Maryland Board of Pharmacy
Public Meeting
Minutes
Date: January 21, 2009

		Today's Attendance		Fiscal Year-to-Date Attendance	
Name	**Title**	**Present**	**Absent**	**Present**	**Absent**
Anderson, C.	Commissioner	x		6	1
Bradley-Baker, L.	Commissioner	x		6	1
Chason, D.	Commissioner/Secretary	x		7	0
Finke, H.	Commissioner	x		7	0
Handelman, M.	Commissioner	x		6	1
Israbian-Jamgochian, L.	Commissioner	x		7	0
Leandre, A.	Commissioner	x		7	0
Matens, R.	Commissioner	x		6	1
Souranis, M.	Commissioner/Treasurer	x		6	1
Taylor, D.	Commissioner/President	x		7	0
Taylor, R.	Commissioner		x	6	1
Zimmer, R.	Commissioner	x		6	1
Bethman, L.	Board Counsel		x	6	1
Schadt, D.	Board Counsel (Alternate)	x		1	0
Banks, T.	MIS Manager	x		6	1
Costley, S.	Licensing Manager	x		6	1
Eversley, C.	Compliance Investigator	x		6	1
Gaither, P.	Administration and Public Support Manager	x		6	1
Goodman, S.	Public Information Officer	x		5	2
Jeffers, A.	Legislation/Regulations Manager	x		7	0
Naesea, L.	Executive Director	x		7	0
Simmons, L.	Executive Secretary		x	4	2
Taylor, A.	Compliance Officer	x		7	0
Neal, S.	Intern, University of Maryland	x		1	0

Subject	Responsible Party	Discussion	Motion	Action/Results
I. Introductions	Donald Taylor, Board President	1.D. Taylor brought the Public Meeting to order at 9:00 A.M. Members of the Board with a conflict of interest relating to any item on the agenda were advised to notify the Board at this time or when the issue is addressed in the agenda. 2. D. Taylor described the impact on the Board's and Staff's workload of the implementation of the Distributor Regulations and Technician Registrations. 3. D. Taylor asked that all guests introduce themselves and sign in on the attendance list. 4. A. Jeffers distributed packets of the draft regulations to be discussed to all guests with the request that the packets be returned at the end of the meeting. 5. D. Taylor announced that the agenda would be rearranged to allow A. Jeffers to attend a meeting with Legislators in Annapolis. 6. D. Taylor offered condolences to L. Naesea on the death of her brother-in-law, P. Gaither on the death of her brother-in–law, E. Lin on the death of her sister-in-law and announced the passing of Delegate Donald Elliott's wife, Jeanne Elliott.		

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		7. D. Taylor introduced Baltimore City Deputy Health Commissioner Dr. Laura Herrera. Dr. Laura Herrera requested the support of the Board for legislation that has been submitted to the Legislature by the Baltimore City Department of Health. The Legislation, as submitted, would permit the Baltimore City Department Health staff to provide intranasal naloxone prescriptions and provide training on the appropriate use of the drug to city residents, friends and families with the goal of reducing drug overdoses and deaths from illicit drug use. The proposal is based on successful initiatives in New Mexico, New York and Massachusetts.		
II. Legislation and Regulations	**Anna Jeffers, Legislation and Regulation Manager Report**	**Maryland Regulations** **1. Ratification of Letter to Secretary Colmers providing additional information on COMAR 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties, sent January 8, 2009. Signed Letter to Secretary regarding 10.34.17.** **The Board submitted the following responses to the Secretary's concerns:** **1) The Regulation Background Information Form mentioned that the regulations are potentially controversial in that they may disqualify some current waiver permit holders. Can you explain who these permit holders are?** **RESPONSE:** **Current waiver permit holders will not be disqualified. Some new waiver applicants and renewal waiver applicants will not be granted a waiver permit unless the applicants meet the new criteria. Long term care pharmacies, hospital pharmacies and small specialized pharmacies that dispense unusual or specialty medications obtain specialized pricing from wholesale distributors if they have a waiver permit. The intent of the waiver permit regulations was for pharmacies that met these criteria. However, language in the existing regulations is not clear and some full service pharmacies have taken advantage of the vague language in the current regulations in order to receive the specialized pricing. Subsequent site inspections revealed that those pharmacies failed to meet the original intent of the waiver pharmacy permits language.** **2) Additionally, why weren't industry experts and officials engaged in the development of the regulations?** **RESPONSE:** **The Board followed the usual course for revising or promulgating regulations. After internal committee consideration, the revised regulations were deliberated and discussed at the November 2008 monthly Public Board Meetings that was advertised in the Maryland Register as required by State Government Article, § 10-506(c), Annotated Code of Maryland. The Public Meeting Agenda was also made available to the public in advance through the Board's website. Stakeholders in attendance at the Public Meeting had an opportunity to provide informal comments concerning the regulatory proposal, as well as to provide written comments after the meeting. As with discussion of all Board regulatory proposals during Public Meetings, the Board would have considered convening a task force with stakeholders to address any expressed concerns. The Board**	**1. Motion:** **R. Zimmer made a motion to ratify the letter, to Secretary Colmers.** **L. Bradley-Baker seconded the motion.**	**1.Board Action:** **The Board voted to approve the letter.**

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		did not receive any comments concerning this proposal. **3) In 10.34.17.02 (D), the language states that the "The Board's determination of whether a limited practice or setting constitutes a pharmaceutical specialty is Final." Why is it that the Board is making this final decision?** **RESPONSE:** **The Board is mandated to regulate and license pharmacies in Maryland. A waiver pharmacy, however; is not considered another license under the statute. Under Health Occupations Article, 12-403(c)(2), Annotated Code of Maryland, the Board may waive the requirements for pharmacies that are engaged in pharmaceutical specialties which are recognized by the Board under rules and regulation adopted by the Board. Specifically, under HO 12-403(b)(5) and (6), the Board is allowed to waive a pharmacy from:** **-providing complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist; and** **-providing services to the general public and may not restrict or limit its services to any group of individuals unless granted a waiver from this requirement by the Board.** **The regulations the Board adopted COMAR 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties; define what conditions the Board will grant such waivers which are allowed by the Board to be the final determination.** **2. COMAR 10.34.32 Pharmacist Administration of Vaccinations, Published December 5, 2008. NACDS submitted comments:** **NACDS Comments on COMAR 10.34.32** **NACDS – Supplemental Comments COMAR 10.34.32 No.2** **a. Board approval requested for NACDS Board Response to Comment 10.34.32** **The Board approved the response to NACDS concerning COMAR 10.34.32, with one amendment removing "*physician, or nurse"* from the quoted sections of COMAR 10.34.32.05C and D located on pages 2 and 3 of the response. The response included the following:** **Continuing Education (COMAR 10.34.32.03A(5)** **Your understanding is correct that a pharmacist who was registered before October 1, 2008 would be required to complete four (4) hours total for their first renewal and that the four (4) hours include information on herpes zoster and pneumococcal pneumonia vaccines along with influenza vaccines. The Board of Pharmacy thanks you for your suggested rewording but does not believe that further clarification is necessary.** **Disclosure of pharmacist credentials (COMAR 10.34.32.06C)** **You asked the Board of Pharmacy to specify the credentials that should be disclosed on the consent form. The credentials to be disclosed on the consent** **(Continued for previous page)**	**2.a. Motion:** **R. Zimmer made a motion to approve the letter, as amended, to NACDS.** **L. Israbian-Jamgochian seconded the motion.**	**2.a.Board Action:** **The Board voted to approve the letter.**

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		form are outlined in COMAR 10.34.32.03 and the Board of Pharmacy does not think it is necessary to repeat them. **Record Keeping (COMAR 10.34.32.05)** **You noted in your comment and your supplemental comment that § D under COMAR 10.34.32.05 refers to § A for the contents of the records on the administration of vaccines, and as a result creates some confusion concerning who maintains documentation when a pharmacist administers a vaccination on behalf of a permit holder at a location that is not a pharmacy. To avoid any confusion the Board of Pharmacy will revise §§ C and D by setting forth subsections (1) – (8) from § A again, following both §§ C and D as follows:** ***C. The pharmacist administering a vaccination as an independent provider at a location that is not a pharmacy shall maintain the documentation [[[as]]] set forth [[[in §A of this regulation.]]] below for a minimum of 5 years:*** ***(1) Name, address, and date of birth of the individual receiving the vaccination;*** ***(2) Date of administration and route and site of vaccinations;*** ***(3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;*** ***(4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;*** ***(5) Name of the pharmacist or pharmacy student administering the vaccination;*** ***(6) Version of the vaccination information statement provided to the individual receiving the vaccination;*** ***(7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered; and*** ***(8) Nature and outcome of an adverse reaction and documentation that the adverse reaction was reported to:*** ***(a) The primary care physician; and*** ***(b) The Vaccine Adverse Event Reporting System.*** ***D. The pharmacist administering a vaccination on behalf of a permit holder at a location that is not a pharmacy shall maintain the following documentation with the permit holder [[[as set forth in §A of this regulation.]]] for a minimum of 5 years:*** ***(1) Name, address, and date of birth of the individual receiving the vaccination;*** ***(2) Date of administration and route and site of vaccinations;*** ***(3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;*** ***(4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;*** ***(5) Name of the pharmacist or pharmacy student administering the vaccination;*** ***(6) Version of the vaccination information statement provided to the individual receiving the vaccination;*** ***(7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered; and*** ***(8) Nature and outcome of an adverse reaction and documentation that the adverse reaction was reported to:*** ***(a) The primary care physician; and*** ***(b) The Vaccine Adverse Event Reporting System.*** **Patient Information and Consent (COMAR 10.34.32.06** **(Continued for previous page)**		

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		Upon further consideration, the Board of Pharmacy would like to make a substantive change to the regulations requiring that a copy of the consent form be given to every patient receiving a vaccination. **This consent form may be helpful to the patient as a reminder of when, where and by whom the vaccination was given. The revision to COMAR 10.34.32.06B follows:** **B. Every patient receiving [an influenza vaccine] *a vaccination* shall [[[sign]]]*:*** ***(1) Sign* a consent form consenting to the administration of the [[[vaccine.]]] *vaccine; and*** ***(2) Be given a copy of the consent form for the patient's future reference.*** **Because this is a legally substantive change, the regulations will be re-proposed in the Maryland Register upon approval by the Maryland Board of Physicians and the Maryland Board of Nursing.** **b. Board approval requested for Re-proposal for COMAR 10.34.32** **The Board approved the re-proposal for COMAR 10.34.32 with the amendment to remove "*physician, or nurse"* from COMAR 10.34.32.05C and D.** **c. Comment, response and re-proposal to be submitted to Board of Physicians and Board of Nursing for approval.** **3. COMAR 10.34.28 Automated Medication Systems.** **a. HOLD revisions until after the 2009 Legislative Session.** **b. Ratification of response to Omnicare.** **Informal Comment: Omnicare** **DRAFT Omnicare – 10.34.28 Response to Comment.** **The Board submitted the following responses to Omnicare's comment:** **.04C** **You had suggested that .04C be revised to require electronic "or" visual means as the method a licensed pharmacist, not physically present where the automated medication system is located, would use to perform final checks of medications distributed from the system in order to insure the safe and efficient operation of the system. Health Occupations Article, 12-605(b) (2), Annotated Code of Maryland, requires that if "a pharmacist is not physically present where the remote automated medication system is located in a health care facility, the pharmacist shall have access to the system by electronic and visual means in order to ensure the safe and efficient dispensing, repackaging, delivery, control, bar coding, transaction records, dispensation records, labeling, and accountability for all medications in the system."** **Therefore, the regulation may not deviate from the law as written.** **.04D**	**3. Motion:** **L. Israbian-Jamgochian made a motion to ratify the letter, as amended.** **A. Leandre seconded the motion.** **C. Anderson and M. Handelman was recused.**	**3. Board Action:** **The Board voted to approve the letter.**

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		You had questioned why the requirements for a remote automated system would be more stringent than the current manual medication cabinet regulations. The regulations are more stringent because some remote automated medication systems allow access to all the medications at a particular health care facility. **You also mentioned that remote automated medication systems currently in use for "interim" or "starter doses" may not currently have the ability to limit simultaneous access to multiple drug strengths, dosage forms or drug entities. You questioned why the implementation of automated devices for use to store and document use of starter doses should result in more stringent requirements concerning limiting access to multiple items than is currently the case with manual starter dose systems. The Board would like to emphasize that an interim box contains a limited number of products. Remote automated medication systems may allow access to all the medications at a particular health care facility and therefore; there is a greater need to limit access.** **To avoid confusion the Board has restructured the regulations to create a new Regulation .05 that would address decentralized systems and will renumber Regulation .05 to be .06 to address only remote automated medication systems. Therefore, the Board will be moving Section .04B and C into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04B and C only apply to remote systems. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both.** **.05A(3) and .06B and C** **You had suggested in your comment that licensed nurses be allowed to stock an automated medication system. The Board has revised its proposed regulations to allow a licensed nurse to stock an automated medication system that uses unit dose packages. Keep in mind that Regulations .05 and .06 will be renumbered to be Regulations .06 and .07.** **The Board would like to thank you again for your thorough reading of, and informal comments to, the proposed COMAR 10.34.28 Automated Medication Systems. The proposed regulations are still under consideration by the Board and will be presented at a future Board Public Meeting for approval, pending the 2009 Legislative Session.** **4. COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee, submitted to DHMH November 20, 2008.** **Pre-Submission Comments were received from the Boards of Physicians, Podiatrists and Dentists. M. Souranis submitted comments.** **Post-Submission Comments were received from the Boards of Physicians and Podiatrists. The D.D.C. also submitted comments.** **Board approval was requested for the Joint Response to Comments for COMAR 10.13.01.** **(Continued for previous page)**	**4. Motion:** **D. Chason made a motion to ratify the letter.** **L. Israbian-Jamgochian seconded the motion.**	**4. Board Action:** **The motion was withdrawn.** **Action Item:** **Commissioners to send proposed revisions by e-mail by January 26, 2009 for inclusion in the revised letter.**

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		Discussion ensued concerning the content of the Joint Response. It was decided to allow Board Members to submit continued revisions until close of business on January 26, 2009. **5. Status Update:** **a. COMAR 10.34.19 Sterile Pharmaceutical Compounding, Published December 5, 2008. Notice of Final Action signed and submitted January 8, 2009.** **b. COMAR 10.34.25 Delivery of Prescriptions – Solicitation of stakeholder's comments to be forthcoming.** **d. COMAR 10.27.04 Dispensing in Methadone Clinics. Published October 24, 2008. Notice of Final Action signed and submitted January 7, 2009.** **LEGISLATION** **1. HB 83 - Health Occupations - Pharmacies - Display of SMARxT Disposal Campaign Poster.** **Discussion ensued concerning posters in pharmacies and the limited space available to display them. The Board indicated that an insert in the bag containing the prescription might be more noticed by the patient than a poster. The Board's position on this legislation is to respond with a Letter of Education that addresses 1) the use of an insert in lieu of a poster; 2) the limited space available for a new poster in a pharmacy; and information concerning the Environmental Protection Agency's proposed new rule to add hazardous pharmaceutical wastes to the Agency's Universal Waste Rule.** **2. Delegate Bobo has requested that the Board consider a 90 day extension for the wholesale distributor applicants to submit their application materials, specifically the surety bond.** **After discussion the Board voted to approve a 90 day extension for the approval of incomplete applications received for permits under the Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act. This decision was made in order to provide applicants sufficient time to meet new surety bond and other important new requirements.** **(Continued for previous page)**	**1. Motion:** **D. Chason made a motion to send the letter.** **R. Matens seconded the motion.** **2. Motion:** **H. Finke made a motion to ratify recommendation for a 90 day postponement of the implementation of the Distributor Regulations.** **M. Sournais seconded the motion.** **R. Matens abstained from voting on the motion.**	**Anna Jeffers will e-mail the existing letter to the Board after January 26, 2009 will revise the letter accordingly.** **1. Board Action: The Board voted to approve the letter.** **2. Board Action: The Board voted to approve the motion.**

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		3. Profiles of pharmacy bills for Board consideration will be provided at future Board meetings as available.		
III. PEAC Report	**Anthony Tommasello, P.E.A.C.**	**1. A. Tommasello presented the P.E.A.C. statistical report for December 2008. See Attachment 1, Section D.** **2. A. Tommasello requested that a meeting be scheduled with Board representatives to discuss how P.E.A.C will bill the Board for additional clients after they reach the maximum number of clients listed in the current contract.** **3. D. Taylor apologized to A. Tommasello regarding the time lag in scheduling of the meeting due to Board scheduling conflicts, and indicated that the meeting is planned for the week of January 26, 2009.**		
IV. Approval of the Minutes	**Donald Taylor, Board President**	**1. Page 1, Attendance Section, change attendance for R. Matens to "5" attended and "1" absent.** **2. Page 3 to 8, A. Jeffers requested that legislative Sections not be retain original numbering sequence.** **3. Page 7, Section VII, Item e, "that detail in the letter includes preliminary reports from D.D.C inspections and direct references to the Statute."** **4. Page 7, Section VII, Motion, Item a, Remove "approve the report for submission to the Legislature" and substitute "return to the Executive Committee for final approval of the report."** **5. Page 10, Section XI, Item 1, Remove "1. A. Jeffers presented the draft Annual Report on Monitoring the Experience of Remote Automated Medication Systems in Nursing Homes in Maryland" and the reference to approval of the motion.** **6. Page 8, Section VIII, Item 1 and 2, Change the spelling to "P. Gaither."** **7. Page 8, Section VIII, Action/Results, Item 2, Change the spelling of "Ethics."** **8. Page 12, Section XII, Motion, Item 4, Change "Walgreen's" to "Your Community Pharmacy."**	**Motion:** **M. Handelman made a motion to approve the December 17, 2008 minutes as amended.** **L. Israbian-Jamgochian seconded the motion.**	**Board Action:** **The Board voted to approve the minutes as amended.**
V. Announcements	**Donald Taylor, Board President**	**1. D. Taylor announced that he, A. Jeffers and S. Neal attended meetings in Annapolis with Delegate Hammen, Chair of the House Health and Government Operation Committee and Patrick Dooley; and with Senator Conway, Chair of the Senate Education, Health and Environmental Affairs Committee and Sarah Fidler to provide an update on the status of Board of Pharmacy programs and to request support for new legislation to change the schedule for issuance of pharmacy permits based on the recent Board decision.**		
VI. Executive Director	**LaVerne Naesea, Executive Director**	**1. L. Naesea introduced S. Neal, a pharmacy intern from the University of Maryland, Baltimore.** **2. L. Naesea reported the Board's response to Senator Hollinger on the final audit report for the Department of Health and Mental Hygiene (D.H.M.H.) and asked for ratification of the final response letter.** **Procedures have been instituted to provide the following:** **a. Independent verification to confirm receipt of deposits to the shared fiscal officer.** **b. Monitoring of authority to access to the Licensing System** **c. Uniform policies for legislative fiscal issues**	**2. Motion:** **M. Souranis made a motion to ratify the response letter.** **L. Israbian-Jamgochian seconded the motion.**	**2. Board Action:** **The Board voted to approve the motion.**

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		The letter indicated that the Board did not agree with the recommendation to consolidate the fiscal functions of the various Boards and provided an explanation of the delay in meeting the deadline of January 1, 2007 to register technicians. **3. L. Naesea reported on the progress of the D.H.M.H. Task Force. The current issues decided were as follows:** **a. Three recommendations were voted on and defeated. These recommendations were to standardize disciplinary functions, to bring the Boards under the D.H.M.H. Secretary and to authorize the D.H.M.H. Secretary to appoint the Board's Executive Secretaries.** **b. The Task Force approved the recommendation to standardize disciplinary actions, improve public relations activities of the Boards, develop guidelines for sanctions, statutes of limitations and develop procedures to assure racial and ethnic fairness.** **4. L. Naesea announced that the fourth inspector and the computer specialist positions received permanent status (PINs).**		
VII. Inspection Program Report	**Ann Taylor, Compliance Officer**	**1. A. Taylor presented the December Compliance monthly statistics for the Board.** **See Attachment 1, Section C.** **2. A. Taylor reported that inspections of distributors began during the month of January.** **3. A. Taylor reported on the results of the meeting on January 9, 2009 of the Advisory Council on Drug Monitoring in Maryland. The D.E.A. supports the program based on the opinion that because surrounding states have electronic monitoring programs in place, there has been an increase in movement of drug-seeking individuals into Maryland. The goal is improved patient monitoring and not the tracking of pharmacies. H. Finke asked if physicians would be monitored and expressed concern that the program will focus on pharmacists when it should be intended to reduce the number of patients who use physician shopping to obtain medications illegally.** **The proposed program is based on successful programs in Kentucky and other states.**		
VIII. Management Information Services	**Tamarra Banks, MIS Manager**	**1. T. Banks presented the MIS statistical report for December 2008.** **See Attachment 1, Section F.** **2. T. Banks reported that the server has been set up at the Maryland Archives. The internet access has back up systems, but there will still be some vulnerability if the internet is not available.** **3. T. Banks reported the Board software system for the disciplinary program developed by Towson is in the testing stage. The program for the distributor program is in development. Towson has provided a graduate student to work twenty (20) hours a week until May to assist with testing and start up.**		

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		4. Senator Hollinger asked for confirmation that all Board Public Orders are available on the Board's website. **5. T. Banks reported that new features have been added to the Inspection software and that the retail pharmacy inspection form is in operation.** **6. T. Banks reported that the Disaster Recovery Program needs to be updated to include the changes to the inspection system and the new software.** **7. T. Banks reported that the State is requiring an update to the GroupWise e-mail system.** **8. T. Banks reported that the Board's request for 2 additional ports for the inspectors use has not been completed.** **9. T. Banks reported that the cleanup of the website is continuing with the focus currently on the forms section.**		**Action Item:** **N. Naesea to confirm and report to Senator Hollinger regarding the status of Public Orders on the Board website.**
IX. Administration & Public Support	**Patricia Gaither, Administration and Public Support Manager**	**1. P. Gaither reported that the two (2) open permanent positions have been granted an exception for the hiring freeze on new positions but that final approval to hire has not been provided by D.H.M.H.** **2. P. Gaither reported that no new information has been received on the requests to approve new vehicles for use by the inspectors.** **3. P. Gaither reported that approximate 85% of the annual projected budgeted Board revenue has been received as of December 31, 2008.**		

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X. Public Relations Committee Report	**Summar Goodman, Public Information Officer**	**1. S. Goodman reported on the analysis of the costs and benefits of converting to a professionally produced Board Newsletter. The Board's current program experiences significant time delays because of the backlog at the State sorting facility and errors in layout and printing that occur with the current vendor. Based on the additional cost to mail newsletters to technicians and distributors, the annual cost is projected to rise to $36,000.** **There was Board discussion regarding using an electronic version exclusively.** **2. S. Goodman reported that the Acetaminophen Task Force will meet on Wednesday, February 11, 2009 at 1 P.M. The Task Force will focus on education of the public on the appropriate use of acetaminophen. The Task Force has members from the University of Maryland School of Pharmacy Notre Dame, MPha V.A in Baltimore, NCPIE and a physician.** **3. S. Goodman reported that planning has started for the Board of Pharmacy's educational program scheduled for October 2009. Suggestions for topics should be forwarded to S. Goodman.** **4. S. Goodman announced that the Flower Mart is scheduled for May 1, 2009, and that the Board has agreed to participate.**	**1. Motion:** **R. Matens made a motion to approve the use of a magazine~~,~~ format with Board approved advertising, beginning July 1, 2009. An electronic version would be made available through the Board's website.** **R. Zimmer seconded the motion.**	**1. Board Action:** **The Board voted to approve the motion.** **3. Action Item:** **Commissioners and staff to forward suggestions for topics to S. Goodman.**
XI. Practice Committee	**Reid Zimmer, Chair**	**1. R. Zimmer reported that revisions to COMAR 10.34.20, Format of Prescription Transmission are to be finalized at the January 28, 2009 Practice Committee meeting. Dr. David Sharp, Executive Director of the Maryland Health Care Commission, will attend the meeting to participate in the final discussion for the revisions.** **2. M. Handelman reported that COMAR 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities Task Force will meet again on January 26, 2009. The plan is to have a final version of the revised regulations for review by the Practice Committee in February.** **3. R. Zimmer reported that representatives from the American Society of Consultant Pharmacists (ASCP) plan propose revisions to the Legislature to change provisions relating to visual inspection as currently written for automated medication systems. This would make any Board revisions to the regulations in COMAR 10.34.28, Automated Medication Systems, ~~to~~ be premature. C. Anderson reported that she had met with Arnold Clayman and Bruce Krug to discuss the proposed revisions.**	**3. The Practice Committee recommended changes to the regulations be postponed.**	**3. Board Action:** **D. Taylor postponed discussion on revisions to the regulations until after the Legislative Session.**

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XII. Licensing Committee	**Cynthia Anderson, Chair**	**1. C. Anderson presented the Licensing Committee statistics for December 2008. See Attachment 1, Section A and E.** **2. C. Anderson reported that the documents for Distributor applications have been completed and are posted on the Board's website.** **3. C. Anderson presented the Technician Training Program Update with the Committee's recommendation that Wegman's Pharmacy training program be approved since they are using the P.T.C.B. manual.** **4. C. Anderson presented the Technician Training Program Update with the Committee's recommendation that the Safeway training program be approved.** **5. L. Naesea reported that the Drug Therapy Management (DTM) Committee approved the proposed programs submitted by Peoples Community Health Center with the exception of the suboxone protocol.** **6. S. Costley reported that approximately 200 additional technician applications had been received after the publication of the December statistics.** **7. D. Taylor reported that the process for updating a pharmacists' status in the Board's database is in place. Once the completed Consent Order is received, Disciplinary office staff notifies Licensing office staff to make the change in the database. There may be a time lag from the time that the Board votes until the**	**3. Motion:** **Motion by the Licensing Committee to approve the Wegman's training program.** **D. Chason seconded the motion.** **4. Motion:** **Motion by the Licensing Committee to approve the Safeway training program.** **M. Souranis seconded the motion.** **L. Israbian-Jamgochian was recused.** **5. Motion:** **D. Chason made a motion to approve the protocols recommended by the DTM Committee.** **M. Handelman seconded the motion.**	**3. Board Action:** **The Board voted to approve the Wegman's training program.** **4. Board Action:** **The Board voted to approve the Safeway training program.** **5. Board Action:** **The Board voted to approve the DTM protocols.**

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		completed Consent Order is received.		
XIII. Disciplinary Committee	**Ann Taylor, Compliance Officer**	**1. A. Taylor presented the Disciplinary Committee's monthly statistics for December 2008.** **See Attachment 1, Sections A and C.** **2. D. Taylor reported that A. Jeffers had spoken with Delegates Montgomery and Morhaim and that they supported the Board's recommendation to provide an extension of the licenses of existing distributors for 90 days while the Legislature re-evaluates the surety bond issue.** **3. A. Taylor reported that the Board will need to develop methods to inspect out of state distributors through cooperative contracts with other states, the D.E.A. and the F.D.A.**		
XIV. Long Term Care Committee	**Mayer Handelman, Chair**	**1. M. Handelman reported on the January 14, 2009 meeting with representatives of the Office of Health Care Quality (O.H.C.Q) regarding the need for pharmacists to participate in medication reviews for all patients receiving 9 or more medications in assisted living facilities. There was an educational conference for assisted living facility managers on January 16. There will be additional conferences scheduled. The next educational session will be held on February 11.** **The O.H.C.Q will perform audits to determine if pharmacist reviews have been conducted.** **2. M. Handelman requested that the Board's website provide information on the training conferences.**		**2. Action Item:** **S. Goodman to add a reference to the programs on the website.**
XV. New Business	**Donald Taylor, Board President**	**1. D. Taylor reported that the Board's Emergency Preparedness Committee will meet on an every other month basis beginning in March 2009. The State of Maryland has included the Board in recent activities and planning.** **2. D. Taylor reported that the F.D.A. has announced that a contract has been awarded to Novartis for a cell based influenza vaccine. This new method of producing vaccines should result in an increase in the amount of vaccine available and a decrease in the time necessary for production. The National Pharmaceutical Stockpile will utilize this new vaccine as it can be mass produced, frozen and stored for longer periods.** **3. D. Taylor announced that the Maryland Professional Volunteers Program has scheduled a training session in Cambridge, Maryland for January 27, 2009 at the Hyatt Hotel.** **4 D. Taylor reported that the F.D.A. has approved a two (2) year voluntary pilot project to study prevention of the unauthorized importation of drugs into the country.**		

Subject	Responsible Party	Discussion	Motion	Action/Results
XVI. Adjournment	**Donald Taylor, Board President**	**1. D. Taylor asked for a motion to close the Public Meeting and open a Closed Public Session for the purpose of engaging in medical review committee deliberations of confidential matters contained in technician applications in accordance with State Government, Sect. 10-508(a)(13).** **The Public Meeting was adjourned at 12:26 P.M.** **2. At 12:41 M. Donald Taylor convened a Closed Public Session to conduct a medical review of technician applications.** **3. The Closed Public Session was adjourned at 12:49.M. 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.**	**1. Motion:** **R. Matens made a motion to close the Public Meeting and open a Closed Public Session.** **R. Zimmer seconded the motion.** **3. Motion:** **R. Zimmer made a motion to adjourn the Closed Public Session.** **H. Finke seconded the motion.**	**1. Board Action:** **The Board voted to approve closing the Public Meeting and opening a Closed Public Session.** **3. Board Action:** **The Board voted unanimously to adjourn the Closed Public Session.**

ATTACHMENT 1

Department of Health & Mental Hygiene
Board of Pharmacy
Reporting Period: Fiscal Year 2009

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
SECTION A -LICENSING COMMITTEE								
Number of Current Licensees	20361	21219	21984	22896	22953	23075	23120	N/A
Number of Active Licensees	11598	12426	12491	14112	14267	14367	14289	N/A
Number of Inactive Licensees	519	520	551	493	356	364	8949	N/A
Numberof Pharmacist Licensees	14045	14138	14159	14102	14251	14278	14300	N/A
Number of Pharmacy Establishment Licenses	3169	3175	3179	3208	3222	3241	3255	N/A
Numberof Distributor Licenses	2052	2062	2077	2094	2109	2120	2129	N/A
Number of Pharmacy Technician Licensees	1095	1844	2569	3452	3371	3436	3607	N/A
Number of Non-renewed Licensees	8244	8273	8312	8237	8330	8344	8424	N/A
Numberof New Applications Received	1174	982	895	228	152	101	135	N/A
Number Out-of-State Applications Received	108	112	71	0	55	58	50	454
Number of Out-of-State Applicants Approved	55	84	35	0	80	38	35	327
Numberof Foreign Applications Received	8	13	14	0	15	8	7	65
Number of Foreign Applicants Approved	73	94	6	8	5	1	11	198
Numberof License Renewals Current	310	339	333	344	352	1155	1858	4691
Number of Formerly Inactive or Reinstated Licenses	10	17	17	18	10	11	13	96
SECTION B-DISCIPLINARY COMMITTEE								
Complaints--Summary								
Number of Complaints Received	13	7	14	5	11	13	13	76
Boundaries (Harassment)	1	0	0	0	0	0	0	1

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
Drugs/Alcohol	2	1	0	1	0	1	0	5
Fraud	2	1	2	0	0	0	0	5
Standard of Care	7	3	6	1	6	5	8	36
Other	1	2	6	1	5	7	4	26
Numberof Complaints Closed Administratively	0	0	0	0	0	0	0	0
Number of Investigations Initiated	13	7	14	5	11	13	13	76
Number of Investigations Pending	16	23	17	9	7	15	0	87
Number of Complaints Adjudicated by the Board	12	10	7	13	13	5	11	71
Number of Complaints where Board investigated complaint and took no formal or informal action	0	1	3	9	8	0	1	22
Number of Complaints where Board referred the case for prosecution	8	6	2	3	0	0	0	19
Number of Complaints Adjudicated within Goal	12	10	7	7	9	5	11	61
Number of Complaints Pending Action by the Board (unresolved)	2	0	2	2	2	1	0	9
Number of Complaints Referred by Board to another agency	2	1	0	0	0	0	1	4
Attorney General's Office								
Number of Complaints Awaiting Action from Board Counsel	0	0	0	0	0	0	0	0
Number of Complaints Awaiting Action for more than 30 days	0	0	0	0	0	0	0	0
Number of Complaints Awaiting Action for more than 60 days	0	0	0	0	0	0	0	0
Number of Complaints Awaiting Action for more than 90 days	0	0	0	0	0	0	0	0
Number of Complaints Awaiting Action for more than 120 days	0	0	0	0	0	0	0	0
Number of Complaints Awaiting Action from Board Prosecutor	3	1	8	5	4	1	1	23
Number of Complaints Awaiting Action for more than 30 days	0	0	0	1	1	0	0	2
Number of Complaints Awaiting Action for more than 60 days	0	0	0	1	1	0	0	2
Number of Complaints Awaiting Action for more than 90 days	0	0	0	1	1	0	0	2
Number of Complaints Awaiting Action for more than 120 days	1	1	1	1	1	1	1	7
Audit/Quality Assurance								

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
Numberof Licensees Reviewed	32	38	37	35	37	35		214
Numberof Patient Records Reviewed	0	0	0	0	0	0		0
Number of Inspections/surveys conducted	82	79	70	83	85	60	67	526
Disciplinary Action--Summary								
Formal Actions Taken by Board	3	5	5	2	3	5	3	26
Numberof Fines	0	2	2	2	1	2	0	9
$ Amount of Fines	$0	$3,000	$1,000	$10,000	$3,000	$7,500	$0	$24,500
Numberof Probations	1	0	0	0	0	1	1	3
Number of Suspensions	0	3	3	1	1	0	0	8
Number of Licenses Revoked	2	1	0	0	0	0	0	3
Number of Letters of Reprimand	0	0	0	0	0	1	0	1
Informal Actions Taken by Board	6	0	3	10	7	3	9	38
Number of Cease and Desist Letters	0	0	1	2	0	0	0	3
Number of Letters of Admonishment	3	2	0	3	1	0	0	9
Number of Letters of Education	3	2	2	2	2	2	0	13
Other	0	0	2	3	4	0	8	17
Post Adjudicatory Compliance								
Number of Cases under Supervision	13	12	12	12	12	12	12	N/A
SECTION C-COMPLIANCE								
Board Statistics								
Inspection Report								0
Regular Inspections								0
Retail/Community	0	0	0	67	51	52	51	221
Long Term Care	0	0	0	1	0	1	0	2
Hospital	0	0	0	2	0	0	0	2
Waivered	0	0	0	1	0	1	1	3

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
Distributor	0	0	0	0	0	0	3	3
Opening Inspections	0	0	0				0	0
Retail/Community	0	0	0	6	5	2	6	19
Long Term Care	0	0	0	0	0	0	0	0
Hospital	0	0	0	0	1	1	0	2
Waivered	0	0	0	2	6	1	0	9
Distributor	0	0	0	0	0	0	0	0
Closing Inspections	0	0	0			0	0	0
Retail/Community	0	0	0	0	4	0	0	4
Long Term Care	0	0	0	0	0	0	0	0
Hospital	0	0	0	0	0	0	0	0
Waivered	0	0	0	0	0	0	0	0
Distributor	0	0	0	0	0	0	0	0
Special Investigations	0	0	0	0	3	1	0	4
SECTION D-P.E.A.C. REPORT								
Pharmacists' Education and Advisory Council (PEAC)								
Self Referred Pharmacists	13	13	14	15	15	15	15	N/A
Self Referred technicians	1	0	2	2	2	2	3	N/A
Referred Pharmacy Students	2	2	2	2	2	1	2	N/A
Self Referred transferred to Board of Pharmacy	0	0	0	0	0	0	0	N/A
Board Cases Requesting PEAC Assistance	8	6	6	6	6	6	6	N/A
New Cases This Month								
Pharmacist	1	1	2	1	1	2	1	9
Student	0	0	0	0	0	0	0	0
Technician	0	0	0	0	0	0	0	0
Client Discharges	0	0	0	0	0	0	0	0
Drug Tests Ordered	44	42	46	42	44	46	48	312
Number of Positive Results	0	0	0	1	0	1	1	3
Total Combined Cases Being Monitored by PEAC	24	21	24	25	24	26	26	N/A

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
Cases under Board Monitoring	13	12	12	12	12	12	12	N/A
Drug Tests Ordered	30	30	30	30	27	22	22	191
Number of Positive Results	0	0	0	1	0	0	0	1
SECTION E LICENSING COMMITTEE REPORT(CONTINUED)								
Reinstatements								
Less then 2 Years	16	8	17	17	10	11	13	92
2 to 5 Years	1	0	0	1		0	0	2
5 + Years	0	0	0	0		0	0	0
Vaccine Certifications								
Received To Date	278	278	334	385	461	481	494	N/A
Renewed This Month	13	13	13	13	8	15	12	87
Certified This Month	7	7	26	77	47	36	20	220
Pending This Month	12	12	42	16	45	25	20	172
Total Certified To Date	246	266	292	369	416	462	474	N/A
Pharmacy Technicians								
Applications for Grandfathered Status	1409	1409	1489	1527	1548	1567	1572	N/A
Applications for Nationally Certified	2028	2028	2088	2216	2286	2338	2652	N/A
Applications for Student Exemption	196	196	241	251	256	258	260	N/A
Applications received	3633	3633	3818	3994	4090	4163	4484	N/A
Registered To Date		2080	2569	3122	3371	3512	3651	N/A
Registrations Pending		1553	1249	872	719	651	833	N/A
Technician Training Programs								
Total Programs Submitted	21	0	21	0	23	23	24	N/A
Total Programs Approved	7	0	8	0	12	14	15	N/A
Total Pending Review	11	0	4	0	11	0	1	N/A
Total Under Re-work						8	8	N/A

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
New Pharmacies								
New In State	2	4	3	2	2	6	2	21
New Out of State	2	4	8	5	9	4	7	39
New Waiver	0	1	1	1	0	0	0	3
Total New Pharmacies	4	9	12	8	11	10	9	63
Closed Pharmacies								
Closed In State	1	0	4	2	1	0	0	8
Closed Out of State	0	1	2	1	1	2	3	10
Closed Waiver	0	2	1	0	0	0	0	3
Total Closed Pharmacies	1	3	7	3	2	2	3	21
Total In State Pharmacies	1134	1134	1133	1132	1133	1139	1141	N/A
Total Out of State Pharmacies	112	367	373	377	385	387	391	N/A
Total Waivered Pharmacies	103	103	102	104	104	104	104	N/A
Total Pharmacy permits	1349	1604	1608	1613	1622	1630	1636	N/A
Distributors								
New in State	1	0	0	6	1	3	0	11
New Out of State	8	3	15	7	12	6	2	53
Total New Distributors	9	3	15	13	13	9	2	64
Closed Distriburors								
Closed In State	0	0	0	1	0	0	0	1
Closed Out of State	0	0	0	0	0	2	1	3
Total In State Distributors	167	187	187	192	193	196	196	N/A

StateStat Statistics	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Total 2009
Total Out of State Distributors	726	726	741	748	760	764	765	N/A
Total Distributors	893	913	928	940	953	960	961	N/A
Rx Respository Program								
Applications received	0	3	3	3	3	3	3	N/A
Applications Approved	0	0	0	0	0	1	1	N/A
Applications Pending	0	0	2	2	2	1	1	N/A
Applications Withdrawn	0	0	1	1	1	1	1	N/A
Total Repositories	0	0	3	3	3	3	3	N/A
Drop Off Sites								
Applications received	0	0	0	0	4	4	4	N/A
Applications pending	0	0	0	0	2	1	1	N/A
Applications Approved	0	0	0	0	0	1	1	N/A
Applications Withdrawn	0	0	0	0	2	2	2	N/A
Total drop Off Sites								
Drug Therapy Management Protocols								
Total Applications Received	8	0	8	8	8	8	8	N/A
Applications Approved	4	0	4	4	4	4	5	N/A
Applications Not Approved	3	0	3	3	3	3	3	N/A
Applications pending	1	0	1	1	1	1	0	N/A
SECTION F-MANAGEMENT INFORMATION SYSTEMS REPORT								
Number of e-mails received	505	494	333	285	398	437	468	2920
Number of website visitors	18180	15281	12832	12707	13688	6628	11798	91114