June 15, 2005

<u>Attendance</u>

Officers Present: John Balch, President; Jeanne Furman, Secretary; Mark Levi, Treasurer;

Commissioners Present: Donald Taylor, Mayer Handelman, Don Yee, Margie Anne Bonnett, David Chason, and Michael Souranis

Commissioners Absent: Joseph DeMino, Rodney Taylor (new appointee), Claytawn Richmond (new appointee)

Staff: LaVerne Naesea, Executive Director; Shirley Costley, Licensing Unit Manager; Patricia Gaither, Administrative Service Manager; Christina Harvin, Legislative and Regulation Manager; Anna Jeffers, Legislative and Regulation Officer; Chandra Mouli, Pharmacist Compliance Officer; Colin Eversley, Compliance Investigator; Linda Prince-Garrison, Compliance Specialist; Linda Bethman, Assistant Attorney General; Jessica Acevedo, Legal Secretary; Britney Jenkins, Executive Secretary

Guest: Melvin Rubin, John McGrath, PEAC; Zhirayr Petrosyan, Pharmacy Student; Homan Pazwash, Pharmacy Student; Kiesha Wise, BOP Receptionist; and Stacy Wallace, Licensing Clerk,

<u>Record of Conflict of Interest</u>- President John Balch called the Public Meeting to order at 9:08. There was no record of any conflict of interest.

II. <u>Correction of the Minutes (5/19/2005)</u>

Page 3

Under President/Executive Committee Report, 6th paragraph, 2nd line, add "es" to the word "weakness."

Page 4

Under PEAC, 1st paragraph, delete the statement: "LaVerne Naesea stated that quarterly summaries were not adequate to give an aggregate overview of the monthly reports. She said that the monthly reports will not provide information that could be reconciled with expenditures reported on PEAC's quarterly fund requests. She said that the individual summaries do not support the quarterly invoices submitted,"

Add the statement "LaVerne Naesea stated that quarterly summaries are required by the contract with PEAC and provide an aggregate overview of the monthly reports. The

Board concluded that PEAC should provide an efficient answering system to eliminate this increasing problem related to the Board's and pharmacist clients' inability to contact PEAC and its monitors. John McGrath responded that there is a contact number available for immediate use, but PEAC is creating a new means of communication for external calls."

III. President/Executive Committee Report

President Balch noted that two new Board Members, David Chason and Michael Soranis, were present at the meeting. They were appointed to replace former commissioners Raymond Love and Melvin Rubin, respectively. President Balch thanked each for their interest in becoming Board members, and wished them luck on their appointed position.

President Balch announced that he held the monthly meet with the Executive Committee to discuss the issues pertaining to the Board of Pharmacy renovation. He explained that he did speak with Deputy Secretary Mitchell to decline the floor plan that was presented to the Board. He furthered explain that the intended project is pending further negotiation.

Board Action

Board voted to accept the approved minutes as amended.

IV. Executive Director's Report- LaVerne Naesea

LaVerne Naesea informed the Board that DHMH must cut 49 permanent positions department-wide, to assist in balancing the state budget. She explained that the Board was informed it may lose two permanent positions as a result, if there were no incumbents in the two positions, Public Relations Officer and Compliance Investigator, that are under consideration. Colin Eversley, board contractual Investigator, is the incumbent for the latter position. Thus, Ms. Naesea noted that DHMH might reduce the Board's cut to one position instead of the two originally scheduled. Further information will be provided at the next Public meeting.

Ms. Naesea asked Jeanne Furman to review the annual NABP meeting that was held in New Orleans, Louisiana in May. Several issues were discussed at the meeting. She reviewed and distributed the proposed amendments considered to the NABP Constitution and Bylaws, and noted which amendments and resolutions were adopted by NABP. Ten out of twelve resolutions submitted to the NABP Board were passed. Passed submissions included Effective Communication in Pharmacy Practice and in the Provisions of Pharmacist Care; Sterile Compounding and the NABP Model State Pharmacy Act and Model Rules; Reporting of NAPLEX Scores to Schools and Colleges of Pharmacy; Medication Assistance Programs; Reporting of Pharmacy Personnel Termination to the Board of Pharmacy and the NABP Model State Pharmacy Practice Act and Model Rules; Repackaging of Medications; Electronic Pedigrees; NABP and DEA Collaboration; Implementation of the Medicare Prescription Drug Improvement and Modernization Act of 2003; and Effective Communication in Pharmacy Practice and in the Provision of Pharmacist Care. (See attached documentation for detailed synopsis)

V. PEAC (Pharmacists Education and Assistance Committee) Update Client

A. Currently PEAC has twenty-eight patients and two of those patients have been reclassified as "Board referred" in place of "Self-referred." One patient has been referred to the Disciplinary committee as being non-compliant. Subsequently after reporting the noncompliant patient it was referred over to Chandra Mouli for further investigation.

B. Mayor Handelman and John Balch suggested that in order for pharmacy professionals to be more aware of the nature of PEAC they must develop advertisement mechanisms both oral and concrete. They also suggested to PEAC that they establish a more stable environment for their clientele and increase their professionalism by establishing an independent office. Mr. McGrath assured the Board that PEAC is currently in the process of making improvements with in their organization. The Board delegated all recommendations related to changes to PEAC operations to the Disciplinary Committee.

VI. Administration and Public Support Unit Report - Patricia Gaither

Patricia Gaither informed the Board of the new Licensing Unit staff, Stacey Webber-Wallace who was assigned in June. She welcomed Ms. Webber-Wallace as part of the Licensing staff and the Board of Pharmacy.

Ms. Gaither informed Board members that the Board newsletter has not been posted due to the delay in submissions, but that the summer edition newsletter should be published during the month of July.

Ms. Gaither also discussed the Board's participation in the annual MPhA Annual Meeting exhibition. She noted that the Boards exhibit was a success, but there could have been some additions to the exhibit. She added that in the future the pre-inspection book, Board of Pharmacy display panel, and volunteer forms would enhance the Board presentation at the next exhibition.

Don Taylor informed the Board of the change in Emergency Preparedness Committee Meetings. The meetings will be held on the 2nd Wednesday instead of 2nd Fridays of each month. The next meeting is scheduled on July 1, 2005 at 9:00 a.m. He added that training and registration are now accessible online for the Emergency Preparedness Volunteers. In addition, he informed the Board that the committee is working on plans to develop a patient dosage chart, as well as a pediatric flow chart for use during emergencies.

VIII. Legislative and Regulation Unit Report- Christina Harvin

A. COMAR 10.32.23 Pharmaceutical Services to Residents in Long Term Care Facilities

The repackaging provision that was established in this proposal may have an economic impact on the public. Some residents in LTCF use medications in significant quantities

for minimal or no charge from entities such as the Veterans Administration. These residents may choose to have medications repackaged into manageable quantities rather than purchasing the pre-packaged medications in individual manageable quantities. The residents may pay a fee to a pharmacy to have the medications repackaged, but the fee is expected to be much less than purchasing the medications individually. The Board may want to withdraw the proposed regulations, revise them without inclusion of the repackaging section and then amend them if the new Medicare Part D does not resolve related issues.

B. COMAR 10.34.32 Pharmacist Administration of Influenza Vaccination

The currently proposed regulations state the following: influenza vaccines can only be administered pursuant to an agreed upon protocol; a licensed pharmacist can administer influenza vaccines to anyone 18 years old or older, if the pharmacist has successfully completed a course approved by the American Pharmacists Association (APHA) or a course approved by the Board of Pharmacy that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention.

C. HB 317 Prescription Drug Repository Program (Summer Study)

HB 317 was a proposal designed to allow the acceptance and re-dispensing of prescription drugs that are donated for the purpose of dispensing to certain individuals. During the recent legislative session, HB 317 was problematic to legislative officials therefore Delegate Rudolf subsequently decided to send it for summer study. Christina Harvin has been in contact with officials from the office of Governmental Affairs concerning recommendations for what types of drug dispensing should be included in the program. LaVerne Naesea reminded the Board that a representative should be appointed from the Board. President Balch appointed Don Taylor to participate on the task force.

D. HB 433 Legibility of Prescription Work Group Update

Ms. Harvin reported that proposed legislation passed during the 2004 session required a work group under HB 433, to review formatting and the content of prescriptions to provide greater patient safety. In November 2004, the Board of Pharmacy worked with the Health Care Commission and several other state agencies to provide an interim report to legislative officials which was submitted February 1, 2005. Among the recommendations in the interim report was the need to encourage e-prescribing. The report provided an overview of the work group's strategies for e-prescribing. Subsequently, the 2005 legislature passed HB 233, which provided additional timelines that the HB 433 work group should meet including developing a timeline for mandating e-prescribing in Maryland. They have met and collaborated with experts from pharmaceutical corporations, e.g., Surscripts and Medci, to address the cost, benefits and problems with e-prescribing, and ways to implement it here in Maryland. The next interim report will be completed by July 1, 2005.

Jeanne Furman continued that there are specific recommendations that legislation might want to include regarding written or verbal prescription. She said that realistically, eprescribing as the primary method of prescribing, is not going to become a reality within the next couple of years because of the cost. In lieu of developing a timeline, the task force is developing an analysis based comments and reports submitted from the experts with regards to accessibility to technological advancements, problematic issues, cost efficiency for both prescriber and pharmacy and financial supports.

Mark Levi questions the pharmacist's ability to rely on the accuracy and sufficiency of eprescribing in order to safely fill prescriptions. Ms. Furman responded that there are several ambiguities to e-prescribing, but noted that pharmacists should plan to execute normal procedures in ensuring that medicines are dispensed to the correct patients. She said, if in doubt, pharmacists should phone physicians for verification of correct dates and patients' information before filling the prescription. In short, e-prescribing in comparison to manually written prescriptions is going to have certain precursors in order to adequately carry out its purpose. Ms. Harvin noted that the Interim Report lists some strategies to insure that medication errors would be lessened.

Mark Levi questioned whether the Board should penalize pharmacists if they do not receive and include all of the patient information on the prescription label. Ms. Furman responded that how to enforce recommended requirements is not discussed by HB 433 legislation as a task force assignment. She indicated that recent task force discussions were centered on educational measures rather than enforcement issues. There will be one more meeting in the month of July.

Don Taylor mentioned that labeling legislation was recently passed in Delaware. He said that identifying patient information, including the patient name, physician signature, name of drug, and drug strength have to be presented at the time a prescription is refilled. In Delaware, if the pharmacist cannot read just one required piece of information, the pharmacist is instructed to call the physician before dispensing the medication. Thus, a patient must go without medication until a physician is successfully contacted. In most cases, the availability of a doctor is uncertain for verifying missing information on a prescription. Therefore, patients are turned away because of illegible prescriptions.

Ms. Furman assured the Board that required information would be that which pharmacists are already required to receive in a manually submitted prescription. She noted that minimal information is essential in order to safely fill a prescription. If in any case that a prescription is illegible there may be other ways to compile this information without consulting the physician.

VIII. Committee Report

A. Pharmacy Practice Committee- Mark Levi

Mark Levi summarized issues presented by Christina Harvin under the Legislation and Management report and asked the Board to take actions on the proposed regulations for Influenza Vaccination and the withdrawal of the proposed Long Term Care regulations.

Board Action

Mark Levi move to accept the finalized copy of the Influenza Vaccination regulation. Don Taylor seconded the motion and it was carried by the full Board.

Board Action

Mark Levi moved to withdraw the current Long Term Care regulation and then reintroduce the Long Term regulation in an amended format. Mayer Handelman seconded the motion which was carried by the full Board.

1. SB 372- Crimes-Pseudoephedrine-Prohibition – The Practice Committee is currently considering recommending regulations to the Board to address the distribution of Pseudoephedrine. Several states have instituted distribution and dispensing restrictions to help prevent illegal abuse of the over-the-counter medications. The Maryland Board would support any legislation that would limit the sell of Pseudoephedrine to being performed by licensed pharmacies only. The legislation may require the use of identification cards and the maintenance of purchase logs made by consumers. There may also be an age requirement for consumers purchasing Pseudoephedrine. Boardproposed regulations could provide how pharmacies should store the O-T-C meds so they would not be freely accessible to consumers, as well as require training to educate employees on the applicable laws and regulations regarding the sale and storage of Pseudoephedrine.

2. Long Term Care - John Balch reported that there was a meeting held on June 14, 2005 with CMS discussing major issues with assisted living. Presently assisted living residents do not have special provisions regarding packaged medications. John Balch stated that the Task Force suggested that correspondence be sent to CMS explaining that the State of Maryland feels the safety and health of residence in assisted living institutions would be better served if there was a provision for pharmacies to package medications for assisted living patients. Mr. Balch noted that CMS was verbally receptive of the suggestion at the meeting. He said that Ms. Naesea suggested sending a copy of the letter that the Board will send to NABP to gain national support of the concept.

3. USP 797 - Don Yee reported that the Task Force decided not to distribute the survey and instead use the survey report as a guide for reviewing regulations. The next 797 Committee meeting will concentrate on specific revision to the Board regulations.

B. Licensing Committee - Written report of monthly statistics were distributed to Board Members

C. Disciplinary Committee- No recorded report.

The June 15, 2005 Public Meeting adjourned at 11:23am by President John Balch