Maryland Board of Pharmacy

Public Board Meeting Minutes October 19, 2005

Attendance: John Balch, President; Jeanne Furman, Secretary; and Mark Levi; Treasurer

<u>Commissioners</u>: Margie Anne Bonnett; David Chason; Joseph DeMino; Mayer Handelman; Donald Taylor; Rodney Taylor; Michael Souranis; and Donald Yee

<u>Staff</u>: LaVerne Naesea, Executive Director; Linda Bethman, Board Counsel; Chandra Mouli, Pharmacist Compliance Officer; Colin Eversley; Compliance Investigator; Shirley Costley, Licensing Manager; Patricia Gaither; Administrative Manager; Summar Goodman; Public Information & Education Officer; and Tamarra Banks; MIS Manager

Absent: Christina Harvin, Regulations & Legislative Manager, and Anna Jeffers, Regulations & Legislations Officer

<u>Volunteers Award Recipients</u>: Matthew T. Durkin; Chris Falato; Mel Rubin; Rachel Strand; Tim Lubin; Joe Loetell, Hitesh Patel; Steve Lauer; Chris Musser; Crystal Henderson; Deborah McNutt; Peisah Upshaw; Nneka Ezekaueche

| <u>Guests:</u> Regina Muljadi; Jonathan Ratley; Jen Zucco; Erin Hachey; Stephen Riggin; Raymond Love and Steve Berberich from Business Gazette

Louisiana Deployed Volunteers Recognition Ceremony

President John Balch, LaVerne Naesea and Donald Taylor congratulated and thanked the 14 pharmacist volunteers, who traveled to Louisiana to assist victims of the Katrina Hurricane disaster. Certificates and pendants were given to each volunteer. Lead volunteer, Melvin Rubin, shared information about another group that volunteered at the Du Burn's Center in Baltimore assisting displaced Katrina victims. Other honored volunteers gave accounts of their experiences and described how humbling it was. Summar Goodman acknowledged those volunteers who had been scheduled for deployment, but were not sent to Louisiana.

I. Record of Conflict of Interest

President Balch called the Public Meeting to order. There were no conflict of interest declarations. Guest attendees were asked to introduce themselves (see above).

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II a. Corrections to Minutes 8/17/05

Page 1

- The use of semi-colons and commas in the board and staff member listing of names and the use of uppercase and lowercase letters in the guest listing of names need to be made consistent
- Under Record of Conflict add the word 'declarations' at the end of the second sentence.

Page 2

- -Under *Board of Pharmacy Update*, add 'of Health and Mental Hygiene' after the word 'Department'.
- -Add a space after District II Meeting.
- -Second sentence under *District II Meeting Fall 2006*, add a space after '2006'.
- -Under *Legislative Audit Update*, last sentence, delete the 's' on the word 'concerns' and change the word 'are' to the word 'be'.
- -Under *Introduction of New Staff Member*, create a new heading ' *Citation*' and move last sentence, 'John Balch awarded...' under the new heading.

Page 3

- -Under *PEAC*, second paragraph, change 'Downtown' to 'downtown'.
- -Under *Staffing Update, change* fourth sentence to say, 'The Board is currently changing Colin Eversley to a permanent status.'
- Under *Newsletter*, first sentence, add word 'a' after establish; second sentence, add the word 'to' after the word 'September'.

Page 4

- Under VII, change 'Statistics' to 'statistics'.
- Under *In-house Database Update*, last sentence, change word 'between' to the word 'during'.
- Under *Automation System Audit*, second sentence, delete the phrase 'there is no way the general public can obtain access to any confidential information' and add, 'that confidentiality can be assured.'
- Under *Influenza Vaccination Regulations*, delete 'for approval' in the last sentence.

Page 5

- 3rd whole sentence, change 'The Repackaging Section would be added following...' to 'The repackaging section would be revised following...'; delete all the language in parentheses following that sentence.
- Under *Methamphetamine and Dextromethorphan Production Workgroup Meeting*, change spelling of 'Methampetamine' to 'Methamp<u>h</u>etamine' throughout the section; change name 'Menase' to "Menes' throughout section; and at the end of the third sentence, change '...in a Workgroup' to 'in the Workgroup'.
- Under *Legibility of Prescriptions Final Report*, fifth sentence, change 'present' to 'presented'; delete the last sentence and add, 'In order to educate prescribers and consumers, it was further recommended that an educational period be implemented using a phase-in approach.'

- Under *SB 885 Mail Order Purchase of Prescriptions*, 1st sentence, add 'the report' after the word 'presented'.

Page 6

- Last sentence under, *Long-Term Care Letter to CMS*, change 'notification in changes *of* ...' to 'notification in changes *occur in*'
- Last sentence under B. Licensing Committee, change from '...it could have...' to 'it could be...'
- Under *Reinstatement Requests*,

1st paragraph - second sentence, add 'Gasdia's after the word 'Mr.', delete '(S.G.)', next to last sentence, add 'Ms.' Before 'Bethman's', last sentence delete the word 'draft';

2nd paragraph, add 'in Maryland' after the word 'reinstated'; First *Board Action*, delete the word 'hours' and replace with 'experiential service'; 2nd *Board Action*, change sentence from 'The Board voted to ...Ms. Webster.' to 'The Board voted to require Ms. Webster to complete the required supervised hours in order to become licensed in Maryland.'

Board Action: Unanimous vote of approval of August 17, 2005 Minutes, with corrections.

II b. Corrections to Minutes 9/21/05

Page 1

-Under A. COMAR 10.34.32, under #2, change 'certified' to 'certify'; under #3 add 'have' after the word 'will'; under #4 change word 'distinguish' to the word 'identify' and change the word 'specifically' to the word 'i.e.,'

Page 2

- -Under Section B, change 'Psudoephedrine' to pseudoephedrine (lowercase throughout).
- Under *Section C*, 3rd paragraph, change 'Don's' to Mr. Taylor's'; change 'Pharmacy Technician' to 'Pharmacy technician'

Page 3

- First full sentence, delete the word 'the' after the word 'current' and add the word 'the' before the phrase 'Code of Conduct Regulations'.
- Third paragraph make 'Pharmacy Students' lowercase throughout paragraph.
- Under *Practice Committee*, a., 2nd paragraph, change 'Her concern...' to 'The pharmacist's concern...'; add word 'on' after the word 'depends'.

Page 4

- Delete 'a. Official written...system.', which is a duplication of language on the previous page; under second paragraph, add the word 'by' after the word 'advised'.
- Under New Business, change lettering for each section; last line under 'b.', delete ',' after word 'use'.

Under 'c.', add the word 'the' before the words 'pharmacy permit'.

Board Action: Unanimous approval of September 21, 2005 minutes, with corrections.

III. President/Executive Committee Report - John Balch

Public Board Meeting Schedule

The next Public meeting will take place on December 21, 2005 and then the public Board meetings will resume on a monthly basis, although in some months they may be abbreviated. The Board and staff members will engage in an all day Retreat on November 16, 2005.

Influenza Vaccination Regulations

The Flu Vaccination Regulations have been jointly approved by the Boards of Pharmacy, Nursing and Physicians, and will likely be submitted as emergency regulations in order to be implemented before the end of the 2005 influenza season. Thank-you letters will be sent to all of those who aided and supported the Board in the development of the regulations.

It was noted that if the regulations are passed as proposed, pharmacists must complete four CE credits, dealing with immunization, when renewing their certification to be eligible to administer the influenza vaccine.

Prescription Monitoring

Members of the Board's Executive Committee met with Attorney General Curran and members of his staff to discuss concerns regarding diversion and abuse of prescription drugs. The Attorney General's (AG) office has launched an initiative against the abuse of prescription medications. He also indicated that he will lend his support to the proposed pharmacy technician bill during the next session. The AG has issued a paper entitled, *Prescription for Disaster*, which suggests steps that Maryland should take in developing a Prescription Monitoring Program. Copies of the document are available upon request from the AG's office. The AG's office further requested that the Board provide comments on the position and recommendations put forth in the report regarding drug diversion and implementing a prescription monitoring program. Mr. Levi expressed some concerns with the recommendations and will forward his comments in writing to Mr. Balch. Board members who wish to comment should e-mail President Balch prior to the formal response from the Board being prepared.

Sub-committee Hearing on Pseudoephedrine and Wholesale Distributors

Mark Levi and Christina Harvin participated in a Subcommittee on Pharmacy hearing
concerning possible legislation for pseudoephedrine during the next session. Delegate
Menes, Chair for the subcommittee was informed that the Board had recently proposed
regulations restricting how pharmacies store and dispense pseudoephedrine. However,
the sub-committee was reminded that establishments other than pharmacies (gas stations,
convenience stores, etc.) also sell these drugs and that the Board has no regulatory
authority over those entities.

Mr. Levi also provided testimony during the hearing to conceptually support the NABP Model Wholesale Distributor regulations. He suggested that the Board be provided time to complete its review of the regulatory needs in Maryland before presenting its recommendations. Jeanne Furman has been assigned to the Board's Licensing Committee to chair a Task Force that will review the current regulation of wholesale distributors in Maryland and review NABP's Model Regulations. The task force will make recommendations to the Board through the Licensing Committee.

Board Action: Unanimous approval of the Task Force on Wholesale Distributors

IV. Executive Director's Report - LaVerne Naesea

Board Renovation and Moving Plans

The renovation of the new Board offices on the first floor should be completed for move in by mid-December. The Board of Pharmacy staff will be making necessary preparations for the move. The Department of Health and Mental Hygiene (the Department) has been notified that the Board is in the process of mass renewals of establishment permits. A dual database system may be required if moving interferes with the processing of renewal applications. The Department assured the Board Executive Director that the move would not interfere with the processing of applications. The Licensing Unit will prepare and send a letter to pharmacists notifying them of the planned Board move and suggesting that applications and payments be submitted as early as possible to avoid potential processing problems.

NABP District Meetings

The District II meeting will be held Thursday, October 20 through Saturday, October 22 in Washington DC. In addition to Ms. Naesea, three Board members and three professional staff members will also be able to attend because due to of the the close location.

The Maryland Board has begun to plan the joint District I and II meeting that will be hosted in Baltimore in 2006. The Renaissance Inner Harbor Hotel has been reserved for October 12th – 14th 2006, pending approval from NABP. The Board Public Information and Education staff will be working with the Baltimore Area Convention and Business Association to acquire give-away bags, assist with obtaining vendor discounts, and help in planning activities. A committee, comprised of Jeanne Furman, Rodney Taylor, Summar Goodman, LaVerne Naesea, Patricia Gaither, representatives from the University of Maryland School of Pharmacy, and a consultant – Anna Leonhardt, will be working with NABP representatives from District I and II to plan the 2006 meeting.

Board/Staff Retreat

Board and staff members were reminded of the retreat and appreciation dinner honoring previous board members, which will be held on November 16, 2005, at the Belmont Conference Center. Board staff members are planning a subsequent retreat in order to develop strategies for organizing and carrying out the decisions made during the Board/staff retreat.

Drug Repository Task Force

The Department of Health and Mental Hygiene has assigned the Board of Pharmacy to staff the Drug Repository Task Force. Ms. Naesea will meet with Robin Elliott in the near future to discuss approaches to conducting and reporting on the progress of the Task Force. The first interim report is due by December 31, 2005. An extension will be requested. Background research has been completed and will be placed on the Board's web site. The Governor's appointments to the Task Force were not completed as of the October 19, 2005 Board meeting.

Assistant Attorney General Report on FARB Conference Attendance – Linda Bethman

Board Counsel attended a national conference for attorneys that support regulatory boards. The conference sessions covered various topics including: Consent Orders for purposes of reciprocal discipline; forthcoming federal regulations that will provide federal protection from discoverability of information reported to patient safety organizations; recusal and immunity issues for board members; and processing issues related to licensure discipline.

V. PEAC Client Update - John McGrath - no report

VI. Administration and Public Support - Patricia Gaither

Budget Report FY'05 EOY/FY'06 Appropriations

The FY 2005 expenditure report was provided. During FY 2005, a total of \$1,480,609 was collected and \$1,364,165 was expended. The FY 2006 appropriation was \$1,639,161.

Personnel Report

Of eighteen approved positions, (14) permanent and (4) contractual, there are presently four vacancies. Three new contractual positions (two licensing staff and one administrative specialist) were approved during the 2005 legislative session, of which two should be filled by the end of December 2005. The third position for the Licensing Unit will not be filled until after the anticipated passage of the pharmacy technician bill during the 2006 session. The Board is currently recruiting for the contractual Board Secretary position.

Public Information & Support – Summar Goodman

All of the emergency preparedness goals were met during the deployment of volunteer pharmacists to Jefferson Parrish, LA. to assist Katrina victims. One problem identified was that a two-week_commitment proved difficult for many potential volunteer pharmacists. In the future, it would be preferable to have one-week assignments. Governor Ehrlich is planning a volunteer awards ceremony sometime in November 2005.

The draft copy of the fall newsletter was returned from the printer. Ms. Furman and Mr. Don Taylor will perform final reviews. The newsletter should be distributed within 2 weeks of the Board meeting. The due date for Annual Report submissions is October 30, 2005. A draft of the report should be prepared by mid-November.

Public Relations Events/Opportunities

MSHP will host its annual conference in Columbia, MD on November 5, 2006. The Board is considering hosting a booth at this event. National Pharmacy Week is October 24-29, 2005. The Board will issue a related press release to various media outlets and post pictures from the Volunteer Recognition Ceremony on its web site.

VII. Management Information Services – Tamarra Banks

Online Renewal Payment System – No significant problems have been reported regarding use of the Online Establishment Renewal system that opened in early October 2005 for annual renewals by pharmacies and distributors.

New In-House Database - The Towson University <u>work under the</u> contract to develop a Board-operated database is in continued development.

Board Website Updates – The Board site is being updated. Board members were asked to review and update biographical information.

Group Wise E-mail – There were problems reported in sending e-mails to key state personnel (i.e., Linda Bethman) through the GroupWise system. Board staff is aware of the problem and working to resolve it in the near future.

Hardware/Software - The purchase of a color printer and three laptops have been budgeted for FY 2006. The printer has already been requisitioned.

Special Projects - Electronic Meetings and Scanning Board Legal Documents

The Board and staff members tested an electronic meeting system in early October. The Board may elect to utilize the 'electronic' board meeting tool in conjunction with on-site meetings. For example, the Board could purchase a few slots (5 or 6) for members or staff who might not be able to physically attend meetings on various occasions. Each participant would be required to have access to a laptop or PC. The cost would be \$60 per/seat per/month, totaling approximately \$10,800 per year (assuming all Board members purchased seats monthly).

The Board staff has contracted a scanning company to scan legal documents and materials on file at the Board in order to reduce the number of items moved to the first floor when the Board relocates.

VIII. Legislative/Regulations Report – Mark Levi

The report was incorporated in the Practice Committee report provided below by Committee Chair, Mark Levi.

IX. Committee Reports

Practice Committee - Mark Levi

NABP's Model Rules for the Licensure of Wholesale Distributors

Mr. Levi and Ms. Harvin met with the sub-committee on pharmacy to discuss the National Boards of Pharmacy's (NABP) Model Wholesale Distributor regulations. Delegate Rudolph has expressed interest in related possible legislation and gave indication that he would support the Board's position. EightEight to 10 four states have already implemented the Model rules.

Long Term Care Taskforce - Meeting rescheduled for November 14th

Drug Therapy Management – A meeting of the joint Board of Pharmacy and Board of Physicians review committee is planned in early November 2005.

Drug Repository Task Force - The committee will request an extension for the interim Drug Repository Task Force Report due December 31, 2005. (See above under Executive Director's Report.)

USP 797 - The Task Force is in the final stages of its work. A meeting is scheduled for later in October 2005.

Recommended Responses to Board Inquiries

Question: What font size should be used for the Controlled Substance label statement "Caution: Federal Law Prohibits Dispensing without a Prescription"?

Answer: When the size of a label space requires a reduction in type, the reduction shall be made to a size no smaller than necessary and in no event to a size smaller than sixpoint type. [COMAR 10.19.03.08D(1)]

Question: What recourse would a patient have against a nursing facility that disallows medications to be brought in from home by the patient and then destroys leftover medications that were ordered by the facility, paid for by the patient, but not released with the patient upon discharge?

Answer: Since the Board does not regulate nursing homes or long-term care facilities; the inquirer should be referred to the Office of Health Care Quality.

Question: Please cite the law that states a prescription for a non-controlled drug may not be refilled after 1 year from its date of issuance; specifically, pertaining to a prescription that has been written with "prn" refills or for a prescription that is over one year old but still has remaining refills.

Answer: Maryland law does not address this issue, but the standard in most practice sites is not to refill prescriptions after one year. This practice may be driven by third party reimbursement and insurance provider policies.

Question: Can Wegmans pharmacy's call center in New York be used for one of its pharmacies in Hunt Valley, Maryland?

Answer: Yes, as long as the pharmacy in New York has a Maryland permit to operate.

Question: Can a Giant pharmacy make use of a prescription vending machine as long as a pharmacist is on duty when the machine is accessible to patients?

Answer: Maryland pharmacy regulations do not prohibit, but the Department of Health and Mental Hygiene has certain prohibitions against the use of vending machines to which the inquirer must adhere. (The response letter will cite the related laws)

C. <u>Licensing Committee – Joesph DeMino</u>

- 1. Mr. DeMino reported on his attendance at the NACDS forum on Medicare.
- 2. The mailing of establishment renewal applications was outsourced to a state volunteer unit. The unit sent the wrong type of application to some pharmacies and distributors. Board staff has prepared a letter to request that applicants ensure that they have received the right application before completingon. A second letter will be mailed to notify establishments of the Board's planned office relocation in December and to suggest that they consider submitting renewal applications early to avoid delays.
- 3. The Licensing Committee has established a Wholesale Distributor Task Force. Ms. Jeanne Furman will chair the task force.
- 4. The Licensing Committee has assigned an Inspection Process Task Force to review the Board processes for reviewing and responding to inspection reports. Mr. Michael Souranis will chair the task force.
- 5. Reciprocity Candidate, Robert Tremmel's license was suspended in December 2002, by the New York Board of Pharmacy for maintaining 60 overfilled bottles of medications in his pharmacy, that were filled in part with stolen sample drugs. He admitted to the violation.

Board Action: A motion was supported to deny the candidate reciprocity to Maryland.

X. New Board Business

Per Diem Increase

Board members discussed concerns related to attracting and retaining the interest of potential pharmacists and consumers who may be nominated for Board membership but who would need to travel a distance of 200 or more miles per round trip in order to participate in meetings.

Board Action: A motion was supported to provide an additional \$100.00 per diem for Board members who reside 200 or greater miles roundtrip in order to participate in Board sponsored or supported meetings and activities. John Balch and Donald Taylor recused from voting on this matter.

The meeting was adjourned at 11:30 a.m.