

**Maryland Board of Pharmacy
Public Board Meeting**

**Meeting Minutes
January 20, 2016**

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

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"> 1. M. Gavgani called the meeting to order at 9:34 A.M. and requested Board Commissioners and staff members introduce themselves. 2. M. Gavgani reminded all guests to sign the guest log, indicating whether they would like continuing education credits. 3. M. Gavgani informed public attendees that the meeting agenda and packet materials were available for review. She advised guests that all packets must be returned at the end of the meeting. 4. Review and approval of December 2015 Public Meeting Minutes. 	<p>4. Motion by d. Ashby to approve December Public Meeting Minutes, 2nd by E. Yankellow.</p>	<p>4. The Board voted to approve this motion.</p>
II. A. Executive Director Report	R. Proctor, Acting Executive Director	<ol style="list-style-type: none"> 1. Operations Updates Financial Disclosure Filing BithGroup Report 2nd Quarter Financial Report 2. Meetings Update <i>D. Ashby</i> <i>American Society of Health Systems Pharmacists</i> 	<p>Introduction of the new Executive Director, Deena Speights-Napata, by D. Jones. Mrs. Speights-Napata official start date is February 3, 2016.</p>	

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B. Operations Report	S. Ennels, Deputy Director of Operations	<ol style="list-style-type: none"> 1. APS Unit Updates Lockbox Implementation Personnel Updates – <i>L. Waddell</i> 2. MIS Unit Updates – J. Johnson Website Updates Online Pharmacy Renewal 3. Data Integrity Unit Updates 																																					
C. Licensing	Y. Wu, Compliance Manager	<ol style="list-style-type: none"> 1. Unit Updates 2. Monthly Statistics <table border="1" data-bbox="621 691 1249 1323"> <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>15</td> <td>0</td> <td>1047</td> </tr> <tr> <td>Pharmacy</td> <td>49</td> <td>2</td> <td>0</td> <td>2067</td> </tr> <tr> <td>Pharmacist</td> <td>64</td> <td>408</td> <td>0</td> <td>10907</td> </tr> <tr> <td>Vaccination</td> <td>17</td> <td>39</td> <td>0</td> <td>4119</td> </tr> <tr> <td>Pharmacy Intern - Graduates</td> <td>1</td> <td>0</td> <td>0</td> <td>27</td> </tr> <tr> <td>Pharmacy Intern - Students</td> <td>54</td> <td>0</td> <td>0</td> <td>498</td> </tr> </tbody> </table>	License Type	New	Renewed	Reinstated	Total	Distributor	24	15	0	1047	Pharmacy	49	2	0	2067	Pharmacist	64	408	0	10907	Vaccination	17	39	0	4119	Pharmacy Intern - Graduates	1	0	0	27	Pharmacy Intern - Students	54	0	0	498		
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		Pharmacy Technician	129	307	1	9159			
D. Compliance	Y. Wu, Compliance Manager	<p>1. Unit Updates</p> <p>2. Monthly Statistics</p> <p>Complaints & Investigations:</p> <p>New Complaints - 32 Resolved (Including Carryover) – 17 Final disciplinary actions taken – 7 Reversals – 0 Summary Actions Taken – 1</p> <p>Inspections:</p> <p>Total - 159 Annual Inspections - 116 Opening Inspections - 2 Closing Inspections - 2 Relocation Inspections - 1 Board Special Investigation Inspections – 2 Division of Drug Control Closing Inspections – 6</p> <p><i>PEAC Update</i></p> <p><i>The PEAC report for the month of December was not received.</i></p> <p>Total Pharmacist Rehabilitation Clients – Pharmacist – NA Technician – NA Pharmacy Student – NA Clients Monitored by Board Req. PEAC Assistance</p>							

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		<p>- NA</p> <p>Drug Test Results - Number of Positive Results- NA</p> <p>Discharged Clients/Closed Cases- NA</p>		
<p>E. Legislation & Regulations</p>	<p>A. Jeffers, Legislation & Regulations Manager</p>	<p><u>REGULATIONS:</u></p> <p><u>Status Update:</u> <u>10.34.10 Pharmacist, Pharmacy Intern and Pharmacy Technician Code of Conduct</u> The chapter was revised pursuant to Board recommendation. Published November 13th. No comments received. Notice of Final Action to be published January 22nd with an Effective Date of February 1st.</p> <p><u>Status Update:</u> <u>10.34.19 Sterile Pharmaceutical Compounding</u> This chapter was revised pursuant to 2015 Legislation. Published November 13th. Two comments received and responded to on December 22nd. Notice of Final Action to be published January 22nd with an Effective Date of February 1st.</p> <p><u>10.34.29 Drug Therapy Management</u> This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. Published November 13, 2015. Three comments have been received and Practice recommends the following responses:</p> <p><u>Bd of Pharm - MD Academy of Phy Assistants</u></p> <p><u>UM School of Pharm board of pharmacy letter pdf</u></p>	<p><u>10.34.29</u> Motion to approve by D. Ashby, 2nd by C. Rochester that the letter will be revised and approval deferred to Practice Committee.</p>	<p><u>10.34.29</u> The Board voted to approve this motion.</p>

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		<p><u>NACDS Comments Drug Therapy Management proposed rule dec 15 2015</u> Copied on the other responses.</p> <p>The Board approved the following responses:</p> <p><u>DRAFT Bd Response to comment - 10.34.29 MdAcadPA</u></p> <p>Theresa Neumann, PA-C, Director of Legislative Affairs Maryland Academy of Physician Assistants Legislative@mdapa.org</p> <p>Dear Ms. Neumann, PA:</p> <p>Thank you for submitting a comment concerning the proposed Code of Maryland Regulations (COMAR) 10.34.29 Drug Therapy Management, as published in 42:23 Md. R. 1456 - 1458 (November 13, 2015).</p> <p>The Maryland Academy of Physician Assistants recommended in its comment to the Board that the Department of Health and Mental Hygiene (DHMH) add “physician assistant with prescriptive authority” to the proposed regulations as an “authorized prescriber” and also wherever “certified advanced practice nurse with prescriptive authority” appears.</p> <p>The Board or DHMH may not add other prescribers to the proposed regulations as the statute limits “authorized prescribers” to licensed</p>		

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		<p>physicians, licensed podiatrists and certified advanced practice nurses with prescriptive authority. In order to add “physician assistants with prescription authority” the law would have to be revised.</p> <p>See Health Occupations Article, 12-6A-01, Annotated Code of Maryland: http://mgaleg.maryland.gov/webmga/frmStatutesText.aspx?article=gho&section=12-6A-01&ext=html&session=2016RS&tab=subject5</p> <p>The Board would like to thank you again for your thorough reading of, and comment to, the proposed COMAR 10.34.29 Drug Therapy Management. The Board considered your comment at the January 20, 2016 Board Meeting and voted to adopt the regulations as proposed.</p> <p><u>DRAFT Bd Response to comment - 10.34.29 UMSoPharmacy</u></p> <p>Jill A. Morgan, PharmD, BCPS, BCPPS, Chair Department of Pharmacy Practice and Science University of Maryland School of Pharmacy 20 N. Pine Street, Room S445 Baltimore, MD 21201 jmorgan@rx.umaryland.edu</p> <p>Dear Dr. Morgan:</p> <p>Thank you for submitting a comment concerning the proposed Code of Maryland Regulations</p>		

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		<p>(COMAR) 10.34.29 Drug Therapy Management, as published in 42:23 Md. R. 1456 - 1458 (November 13, 2015).</p> <p>1. Protocols by a physician and a pharmacist – initiation of therapy 10.34.29.02B(4). You asked for clarification whether the intention of COMAR 10.34.29.02B(4) is that disease states would also include conditions. It does. Your interpretation that the initiation of therapy may occur under written, “disease state or condition” specific protocols is correct.</p> <p>The definition of “Condition” in 10.34.29.01B(4) includes “a disease-state or health circumstance necessitating monitoring or intervention.” See the existing text in COMAR 10.34.29.01B(4): http://www.dsd.state.md.us/comar/comarhtml/10/10.34.29.01.htm</p> <p>2. Consent of Prescriber – Pharmacist Agreement 10.34.29.03A(1)</p> <p>You asked if your assumption was correct that, if necessary, a hospital may develop policies and procedures to address who may sign on behalf of authorized prescribers allowing a unit director or chief of service with authority over that specific area to sign on behalf of authorized prescribers.</p> <p>For the Physician-Pharmacist Agreement referenced in 10.34.29.03, the hospital may develop its own policies and procedures to address</p>		

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		<p>who may sign on behalf of the authorized prescribers. It would behoove the hospital to have the hospitals internal risk management team review this policy.</p> <p>For the Therapy Management Contract referenced in 10.34.29.06, the authorized prescriber, pharmacist, and patient are still required to individually sign.</p> <p>The Board would like to thank you again for your thorough reading of, and comment to, the proposed COMAR 10.34.29 Drug Therapy Management. The Board considered your comment at the January 20, 2016 Board Meeting and voted to adopt the regulations as proposed.</p> <p>The Board deferred the revision of the DTM forms after Ms. Jeffers and Ms. Page reviewed them. Major revisions will go before the Board in the future.</p> <p><u>Status Update:</u> <u>10.34.33 Prescription Drug Repository Program</u> This chapter was revised pursuant to Federal law and regulations. Published December 28, 2015.</p> <p><u>Status Update:</u> <u>10.34.39 Pharmacist Administration of Self-Administered Drugs</u></p>		

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		<p>This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. Published December 28, 2015.</p> <p><u>Regulatory Review and Evaluation Act</u></p> <p>Board approval requested for the RREAct Work plan.</p> <p><u>10.34.02,04,16,24,26,27,31 WORK PLAN</u></p> <p>The Board approved the above Regulatory Review and Evaluation Act Work Plan.</p> <p><u>Expedited Partner Therapy Regulations</u></p> <p><u>Update on Expedited Partner Therapy regulations</u></p> <p>In depth discussion for the January 27th Practice Committee.</p> <p><u>LEGISLATION:</u></p> <p>1) Any newly introduced bills with hearings after January 22nd will be distributed by email before the Board Meeting. This information will be available on January 14th.</p> <p>HB 6 Criminal Law - Improper Prescription of Controlled Dangerous Substance Resulting in Death Board ratified a Letter of Concern.</p> <p>HB 56/SB 63 Investigational Drugs, Biological Products, and Devices - Right to Try Act Board ratified No Position</p>	<p>Motion to approve work plane by D. Jones.</p>	<p>The Board voted to approve this motion.</p>

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		<p>2) MGA Tracking: For Tracking list: Board of Pharmacy To be distributed at the Board Meeting as an update.</p> <p>3) Update on End of Life Option Act</p> <p>The Practice Committee suggestion for "immediate cause of death" on death certificates is "Accelerated Natural Death at End of Life (ANDEL)," which avoids using words related to pharmacy. (was Pharmacologically Accelerated Imminent Natural Death)</p> <p>FYI - Apparently Del Pendergrass may want to strike the language about the death certificate from the bill. The states that have enacted Death with Dignity bills have not prescribed in statute how the death certificate is to be filled out.</p> <p><u>OTHER MATTERS:</u> Anna Jeffers will be speaking at Elizabeth Seton High School on Feb. 1st regarding the law and regulations for pharmacy technicians.</p>	<p>3) Motion from committee to ratify letter of concern, 2nd by D. Jones</p>	<p>3) The Board voted to approve this motion.</p>
<p>III. Committee Reports A. Practice Committee</p>	<p>D. Jones, Chair</p>	<p><i>No Report.</i></p> <p><i>The Practice Committee has not met since the December Board Meeting. Next Practice Committee Meeting is January 27th.</i></p>		

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B. Licensing Committee	J. Smith, Chair	<p><i>This section was presented by S. Roy, in the absence of J. smith.</i></p> <p>1. Review of Pharmacist Applications:</p> <p>a. D. Cines – Pharmacist is requesting refund of reinstatement fee alleging that he did not receive the renewal notice. <u>Licensing Committee's recommendation:</u> Deny the request for the refund of the reinstatement fee.</p> <p>b. M. Leong – Applicant currently on Optional Practical Training (OPT) in AZ and would like to know if the Board could license her. She has an F-1 Visa and I-20. <u>Licensing Committee's recommendation:</u> Approve applicant for submission of pharmacist application.</p> <p>c. M. Sulman – Applicant graduated from pharmacy school in Pakistan, a non-ACPE accredited school and has a pharmacist license in NY and OR. Is requesting an FPGEC waiver for the reciprocity application. <u>Licensing Committee's recommendation:</u> Deny request to waive FPGEC.</p> <p>2. Review of Pharmacy Intern Applications: <i>NONE</i></p>	<p>1a Motion by committee to deny applicant's request, 2nd by D. Jones.</p> <p>1b Motion by committee to approve application, 2nd by C. Rochester.</p> <p>1c Motion by committee to deny applicant's request, 2nd by D. Ashby.</p>	<p>1a The Board voted to approved this motion.</p> <p>1b The Board voted to approve this motion.</p> <p>1c The Board voted to approve this motion.</p>

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		<p>3. Review of Pharmacy Technician Applications:</p> <p>a. M. Boamah – Registrant was issued a registration on 11/10/2010, however, upon the 2015 renewal, it was noticed that SSN was not provided but registrant has an ITIN. <i>Licensing Committee's recommendation:</i> Approve renewal registration using ITIN</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications:</p> <p>a. Pharmedium Services LLC. (in NJ)– Facility submitted relocation application and wrote “FDA Outsourcing Facility” under “Other” for “Check all Applicable Descriptions of the Pharmacy” and was approved at the December 16, 2015 Board. However, subsequent to the Board meeting, information was received indicating that the facility:</p> <p>a. Compounds sterile products and ship only non-patient specific products to hospital pharmacies and outpatient centers. <i>Licensing Committee's recommendations:</i> Facility has 60 days to apply for distributor permit (short form) & once this permit is issued, to return the pharmacy permit for close out. BOP will credit \$700 relocation</p>	<p>3a Motion by committee to approve registration, 2nd by D. Ashby.</p> <p>5a Motion by committee to allow applicant to apply for the proper permit, 2nd by D. Ashby.</p>	<p>3a The Board voted to approve this motion.</p> <p>5a The Board voted to approve this motion.</p>

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		<p>fee towards the distributor application fee.</p> <p>6. Review of Pharmacy Technicians Training Programs: <i>NONE</i></p> <p>7. New Business:</p> <p>a. Dispensary of Hope (Steve Hudson) – Charitable Distributor in TN is seeking advice as to whether they are required to be licensed as a WSD, if so how? TN is a non-reciprocal state and VAWD does not license charitable organizations. <u>Licensing Committee's recommendations:</u> No recommendations (find out if facility is located in a residence). <u>Findings:</u> facility is located in a commercial park and is zoned commercial.</p>	<p>7a Motion by committee to allow the Dispensary of Hope to apply for a distributor permit, 2nd by D. Jones.</p>	<p>7a The Board voted to approve this motion.</p>

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C. Public Relations Committee	B. Zagnit, Chair	Public Relations Committee Update Newsletter Update: Publication anticipated in April	Articles for the upcoming newsletter should be submitted as quickly as possible, with a target date by the end of March.	
D. Disciplinary	T. Robinson, Chair	Disciplinary Committee Update <i>None at this time</i>		
E. Emergency Preparedness Task Force	S. Roy, Chair	Emergency Preparedness Task Force Update Several POD exercises are planned for the spring. Emergency exercises will be held in 2017.		
IV. Other Business & FYI	M. Gavvani, President	English Proficiency Bill introduced on 01/20/16.		
V. Adjournment	M. Gavvani, President	M. Gavvani asked for a motion to close the Public Meeting and open a Closed Public Session at 10:39 AM. for the purpose of engaging in medical review committee deliberations regarding confidential	Motion to close the January Public Meeting by C. Rochester, 2 nd by D. Jones.	The Board voted to approve this motion.

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		<p>information in applications in accordance with the Open Meetings Act, General Provisions Article, Section3-305 (b) (7) and (13).</p> <p>At 11:02 AM, M. Gavgani 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, Section3-305 (b) (7) and (13).</p> <p>The Closed Public Session was adjourned at 1:10 PM. Immediately thereafter, M. Gavgani 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>		