

**Maryland Board of Pharmacy
Public Meeting Minutes
Date: July 15, 2009**

Name	Title	Today's Attendance		Year-to-Date Attendance	
		Present	Absent	Present	Absent
Anderson, C.	Commissioner	x		1	0
Bradley-Baker, L.	Commissioner	x		1	0
Chason, D.	Commissioner	x		1	0
Finke, H.	Commissioner	x		1	0
Handelman, M.	Commissioner	x		1	0
Israbian-Jamgochian, L.	Commissioner	x		1	0
Leandre, A.	Commissioner	x		1	0
Matens, R.	Commissioner	x		1	0
Souranis, M.	Commissioner/Treasurer	x		1	0
Taylor, D.	Commissioner/President	x		1	0
Taylor, R.	Commissioner/Secretary	x		1	0
Zimmer, R.	Commissioner		x	0	1
Bethman, L.	Board Counsel	x		1	0
Gibbs, F.	Board Counsel	x		1	0
Banks, T.	MIS Manager	x		1	0
Eversley, C.	Compliance Investigator	x		1	0
Gaither, P.	Administration and Public Support Manager	x		1	0
Goodman, S.	Acting Licensing Manager	x		1	0
Jeffers, A.	Legislation/Regulations Manager		X	0	1
Kreindler, S.	Compliance Coordinator			1	0
Naesea, L.	Executive Director	x		1	0
Simmons, L.	Executive Secretary	x		1	0

Subject	Responsible Party	Discussion	Motion	Action/Results
I. Call to Order	Donald Taylor, Board President	<p>A. 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.</p> <p>B. D. Taylor asked that all guests introduce themselves and sign in on the guest attendance sheet.</p> <p>C. D. Taylor reported that the Board will be passing out draft documents so that all guests may follow the Board's discussion. Please return the packet when you leave as they are still in draft form.</p> <p>D. D. Taylor reported that Cindy Anderson is recused from voting on any Practice and Regulations issues.</p>		
II. Approval of the Minutes	Donald Taylor, Board President	<p>A. D. Taylor requested additions and corrections to the Minutes for June 17, 2009.</p> <p>1. Page 2, Section III. Discussion Section, Item 4. Remove "M. Handelman."</p> <p>2. Page 3, Section IV. Discussion Section, Item A. Remove "approval requested."</p> <p>3. Page 4, Section V. Discussion Section, Item B. Add "a." and remove "in."</p> <p>4. Page 4, Section V. Discussion Section, Item B. Add "a."</p> <p>5. Page 5, Section V. Motion Section, Item b. 4. Remove "the letter Option II with amendments as proposed by the Practice Committee."</p> <p>6. Page 5, Section V. Motion Section, Item b 5. Remove "the letter Option II</p>	<p>Motion:</p> <p>M. Handelman made a motion to approve the minutes as amended.</p> <p>C. Anderson seconded the motion.</p>	<p>Board Action:</p> <p>The Board voted to approve the minutes as amended.</p>

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		<p>with amendments as proposed by Practice Committee.”</p> <p>7. Page 7, Section V. Discussion Section, Item e. Remove “the proposed revisions to the” and add “recommendations to revise.”</p> <p>8. Page 8, Section V. Discussion Section, Item f. Remove “the proposed revisions to the” and Add “recommendations to revise.”</p> <p>9. Page 8, Section V. Discussion Section, Item g. Remove “the proposed revisions to the” and Add “recommendations to revise.”</p> <p>10. Page 8, Section V. Discussion Section, Item h. Remove “the proposed revisions to the” and Add “recommendations to revise.”</p> <p>11. Page 8, Section V. Discussion Section, Item i. Remove “the proposed revisions to the” and Add “recommendations to revise.”</p> <p>12. Page 8, Section V. Discussion Section, Item j. Remove “the proposed revisions to the” and Add “recommendations to revise.”</p> <p>13. Page 11, Section XII. Action/Results, Item 4a. Add “dis.”</p> <p>14. Page 11, Section XII. Action/Results, Item 4b. Remove “dies” and Add “does.”</p> <p>15. Page 16, Section XVI. Discussion Section, Item B. Remove “Non-licensed” and add “Dispensing.”</p> <p>16. Page 16, Section XVIII. Action/Result Section, Item 1. Add “and opens a Closed Public Board Session.”</p>		
		<p>B. D. Taylor reported that L. Israbian-Jamgochian is the new chair for Disciplinary Committee and M. Souranis is the new chair for the Licensing Committee.</p>		
		<p>C. D. Taylor reported that D. Chason, L. Israbian-Jamogochian, and A. Leandre all have perfect attendance at last year’s Board meeting.</p>		
		<p>D. D. Taylor reported that a meeting on the Drug Therapy Management program was held on June 25, 2009 to discuss eliminating the sunset of the program.</p>		
		<p>E. D. Taylor reported the next meeting of the Prescription Drug Monitoring Taskforce will be held on July 17, 2009.</p>		
		<p>F. D. Taylor reported that the American Society of Consultant Pharmacist (ASCP) has scheduled their annual meeting at Rocky Gap State Park on August 6th through the 9th, 2009.</p>		
		<p>G.. D. Taylor reported that the initial meeting of the Home Infusion Taskforce is scheduled to meet on September 2, 2009 at 1:30 p.m.</p>		
		<p>H. D. Taylor reported the PEAC seminar is scheduled for September 26th at the Maritime Institute.</p>		
III. Executive Director	LaVerne Naesea, Executive Director	<p>A. L. Naesea reported that the Board is short staff and that the Board has 8 positions to fill.</p>		
		<p>B. L. Naesea asked if any Commissioners would be willing to volunteer to be</p>		

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		an on-call person to assist the Board with consulting and addressing daily pharmacy practice questions. M. Handelman, H. Finke, D. Chason, L. Israbian-Jamgochian volunteered to answer questions received by the Board staff.		
		C. L. Naesea reported that M. Handelman is the representative for Long Term Care, H. Finke is the representative for Independent Pharmacy, D. Chason is the representative for Hospital Pharmacy, and Lenna Israbian-Jamgochian is the representative for Chain Pharmacy.		
		D. L. Naesea requested that the Board will need additional help for 3 months until replacement staff is hired.		
		E. L. Naesea reported that F. Gibbs helped with the inspection process for out of state Wholesale Distributors.		
		F. L. Naesea reported that the Board has help from the two students from Youth Works. One in Licensing and the other one in Administration and Public Support unit. The two student's placement will end on July 31, 2009.		
		G. L. Naesea reported that the Board has two volunteers that come in the office on Monday to assist the Inspectors and Friday to assist A. Jeffers. Both volunteers last day will be in August.		
		H. L. Naesea reported that a letter on Dispensing by Authorized Prescribers was received from the Board of Physicians. The letter was regarding suggested changes to the regulations governing dispensing of prescription drugs by licensees, COMAR 10.13.01. The Board's response suggested that the Board's sole interest in submitting suggested changes to COMAR 10.13.01 is to protect Maryland patients.		
IV. Législation and Régulations	Anna Jeffers, Legislation and Regulation Manager	A. Maryland Regulations 1. L. Naesea provided the status report on the Maryland Regulations.		
		a), L. Naesea reported on COMAR. 10.34.09 Fees. Emergency Proposal submitted for sign-off April 27, 2009. Fees adjusted lower to accommodate budget predictions. Re-submitted 6/12/2009. Additional information sent to budget 6/23/2009. Additional explanation sent to the Secretary 6/29/09. Emergency proposal anticipated to be published August 14, 2009.		
		b) L. Naesea reported on COMAR 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties. Proposal published March 27, 2009. Responses to comments sent 6/24/2009. Re-proposal documentation submitted 6/24/2009.		
		c) L. Naesea reported on COMAR 10.34.20 Format of Prescription Transmission, The Board approval is requested for the revised proposal. The next steps are to release for informal comment.	c. Motion: L. Israbian-Jamgochian made a motion to approve the letter as proposed by the Practice Committee. M. Souranis seconded the motion.	c. Board Action: The Board voted to approve the motion.

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		<p>d) L. Naesea reported on COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors. The original proposal was published on June 19, 2009. AELR approved an emergency effective date of June 18, 2009. Notices have been placed on the website.</p>		
		<p>e) L. Naesea reported on COMAR 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities, Revisions occurred at the Long Term Care Workgroup meeting on 6/29/09. COMAR 10.34.23 will be reviewed at the July Practice Meeting.</p>		
		<p>f) L. Naesea reported on COMAR 10.34.25 Delivery of Prescriptions – was released for informal comment. Eight (8) informal comments received. Comments and draft responses to be considered at the July Practice Committee Meeting.</p>		
		<p>g.) L. Naesea reported on COMAR 10.34.28 Automated Medication Systems – Approved by the Board at the May 20, 2009 Board meeting and released for informal comment on May 21, 2009. One response was received. The comments were regarding the definition (.02) of “unit dose”, Stocking of Automated Medication Systems (.07.B, and the Return of Unused Medication (.08). L. Naesea reported that the following responses were given by the Board</p> <p><u>.02 Definitions</u></p> <p>Kaiser Permanente has indicated that the definition of “Unit Dose” was unclear. The definition of “Unit Dose” in the regulations does not refer to one complete multi-dose filled prescription. It refers to one pharmaceutical dose in a packaged form.</p> <p><u>Stocking of Automated Medication Systems</u></p> <p>Kaiser Permanente (KP) indicated that it believed that pharmacy technicians should be allowed to stock bulk medications in automated medication systems without a prior pharmacist check. In Health Occupations Article, 12-605(c), Annotated Code of Maryland, a licensed pharmacist is required to verify the accuracy of medications selected for stocking and replenishment of remote automated medication systems (not robotic systems in a retail pharmacy) before the medications are stocked in the system.</p> <p><u>.08 Return of Unused Medication</u></p> <p>KP indicated that it did not support the requirement that only automated medication systems that distribute medications in a single-drug unit dose packaging may allow for return of unused medications to the system. KP suggested that systems which use bar coding for positive drug identification allow for the return of unused medication, even when it is not packaged as a single-unit dose.</p>	<p>g. Motion: M. Handelman made a motion approve the letter as proposed by the Practice Committee.</p> <p>D. Chason seconded the motion.</p>	<p>g. Board Action: The Board voted to approve the motion</p>

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		h) L. Naesea reported on COMAR 10.34.32 Pharmacist Administration of Vaccinations, Re-proposal published May 8, 2009. Notice of Final Action documentation submitted 6/19/2009 with a requested August 1, 2009 effective date.		
		i) L. Naesea reported on COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee, submitted to DHMH November 20, 2008. Board of Physicians responded to Board of Pharmacy's April 7, 2009 Letter <u>Board approval requested for the Board of Pharmacy response to the Board of Physician's April 28, 2009</u>	i. Motion: H. Finke made a motion to ratify the letter. D. Chason seconded the motion.	i. Board Action: The Board voted to approve the motion. M. Souranis recused
		2. L. Naesea reported that the Regulatory Review and Evaluation Act Reports submitted 06/22/2009. Revisions to 8 COMAR chapters to begin in August. Total of 17 COMAR Chapters are to be revised in FY 2010.		
		<u>B. Legislation:</u> L. Naesea presented the following letters for ratification by the Board. 1. Approval requested for the Legislative Proposal Packet for the continuation of the Drug Therapy Management Program. The workgroup meeting was held on June 25, 2009 to complete the proposal for submission to the July Board meeting. The following proposal was submitted to the Board: Draft Bill – Continuation of DTM 060909 FORM A 2010 DTM Program Drug Therapy Mgmt fiscal note 070209	B.1. Motion M. Souranis made a motion to approve the legislative proposal for continuation of the Drug Therapy Management Program. L. Bradley-Baker seconded the motion	B.1. Board Action: The Board voted to approve the motion
		2. Approval requested for the Legislative Proposal Packet for requiring out-of-state wholesale drug distributors to be accredited by an accreditation organization. L. Naesea reported that 2 inspectors were sent to Pennsylvania to do 12-14 inspections. L. Naesea suggested that the out-of-state inspections should be performed by an accreditation organization. F. Gibbs reported that NABP was called and the Board asked if NABP could provide inspections to cover the out-of-state distributors until the law passes. The following proposals were submitted to the Board: Draft Bill-Accreditation of Out-of State Distributors Form A 2010-Wholesale Distributors Wholesale Distributors Bill Fiscal note 071009	B. Motion R. Matens made a motion to approve the legislative proposal for Out-of-State Wholesale Drug Distributors. L. Israbian-Jamgochain seconded the motion.	B.2. Board Action The Board voted to approve the motion.
V. Inspection Program Report	Rodney Taylor, Disciplinary Committee	R. Matens presented the Compliance monthly statistics for the Board. See Attachment 1, Section C.		

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	Chair			
VI. PEAC Report	Anthony Tommasello, PEAC	A. A. Tommasello presented the PEAC monthly statistics for the Board. See Attachment 1, Section D.		
		B. G. Cohen reported that PEAC continuing education program will be September 26, 2009. Seminars will be held on August 19, 2009 at the University of Maryland at 12:00 p.m. and at the College of Notre Dame at 2:00 p.m., both seminars will be discussing topics concerning Substance Abuse.		
		C. G. Cohen reported that PEAC mailed a letter to the Board regarding the shortage of fees that are received from the Board. PEAC has more participants than the amount of funds that are paid by the Board.		
VII. Administration and Public Support	Patricia Gaither, Administration and Public Support Manager	A. P. Gaither presented Administration and Public Support monthly statistics for the Board. See Attachment 1, Section G.		
		B. P. Gaither reported that the 4 th Inspector position has been filled. S. Young was hired on July 8, 2009.		
		C. P. Gaither reported that the Board was not able to renew the contract for Agency Temp that was assisting the Licensing Unit because the freeze exemption was not received for that position.		
		D. P. Gaither reported that the Student Summer Youth Works program will end on July 31, 2009.		
VIII. Public Relations Committee Report	Lynette Bradley-Baker, Chair	A. L. Bradley-Baker presented the Public Relations Committee Report 1. L. Bradley-Baker reported that the Newsletter Magazine will be proofed this week and should be published in 2 weeks. L. Bradley-Baker will be the editor for the Fall Magazine. L. Bradley-Baker asked that all Committee members submit their articles for the magazine by August 28, 2009.		
		2. L. Bradley-Baker reported that two representatives of the Acetaminophen Task Force attended the FDA hearing on June 29, 2009. Recommendations were made to lower the daily use dosage. FDA recalled the concentrated drops of Acetaminophen for children.		
		3. L. Bradley-Baker reported that the Continuing Education Program will be held October 4, 2009 at Cross Keys. The CE credits that will be discussed are Over the Counter pain medicine and Trends in disciplinary.		
IX. Management Information Services	Tamarra Banks, MIS Manager	A. T. Banks presented MIS monthly statistics for the Board. See Attachment 1, Section F.		
		B. The BOP of pharmacy is considering using a sole source contractor for database development. The invitations for the proposal must be sent out within 21 days after the language of the contract has been approved.		
		C. T. Banks reported that all Inspectors have been trained on the Inspection System Program.		

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		D. T. Banks reported that the Board performed a Disaster Recovery test run on June 23, 2009 and it was successful. This fiscal year, the Board was unable to obtain MPT for the Disaster Recovery and MIS is in search of another location.		
		E. T. Banks reported that the Group Wise update will be done in two stages. The initial stage was on July 7, 2009 and the second stage will be done on July 15, 2009 with the help of D. James.		
X. Practice Committee	Reid Zimmer, Chair	<p>A. Regulations currently undergoing revisions:</p> <p>1. L. Naesea reported that COMAR 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities is currently undergoing revisions.</p> <p>2. L. Naesea reported that COMAR 10.34.25 Delivery of Prescriptions has been posted for informal comments which will be considered at the next Committee meeting.</p>		
		<p>B. L. Naesea, D Chason, F. Gibbs presented the following public inquiries:</p> <p>1. Hills Pharmacy-Take Back Program</p> <p>We have received numerous inquires from patients, prescribers, and community based organizations concerning the safest way to dispose of expired and unused pharmaceutical medications, which prompted my interest in seeking a solution for disposal in an environmentally friendly manner.</p> <p>An outline of our plan would include:</p> <ol style="list-style-type: none"> 1. The consumer brings in their expired or unused medication in its original vial or container. 2. The pharmacist determines whether it is eligible for return (not an inhaler, ingestible or controlled substance). 3. The Pharmacist presents the Medicine Return Form to the patient 4. Upon completion of the Medication Return Form, the Pharmacist will cross out all PHI and patient identification with a permanent black marker. 5. The Pharmacist will place the medications in the D-Vault bin, which is kept locked at all times and is located in the secured pharmacy department. 6. A Pharmacist will sort the medications in the D-Vault bin weekly or more as needed and place in boxes to be mailed to Pharmalink, our "waste-to energy" reverse distributor. 7. Copies of medication forms will remain in a HIPAA secured file and be readily available to the board at all times. <p>RESPONSE: The Take-Back Program you described in your letter would not be allowed under Maryland law unless it is part of the Board of Pharmacy Prescription Drug Repository Program. The Board recommends that Hill's Drug Store apply to be both a "repository" and a "drop-off site" in order to collect medications for disposal. Under the Prescription Drug Repository Program Hill's Drug Store could collect unwanted/unused medications pursuant to</p>	<p>B. Motion:</p> <p>Practice Committee made a motion to approve the letter as written.</p> <p>H. Finke seconded the motion.</p>	<p>B. Board Action: The Board voted to approve the motion.</p>

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		<p>COMAR 10.34.33.01 - .12. The medications not eligible for re-dispensing could be disposed of through the Take-Back Program you described. As you noted in your letter, controlled dangerous substances would not be collected and are not allowed to be collected under the Prescription Drug Repository Program.</p>		
		<p>C. Legislation-Board Ratification requested for Letter to Maryland Association of Chain Drug Stores (MACDS)</p> <p>1.Legislation- Therapeutic Contacts-Stanton Ades</p> <p>Last year legislation was briefly introduced or considered regarding Therapeutic contact lenses. The issue looks like it may get legs again this year, please see the message below.</p> <p>Since this involves medication (OTC for now, but it could open the door as a vehicle for drug distribution for Rx medications in the future), how does the Board want to be involved in this process?</p> <p>RESPONSE: Thank you for contacting the Maryland Board of Pharmacy concerning whether the Board would like to be involved in the upcoming legislation regarding dispensing of therapeutic contact lenses.</p> <p>Please continue to provide the Board with upcoming information and updates concerning this issue. If legislation on this issue is introduced in Annapolis next year, the Board would be happy to review it thoroughly and will consider its support at that time.</p> <p>2. Legislation-MACDS to Lisa Simpson</p> <p>If Maryland were to move forward in this regard, we would expect an outcome of no less that what our neighboring state requires. Our ability to dispense therapeutic contact lenses is particularly heightened with the advent of more health care responsibilities under “emergency preparedness” legislative and regulatory concepts. We want to continue to be an integral part in the delivery of safe, effective, affordable and available health care that is timely and convenient.</p> <p>Please keep us apprised of any further developments. We remain available for input and in-person discussions if needed. If you could send a copy to us of your correspondence to the Attorney General, it would be greatly appreciated.</p>	<p>2. Motion.</p> <p>Practice Committee made a motion to accept the letter as written.</p> <p>R. Matens seconded the motion.</p>	<p>2. Board Action The Board voted to approve the motion.</p>
<p>XI. Licensing Committee</p>	<p>Cynthia Anderson, Chair Summar Goodman, Acting</p>	<p>A. C. Anderson presented the Licensing Committee statistics for 2009. See Attachment 1, Section A and E.</p>		

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	Licensing Manager			
		B. C. Anderson reported the licensing committee recommends that Pharmacists working for XYZ insurance company who interact with Maryland residents should be required to be licensed in the State of Maryland.	B. Motion: The Licensing Committee made a motion to recommend that are Pharmacist are required to be license in Maryland if they interact with Maryland Patients. M. Handel seconded the motion. L. Bradley-Baker abstained	B. Board Action: The Board voted to approve the motion.
		C. M. Souranis recommends that all non-resident pharmacies who service patients in Maryland should be required to have a pharmacist license in Maryland.		C. Board Action: Board voted to approve motion
XII. Disciplinary Committee	Rodney Taylor, Chair	A. R. Matens presented the Compliance Committee monthly statistics for the Board. See Attachment 1, Section A and C.		
XIII. Long Term Care	Mayer Handelman, Chair	A. M. Handelman reported that Assisted Living Program 101 will be held on Thursday, July 23, 2009.		
XIV. Emergency Preparedness Taskforce	Donald Taylor, Chair	A. D. Taylor reported that the Task Force is working on Protocols and checklist for the Governor.		
XV. Informational	Donald Taylor, Board President	A. D. Taylor reported that NABP sent a letter to FDA. The Board made a recommendation to draft a letter to NABP to address the issue of NABP proposing accreditation for Pharmacies. B. D. Taylor reported that the Senate has passed a bill that permits imports from Canada. The plan was attached to a bill funding the Customs Departments and other homeland security agencies. It's unclear whether the idea will survive House-Senate talks on a final version of the bill.	A. Motion: M. Souranis made a motion to draft a letter to NABP. L. Israbian-Jamgochian seconded the motion.	A. Board Action: The Board voted to approve the motion
XVI. Adjournment	Donald Taylor, Board President	A. D. Taylor asked for a motion to close the Public The Public Meeting was adjourned at 11:20 A.M.	1. Motion M. Souranis made a motion to close the public Board meeting. M. Handelman seconded the motion.	1. Board Action The Board voted to approve the motion