Maryland Board of Pharmacy
Public Meeting Minutes
December 19, 2007

		Today's Attendance		Year-to-Date Attendance	
Name	**Title**	**Present**	**Absent**	**Present**	**Absent**
Anderson, C.	Commissioner	x		11	1
Bonnett. M.	Commissioner	x		7	5
Bradley-Baker, L.	Commissioner	x		4	1
Chason, D.	Commissioner/Secretary	x		12	0
Finke, H.	Commissioner	x		10	2
Handelman, M.	Commissioner	x		11	1
Israbian-Jamgochian, L.	Commissioner	x		5	0
Leandre, A.	Commissioner	x		11	1
Souranis, M.	Commissioner/Treasurer	x		10	2
Taylor, D.	Commissioner/President	x		12	0
Taylor, R.	Commissioner		x	10	2
Zimmer, R.	Commissioner	x		5	0
Bethman, L.	Board Counsel	x		12	0
Costley, S.	Licensing Manager	x		10	2
Jeffers, A.	Legislation/Regulations Manager	x		11	1
Eversley, C.	Compliance Investigator	x		11	1
Naesea, L.	Executive Director	x		12	0
Gaither, P.	Administration and Public Support Manager	x		12	0
Goodman, S.	Public Information Officer	x		10	2
Banks, T.	MIS Manager	x		11	1
Taylor, A.	Compliance Officer	x		2	0

Subject	**Responsible Party**	**Discussion/Recusals**	**Motion**	**Action/Results**
I. Introductions	Donald Taylor, Board President	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.		**Action Item:** No action required

Subject	Responsible Party	Discussion/Recusals	Motion	Action/Results
II. Approval of the Minutes	Donald Taylor	Revisions to November 19, 2007 Minutes: Page 3 -B – 2nd sentence – insert "Statute passed during the 2007 Legislation Session." Page 3 -B – last sentence –after the word "directly" insert "under a Physician's privileges." Page 6 -B. – Status of the Pharmacy Technician Re-proposal delete the last sentence – "The re-proposal will be submitted to the Board for approval at the December Board meeting." Page 7 -A – sentence 5 – delete the "old" and change "MS" to "MIS" Page 7 -D – insert the word "because" after the word "system". Page 8- 2) – 2nd sentence – delete the word "coordinated directly with" and insert " submitted directly to" Page 8 –3)- 2nd sentence – delete the remainder of the sentence after the word "status." Page 12 –A – 2nd sentence delete "the out dated over the counter drugs" and insert "treatment of patients in assisted living facilities." Page 13 – top of the page – 2nd sentence - delete "it's goal" – insert "the goal is"	**Motion:** L. M. Souranis moved to accept the minutes as amended. L. Israbian-Jamgochian seconded the motion.	**Board Action:** The Board voted unanimously to approve the minutes as amended.
III. Executive Director	LaVerne Naesea, Executive Director	A. Ms. Naesea reported that the Board of Pharmacy lost the Investigator and Receptionist positions as part of a Maryland mandated staffing reduction. A request for two (2) contractual positions has been submitted. B. Ms. Naesea informed the Board that the Executive Directors met with representatives from the Maryland Attorney General's Office. At the meeting it was decided that a Task Force should be formed to recommend suggested procedures for referral of cases to the Attorney General's Office. The Executive Directors provided a list of issues and concerns. The meetings will continue with the Attorney General's Office. C. Ms. Naesea also met with Kathleen Ellis, who supervises the DHMH Attorneys supporting all of the Boards. A meeting is planned that includes DHMH Secretary Colmers, Senator Hollinger, and the Executive Directors to discuss issues. Ms. Naesea asked the staff and Board Commissioners to share any concerns with her they want to be addressed by Secretary Colmers.		A. **Action Item:** No action required. B**. Action Item:** No action required C. **Action Item:** Board Commissioners and staff are asked to provide input on issues to be discussed with Secretary Colmers

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		D. The Board 's Retreat and Public Board meeting are planned for January 16, 2008 at the Mt. Washington Conference Center. Following the Retreat, the Public Meeting will be held from 3 pm until 5 pm. Details concerning the meeting will be mailed to public attendees and posted on the Board website. E. Ms. Naesea announced that the NABP Annual National Conference would be held at the Baltimore Marriott Waterfront Hotel. NABP is providing the Maryland Board with three (3) free registrations and has asked for help with the Hospitality booth.		D. **Action Items**: Mail public meeting information to public attendees and place information on website. E. **Action Items:** Board and staff to register to work at the Hospitality Booth.
IV. Division of Drug Control	Ann Taylor	Ms. Taylor provided the monthly report from the Division of Drug Control. There were 81 pharmacy inspections including 20 opening inspections and 10 closing inspections performed during the month of October 2007.		**Action Items:** No action required
V. PEAC Report	Anthony Tommassello P.E.A.C.	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 32 urine samples. All results were negative.		**Action Item:** No action required
VI. Legislation and Regulations	Anna Jeffers	*Legislation* The request for an extension of the Drug Therapy Management Program has been submitted to DHMH. Delegates Elliott and Sophocles will sponsor the renewal legislation if DHMH does not include it in the departmental package. *Regulations* A. The Licensing of Wholesale Prescription Drug or Device Distributors regulations have been submitted to DHMH on December 5, 2007. Publication is estimated for January 18th or February 1st. B. The Practice Committee reviewed the public comments received		A**. Action Item:** No action required

Subject	Responsible Party	Discussion/Recusals	Motion	Action/Results
		regarding the Re-Proposed Pharmacy Technician regulations. 1. VetCentric: 2 comments a. A request for an exemption for mail order pharmacies. The Board indicated in its response that all pharmacies should be held to the same standards. b. A request to clarify the definition of technician "independent practice" and "independently compounding." The Board indicated in its response that it will not be amending the definitions because the language in the proposed and reproposed regulations sufficiently imparts that pharmacy technicians may not compound independently. The Practice Committee recommended making no changes to the current wording of the regulations. 2. NACDS: 4 comments a. A request that the requirement for pharmacy technician training in the area of "extemporaneous compounding" be deleted. The Board indicated it would not remove this requirement because compounding comprises most of what some pharmacy technicians perform on the job. b. A request that the knowledge of special dosing consideration for pediatric and geriatric populations be deleted from the standards for pharmacy technician training programs because it may imply expansion of the pharmacy technician's scope of practice. The Board does not agree and emphasizes the importance of knowledge in an area where many medication errors occur. c. A request to include "pharmacy technician training programs offered by pharmacies licensed by the Board that provide training as required by .06A." The Board does not equate training programs offered by pharmacies licensed by the Board with training programs offered by the U.S. Armed Forces. Additionally the Board has not found consistency among pharmacy technician training programs offered by pharmacies licensed by the Board.	**Motion:** R. Zimmer moved to accept the recom-mendation of the Practice Committee and retain the current wording in the regulations. M. Souranis seconded the motion. **Motion:** M. Souranis moved to accept the recom-mendation of the Practice Committee to retain the current wording in the regulations. C. Anderson seconded the motion.	1. **Board Action:** The Board voted to approve the motion. 2. **Board Action:** The Board voted to approve the motion

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		d. A request to amend the required number of questions for exams back to 50 questions as initially proposed. The Board will not be amending the number of questions back to 50 because it would like the exams to be more consistent with national exams and also have enough questions to cover the various topic areas of the training programs. The Practice Committee recommended making no changes to the current wording of the regulations.		
VII. Administration & Public Support	Patricia Gaither, Admin-istration and Public Support Manager	A. Ms. Gaither reported that the Board Office is preparing to hire four (4) Inspectors to perform the Board's inspections of permit holders. B. The paperwork for the MIS Disaster Recovery position has been submitted.		**Action Item**: The staff is preparing for the interviews.
VIII. Public Information Officer Report	Summar Goodman, Public Information Officer	Ms. Goodman reported that the Board's Retreat would take place at the Mt. Washington Conference Center, Wednesday, January 16, 2008 from 9 AM until 5 pm. The Public Board meeting will begin at 3 pm following the Retreat.		**Action Item**: Ms. Goodman will send reminders to Board members and post details on the Board's website.
IX. Management Information Services	Tamarra Banks, MIS Manager	**A. In-House Database Implementation:** Ms. Banks reported that Towson delivered the new in-house database servers to the Maryland Archives on November 30, 2007. MD Archives currently hosts the Board's online renewal servers, and is the host for most DHMH web site servers. The DHMH server at MD Archives is where the Board's public and secured and web sites also reside. Ms. Banks, L. Naesea, D. Irani, President of RESI, and L. Pachol, Project Manager from Towson University, met and agreed on the contract scope, expectations and cost. RESI plans to place an individual at the Board's office to complete the project.		A**. Action Item:** No action required. B**. Action Item:** Staff to provide follow

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<tr><td></td><td></td><td>
B. HIPDB
Nothing to report.

C. Pharmacist Online Renewal Database
There were 48 problems reported to MIS related to login or database corrections for November. The online renewal update system failed twice in November due to DHMH LAN/WAN issues. MIS is now verifying the upload and downloads several times per day, instead of once per day.

D. Division of Drug Control/Inspections
The Board is looking into recycling older model laptops for DDC use as part of the preparation for the new inspection forms and process. Since DDC currently uses older model laptops, it may be possible to load the form on the machines the Board has in its surplus of out of warranty laptops. Matthew Smith is attempting to update these machines from Windows 95/98 to the highest compatible version of the Windows Operating System. A quote was received from a State approved vendor for new Tablet PC's for use by the Board's new inspectors. If approved, the brand new machines can be delivered with 30-45 days.

E. Pharmacy Technician Database
A paper copy of the database has been re-distributed but use is limited due to HIPAA restrictions as indicated in the June 2007 MIS Report. A copy has been placed on the network for review. The next step is to make the necessary changes, create reports, and begin to enter data.

F. Establishment Database
On December 2nd the online renewal system automatically added the late fee to the pharmacies renewals.

<table>
<tr><th>Renewal Status</th><th>Total</th><th>Renewed</th><th>Non-renewed</th></tr>
<tr><td>Hospitals</td><td>Total 68</td><td>60 - (88%)</td><td>8 - (11%)</td></tr>
</table>
</td><td></td><td>
up report on status if HIPDB reporting.

C. Action Item:
No action required

D. Action Item:
MIS staff to report on conversion to new laptop computers.

E. Action Item:
No Action required

F. Action Item:
No action required
</td></tr>
</table>

Subject	Responsible Party	Discussion/Recusals	Motion	Action/Results

Pharmacy	**Total 1,093 in Maryland**	**1,039 - (95%)**	**54 - (5%)**
	Total 108 Waivers In Maryland	**86 - (79%)**	**22 - (20%)**
	Total 361 Non Resident	**228 - (63%)**	**133 - (36%)**
Distributors	**Total 191 in Maryland**	**117 - (61%)**	**74 - (38%)**
	Total 661 Distributors Out Md	**382 - (57%)**	**279 - (42%)**

Online Processing: 52% of the total establishments renewed online including 96% of the chains (673 pharmacies). The total Establishments in the Online database are 2,502 – A total of 1,309 renewed online and 543 renewed by paper applications.

Establishment Online Database Problems Reported/Fixed (150). Most problems related to information that was not updated, such as how to respond to questions or differences in Federal Tax ID numbers. There were many first time users during this renewal period.

G. Personnel
MIS will be contracting with a consultant to assist with the implementation of the new establishment inspections and pharmacy technician registrations scheduled to begin in January 2008. The consultant will also recommend and help create Disaster Recovery systems associated with these tasks.

H. Contracts:
On November 30th, when the Board's backup servers were delivered to MD Archives, a discussion was held on the services that would be provided by the Archives. A signed contract proposal with Maryland

G. **Action Item:**
No action required

H. **Action Items:**
No action required

I. **Action Items:**
No action required

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I. Emergency Preparedness
On December 6, 2007, Pam Leonard from the Office of Legislative Auditors approved the Board's Disaster Recovery plan as submitted to OLA and DHMH, Information Resources, (IRMA).

J. Internet/Web Site

a. Number of e-mails for:

<table>
<tr><td>Jan</td><td>336</td><td>Feb</td><td>271</td><td>Mar</td><td>295</td><td>Apr</td><td>264</td></tr>
<tr><td>May</td><td>374</td><td>June</td><td>341</td><td>July</td><td>356</td><td>Aug</td><td>303</td></tr>
<tr><td>Sept</td><td>337</td><td>Oct</td><td>392</td><td>Nov</td><td>364</td><td></td><td></td></tr>
</table>

b. Web site visitors for November 2007, popular pages and frequent visitors:

<table>
<tr><td>1. MDBOP.ORG - 1,878 (2,725 in October)</td><td>2. DHMH.STATE.MD. US/PHARMACY BOARD – 8,519 (9,203 in Oct)</td><td>3. MDBOP.COM - 1,113 (709 in Oct)</td></tr>
</table>

c. Secured Web Site Recommendations
1) Post of all upcoming hearings and CRCs chronologically with name, date, time, and Board member assignment.
2) Post Public and Confidential meeting agendas.
3) Post all materials, which accompany the agendas for the Board meetings. If the Board owns a scanner than this process would completely eliminate the need to mail packets.

4) Post pertinent articles from mass e-mailings.

5. Post on line Inspection forms for Board Inspectors</td><td></td><td>J.-a. Action Items: Revise format of chart to two columns.</td></tr>
<tr><td>X. Practice Committee</td><td>David Chason, Chair</td><td>1. Constituent Questions and Responses

a. David Barr - Advanced Pharmacy
Mr. Barr contacted the Board asking the Board to meet with Advanced</td><td>Motion:
D. Chason moved to recom-</td><td>a. Board Action:
The Board voted to</td></tr>
</table>

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		Pharmacy regarding the (AP PassPort) automated medications system Mr. Chason quoted from the letter approved by the Practice Committee. The Practice Committee's recommendation to the Board was not to approve the request for a product demonstration because of the Board's Policy regarding approval of products. Cynthia Anderson requested that a sentence be added to the letter "The pharmacist's check process allows the nurse to identify or verify the drug, dosage and strength of the medication prior to administration." M. Handelman was recused.	mend not granting the demon-tration of the product but approving the system with a final check by a pharmacist. R. Zimmer seconded the motion.	approve the motion.
		b. Al Goldstein, NeighborCare Mr. Goldstein wrote the Board for clarification of a Fall 2007 Maryland Board of Pharmacy Newsletter, Practice Committee Corner response, concerning placing two generically equivalent tablets from different manufacturers in one bottle. Mr. Chason quoted from the Practice Committee's amended letter to Mr. Goldstein. The letter clarified the newsletter response and offered other alternate methods to accomplish the same goal while assuring patient safety.	**Motion:** M. Souranis made a motion to approve the letter as amended. L. Israbian-Jamgo-chian seconded the motion.	b**. Board Action:** The Board voted to approve the motion.
		c. Linda Kaye, Pharmacist Ms. Kaye wrote the Board for clarification of a Fall 2007 Maryland Board of Pharmacy Newsletter, Practice Committee Corner response concerning placing two generically equivalent tablets from different manufacturers in one bottle.	**Motion:** C. Anderson Made a motion to approve the letter	c. **Board Action:** The Board voted unanimously to approve the motion.

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<tr><td></td><td></td><td>Mr. Chason quoted from the Practice Committee's amended letter to Mr. Goldstein The letter clarified the newsletter response and offered other alternate methods to accomplish the same goal while assuring patient safety.</td><td>as amended. L. Israbian-Jamgo-chian seconded the motion.</td><td></td></tr>
<tr><td>XI. Licensing Committee</td><td>Michael Souranis, Chair</td><td>M. Souranis provided the Licensing Report for the month of November.

Establishments:
<table><tr><td></td><td>November 2007</td><td>November 2006</td></tr><tr><td>New:</td><td>20</td><td>17</td></tr><tr><td>Distributor- In State</td><td>1</td><td>-</td></tr><tr><td>Distributor-Out-of-State</td><td>7</td><td>10</td></tr><tr><td>Resident Pharmacy</td><td>6</td><td>3</td></tr><tr><td>Non-Resident Pharmacy</td><td>5</td><td>4</td></tr><tr><td>Pharmacy w/Waiver</td><td>1</td><td>-</td></tr></table>
<table><tr><td>Closed</td><td>2</td><td>5</td></tr><tr><td>Distributor- In State</td><td>0</td><td>-</td></tr><tr><td>Distributor- Out-of-State</td><td>1</td><td>-</td></tr><tr><td>Pharmacy</td><td>0</td><td>1</td></tr><tr><td>Non-Resident Pharmacy</td><td>1</td><td>3</td></tr><tr><td>Pharmacy w/Waiver</td><td>1</td><td>-</td></tr></table>
S. Costley reported that L. Cohen, Secretary would be contacting Hospital Pharmacies that have not renewed this morning.</td><td></td><td>Action Items:
No action required</td></tr>
<tr><td>XII. Long Term Care</td><td>Mayer Handelman, Chair</td><td>Mayer Handelman provided a report regarding the Long Term Care meeting November 8th. Mr. Handelman spoke about a television news article. He informed the Board that Wendy Kronmiller made a statement concerning the high level of care required for patients who live in Assisted Living facilities.</td><td></td><td>Action Items:
No action required</td></tr>
<tr><td>XIII. Disciplinary</td><td>Mayer Handelman, Chair</td><td>Mayer Handelman recommended that a subcommittee of the Disciplinary Committee be formed to handle the impact of the Technician Regulations.</td><td></td><td>Action Item:
The Board will discuss this issue</td></tr>
</table>

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				and develop a recommendation at the retreat in January.
XIV. Informational	Donald Taylor, Board President	Mr. Taylor presented some recent pharmacy issues. 1. The AMA published a warning against switching from brand name medications as it applies to any physician who accepts any type of payment for switching a patient from a brand name to a generic medication. A physician could face criminal and civil liability plus be barred from all federal programs. 2. Proposed new FDA rules: a. A proposed rule is expected in January 2008 requiring periodic revisions to the HIPAA transactions and code standards. b. A proposed rule is expected in September 2008 requiring a standardized electronic format for submission of clinical trial data. c. A final rule is expected in July 2008 to change safety-reporting requirements for human drug and biological products. 3. The DEA Published a Rule on Issuing Multiple Prescriptions for Controlled Substances: Effective December 19, 2007, the rule amends DEA regulations to allow practitioners to provide an individual patient with multiple prescriptions for a specific Schedule II controlled substance, written on the same date, to be filled sequentially. The change will allow patients to receive up to a 90-day supply of a prescribed controlled substance. 4. "Manufacturers Agree to Restrict Distribution of Methadone: As of January 1, 2008, manufacturers of methadone hydrochloride 40 mg tablets have voluntarily agreed to restrict distribution of this formulation to only addiction programs and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria. The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. 5. "USP Publishes Final Revised Standards for Compounding Sterile		**Action Items:** No action required

Subject	Responsible Party	Discussion/Recusals	Motion	Action/Results
		Preparations:" US Pharmacopoeia published the final revisions to Chapter 797 "Pharmaceutical Compounding – Sterile Preparations" on December 3, 2007. These revisions revise standards and conditions for sterile compounding contained in the previous version of Chapter 797. The revisions will become official on June 1, 2008. 6. "DEA Proposes New Single-Sheet Order Form for Controlled Substances:" The DEA is proposing to implement a new format for order forms (DEA Form 222) for registrants to use when ordering Schedule I and/or II controlled substances. The newly proposed format will use a single-sheet form. The new form includes enhanced security features and is designed to be easier to use. 7. TriCare Program: House and Senate negotiators issued a final conference report for the Fiscal Year 2008 National Defense Authorization Act, which contains two provisions related to the TRICARE prescription drug benefit for military beneficiaries. The portion of the bill related to the TRICARE pharmacy program: 1) extends the current freeze on increases to retail pharmacy co-payments; and 2) includes language that would clarify that the Department of Defense (DoD) may negotiate with drug manufacturers for federal pricing discounts for TRICARE prescriptions filled at retail pharmacies, in the same manner as they do today for TRICARE prescriptions filled at military bases or by mail order. These provisions will help to ensure that TRICARE patients will continue to have freedom of choice which is important to ensure continued quality health care through convenient access to medications and counseling on their proper use. 8. Pharmacy Times article: Lance Rodewald, MD director of immunization services at the CDC has stated that poor refrigeration at clinics, hospitals, and physicians' offices is resulting in ruined vaccines. The Centers for Disease Control and Prevention (CDC) estimates hundreds of thousands of doses of vaccines are thrown away each year. The waste also costs the federal Vaccines for Children Program about $20 million a year, with inadequate refrigeration being the leading cause. For the past 7 years, the CDC has urged state health departments to visit clinics and check their refrigerators. Dr. Rodewald explained that a majority of states require clinics to use refrigerators with reliable thermometers that can be monitored, and staff members		

Subject	Responsible Party	Discussion/Recusals	Motion	Action/Results
		are required to know the procedure when temperatures are above or below the proper range. 9. Tamper Resistant Rx Pads New deadline April 1, 2008: – Prescription forms must contain at least one of the following: 1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank Rx form 2. One or more industry-recognized features designed to prevent the erasure or modification of written info by the prescriber 3. One or more industry-recognized features designed to prevent the use of counterfeit Rx forms After 10-1-2008, all of the above requirements must apply. This rule does not apply to electronic, verbal or faxed prescriptions, when a managed care entity pays for the prescription or for designated institutional or clinical settings. Pharmacies may still use old pads as long as a verbal, faxed, electronic, or complaint prescription is provided within 72 hrs. 10. DMEPOS Competitive Bidding & Accreditation Processes Suppliers of DME must be accredited by 2009. This involves 150,000 suppliers of which 52,000 are pharmacies. There are only 10 CMS approved accrediting organizations. No Medicare payments will be made if the provider not accredited. Suppliers must submit bids to CMS to provide items & services to Medicare beneficiaries. CMS will select just the number of suppliers in a given area to meet the needs of the beneficiaries. Price will be the mean price for each item from the submitted bids. 11. CMS has published the final rule on AMP for the Medicaid program: The payment will be below the cost for many drugs. The program appears to favor brand name medications over generics. Generics have been shown to save the program money. H.R. 3140 (Saving our Community Pharmacies Act of 2007) has been submitted by Rep. Boyda & Emerson to replace AMP with RAC (retail acquisition costs). **A federal judge ruled in favor of the National Association of Chain Drug Stores and the National Community Pharmacists		

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		Association regarding reimbursement reductions on community pharmacies. Those reductions were set to take effect early next year. U.S. District Court Judge Royce Lamberth ruled that the Centers for Medicare & Medicaid Services will not be permitted to post data on the Internet related to the average manufacturer price [AMP] of generic pharmaceuticals. Judge Lamberth also granted an injunction that will prevent CMS from adopting the reduced AMP-based reimbursement formula for generic prescriptions, which is set to take effect Jan. 30, 2008, until he's had an opportunity to fully review the new payment plan. The court's decision came in response to a lawsuit and an urgent motion for a preliminary injunction, filed last month by NACDS and NCPA.		
XV. Adjournment	Donald Taylor, Board President	The Public Meeting was adjourned at 10:18 am. Immediately thereafter, Donald Taylor convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session. Alland Leandre was absent for the Public Session but attended the Administrative Session	**Motion:** R. Zimmer moved to adjourn the Public Meeting. M. Souranis seconded the motion.	**Board Action**: The voted unanimously to adjourn the Public Meeting.