

**Maryland Board of Pharmacy  
Public Board Meeting**

**Meeting Minutes  
Date: November 18, 2015**

Name	Title	Present	Absent	Present	Absent
<b>Board Committee</b>					
Ashby, D.	Commissioner	X		8	2
Bouyoukas, S.	Commissioner	X		4	
Gavgani, M. Z.	Commissioner/President		X	8	2
Jones, David H.	Commissioner/Secretary	X		10	
Peters, R.	Commissioner	X		10	
Robinson, T.	Commissioner	X		10	
Rochester, C.	Commissioner	X		10	
Roy, S.	Commissioner		X	9	1
Smith, J.	Commissioner/Treasurer	X		9	1
St. Cyr, II, Z. W.	Commissioner	X		10	
Yankellow, E.	Commissioner	X		3	1
Zagnit, B.	Commissioner	X		10	
<b>Board Counsel</b>					
Bethman, L.	Board Counsel	X			
Felter, B.	Staff Attorney	X			
<b>Board Staff</b>					
Naesea, L.	Executive Director	X			
Ennels, S.	Deputy Director of Operations	X			
Wu, Y.	Compliance Manager	X			
Page, A.	Executive Administrative Associate	X			
Waddell, L.	Administration and Public Support Manager				
Jeffers, A.	Legislation/Regulations Manager	X			
Johnson, J.	MIS Manager				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	<p>A.) M. Gavgani, Board President</p> <p>B.) D. Jones, Secretary</p>	<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"> <li>1. D. Jones, acting on behalf M. Gavgani, called the meeting to order at 9:37 AM.</li> <li>2. D. Jones reminded all guests to sign the guest log, indicating whether they would like continuing education credits.</li> <li>3. D. Jones requested that all guests introduce themselves and also informed them that the meeting agenda and packet materials were available for review. He advised them that all packets must be returned at the end of the meeting.</li> <li>4. Review and approval of October 2015 Public Meeting Minutes.</li> </ol>	<p>4. Motion to approve by D. Ashby, 2<sup>nd</sup> by C. Rochester.</p>	<p>4. The Board voted to approve this motion.</p>
II. A. Executive Director Report	L. Naesea, Executive Director	<ol style="list-style-type: none"> <li>1. Operations Updates New Deputy Director of Operations, S. Ennels J. Towles, Reengineering project PEAC Contract</li> <li>2. Meetings Updates System Automation Executive Directors</li> </ol> <p><i>D. Jones, CAC Meeting</i></p> <p><i>L. Bethman, FDA Meeting</i></p>		

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		<b>Z. St. Cry, II, New Board Member Orientation</b>																																					
<b>B. Operations Report</b>	<b>S. Ennels, Deputy Director of Operations</b>	<ol style="list-style-type: none"> <li>1. APS Unit Updates</li> <li>2. MIS Unit Updates</li> <li>3. Data Integrity Unit Updates</li> </ol>																																					
<b>C. Licensing</b>	<b>Y. Wu, Compliance Manager</b>	<p><i>Presented by C. Jackson in the absence of Y Wu</i></p> <ol style="list-style-type: none"> <li>1. Unit Updates</li> <li>2. Monthly Statistics</li> </ol> <table border="1" data-bbox="621 678 1383 1310"> <thead> <tr> <th>License Type</th> <th>New</th> <th>Renewed</th> <th>Reinstated</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Distributor</td> <td>24</td> <td>35</td> <td>0</td> <td>1022</td> </tr> <tr> <td>Pharmacy</td> <td>27</td> <td>1</td> <td>0</td> <td>2062</td> </tr> <tr> <td>Pharmacist</td> <td>71</td> <td>468</td> <td>0</td> <td>10881</td> </tr> <tr> <td>Vaccination</td> <td>120</td> <td>48</td> <td>0</td> <td>4117</td> </tr> <tr> <td>Pharmacy Intern - Graduates</td> <td>13</td> <td>0</td> <td>0</td> <td>22</td> </tr> <tr> <td>Pharmacy Intern - Students</td> <td>236</td> <td>0</td> <td>0</td> <td>368</td> </tr> </tbody> </table>	License Type	New	Renewed	Reinstated	Total	Distributor	24	35	0	1022	Pharmacy	27	1	0	2062	Pharmacist	71	468	0	10881	Vaccination	120	48	0	4117	Pharmacy Intern - Graduates	13	0	0	22	Pharmacy Intern - Students	236	0	0	368		
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			Pharmacy Technician	174	300	7	9163		
<b>D. Compliance</b>	<b>Y. Wu, Compliance Manager</b>	<p><i>Presented by C. Jackson in the absence of Y. Wu</i></p> <p><b>1. Unit Updates</b></p> <p><b>2. Monthly Statistics</b></p> <p><b>Complaints &amp; Investigations:</b></p> <p>New Complaints - 17  Resolved (Including Carryover) – 32  Final disciplinary actions taken – 7  Reversals – 0  Summary Actions Taken – 2</p> <p><b>Inspections:</b></p> <p>Total - 158  Annual Inspections - 146  Opening Inspections - 5  Closing Inspections - 0  Relocation Inspections - 2  Board Special Investigation Inspections – 5  Division of Drug Control Closing Inspections – 1</p> <p><b><i>PEAC Update</i></b></p> <p><b>Total Pharmacist Rehabilitation Clients – 16</b>  Pharmacist – 16  Technician – 0  Pharmacy Student – 0  Clients Monitored by Board Req. PEAC Assistance – 2</p>							

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		<p><b>Drug Test Results - 8</b> Number of Positive Results- 0</p> <p><b>Discharged Clients/Closed Cases- 2</b></p>		
<p><b>E. Legislation &amp; Regulations</b></p>	<p><b>A. Jeffers, Legislation &amp; Regulations Manager</b></p>	<p><b><u>REGULATIONS:</u></b></p> <p><b><u>10.34.09 Fees</u></b> This chapter was revised pursuant to the Governor’s initiative and chapter clean up. Proposal submitted September 17<sup>th</sup> for DHMH sign-off and publication. Published October 16<sup>th</sup>.</p> <p><i>Does the Board want to select a future effective date or is sometime in December acceptable?</i></p> <p><b>The Board voted to not delay the effective date.</b></p> <p><b><u>10.34.10.10 Pharmacist, Pharmacy Intern and Pharmacy Technician Code of Conduct</u></b> The chapter was revised pursuant to Board recommendation. Proposal submitted September 23<sup>rd</sup> for DHMH sign-off and publication. The publication date was November 13th.</p> <p><b><u>10.34.19 Sterile Pharmaceutical Compounding</u></b> This chapter was revised pursuant to 2015 Legislation. Proposal submitted on September 2<sup>nd</sup>, for DHMH sign-off and publication. The publication date was November 13th.</p> <p><b><u>10.34.29 Drug Therapy Management</u></b> This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. Proposal</p>	<p>10.34.09 Motion by D Ashby for effective date, 2<sup>nd</sup> by S Bouyoukas.</p>	<p>10.34.09 The Board voted to approve this motion.</p>

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		<p>submitted on September 25<sup>th</sup> for DHMH sign-off and publication. The publication date was November 13th.</p> <p><b><u>10.34.33 Prescription Drug Repository Program</u></b>  This chapter was revised pursuant to Federal law and regulations.  Proposal submitted on October 22nd for DHMH sign-off and publication. The anticipated publication date is December 28th.</p> <p><b><u>10.34.39 Pharmacist Administration of Self-Administered Drugs</u></b>  This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. Proposal submitted on October 22nd for DHMH sign-off and publication. The anticipated publication date is December 28th.</p> <p><b><u>LEGISLATION:</u></b></p> <p>Anna Jeffers to attend two meetings in Annapolis on November 19<sup>th</sup>.</p> <p>1) Biosimilars: Meeting with Chairman Hammen and Gil Genn (NACDS), Aliyah Horton (MPhA), and other interested parties.</p> <p>2) Briefing - NC Board of Dental Examiners v. Federal Trade Commission</p> <p><b><u>OTHER MATTERS:</u></b></p> <p><b>The Board approved the following Annual Reports:</b></p> <p><b>The Prescription Drug Repository Program</b></p>		

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		<p><b><u>DRAFT RxDrugRepReport to GenAssembly 101615</u></b></p> <p><b>The Wholesale Distributor Prescription Drug and Integrity Act</b></p> <p><b><u>Draft Report WholesaleDist Program 101615</u></b></p>	<p>RxDrugRepReport Motion to approve by C. Rochester 2<sup>nd</sup> by B. Zagnit.</p>	<p>RxDrugRepReport The Board voted to approve this motion.</p>
<p><b>III. Committee Reports</b> <b>A. Practice Committee</b></p>	<p><b>D. Jones, Chair</b></p>	<p><b><u>Inquiries:</u></b></p> <p><b>1) Dr. Margaret Miklich, PGY-2 Ambulatory Care Pharmacy Resident, University of Maryland School of Pharmacy</b></p> <p><b><u>Collaborative Practice Scope 102715</u></b></p> <p><b><u>Draft Bd Response – DTM Scope – no prescriber</u></b></p> <p><b>The Board approved the following response:</b> Dear Dr. Miklich:</p> <p>Thank you for contacting the Maryland Board of Pharmacy concerning whether it is within the scope of a collaborative practice agreement in Maryland for a pharmacist to initiate drug therapy in patients who are not under the care of a specific physician/prescriber.</p> <p>A prescriber and a pharmacist who wish to enter into a therapy management contract are required to have a 1) prescriber-pharmacist agreement; 2) a disease state specific protocol; and 3) a therapy management contract signed by the prescriber, the pharmacist and the patient.</p>	<p>1) Motion to approve by J. Smith, 2<sup>nd</sup> by T. Robinson.</p>	<p>1) The Board voted to approve this motion.</p>

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		<p>The initiation of drug therapy in patients who are not under the care of a specific prescriber, does not meet the intent or the requirements of Drug Therapy Management as set forth in Health Occupations Article, Title 12, Subtitle 6A, Annotated Code of Maryland and COMAR 10.34.29.01 - .07.</p> <p><a href="http://mgaleg.maryland.gov/webmga/frmStatutesText.aspx?article=gho&amp;section=12-6A-01&amp;ext=html&amp;session=2016RS&amp;tab=subject5">http://mgaleg.maryland.gov/webmga/frmStatutesText.aspx?article=gho&amp;section=12-6A-01&amp;ext=html&amp;session=2016RS&amp;tab=subject5</a></p> <p><a href="http://www.dsd.state.md.us/COMAR/SubtitleSearch.aspx?search=10.34.29.*">http://www.dsd.state.md.us/COMAR/SubtitleSearch.aspx?search=10.34.29.*</a></p> <p><b>2) Veterinarian Association</b></p> <p><b><u>Veterinarian Association Letter</u></b></p> <p><b><u>Draft Bd Response – Veterinarian Association</u></b></p> <p><b>The Board approved the following response:</b> Dear Mr. Eaton:</p> <p>Thank you for contacting the Maryland Board of Pharmacy concerning the FDA proposed “Guidance for Industry-Compounding Animal Drugs from Bulks Drug Substances. The Board has received numerous letters of concern from Maryland veterinarians concerning the inability to obtain office use compounds of prescription drugs from pharmacies for animal use.</p>	<p>2) Motion to approve by T. Robinson, 2<sup>nd</sup> by D. Ashby</p>	<p>2) The Board voted to approve this motion.</p>

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		<p>Both Maryland and federal laws state that a pharmacist may only compound animal drugs pursuant to an order of a veterinarian based on a valid veterinarian-client-patient relationship. Pharmacists may not compound animal drugs for office use. See 21 CFR 530.13 and Health Occupations Article, 12-101(d), Annotated Code of Maryland. If a veterinarian is in need of a certain drug for office use inventory, she must purchase that drug from a licensed wholesale distributor. A pharmacy may compound an animal drug pursuant to a prescription for an identified patient, provided that the drug is not compounded from bulk substances and is otherwise in conformance with the requirements of 21 CFR 530.13.</p> <p>Having provided the current law, the Board, however, realizes that veterinarians are in a very difficult position since they cannot obtain necessary compounded prescription drugs for office use required for various species, breeds, body chemistry, and sizes of companion animals in emergency situations. The Board's understanding is that the types of compounded drugs at issue are not commercially available for animal use.</p> <p>Although federal law does not allow pharmacists to engage in animal drug compounding for office use, there appears to be sufficient safety concerns to warrant a change in Maryland law to allow it under certain circumstances. Should the Maryland</p>		

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		<p>Veterinarian Medical Association (MVMA) agree with the safety concerns posited by the veterinarians, the Board would not likely oppose legislation to amend the law in Maryland by adding an exemption to the definition of compounding in Health Occupations Article, 12-101(d), Annotated Code of Maryland, to permit office use compounding for companion animals. A contact at the MVMA is James Reed, DVM. The Board is also available to informally review and comment on proposed legislation to help identify potential conflicts with the intent of HO 12-101(d) as it pertains to human drug compounding.</p>		
<p><b>B. Licensing Committee</b></p>	<p><b>J. Smith, Chair</b></p>	<p><b>1. Review of Pharmacist Applications:</b></p> <p><b>a. S. Farrokh</b> – Reciprocity applicants are required to provide 520 hours of pharmacy experience after graduation. The applicant has worked since August 2013 as faculty at a pharmacy school. She says that she is an instructor that precepts pharmacy students and also works as a staff pharmacist on some weekends at a hospital. Does this suffice for the pharmacy experience?  <i>Licensing Committee's recommendation:</i> The 520 hrs. pharmacy experience must be performing actual pharmacist duties.</p> <p><b>b. D. Ranade</b> – Reciprocity applicants are required to provide 520 hours of</p>	<p>1a. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>1b. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p>	<p>1a. The Board voted to approve this motion.</p> <p>1b. The Board voted to approve this motion.</p>

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		<p>pharmacy experience after graduation. Applicant has been the president of Skyemed Pharmacy since May 1999. When asked, he explained that he does dispense and perform pharmacist duties within the pharmacy. It was requested that he document the approximate number of hours he has spent doing pharmacist duties and for detail in what those duties are.</p> <p><u>Licensing Committee's recommendation:</u> The 520 hrs pharmacy experience must be performing actual pharmacist duties.</p> <p>c. <b>S. Patel</b> – License expired in 1999 and is interested in reinstating. Is asking what additional requirements that he may need to meet before reinstating, and allow him to register for the MPJE in January 2016 even though he only forecasts that he'll have 900 of the required 1000 experience hours.</p> <p><u>Licensing Committee's recommendation:</u> Apply for intern registration, complete the 1000 required hours, and apply as a reinstatement applicant</p> <p>d. <b>S. Parsaee</b> – Applicant is a practicing pharmacist in Canada, requesting an exemption/reduction of required intern hours. She graduated “Doctor of Pharmacy” from Azad University in Tehran, Iran 1996.</p>	<p>1c. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>1d. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p>	<p>1c. The Board voted to approve this motion.</p> <p>1d. The Board voted to approve this motion.</p>

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		<p><u>Licensing Committee's recommendation:</u> Must apply as a foreign graduate</p> <p><b>2. Review of Pharmacy Intern Applications:</b></p> <p><b>a. M. Khair</b> – Foreign Grad Student is currently obtaining intern hours as a technician. Requesting to be allowed to earn her remaining intern hours (about 200) under her technician license because she has found it extremely difficult to find an intern position.</p> <p><u>Licensing Committee's recommendation:</u> Deny request to earn the remaining 200hrs as a technician. Must apply for intern registration.</p> <p><b>b. How long after graduation can someone apply for the intern registration?</b></p> <p><u>Licensing Committee's recommendation:</u> Can apply any time</p> <p><b>3. Review of Pharmacy Technician Applications:</b> <i>None</i></p> <p><b>4. Review of Distributor Applications:</b> <i>None</i></p> <p><b>5. Review of Pharmacy Applications:</b> <i>None</i></p> <p><b>6. Review of Pharmacy Technicians Training Programs:</b> <i>None</i></p>	<p>2a. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>2b. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p>	<p>2a. The Board voted to approve this motion.</p> <p>2b. The Board voted to approve this motion.</p>

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		<p><b>7. New Business:</b></p> <p>a. <b>Ohio Northern University Immunization Certification</b> – Seeking to become a Board approved immunization course. <i>Licensing Committee's recommendation:</i> Approve Immunization course.</p> <p>b. <b>Review of Resident Pharmacy Application</b> <i>Licensing Committee's recommendation:</i> Approve the amended application.</p> <p>c. <b>Review of Resident Waiver Pharmacy Application</b> <i>Licensing Committee's recommendation:</i> Approve the amended application.</p> <p>d. <b>Review of Non-Resident Pharmacy Application</b> <i>Licensing Committee's recommendation:</i> Approve the amended application.</p> <p>*Late Addition</p> <p>License #20318 licensee would like to be able to renew the license early due to being out of the country during the regular renewal time frame.</p>	<p>7a. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>7b. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>7c. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>7d. Motion by committee, 2<sup>nd</sup> by D. Ashby.</p> <p>Motion by committee to approve, 2<sup>nd</sup> by D. Ashby.</p>	<p>7a. The Board voted to approve this motion.</p> <p>7b. The board voted to approve this motion.</p> <p>7c. The Board voted to approve this motion.</p> <p>7d. The Board voted to approve this motion.</p> <p>The Board voted to approve this motion.</p>

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<b>C. Public Relations Committee</b>	<b>B. Zagnit, Chair</b>	<b>Public Relations Committee Update</b> January newsletter		
<b>D. Disciplinary</b>	<b>T. Robinson, Chair</b>	<b>Disciplinary Committee Update</b> <i>None at this time</i>		
<b>E. Emergency Preparedness Task Force</b>	<b>S. Roy, Chair</b>	<b>Emergency Preparedness Task Force Update</b> <b>Maryland Response Corps exercise</b>		
<b>IV. Other Business &amp; FYI</b>	<b>M. Gavvani, President</b>	<i>None at this time.</i>		
<b>V. Adjournment</b>	<b>M. Gavvani, President</b>	<p><b>D. Jones asked for a motion to close the Public Meeting and open a Closed Public Session at 11:03 AM.</b></p> <p><b>At 11:35 AM, D. Jones convened a Closed Public Session for the purpose of engaging in medical review committee deliberations regarding confidential information in applications in accordance with the Open Meetings Act, General Provisions Article, Section 3-305 (b) (7) and (13).</b></p> <p><b>The Closed Public Session was adjourned at 12:24 PM and immediately thereafter, D. Jones 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.</b></p>	Motion to close the Public Board Meeting by D. Ashby, 2 <sup>nd</sup> by J. Smith.	The Board voted to approve this motion.