Maryland Board of Pharmacy
Public Meeting Minutes
October 17, 2007

		Today's Attendance		Year-to-Date Attendance	
Name	**Title**	**Present**	**Absent**	**Present**	**Absent**
Anderson, C.	Commissioner		x	9	1
Bonnett, M.	Commissioner		x	6	4
Bradley-Baker, L.	Commissioner	x		2	1
Chason, D.	Commissioner/Secretary	x		10	0
Finke, H.	Commissioner	x		9	1
Handelman, M.	Commissioner	x		9	1
Israbian-Jamgochian, L.	Commissioner	x		3	0
Leandre, A.	Commissioner	x		9	1
Sournais, M.	Commissioner/Treasurer	x		8	2
Taylor, D.	Commissioner/President	x		10	0
Taylor, R.	Commissioner	x		9	1
Zimmer, R.	Commissioner	x		3	0
Bethman, L.	Board Counsel	x		10	0
Costley , S.	Licensing Manager	x		8	2
Jeffers, A.	Legislation/Regulations Manager	x		9	1
Eversley, C.	Compliance Investigator	x		10	0
Naesea, L.	Executive Director	x		10	0
Gaither, P.	Administration and Public Support Manager	x		9	0
Goodman, S.	Public Information Officer	x		9	1
Banks, T.	MIS Manager		x	9	1

Subject	Responsible Party	Discussion	Motion	Action/Results
I. Introductions	Donald Taylor	Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals.		No Action Required
II. Approval of Minutes	Donald Taylor	Page 3 – under the Division of Drug Control Statistics, 3rd sentence, delete "September" insert "August". Page 3 – Under PEAC, 2nd sentence, move "(1)" next to the word "one". Page 4 – Under A. Legislation – spell out the word "DTM" - "Drug Therapy Management" Page 4 – Under Wholesale Prescription Drug or Device Distributors Regulations – delete 2nd period. Page 5 – Under Management Information Services – change "University of Towson" change to "Towson University" Page 6 – Under Establishment Database, 3rd sentence, delete the word "and", 4th sentence delete the word "to". Page 10 – Under Informational - #4 – 11th sentence "correct spelling of the word "prescription".	Motion: Harry Finke, Jr. Moved to accept the minutes as amended Reid Zimmer seconded the motion.	The Board voted unanimously to approve the minutes as amended.
III. Reports A. President/ Executive Committee Report	Donald Taylor, Board President	A. Donald Taylor provided an update on the DHMH Dispensing Protocol request. Based on the Wholesaler Legislation due to become effective in January 2008, this Board will no longer have the authority to approve protocols that waive the requirements for distribution of pharmaceuticals. B. Mr. Taylor announced that a staff retreat is tentatively scheduled for January 16, 2008. Prior to the retreat there will be a short Public Meeting.		No Action Required
A. Executive Director's Report	LaVerne Naesea, Executive Director	Ms. Naesea reported on the District II Meeting in Wilmington, Delaware. Donald Taylor, David Chason, and Ms. Naesea attended the meeting. The meeting featured roundtable sessions between NABP and AACP. Ms. Naesea stated that AACP is looking at the expanding role of the pharmacist in specialty areas such as immunization. There was also a joint session where NABP members and AACP members were presented with a recap of the roundtable meetings. Ms. Naesea discussed the new proposed NABP post licensure competency self evaluation test. Ms. Naesea provided the monthly report from the Division of Drug		No Action Required

		Control: There were 60 pharmacy inspections including 17 opening inspections,14 closing inspections performed during the month of September.		
B. P.E.A.C.	Tony Tommassell oP.E.A.C.	A. Dr. Tommassello reported that PEAC's caseload consists of 11 cases, of which two (2) are pharmacy students and one (1) is a technician. PEAC received reports on 20 urine samples with no positive results. B. Dr. Tommassello reminded everyone of PEAC's annual seminar on Thursday, October 18th at Riderwood Village in Silver Spring, Maryland. The seminar is entitled "The Bottom Line on Addiction and Recovery: Practical Lessons and Guidance for Pharmacists, Colleagues and Employers". The Board is scheduled to staff a booth.		No Action Required
C. Legislation and Regulations	Anna Jeffers Legislation & Regulation Manager Report	A. Legislation: Ms. Jeffers provided an update on the legislative proposal – Physicians and Pharmacists – Therapy Management Contracts – Extension of Program. The proposal has been submitted to the Governor's Office by DHMH and it has not been determined at this time the DHMH will sponsor the bill. B. Regulations: 1. COMAR 10.34.01,.08.09,.10,.11,.21 and .34 Pharmacy Technician and Reinstatement Re-proposal's comment Period will end October 29, 2007. No official comments have been received by the Board at this time. 2. COMAR 10.34.22.01 - .08 Licensing of Wholesaler Prescription Drug or Device Distributors was presented for Board approval. The draft regulations were initially prepared by a Board subcommittee during 2006 before the enactment of SB 759 during the 2007 Legislative Session. Draft regulations were then developed by the Wholesale Distributor WB 759 Workgroup and the Board's Practice and Licensing Committees. The Workgroup Discussed and/or made the following changes: 1) Added definitions from the statue. The Workgroup reworded some definitions (a. Repacking – added "does not include Intra-Company Sales"; and	Motion: Alland Leandre moved to accept the Licensing of Wholesaler Prescription Drug or Device Distributors regulations as amended.	The Board voted unanimously to approve the motion.

		b. Drop Shipment – added "manufacturer's co-licensed partner to B(402)(b)(iii)2."). Since definitions need to mirror the Statue, the definitions were returned to original language. 2) Required Shareholder information only for Non-publicly traded corporations; 3) Did not require mandatory continuing education; 4) Used NABP and PhRMA Model Act to complete the list of violations; 5) Under Minimum Requirements for Storage and Handling, Reworded the "Security Section" regarding: a. A security system that protects from theft and diversion b. Requiring Security Software c. Adding Video monitoring of entrances and exits; and 6) Under Minimum Requirements for Maintenance of Records, added in language from the DEA for what constitutes a significant loss. The Practice and Licensing Committees made the following changes: - Removed the word "human" from the Scope; - Added more detail from the statue so that all application requirements would be consolidated in one place in the regulations; - Added the definition of "Co-licensed Partner" from SB 759; - Requested additional contact information from applicants; - Revised language so that the designated representative would be required to have documented training sufficient to ensure that the operations of the wholesale distributor are in compliance with applicable State and federal laws; - Under the Personnel Section, Registered Agent: removed B(3) since the Board will not be acting as a resident agent - Under the Prescription Drug Repository Program, Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland; - Required that if no storage requirements are established for a prescription drug or device, that the drug or device shall be held at a controlled room temperature as defined in an official compendium as set	Mayer Handelman seconded the motion.	

		forth by the United States Pharmacopeia/National Formulary (USP/NF) under 21 CFR §205.50(c); - Reworded "shortages or losses" to "inventory losses." and - Required that wholesale distributors consider the factors listed in the regulations regarding what constitutes a significant inventory losses.		Action Item: Linda Bethman to research whether .03G was quoted from the statue. If not, then reword it so that "rejection of the application" is deleted and "Notice of Intent to Deny" is substituted, or similar language.
D. Admin & Public Support	Patricia Gaither, Administration and Public Support Manager	Ms. Gaither reported that a request to appoint a Pharmacy Compliance Officer with approval of the salary has been sent to DHMH. She expects to receive a response next week. Recruitment for pharmacy inspectors is ongoing. Ms. Gaither also reported that she is waiting for reclassification for the inspector positions. There will be an Administrative Officer III who will have supervisory duties. After the inspector positions have been reclassified, recruitment will begin.		**Action Item**: Ms. Gaither will continue the process for recruitment for pharmacy inspectors.
E. Admin & Public Support	Summar Goodman, Public Information Officer	Ms. Goodman reminded everyone of the dinner to honor previous Board members at Liberatore's. The members that will be honored at tonight's dinner are Jeanne Furman, Donald Yee, Mark Levi, John Balch & Joe DeMino Ms. Goodman reported that the newsletter is the final stage and will be distributed by the next month's Board meeting.		**Action Item**: Newsletter to be published in November 2007.

		There will be an Emergency Preparedness Training Sunday, October 28, 2007 at the Radisson Hotel from 7:30 am until 1:00 pm. Ms. Goodman reported that she has 25 slots available.		
F. Management Information Services	Michelle Hsu, Data Base Specialist	Ms. Hsu provided the MIS report for Ms. Banks in her absence. <u>In-House Database Implementation:</u> Ms. Hsu reported that the section of the online licensing was missing from technical documentation and required additional programming. The section has been added. She also reported that the revised contract database is ready for submission to Towson University. There was nothing to report on HIPDB. <u>Pharmacist Online Renewal Database</u>: Ms. Hsu reported that MIS is still receiving approximately 40 requests each month to reset forgotten passwords. MIS will look into the suggestion to reset the entire database back to the last 4 digits of the Social Security Number as discussed last month. <u>Division of Drug Control/Inspections:</u> MIS is working with Licensing and Compliance to establish protocols for obtaining inspection statistics and to prepare for the database design. Initial and routine MIS job functions will be determined during this phase of implementation. Copies of the inspections have been received, however input is not completed. MIS is still experiencing some synchronization problem between the DDC and the Board's the current system. There was nothing to report on the Pharmacy Technician Database. <u>Establishment Database:</u> MIS reviewed the changes made to the new renewal forms the 1st week of October. Another couple of weeks will be required to resolve all the issues. The system runs on two (2) separate servers, one being a copy of the other. MIS will need to perform the re-design on the main server, then ensure that the data on the replicated servers is also updated with the changes. The new online system has been turned on and is being updated daily with new renewal data. The		**Action Item**: Tamarra will report on forgotten passwords received by MIS unit monthly. **Action Item:** Tamarra will report on protocols to obtain inspection statistics for database design and update on synchronization problem between DDC and the Board's current system. **Action Item:** Tamarra will report on the online system.

		database specialist recommended that no changes be made at this time, and modifications should be made at the end of the renewal period.		
		Personnel: The Disaster Recovery/Help Desk contract ends in December 2007. MIS will submit a new contract specification for additional services to be performed related to testing Disaster Recovery systems, and implementing the technician and inspection data into the Disaster Recovery process for approval.		**Action Item:** Tamarra will report on new contract for for the Disaster Recovery/Help Desk.
		Contracts: The Board will begin the process to contract with State Archives and possibly Spring Grove for Disaster Recovery off-site locations.		**Action Item:** Tamarra will report on the contract with State Archives and Spring Grove.
		Internet/Website: Ms. Hsu reported on the monthly count of emails received. The establishment online renewal system was turned on October 16th. A button was placed on the Home Page that goes directly to the online page, as well as on the Licensing pages. The Establishment renewal application can be downloaded from the forms page as of October 15th. Proposed regulation changes have been posted. MIS is awaiting Board approval for the format change to the webpage listing missing and stolen prescription pads.		**Action Item:** Tamarra will report on the Establishment online renewal system./
		MIS is awaiting recommendations from the Board for information to be placed on the secured site. MIS reviewed all e-mail in the Board's general mailbox, MDBOP@dhmh.state.md.us. The purpose was to determine the distribution between units and check for e-mail that may need further attention. E-mail was forwarded to managers and the executive director for additional follow-up. Currently, this e-mail account is being checked by the Licensing Unit.		**Action Item:** Tamarra will report on the secured website.

G. Practice Committee	Dave Chason, Chair	1. Constituent Questions and Responses a. Mr. Jon Jordan contacted the Board asking whether, when repackaging from mail order prescriptions for a long term care facility, the lot number assigned by the distributor or manufacturer has to be included in the log when there is no way to know that lot number. The Practice Committee proposed: At the present time repackaging is not prohibited by Board regulations. The Board, however, has concerns regarding the safety of repackaged products. That concern includes the difficulty in determining what expiration date should be used. The quality of the prescription medication may be compromised by repeated heating to create additional blister packs. Furthermore, the repeated handling of the prescription drugs with multiple repackaging makes the entire process more prone to error. The National Association of Boards of Pharmacy (NABP) and the American Society of Consultant Pharmacists (ASCP) have urged that this practice be discontinued, as well, due to substantial concern regarding the safety of repackaged products. Please refer to NABP at www.napb.net and www.ascp.com for further information. b. Matthew T. Slimp, Esq. contacted the Board to determine whether clients may engage in the activities outlined in his letter of September 12, 2007. Those activities include: - Provide a medication order form to the prescribing veterinarian; - Ask the prescribing veterinarian to inform the pharmacy how much profit margin (if any) the prescribing Veterinarian would like to earn on the medication; - Add the veterinarian's specified profit margin to the total base price of the prescription - Send the veterinarian's specified profit margin obtained as	Motion: M. Souranis moved to accept the Practice Committee's letter as written. M. Handelman seconded the motion. Motion: R. Zimmer moved to accept the Practice Committee's letter as amended. M. Souranis seconded the motion.	Board Action: The Board voted unanimously to accept the motion. Board Action: The Board voted unanimously to amend to remove the sentence referring to legal counsel.

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<td>Part of the total enhanced prescription price paid by the patient back to the prescribing veterinarian; and
- Not disclose this arrangement to the purchasing patient.

The Practice Committee responded:
Please be advised that the Board would consider what you have outlined above to be a violation of the Maryland Pharmacy Act. See Health Occupations Article, 12-313(b)(12). Annotated Code of Maryland.</td>
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<td>H. Licensing Committee</td>
<td>Michael Souranis, Chair</td>
<td>Mike Souranis provided the Licensing Report for the Month of September. Mr. Souranis asked for approval of the USP 797 Supplemental Sterile Processing, Hospital and Long Term Care inspection forms. The suggestion was made to change the title of the Board's USP 797 Sterile Compounding Inspection form. It was also suggested that a cover sheet be included. Page numbers should be added as well as deleting "Action Plan" from each section.

Licensing Statistics:

Establishments:

<table>
<tr><th>New:</th><th>September 2007</th><th>September 2006</th></tr>
<tr><td></td><td>11</td><td>New: 28</td></tr>
<tr><td>Distributor-In State</td><td>1</td><td>3</td></tr>
<tr><td>Distributor- Out-of-State</td><td>5</td><td>9</td></tr>
<tr><td>Resident Pharmacy</td><td>3</td><td>4</td></tr>
<tr><td>Non-Resident Pharmacy</td><td>2</td><td>2</td></tr>
<tr><td>Pharmacy w/Waiver</td><td>0</td><td>2</td></tr>
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<tr><th>Closed:</th><th>2</th><th>4</th></tr>
<tr><td>Distributor – In State</td><td>0</td><td>-</td></tr>
<tr><td>Distributor – Out-of-State</td><td>0</td><td>-</td></tr>
<tr><td>Pharmacy</td><td>0</td><td>3</td></tr>
<tr><td>Non-Resident Pharmacy</td><td>2</td><td>1</td></tr>
<tr><td>Pharmacy w/Waiver</td><td>0</td><td>-</td></tr>
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Dave Chason volunteered to work with Mayer Handelman on revising the Long Term Care inspection form.

New inspection forms are scheduled for implementation in January 2008.</td>
<td>Motion: M. Handelman moved to accept the Licensing Committee's report A. Leandre seconded the motion</td>
<td>Board Action: The Board vote unanimously to approve the Licensing Committee's report.

Action Item:
Dave Chason volunteered to work with Mayer Handelman on revising the Long</td>
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		Ms. Costley reported that the system for automated establishments is operational. The Licensing unit has received 75 renewals to-date. The on-line system was turned on Tuesday, October 16th. The Licensing unit has asked the Practice Committee to determine whether a Wholesale Distributor is permitted to distribute in Maryland if they are not licensed in the State in which they reside. The Practice Committee is to respond in writing to Licensing Unit.		Term Care inspection form. **Action Item:** The Practice Committee to review proposed regulations.
I. Long Term Care Task Force	Mayer Handelman, Chair	Mr. Handelman reported that the proposed Office of Health Care Quality (OHCQ) regulations for Assisted Living Facilities contained language that should be revised to protect patient. Mr. Handelman recommended quarterly reviews for patients who receive nine (9) or more medications. Mr. Handelman stated that he felt it was unacceptable to have reviews every six (6) months. He recommended 4 months as a reasonable limit. He also stated that a shift count of control drugs should be instituted. He expressed concern in having the medications properly labeled.		Board Action: Donald Taylor asked Board members to recommend revisions to the proposed regulation and send comments to Anna Jeffers
J. Disciplinary Committee	Mayer Handelman, Chair	To be discussed at the Administrative Session.		
IV. New Business		M. Handelman proposed that the Board develop regulations requiring a pharmacist in-charge regulations. The recommendation was sent to the Licensing Committee.	Motion: M. Handelman moved that the Board propose regulations to have a pharmacist in-charge. M. Souranis seconded the Motion	Board Action: The Board voted 5-4 to approve the motion and refer to Licensing Committee.

		Harry Finke, Jr. proposed that the Board develop regulations to ensure patient safety for patients receiving medications from Mail Order pharmacies. It was proposed that the recommendation be sent to the Practice Committee.	Motion: Harry Finke, Jr. moved to have the Board assign a Committee to develop regulations for Mail Order pharmacies. R. Taylor seconded the motion.	Board Action: The Board voted unanimously to approve the recommendation and refer it the Practice Committee.
V. Informational	D. Taylor	Mr. Taylor discussed issues of general interest. a. The Tamper Resistant Prescription Pad regulations have been postponed for six months. b. The NABP has announced the NAPLEX exam has been reinstated effective October 5th. c. The FDA reform legislation was signed on September 27.submitted. The legislation expanded the authority of the FDA. d. The DEA reported a increase enforcement on unapproved hydrocodone products. e. The labor department announced lower inflation of pharmaceuticals. f. The FDA is taking action to control the potency of thyroid medications.		

		g. The FDA will hold hearings regarding a third class of pharmaceuticals requiring the intervention of pharmacists. h. The DMEPOS competitive bidding and accreditation process will be in effect by 2009. i. CMS will publish a final rule on AMP for Medicaid by 1/2008 j. Secretary Leavitt of HHS has published a proposed rule effective 1/1/2009 that prescriptions may not be sent by computer generated fax machine.		
VI. Adjournment		The Public Meeting was adjourned at 12 noon. Immediately thereafter, Donald Taylor convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of Margie Anne Bonnett and cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion: M. Sournais moved to adjourn the Public Meeting. M. Handelman seconded the Motion.	Board Action: The Board voted unanimously to adjourn the meeting.