

Maryland Board of Pharmacy
Public Board Meeting

Agenda
 Date: November 28, 2012

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	Commissioner/Treasurer				
Chason, D.	Commissioner				
Finke, H.	Commissioner				
Gavgani, M. Z.	Commissioner				
Hammonds, S.	Commissioner				
Handelman, M.	Commissioner				
Israbian-Jamgochian, L.	Commissioner				
Matens, R.	Commissioner				
Souranis, M.	Commissioner//President				
St. Cyr, II, Z. W.	Commissioner				
Taylor, D.	Commissioner				
Taylor, R.	Commissioner/Secretary				
Board Counsel					
Bethman, L.	Board Counsel				
Felter, B.	Staff Attorney				
Board Staff					
Naesea, L.	Executive Director				
Wu, Y.	Compliance Manager				
James, D.	Acting Licensing Manager				
Gaither, P.	Administration and Public Support Manager				
Jeffers, A.	Legislation/Regulations Manager				
Johnson, John	MIS Project Manager				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	A. M. Souranis, Board President B. R. Taylor Secretary	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> 1. Call to Order 2. Sign-in Introduction and of meeting attendees – <i>(Please indicate on sign-in sheet if you are requesting CE Units for attendance)</i> 3. Distribution of packet materials 4. Review and approve October 17, 2012 Minutes Draft Public Minutes 10-17-2012 	
II. Executive Director Report	A. L. Naesea	<ol style="list-style-type: none"> 1. Operations Updates 2. Meeting Updates 	
B. Administration and Public Support	B. P. Gaither, Manager	<ol style="list-style-type: none"> 1. Personnel Updates - Vacancies and Recruits 2. Contracts and Procurement 	
C. MIS	J. Johnson, MIS Manager	1. MIS Manager Introduction	

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D. Licensing	D. James, Acting Licensing Manager	<ol style="list-style-type: none"> 1. Licensing Unit Update 2. Monthly Statistics 	
E. Compliance	Y. Wu, Manager	<ol style="list-style-type: none"> 1. Monthly Statistics 2. PEAC Update 	
F. Legislation & Regulations	A. Jeffers	<p><u>MEETINGS:</u></p> <p><u>1) November 7, 2012 Meningitis Briefing before HGO</u></p> <p><u>Bd of Pharmacy Written Testimony Briefing on Meningitis Outbreak 110812</u></p> <p>Three considerations for legislation to address regulation of out of state compounding pharmacies:</p> <ol style="list-style-type: none"> a) Require accreditation of out of state compounding pharmacies by an accreditation organization that physically inspects those entities; b) Require reporting requirements similar to the Massachusetts emergency regulation; <p><u>247 CMR Pharmacy Emergency Regs As Adopted</u></p> <ol style="list-style-type: none"> c) Add to 12-403 the specific requirement that out of state compounding pharmacies comply with the Board's sterile pharmaceutical compounding regulations – COMAR 10.34.19. <p><u>2) Meetings Scheduled to Seek Sponsors and Support of Proposed Legislation</u></p> <ol style="list-style-type: none"> a) Elimination of workmen's comp exemption from obtaining 	

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		<p>dispensing permits and annual inspections;</p> <p>b) Oversight of out of state compounding pharmacies;</p> <p>b) November 15, 2012 Delagate Hammond;</p> <p>c) November 19, 2012 HGO Special Briefing</p> <ul style="list-style-type: none"> • Vaccines Meeting; and • Biosimilars Meeting. <p>d) December 4, 2012 Drug Shortages Briefing before HGO.</p> <p>Chairman Hammen is looking forward to the Board's recommendation for oversight of out of state compounding pharmacies.</p> <p><u>LEGISLATION:</u></p> <p><u>Health Occupations - Service Members and Spouses - Processes for Temporary Licensure, Certification, and Registration.</u></p> <p>Section 1-702(B)(1).</p> <p>Board's preliminary position on the draft legislation is requested.</p> <p><u>INQUIRY FROM THE VIRGINIA BOARD OF PHARMACY</u></p> <p>What steps is MD taking or plans to take to address concerns regarding sterile compounding?</p> <p><u>REPORTS</u></p>	

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		<p><u>1) Maryland Board of Pharmacy Prescription Drug Repository Program Seventh Annual Report to the Governor and the General Assembly</u></p> <p><u>Maryland Board of Pharmacy Prescription Drug Repository Program Seventh Annual Report to the Governor and the General Assembly</u></p> <p>Board approval requested for the Seventh Annual Drug Repository Report</p> <p><u>2) CDS Monitoring Subcommittee recommendations for prescription requirements in Maryland</u></p> <p><u>CDS recommendations (rev 10-17-12) Carole Catalfo 111412</u></p> <p><u>REGULATIONS:</u></p> <p>10.34.03 – Inpatient Institutional Pharmacies Board approval requested for proposal and to release for informal comment.</p> <p><u>DRAFT 10.34.03.01 Satellite Pharmacies version 8 for 112812 Bd Mtg</u></p> <p>10.34.06 Reporting Pharmacist’s and Pharmacy Technician’s Mailing Address and Location of Employment</p> <p>Proposal sent to OHCQ and MP for sign off 10/23/12.</p> <p>10.34.11 - Disciplinary Monetary Penalties, and Civil Fines</p> <p>Notice of Final Action signed 10/23/12 & returned to DHMH for sign-</p>	

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		<p>off..</p> <p>10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.</p> <p>Proposal released for informal comment 9/25/12 through 10/12/12. Board approval requested for responses to informal comments and submission of the proposed regulations.</p> <p><u>DDC Informal Comment 10.34.14 and .30</u></p> <p><u>Bd Response to DDC informal comment 10.34.14</u></p> <p><u>10.34.14 and 10.34.30 Release for Informal Comment 092512</u></p> <p>10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors –</p> <p>Proposal sent to OHCQ and MP for sign off 10/22/12.</p> <p>10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities</p> <p>Board approval requested for revisions that requires pharmacist final check of interim boxes.</p> <p>Board approval requested to release for informal comments.</p> <p><u>proposed-1-11 10.34.23</u></p> <p>10.34.29 – Drug Therapy Management</p> <p>Has been submitted as an Emergency Proposal.</p>	

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		<p>10.34.36 – Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes - Published September 21, 2012. One comment received.</p> <p>Board approval requested for the response to the comment and the reproposal.</p> <p><u>MACS Comment Letter-Pharmacy Regs 10.22.12</u></p> <p><u>Board Response - Official Comment - 10.34.36 MACS</u></p> <p><u>Reproposal for COMAR 10.34.26.</u></p> <p>10.13. 01 – Dispensing of Prescription Drugs by a Licensee</p> <p>Board approval requested to release for informal comments. <u>COMAR 10.13.01 - Proposed Draft for Nov 28 Bd Meeting</u></p>	
<p>III. Committee Reports</p> <p>A. Practice Committee</p>	<p>H. Finke, Chair,</p>	<p>1) Dr. Jennifer Gudeman, Ther-Rx Corporation</p> <p><u>Compounding of hydroxyprogesterone caproate injections</u></p> <p><u>Mo Board of Pharmacy newsletter august</u></p> <p><u>AZ102012</u></p> <p><u>FDA OA on Makena 062912</u></p> <p><u>FDA Statement 061512</u></p> <p><u>Draft Bd Response - Compounding of hydroxyprogesterone II</u></p> <p>2) Dorene Miles, Cegedim</p>	

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		<p><u>Cegedim - USB Flash Drive</u></p> <p><u>Fwd 10-655 avc prescription device question--Response 1</u></p> <p><u>Re Research on devices</u></p> <p><u>Draft Bd Response - Rx Flash Device</u></p>	
<p>B. Licensing Committee</p>	<p>D. Chason Chair,</p>	<ol style="list-style-type: none"> 1) Review of Pharmacist Applications: None 2) Review of Pharmacy Technician Applications: <ul style="list-style-type: none"> • <u>Jermaine Gilmer</u> – Technician sent in application for reinstatement. Expired 08/31/2011. Wage check clear. Recommendation is to approve reinstatement. • <u>Dawn Daniels</u> - Technician sent in application for reinstatement. Expired 08/31/2011. Wage check clear. Technician previously did n’t send in renewal and reinstatement fees. Recommendation is to approve reinstatement. 3) Review of Distributor Applications: None 4) Review of Pharmacy Technicians Training Programs: <ul style="list-style-type: none"> • Kmart Pharmacy National Pharmacy Technician Training Program – Recommendation is to approve program. 5) New Business: <ul style="list-style-type: none"> • <u>AMKA Pharmaceutical Services, Inc</u> - L. Bradley-Baker was recused. Pharmacy is in violation of Education Article 11-202 with MHEC. MHEC has directed the Board to immediately cease and desist promoting institution and offering training in Maryland. Program is not Board approved. 	

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		<p>Informational Only.</p> <ul style="list-style-type: none"> • Online Renewal CE Approval Process – Discussion of the online renewal process and CE verification process. Committee is not taking a stand. • <u>Maryland National Capitol Homecare Association</u> - MNCHA would like clarification on the requirement of Maryland HME providers who provide medical devices need to hold a pharmacy license. Recommendation is to send letter informing company that we are developing task force to evaluate distribution of medical devices. • <u>Ken Mercer</u> at Northwest Hospital - Company would like to know will they be required to carry a retail pharmacy license to supply pharmaceuticals to the residents in Levindale Geriatric Center and Courtland Gardens if they have a pharmacy license with Sinai Hospital. Also, the small room that acts as a stat dose pharmacy, in the fact that it stores patients' prescriptions, will it also need to be licensed as a pharmacy? Recommendation is to inform company that they do not have to be licensed as a separate pharmacy if the license held under Sinai is a full pharmacy permit; But if it is operating under a PW permit, they will have to inform the Board of an added classification. Regarding the small room, no permit is required as long as a licensed staff member administers these medications. • <u>Requirement of Oral Competency Test</u> - Response from Berlitz on off site verification of oral competency test. Recommendation is to approve Berlitz proposal but add an emergency number for 	

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		<p>applicants to contact for technical support.</p> <ul style="list-style-type: none"> • John Meyers - Applicant, John Meyers, did not have complete CE credits. He was short 5 CE's and 2 live. When notified, he requested a refund of his \$253 payment and requested his license be placed on a non renewed status. D. Daniels told applicant that she would process refund. Board denied refund request and licensee appealed decision. Recommendation is to notify licensee of the option to submit CE to Board for approval but we can not accept it until then and he has to now pay reinstatement fees. • Bruce Bergman - Licensee submitted renewal without required live CE's. Licensee states that he assumed that the courses he took were "Live" but previously recorded. He is asking for a waiver to allow acceptance of the two courses as "Live" for renewal of pharmacist license. Recommendation is to deny request and inform licensee that he has to take 2 "live" CE's and reinstatement fees. 	
C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update.	
D. Disciplinary	L. Israbian-Jamgochian Chair	Disciplinary Committee Update.	
E. Emergency Preparedness Task Force	D. Taylor Chair	Emergency Preparedness Task Force Update.	

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IV. Other Business & FYI	M. Souranis, Board President	None	
V. Adjournment	M. Souranis, Board President	<p>The Public Meeting was adjourned at _____.</p> <p>At _____ P.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>C. The Closed Public Session was adjourned at _____ P.M. Immediately thereafter, M. Souranis 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.</p>	