three one-year renewal options.

Board of Pharmacy Officers & Committees

Ms. Naesea noted that the updated list of Board of Pharmacy Officers and Committees, including the Board members' term expirations, was provided in the Public Board Packet as requested by President Ades.

DHMH BT Certificate Scholarship Program

The Department of Health and Mental Hygiene is offering a Bio-terrorism Certificate Scholarship Program. The program held at Johns Hopkins University would require attendance to 12 sessions over an 18-month duration. Ms. Naesea indicated interest in participating in the course to enhance the Board's coordination with the State Bio-terrorism team. If selected, there would be no cost to the Board because the state would pay the entire tuition out of federal grant funds.

Board Action

The Board referred approval of Ms. Naesea's request to the Executive Committee.

Error Data Collection Form

The National Association of Chain Drug Stores (NACDS) wrote a letter on behalf of Maryland Chains Drug Stores to request the Board of Pharmacy to obtain a legal opinion from the Maryland Attorney General on confidentiality issues related to the Board's Error Data Collection form. Ms. Naesea noted that the Board requested Board Counsel, Linda Bethman to describe the Board's investigation process, as well as the confidentiality requirements for information collected on the Error Data Collection form, to NACDS representatives.

Linda Bethman reported that she discussed the issue with Ms. Diane Darvey, attorney for NACDS. Ms. Bethman informed Ms. Darvey that the Board is entitled to request or subpoena information as long as it is relevant to the investigation. Ms. Darvey responded that the members of NACDS are not comfortable with the phrasing of the questions on the form. She continued

that the chains would like the opportunity to meet with the Board to talk over the questions on the form, format, etc. Ms. Bethman suggested that the Disciplinary Committee review the Error Data Collection Form and make revisions necessary to clarify questions, mail it to the Board members, and place it on the agenda for the January 2004 Public Board Meeting. Interested members would be able to discuss the form on record. The Board will take all input into consideration and move forward.

Board Action

The Board passed a motion that the Error Data Form be placed on the agenda during the January 2004 Public Board meeting for open discussion with the public.

Summit with Chains

The Board requested the Disciplinary Committee to organize a summit and develop agenda items to include the MBOP and the Chains, addressing items of concern. The Disciplinary Committee will draft a letter inviting the Chains to attend the summit. Ray Love suggested surveying interested parties for the best dates to hold the summit and agenda items of mutual concern.

Board Action

The Board passed a motion for the Executive Director to survey interested parties to arrange a convenient date and time to schedule the Summit.

Pre-Inspection Form

Mr. Rubin reported that the pilot pre-inspection form was mailed to ten pharmacies. Responses were received from five independents and one chain pharmacy. No response from other chains had been received. Based on information received to date, the form does not seem to be difficult to use. Mr. Rubin stated that the Division of Drug Control inspectors would use the pre-inspection form to see if it helps during the next inspection of the pharmacies that responded.

Guest Presenter – Dr. Matthew Gainey – Purdue Pharma, L.P.

Dr. Matthew Gainey, Purdue Pharma, L.P. asked the Board to allow him to summarize the newly created RxPATROL program. Dr. Gainey stated that RxPATROL is designed to collect, analyze, and share information on pharmacy robberies, burglaries, and theft of controlled substances. By gathering information from pharmacies, RxPATROL will be enabled to conduct an assessment from a national perspective. The assessment will reveal a profile of what makes pharmacies most vulnerable and why, as well as what physical security assets are most effective in deterring theft. The RxPATROL Pharmacy Theft Report will be posted on the RxPATROL website www.rxpatrol.org, as well as on the websites of NADDI www.naddi.org, NCPA www.ncpanet.org and the Pharmaceutical Security Institute www.psi-inc.org.

The Board will consider placing RxPATROL on the Maryland Board of Pharmacy's website. The Board suggested that Dr. Gainey work with Jack Freedman of the Division of Drug Control, for support in any capacity required regarding RxPATROL reports.

Regulations/Legislative Officer Report – James Slade

General Assembly of Maryland Official Dates of Interest

Mr. Slade reported that the General Assembly convenes on Wednesday, January 14, 2004 at noon and will adjourn Monday, April 12, 2004 unless extended. He noted that dates of interest for the session were included in the Board Packets.

Regulations Status Report

Mr. Slade reviewed the Board of Pharmacy Regulations Status Report updated December 8, 2003. The following regulations and their effective dates were presented:

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| Tax Compliance Regulations (10.31.02) | Effective December 11, 2003 |
| Disciplinary Proceedings (10.34.02) | Effective September 1, 2003 |
| Examination for Licensure and Professional Experience Programs (10.34.02) | Effective February 17, 2003 |
| Reciprocity fee (10.34.09) | Effective March 3, 2003 |
| Name Change Late Fee (10.34.09) | Effective November 10, 2003 |
| Monetary Penalties (10.34.11) | Effective January 20, 2003 |
| Reinstatement (10.34.13) | Effective February 17, 2003 |
| Patient Safety Improvement (10.34.26) | Effective October 27, 2003 |
| Compelling Purpose Disclosure (10.34.27) | Effective December 11, 2003 |
| Drug Therapy Management | Effective December 11, 2003 (With one non-substantive change) |
| Name Change-Pharmacy or Distribution Permit Holder | Effective November 10, 2003 |

Copies of the Tax Compliance Regulations, Compelling Purpose Disclosure, 10.19.03 Controlled Dangerous Substances and Drug Therapy Management were included in the Public Board Meeting Packet.

The Board applauded Mr. Slade for the great work on Drug Therapy Management.

Drug Therapy Management Joint Committee

LaVerne Naesea reported that the Board received a letter from Magaly Rodriguez de Bittner, the Chair, MPhA Collaborative Practice Task Force, to request prompt action by the Maryland Board of Pharmacy to appoint two members to the Drug Therapy management Joint Committee. The goal of the Committee is to (a) review physician-pharmacist agreements, protocols, and other relevant documentation; (b) make recommendations to the Boards and the applicants; and c) Perform any other task relating to therapy management contracts that is delegated to the Joint Committee by Boards.

Board Action

Jeanne Furman moved to nominate Ray Love and Don Yee to represent the Board on the Drug Therapy Management Joint Committee. Ramona McCarthy-Hawkins seconded the motion. The Board passed the motion.

James Slade will send a letter to the Maryland Board of Physicians requesting them to appoint two Board members to the Committee and notify them of the two Board members appointed from the Maryland Board of Pharmacy.

DEA Notice of Proposed Rulemaking

The Proposed Rules from the Drug Enforcement Administration concerning “Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities” was provided for the Board to comment. Written comments must be postmarked on or before January 2, 2004. Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: Federal Register Representative/CCR.

Department of Licensing & Regulations

Mel Rubin announced that the Department of Licensing and Regulations would like to get the pharmacy technicians into a program. Presently, there is an apprenticeship program at CVS in Washington, D.C. The program would consist of 200 hours of directed work and is voluntarily.

President/Executive Committee Report – Stanton Ades

Following Mr. Slade’s report, Secretary Rubin turned the meeting over to President Stanton Ades. President Ades’ report had been deferred until his arrival.

Bio-terrorism Task Force Update

The Bio-terrorism Task Force meeting was held on December 12, 2003. Issues discussed at the meeting were the pharmacist liaisons assigned to work with Local Health Department emergency preparedness task forces in Cecil, Hartford, Dorchester, Somerset, Wicomico and Montgomery Counties.

The Board has about 400 volunteers that need to be trained. A letter/survey was sent to 400 untrained volunteers to try to determine the best date, time and location for the next Phase I training to maximize attendance. Approximately 100 – 150 volunteers are expected to attend the training. A second Liaison training is tentatively scheduled for January or February 2004.

The Governor’s office requested a training schedule for 2004. The Committee will put together a packet to make the Governor aware of exactly what was done in the past and how the Committee will proceed.

The Maryland Emergency Management Administration (MEMA) has a new Director, John W. Droneburg, effective January 5, 2004.

DHMH received a \$50,000 grant from the Medical Reserve Corp, which requires the Boards of Physician, Nurse, and Pharmacy to implement training in 2004 to activate volunteers to respond in emergencies and to develop and distribute communications. The Task Force discussed the need to hire a staff person to carry out Board activities. It is considering requesting support through federal grant funding received by DHMH.

Bruce Anderson, a Board Taskforce member and Director of the Maryland Poison Center, produced a very informative Bio-terrorism CD-Rom demonstration and presented it at the Task Force meeting. Mr. Anderson is developing a proposal, including cost estimates with the types of training elements that the Task Force uses as a training module, as an alternate requiring the physical attendance of 50+ pharmacists at training sessions.

The Maryland Board of Pharmacy Bio-terrorism Task Force will be known as Maryland Board of Pharmacy "Emergency Preparedness Committee". The next meeting is scheduled for January 16, 2004.

Meeting on Counterfeit Drugs – Update

Mr. Ades reported that the Board met with special agents from the Drug and Food Administration. Products tampering, selling products into the country without FDA clearance, counterfeit drugs and medical devices were topics discussed. The agents agreed that FDA would send the Board reports of persons in violation of federal law. The Board agreed to send FDA a list of people accused of these types of actions.

Pharmacy Practice Committee- Dr. Ray Love

The Pharmacy Practice Committee met on December 3, 2003.

Long Term Care Regulations

The Committee reviewed the Long Term Care Regulations (LTC) and decided they should be reorganized. The Committee will complete the LTC Regulations at the January 2004 meeting.

Assisted Living Regulations

The Committee reviewed and commented on the Assisted Living Regulations in regard to Medication Administration.

Consumer Brochure

The Committee reviewed the brochure "Consumer Information" "Pharmacy Related Concerns" which is distributed by the Board to pharmacies. The Committee considered adding information on new laws and the availability of generics, but decided the information did not belong in the

brochure. The brochure describes the Board of Pharmacy, pharmacists' responsibilities; information complainants should receive from pharmacies, and the Board complaint process.

Administration of Medication

The Board of Pharmacy – Administration of Medications bill was referred to the Committee for review and comment. The Committee reviewed the bill and found it to be acceptable, with one simple amendment to the Scope of Practice section of the Pharmacy Practice Act.

Board Action

The Board passed a motion to send a second letter to the Board of Nursing requesting a meeting to discuss the Administration of Medication Bill.

Registration of Pharmacy Technicians and Act Revision

The Committee discussed the Registration of Pharmacy Technicians and Act Revision bills. Mr. Slade reported that the Board received permission to seek a sponsor for this bill. However, the issue of the "Role of Pharmacy Students" was raised. Specifically, whether pharmacy students' gaining of professional experiences should be included under the proposed statute. That is, if a pharmacy student were to be employed in a pharmacy other than during their Professional Experience Program rotations, should they be required to pass the same training and certification as a technician working was not addressed. Dr. Love reported that Committee members held differing opinions on the issue. Some members felt that pharmacy students enrolled in an ACPE accredited school of pharmacy should be able to work as technicians. Others felt that the students would still need to attain some required certified technician skills. Dr. Love asked the Board for guidance in appropriate language to include in the bill.

Board Action

The Board passed a motion for the committee to prepare an amendment to the bill that would require pharmacy students who wish to work in pharmacies, but are not registered technicians, to register with the Board as interns. The Board will develop regulations regarding the supervision of interns.

Ms. Diane Darvey volunteered on behalf of NACDS to forward different states' regulations on pharmacist student interns to Mr. Slade for the Practice Committee to review. The Practice Committee will develop language and email them to Board members for comments. The Executive Committee will have final sign off to the language in order to meet the legislation deadline.

New Pharmacy Opening Prescription Kit

The Board was asked whether it would permit pharmacies to use electronic balances in lieu of traditional balances with weights. The Practice Committee recommends that the Board initiate a change in regulations to allow electronic balances to be used in lieu of traditional balances with weights. The Committee asked the Board's permission to interpret the regulations until the

regulations are changed that electronic balances are acceptable, and that other mechanisms may also be interpreted as having weights during the interim.

Board Action

Dr. Love moved that the Board initiate a regulation change to allow electronic balances in lieu of balances plus weights. Furthermore, that the Board accepts electronic balances with tolerance that exceeds those of Class A balances until such time the regulations are amended. Further that a copy of the recommendation be sent to the Division of Drug Control drug inspectors to prevent pharmacies from being held in violation because they use a superior piece of equipment. Mrs. McCarthy-Hawkins seconded the motion. The Board passed the motion.

Maryland Pharmacists Association

The Practice Committee received a letter from Howard Schiff, Executive Director of the Maryland Pharmacists Association, regarding prescriptions with two signature lines. One signature line prohibits substitution of the prescribed drug and the other signature line allows substitution. Mr. Schiff indicated that some pharmacists interpret the signature on the “do not substitute” line as the prescriber requiring the brand name drug, and others do not. He noted that some prescribers sign on the “do not substitute” line even for generics. Specifically, MPhA asked the Practice Committee to clarify the meaning of the word “expressly” as it is used in Health Occupation Article §12-504, Annotated Code of Maryland.

The Committee concluded that when a prescriber signs on the “do not substitute” line, the pharmacist may not substitute unless the prescriber is contacted. The Committee feels that it is not in the public’s best interest to have two signature line prescriptions. The Committee suggested that MPhA go to legislators and discuss the issue of two-signature-line prescriptions with them.

MPhA also asked for clarification as to whether a pharmacist might cut a faxed prescription down to the size of the prescription, instead of requiring the pharmacist to maintain the entire 8 ½ X 11 inch faxed sheet. The Committee saw no problem with reducing faxed prescriptions to an appropriate size as long as the prescription information and signature line and other required information is included.

Board Action

Dr. Love moved that the Board recognize prescriptions by fax reduced in size as long as the prescription information and signature line and other required information is included. Don Yee seconded the motion. The Board passed the motion.

Johns Hopkins Pharmacy

The Committee received an inquiry from Johns Hopkins regarding an outpatient pharmacy located in an oncology outpatient clinic. The pharmacist compounds medications for administration in the clinic for which they have a pharmacy license. Johns Hopkins wants to

know if it can relinquish the license for the pharmacy in the clinic and if they can, with what provisions of law would Johns Hopkins have to comply to allow the pharmacist to compound medications for administration in the clinic. The Committee stated that under current law they could not relinquish the pharmacy permit and still allow the pharmacist to compound.

SACPM Survey

The Committee was asked for guidance to the State Advisory Committee on Pain Management regarding electronic prescribing. The Committee's response was that the Board is in favor of electronic prescribing, but not just for controlled dangerous substances. The Committee feels that electronic prescribing is a means to help reduce medication errors and problems in universal communications.

Illegible Prescriptions

The Committee received an inquiry from Delegate Boutin about a bill that would require a prescription to be written legibly. The Committee's reply will be that such a law needs to have 'teeth' in it and allow the Board of Physicians to take disciplinary action against physicians who write prescription that are illegible. The Committee requested Mr. Slade to prepare a response.

Automation in Transitional Care Units

The Committee received a communication that the Division of Drug Control inspectors are telling hospital pharmacies that they cannot use automation in transitional care units despite the agreement that the Board made with the Office of Health Care Quality. The Committee has requested the complaints about this practice be sent to the Board in writing. Once the Committee receives written complaints it will address them.

Licensing Committee- Wayne Dyke

Mr. Dyke reported that in November 2003 the following people were licensed by reciprocity. They were: Edward Li, Roderick Curtis, Mary Lablanc, Peter Chen, and Gia Tran. As of the Board meeting date, six hundred and fifteen (615) pharmacies and fifteen (15) distributors had renewed online. The Board has prepared a letter to the pharmacies that have not renewed.

A foreign graduate pharmacist made an inquiry to the Board regarding why the Board must wait for NABP to verify his credentials and FPGEC status. Ms. Naesea informed the applicant that if he had a job pending, his potential employer should send a fax to the Board to demonstrate that there is a need to expedite his licensure.

Board Action

Dr. Love moved that the MBOP 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. Ms. McCarthy-Hawkins seconded the motion. The Board passed the motion.

Public Relations - Joan Lawrence

National Conference on Medicine Information and Education (NCPIE) Updates

Ms. Lawrence attended the Be MedWise: A Prescription for Patient Safety, 14th National Conference and Exhibits Showcase on Medicine Information and Education, in December 2003, in Washington, D.C. The keynote speaker was Dr. McClellan, M.D., Ph.D, Commissioner, U.S. Food and Drug Administration whose address was entitled, the “Role of Consumer Information in Today’s FDA.” Ms. Lawrence attended a session on “Communicating to the Public About Counterfeit Medicine” and a second session on Medicine Re-importation. She referenced a booklet from *Pharmacy Today* entitled “Understanding Prescription Drug Importation.”

Media

The Board received calls from *Howard County Times*, *Gazette Gaithersburg*, and the *Baltimore Sun* regarding pharmacists administering FluMist to the citizens of Maryland. Ms. Lawrence noted that the Governor and DHMH Secretary have ordered additional FluMist for MD citizens who are eligible to take this medication.

Newsletter

Joan Lawrence reported that she has received the majority of newsletter articles from Ms. Furman. Ms. Lawrence will give the draft articles to the editorial committee for review and requested a response by the end of the week.

Council of Boards Report

Board Member Training

The New Board Member Training on December 5, 2003 from 8:00 a.m. to 4:00 p.m. at the University of Maryland Baltimore County Technology Center was cancelled due to poor weather conditions. The training is re-scheduled for April 5, 2004. All new Board members will receive notification. All Board members are encouraged to attend.

Consolidation of Conference Rooms 108/109

Mr. Rubin reported that the number of members on the Board of Physicians has increased significantly, so they require larger meeting space. The Board of Physicians wants to knock out the petition between conference rooms 108/109. This will allow them to have adequate space to meet with their extended Board. Permission from the Council of Boards and Commission is required before this can be done. The Physician Board is trying to locate a contractor that can erect petitions that can be moved that are sufficient to block noise out. If so the Council of the Boards and Commission will consider endorsing the project at that time.

Brochure

Adele Hammerman, Vice-chairperson and Consumer member wants each Board to come up with the three most important functions they perform to protect the public. The information will be used in a soon-to-be- developed brochure.

Disciplinary Committee – Catherine Putz

Disciplinary

Ms. Linda Bethman sent Senator Paula C. Hollinger a letter explaining the Board's position on COMAR 10.34.01, Disciplinary Proceedings, in response to the inquiry submitted to Mrs. Hollinger by Judge Fader, dated October 20, 2003. The Board is awaiting a response from Senator Hollinger.

Ms. Putz reported that the Disciplinary Committee met with PEAC and discussed pharmacists who will be presenting for reinstatement. Consumer complaints were discussed during the remainder of the meeting. The Error Data Form was not discussed at the meeting.

Position Paper on Re-importation

Ms. Banks and Mr. Slade are editing the position paper on re-importation. They are close to completion. They have been working with the FDA gathering information. Ms. Furman will prepare a synopsis and place it in the newsletter.

Sanjakumar Radadia – Application

Mr. Radadia submitted an application for a pharmacist license to the Board and included information affirming that he was involved in retail theft of items valued at \$14.40 from a Wal*Mart store and had to pay a court fine of \$136.50. (He pled guilty and had no prior records according to the court records)

Board Action

The Board voted to gather more information before the Board issues a decision. The Licensing Committee will bring a recommendation to the Board at the January meeting.

Guidelines for Unlicensed Practice by Pharmacists

The draft of the guidelines for unlicensed practice by pharmacists was reviewed and it was suggested that the contributing Factors/Criteria be eliminated from the document and that the words “up to” be removed from the statement that reads “more than 60 days, impose a fine up to \$500 per month starting after the 60th day of unlicensed practice” be replaced with “a fine of \$500”. It was also suggested to add the statement “ These guidelines apply to first time offenders only.”

Board Action

The Board passed a motion to work on the guidelines further before voting on any changes.

Postage Expenditures

Ms. Gale presented the issue of the extra cost of postage (approx \$5.00 each) for certified mail associated with mailing subpoenas with the Error Data Collection Form. Ms. Naesea noted that it should not be a significant impact on the Board's total budget.

Public Session closed

Ms. McCarthy-Hawkins moved to close the public session at 12:25 p.m. and begin the reinstatement hearing for Craig Holston. Mr. Yee seconded the motion. The Board passed the motion.

Public Session re-opened

Ms. Furman moved to reopen the Public Session re-opened at 1:00 p.m. Mr. Yee seconded the motion. The Board passed the motion

Craig Holston

Board Action

The Board passed a motion to license Mr. Craig Holston's license under the following conditions:

1. The Board will grant reinstatement provided that he take and pass the reinstatement and law examinations and complete 15 CE's with at least one credit dealing with new drugs of 2002/2003;
2. Once reinstated Mr. Holston will be on probation for at least three years during which time he shall enter into a contract with PEAC;
3. For the first 1000 hours of pharmacy employment:
 - (a) He must work with another licensed pharmacist and provide the Board evidence of such;
 - (b) He cannot work more than 40 hours a week
 - (c) He must inform the Board of his pharmacy employer and any changes in employment
 - (d) He must informed the Employer of the consent order

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