Maryland Board Of Pharmacy
Public Meeting Minutes
November 17, 2004

Attendance

Officers: Melvin Rubin, President; Jeanne Furman, Secretary; Raymond Love, Treasurer

Commissioners: John Balch, Mark Levi, Mayer Handelman, Donald Taylor, Donald Yee, Margie Bonnett, Joseph DeMino, Ramona McCarthy Hawkins

Staff: Shirley Costley, Licensing Unit Manager; Joan Lawrence, Public Information Officer, Patricia Gaither, Administrative Services Manager, Christina Harvin, Regulations Manager, Chandra Mouli, Pharmacist Compliance Officer, Sharon Gordon, Board Secretary, Grant Gerber, Interim Assistant Attorney General.

Absent: LaVerne Naesea, Executive Director, Christiaan Blake, Commissioner, Tamarra Banks, Management Information Services

Guests: Howard Schiff, MPHA, John McGrath, PEAC, Laura Howerton, TARGET, Daniela DeThomasis, TARGET, Jack Freedman, DDC, Lara McAndrew, CVS, Alison Freccia, Pharmacy Student

Melvin Rubin called the Public Board Meeting to order at 9:15 a.m.

1. Record of Conflict of Interest: Melvin Rubin began the first order of business by asking if Board Members had any conflicts of interest with any meeting agenda item. There were no conflicts of interest pertaining to the November Public Meeting Agenda.

2. Corrections to the Minutes - (10/20/04)

Page 2 – Under **A. Formulary,** 1st paragraph, 5th sentence, "hosting hearing" should be "hosting hearings"; 6th sentence, remove "needed"; under **B. DDC Pre-Inspection Booklet**, 2nd paragraph, 4th sentence, "Drug control" should be "Division of Drug Control"
Page 3– 1st paragraph under **B. Office Space Issues**, 3rd sentence, "in the same building", should be "in the current building." Last sentence, "support" should be "supported"; under **V. PEAC (Pharmacists Education and Assistance Committee)**, 1st sentence should be replaced with "Melvin Rubin updated the Board."; under **"Board Action**, 1st sentence, "to explore", should be "exploring"; under **A. Pharmacy Technician Workgroup Update**, 2nd paragraph, "the below", should be "Below".
Page 5 – **VIII. Management Information Services-Tamarra Banks** should be "Management Information Services – LaVerne Naesea".
Page 6 - Under **Nurse Midwives Formulary,** "by the Board of Nursing", should read "by a Board of Nursing representative"; last paragraph before heading **Influenza Administration Statute** should be the heading, **Letter to Practice Committee – Diane Garvey**
Page 8 – Under **B. Licensing Committee – Joseph DeMino**, 2nd paragraph, 1st sentence, remove "the Committee".
Page 9- Under **C. Disciplinary Committee – Jeanne Furman**, 5th sentence, remove "with serious consequences"; under **D. Council of Boards Report – Melvin Rubin**, 2nd sentence, "Margie Bonner" should be "Margie Bonnett".

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Board Action

Don Taylor moved acceptance of the October 20, 2004 minutes as corrected. John Balch seconded the motion. The Board members unanimously supported the motion.

3. President /Executive Committee Report – Melvin Rubin

Melvin Rubin introduced the interim Board Counsel, Grant Gerber, Assistant Attorney General, who is replacing Linda Bethman due to maternity leave. He also stated that the Board packet has been revised due to new information.

Melvin Rubin stated that Annapolis Internal Medicine Group would only send prescriptions electronically through *Sure Scripts, RX Hub*. The notification indicated that any pharmacy could join; however, if a pharmacy did not wish to participate in this important advance in medicine to help protect patients from medical errors, the group would direct patients to other nearby participating pharmacies or continue to receive fax requests and steer their patients elsewhere.

Ray Love stated that the Practice Committee considered this issue at its November 10th meeting and will recommend in its report that the Board of Pharmacy inform the Board of Physicians that this letter could deny patients a free choice of pharmacies and pharmacists which could reduce the ability of a pharmacists to coordinate drug therapy regimen reviews when patients receive medications from multiple physicians (including physicians that may not be members of that group). The Practice Committee further recommended that Christina Harvin, Regulations Officer, draft a letter to Safeway to inform them that this practice does not appear to violate Pharmacy law but that the Board is going to contact the Board of Physicians for feedback.

Committee Updates

Mr. Rubin stated that Mayer Handelman is now the chairman of the Discipline Committee since the whole department is being revamped with the addition of Chandra Mouli, Pharmacist Compliance Officer. Don Yee has scheduled a meeting to discuss Sterile Compounding USP 797 on December 6th at 2:00pm.

Mr. Rubin requested that a consumer member be present at every Licensing Committee and Discipline Committee meeting. This will be to reassure the public that a consumer is monitoring activities and decisions in the meetings.

IV. Executive Director's Report – Jeanne G. Furman

A. NABP District Meeting.
Ms. Furman stated that the meeting was held in West Virginia and presentations were mainly on Sterile Compounding. There were no new issues or resolutions presented by the District. Ms. Furman reminded the Board that any requests to present issues or resolutions at the annual meeting in May should be addressed through the Board to her for drafting and/or to propose with another state Board.

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Public Meeting Minutes
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Fall Educational Conference

Ms. Furman stated that she and Christina Harvin attended the Fall Educational Conference in Florida. The speaker from APHA, Susan Winkler, presented updates on all the federal regulatory and legislative information and topics that will could discussed during the federal *lame duck* Legislative session, but probably deferred until next year; including the Medicare Drug Benefit update and how it will affect reimbursements and electronic transmission. Ms. Furman indicated that there were presentations on Sterile Compounding, Drug Importation, Internet Pharmacies, and undercover Internet drug buys. Ms. Furman will get copies to the Board about the findings of the undercover operations.

Ms. Furman stated that NABP has partnered with *BUZZIO PDMA*, which is a company who is going to inspect and accredit wholesalers. They stated that most of the states do not have the resources to inspect and re-inspect wholesalers. With this program, the wholesaler must pickup the cost of the accreditation.

Carmen Catizone gave a presentation on continuing professional development. Through NABP, a testing program is set up where pharmacists test their knowledge and competency in certain areas of pharmacy practice using an on-line test. Based on the score received NABP would provide suggestions for remediation for targeting the acquisition of CE's. NABP's objective would be for pharmacists to become more specialized by receiving continuing education in the areas where they have practiced. NABP would help pharmacists assemble portfolios retained by NABP. Their portfolio would contain records of experience, education, certifications and residencies.

Following Jeanne Furman's presentation, Joe DeMino supported the concept of NABP having a competency exam. John Balch suggested that the Board have a strategic planning session or the Board could lose some. He suggested that staffing issues, legislation and regulatory issues and keeping Board members involved should be addressed at a strategic planning meeting.

Ms. Furman said that other states such as New York and Massachusetts use ex-office members for hearings suggested the MD Board follow suit. Ray Love stated that a statutory change to cover hearings would be required, but the Board can and has taken steps to retain consultants to help deal with parental medication issues. He said that the increasing sophistication of pharmacy practice is another issue to place on the agenda for a strategic planning meeting. Mr. Rubin stated planning a retreat to discuss all these issues was a good idea and added that the Board should review licensing and inspection of distributors, related to counterfeiters and oxygen.

B. Staffing Updates

Ms. Gaither reported that the Compliance Unit is recruiting an Investigator and a Compliance Specialist. Ms. Christina Harvin has assumed the role of Legislative/Regulations Unit Manager and recruitment of a Regulations Officer has begun. Also, a request has been made for temporary administrative staff to replace Ms. Lakeya Davis, who is on maternity leave.

Mr. Chandra Mouli has military pharmacy technician training and later became a pharmacist with the Department of Health and Human Services. He recently retired from HHS. He said he would do

anything that he can do to help the Maryland consumer gain access to good pharmacy services. He wants to make sure that Quality Assurance measures are in place and enforced.

C. Budget Analyst Meeting

Ms. Patricia Gaither reported that all the Board Directors met at Spring Grove with Andrew Bridger, the new Budget Analyst with the Department of Budget and Management on November 5, 2004. They discussed contractual position conversion requests, budget surplus balances and concerns regarding the loss of surplus balances in previous years. Mr. Bridger responded that conversions of contractual positions to permanent would probably not be approved during the upcoming session, but that he would work diligently to help avoid surplus balances being used by other units within the state.

D. DHMH Anti-Virals Survey

Mr. Ray Love stated that a teleconference took place with DHMH's Division of Epidemiology and Communicable Diseases to help determine when flu outbreaks occur. A number of mechanisms in place to monitor hospital emergency room visits and sentinel physician offices, but it want to also track when anti-viral prescribing starts to increase. The Board was asked whether any of the chain pharmacies had access to conglomerate data from their pharmacies that may indicate the volume of anti-virals being prescribed. Representing chain pharmacies, Mr. Gary Wirth said he would ask MACDS members about the various data elements that they collect and provide to DHMH. DHMH would be enabled to look at specific zip codes where prescribing of anti-virals have increased and project the areas outbreaks of the flu and notify pharmacies. Since the turnaround time for treating someone is 48 –72 hours in most cases, this would allow stocks of anti-virals to be ordered earlier. DHMH also wants ensure that anti-virals are prescribed appropriately and plan to meet with physicians on that issue. Finally, DHMH is developing educational information for pharmacies to distribute, including CDC posters on hand washing, etc.

Mayer Handelman stated that the local health departments know immediately when there are flu outbreaks in LTC facilities. However, the small 6 or 8 bed facilities are more difficult to track. Mr. Handelman stated that four free seminars would be offered around the state for long term care facilities to receive education, specifically covering flu outbreaks in facilities. Mark Levi stated that NDC, who processes 3rd party prescriptions, would be a better source locally to get flu vaccines, because they can target where they are sent through their MIS systems. Ray Love commented that wholesalers project potential rather than actual use. He continued that regimen differences are the only method to determine if the anti-virals are being used for actual treatment or prophylaxis because the data is not collected in any other way. Mr. Love noted receiving a report that the local health departments were going to receive the vaccines and that mental health facilities apparently received more than their initial requests.

V. PEAC (Pharmacists Education and Assistance Committee)

John McGrath stated that PEAC had their 5th Annual Continuing Education conference. Sixty-five persons participated and that costs are still being analyzed. The topics, speakers and materials presented were well received. PEAC has begun to plan its next conference based on feedback from participants. A more centrally located site to accommodate all participants will be identified and the conference may target a variety of health professionals, such as nursing personnel. The topics may be

narrowed and include employment opportunities for the impaired professional both from the employer and potential employee standpoint.

Two new clients have been referred from the Board, bringing the total number of clients to 14. Three Board-referred pharmacists have applied for modifications to their consent orders. One of these clients is of significant concern because of non-compliance with a consent order.

The 1st draft of PEAC's staff-training manual should be finalized by December. A monitor-training program will take place in January. The monitor-training program will allow participants to apply for additional continuing education credits. PEAC is considering creating a sub-committee to its Board with representative membership from chain pharmacies and hospitals. The plan will include mechanisms for fund raising, future budget practices and to receive advice regarding fundraising.

John Balch stated that he would like a monthly aggregate-client report from PEAC in order to measure program quality assurance. Mr. McGrath responded that a report is generated quarterly and that PEAC would work towards monthly reports in order to tract program deviations. Six monitors are employed with PEAC. Ms. Furman suggested that PEAC emphasize certain information required for Board referred cases to monitors and offered Board assistance with its upcoming training. I was suggested that Mr. McGrath provide Mr. Mouli receive a calendar of meetings for PEAC so he may attend some meetings.

VI. 2004 Regulations/Legislative Officer Report – Christina Harvin

Ms. Harvin stated that Maryland has just changed the regulatory process effective in December and the legislature would like for the Board to submit an action plan. She has been in frequent contact with the Governor's office about the Pharmacy Technician Bill and House Bill 433, which was effective this year. The Board of Pharmacy and Maryland Board of Physicians in conjunction with the Maryland Healthcare Commission are required to study the issues of legibility of prescriptions and make recommendations for all statutory and regulatory changes needed to improve legibility of prescriptions written in Maryland. A report to the legislature was due November 1, 2004, however, the Boards wrote a joint letter requesting an extension because of the extensive content that need to be addressed as required by the bill. Specifically:

a. The Appropriate Content and Format of a Prescription
b. Controlled Dangerous Substances – Generally
c. Schedule II Controlled Dangerous Substances
d. Schedule III-V Controlled Dangerous Substances
e. The Best Means to Inform and Educate Prescribers if Changes in Prescription Format or Contact are Enacted
f. Appropriate Time Frame and Procedures to Implement Changes Enacted Based on the Work Group Recommendations
g. Mechanisms for Enforcement
h. The Impact of any Changes to the Content or Format of Prescriptions on Oral Prescriptions
i. Whether Pharmacists Should be Prohibited by Statute from Dispensing Illegible Prescriptions Without Appropriate Format and Content

A meeting is scheduled for December 6, 2004 with the stakeholders. A letter was drafted to send to stakeholders signed by the president of the Board of Pharmacy and the president of the Board of Physicians.

Ms. Harvin stated that she met with Mark Lear, the Vice President of Regulatory Affairs of *Sure Scripts*, and he stated he would be willing to send information and representatives to help expedite the process within the workgroup. The Secretary of DHMH has approved the letter and signed it.

VII. Public Relations – Joan Lawrence

Ms. Lawrence stated that in November the Notre Dame School system had a wellness workshop with 150 people in attendance. The Governor's Conference on Vital Aging took place on November 5, 2004 with over 600 attendees. Newsletter articles for January should be submitted for inclusion in the newsletter are due no later than December 10, 2004.

B. Bio-Terrorism/Emergency Preparedness

Ms. Lawrence reported that the Committee met on November 12, 2004. Don Taylor stated that the Committee should keep the team liaisons and team leaders better advised so that they would know what to expect and maintain a clearer chain of command and to get them more involved with their local Health Departments. The next meeting will be on December 10, 2004.

VIII. Committee Reports

A. Pharmacy Practice Committee – Ray Love

1. Pharmacy Technician Bill

Dr. Love stated that the Committee reviewed the latest version of the Pharmacy Technician Bill and felt it addressed most of their issues.

2. Influenza

The committee also dealt with the developing regulations for the administration of influenza vaccines. The Committee asked Christina Harvin and Cherokee Wolfe to attend the Board of Physicians Practice of Medicine Committee meeting to discuss the fact that the statute does not specifically allow pharmacists to administer epinephrine if necessary in the course of administering flu vaccines. Attorney Counsels for the Boards of Pharmacy and Physicians felt that the bill contained language, which allows the pharmacists to take necessary actions to safely administer influenza vaccine, including administration of epinephrine, when indicated. Ms. Harvin will be meeting again with Cherokee Wolfe and use the Virginia regulations as a starting point to develop an initial draft of regulations for the Practice Committee to review. Once the Practice Committee formulates draft regulations, they will be sent to the Board of Physicians and the Board of Nursing for comments and approval, as required by the statute. Melvin Rubin said that this issue is a high priority and the issues should be resolved and training provided in time for next year's flu outbreak.

3. Annapolis Internal Medicare Group

Dr. Love moved, on behalf of the Pharmacy Practice Committee, that the Board contact the Board of Physicians, and inform them of the communication being distributed by the Annapolis Internal Medicine Group that denies patients' free choice of pharmacists and pharmacies, and reduces the ability of pharmacies to coordinate drug therapy regimen reviews when patients receive medications from multiple physicians. John Balch and Mark Levi seconded the motion, which was unanimously accepted. Also, the Board directed Ms. Harvin to write a letter to Safeway informing them that this practice does not appear to violate pharmacy law, but the Board has contacted the Board of Physicians concerning this matter.

4. Long Term Care Committee

Christina Harvin and John Balch are formulating a response to comments regarding the Long Term Regulations that were printed in the Maryland Register. The Board informed DHMH's Regulations Coordinator, Michele Finney, that would not make changes based on the comments received and submitted the letters from the prospective parties about their concerns. Christina Harvin stated that the 30-day wait period before the regulations are adopted has begun. The deadline for the regulations is mid-December.

5. Drug Therapy Management

The Committee reviewed the final forms regarding pharmacists' qualifications for Drug Therapy Management and directed that all the forms be posted on the Board website. They also directed that Maria Rodriguez-DeBitner, of the University of MD be informed that the forms are approved and posted on the website. The Board can now start accepting applications for Drug Therapy Management. The website link to for the forms will be under the Legislation and Regulation section of the website. The Board of Physicians will incorporate a link to the pharmacy board website.

The Committee recommended the following procedure following receipt of applications: 1) copies should be forwarded to the Board of Pharmacy representatives on the joint physician-pharmacy committee. 2) The representatives will review the applications and determine the content and expertise that required. 3) If additional expertise is required, a peer review committee will be formed. When decided, the peer review committee will be responsible for writing the joint committee and forwarding all applications. 4) The joint committee has 60 days to approve or deny approval.

Board Action: Ray Love, on behalf of Practice Committee, moved that the Board adopt this procedure. Mark Levi and John Balch seconded the motion. The Board unanimously accepted the motion.

6. USP 797 Committee

Dr. Love reported that Ms. Naesea, Executive Director, appointed Mr. Mouli to staff that task force. Don Yee stated that JACHO would enforce USP 797 in institutions they accredit. Many establishments need to have a plan in place to meet the approval of JACHO. Information from other states was presented to the committee to use as a guideline for the Board on how to implement USP 797. An alert message will be presented to the Committee for inclusion in the next newsletter. Once all data on the implementation of USP 797 is complete, the Committee will make recommendations on how Maryland will adopt USP 797 in their regulations. The next task force meeting will take place on December 6, 2004 at 2:00 p.m.

Ms. Furman stated that the Food and Drug Administration has the authority to enforce USP 797, but the Board has discretions regarding how it will regulate Sterile Compounding. Dr. Love stated that the Board should have specific regulations regarding USP 797, reflecting USP it in its entirety or in part. The final report from the task force should be in accordance with state regulations and the task force should make its own interpretation regarding which provisions will be enforced by Maryland Board of Pharmacy and Division of Drug Control. The goal of developing *implementable* regulations should be met. Dr. Love noted that there are not currently many safeguards in place in Maryland regarding Sterile Compounding. Ms. Furman stated that retail owners would find it difficult to comply with USP 797 given the stringent regulations and recommendations that are outlined in it.

7. Questions for the Board

a. Dr. Love stated that the Practice Committee reviewed an inquiry regarding the legality of transmitting prescriptions through specific intermediaries rather than directly from prescriber to pharmacists. The response was that actions needed to comply with HIPAA and the transmission of prescription regulations. A pharmacy cannot enter into an agreement that restricts access to a specific pharmacy or directs prescriptions to a specific pharmacy for a statute.

b. The Committee also reviewed an inquiry regarding pharmacy technicians checking other technicians of anesthesia trays. A response was sent that "technicians" are not legally recognized in Maryland and a Pharmacist is responsible for the accuracy of any dispensing or distribution from the Pharmacy.

c. The committee responded to an inquiry from a law firm regarding whether parts of the dispensing process such as entering labeling information on a computer system could be outsourced to an out of state pharmacy. The Committee's responded that outsource regulations and non-resident pharmacy statute addressed this question. The outsource pharmacy would need to be licensed in Maryland.

d. The Committee received a question from a clinic about dispensing of federal section 340-B drugs. These are drugs with special pricing for indigent patients from a clinic. The Committee responded that the clinic would need to abide with the physician dispensing regulations. Ms. Furman responded that physicians could delegate dispensing and that a nurse practitioner can prescribe and dispense medications based on the law for those types of clinics.

e. The Committee responded to a question from EPIC pharmacy about a tube of "topical medication" for a patient in an assisted living facility still in use when the expiration date was approaching. The label expiration date allowable by state law was shorter than the expiration date provided on the tube by the manufacturer. They write questioned whether the tube could be re-labeled with a new expiration date to allow continued used in compliance with the long-term care regulations. State will not allow the expiration date to be extended.

f. The University of Maryland Hospital asked whether drug samples could be dispensed through an outpatient, non-retail pharmacy. The Committee directed Ms. Harvin to draft

a response referring the inquirer to individuals at the Federal Drug Administration who routinely deal with this issue, because it is not a state issue.

g. An inquiry was received about whether pharmacists must maintain original prescriptions or could reduce an original prescription to an electronic image for its files and destroy the original hard copy. The Committee examined this request with Board Counsel determined that the Board had discretion to interpret the regulation. The Committee recommended that the Board interpret this provision to mean that written prescriptions can be destroyed, if scanned copies of the originals are retained. This also applies to faxed and written prescriptions. Mr. Love noted that questions continue regarding pharmacist-generated prescriptions, telephone calls, or oral orders. The Committee thought that these types of prescriptions would need to be scanned to reflect the handwriting of the pharmacists.

Board Action: Dr. Love moved on behalf of the Committee that the Board accept all of the committee recommended responses to questions to the Board; and that it specifically interpret Section 12403-B13 to allow original hardcopy prescriptions that are faxed, presented as written prescriptions, or reduced to hardcopy by pharmacists following telephone calls or verbal conversations with legitimate prescribers, once scanned and maintained as an electronic image that the hardcopies need not be retained to comply with regulations. However, records must also comply with federal and DEA laws regarding controlled substances. The Board unanimously voted to accept the motion.

B. Licensing Committee – Joseph DeMino

Mr. Joe DeMino reported that a total of 317 applications were mailed to pharmacists due to renew in December. He also stated that 32 pharmacists did not renew their licenses or that the licenses were incomplete for October. Four pharmacists voluntarily did not renew their licenses.

There were a total of 2236 applications mailed for renewal of permits for establishments of which 344 have renewed and 1892 have not renewed to date. There were 16 new applications received for an initial license and 27 licenses issued in October. The number of reinstatements totaled 8. Twenty-two (22) reciprocity applications were received, for which 14 licenses were issued. Twenty-one pharmacists requested to reciprocate to another state. Six (6) new applications were received for new distributor permits/establishments. A total of 7 permits were issued with 5 new and 2 with changes. The pharmacy permits totaled 22 of which 5 new applications were received, 4 applications were for changes in ownership. Mr. Taylor asked Mr. DeMino not to put continuing education credits on website because of other states not following the protocol that Maryland does. He also stated that streamlining of license renewal measures were efficient.

Board Action

Jeanne Furman moved to approve reciprocity for foreign candidate, Betty Abera from New York. Don Taylor seconded the motion, which was approved by the full Board.

C. Disciplinary Committee – Jeanne Furman

Ms. Furman reported on the meeting of the Disciplinary Committee. She stated that in regards to Pharmaquip, Jill Morgan of Division of Drug Control performed a surprise inspection and found that

the location had upgraded their operating procedures. She recommended to the Board that the Board not do a summary suspension but continue with the investigation. Jill Morgan also inspected Washington Hospital with a representative of Division of Drug Control to investigate whether appropriate sterile IV procedures were in place and found the activities were acceptable. A letter was prepared to the hospital that included suggested improvements. The Committee recommends no action on the complaint at this time.

The Public Board session adjourned at 11:30 a.m.

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