

**Maryland Board of Pharmacy
Public Board Meeting**

Meeting Minutes
Date: March 16, 2016

Name	Title	Present	Absent	Present	Absent
Board Committee					
Ashby, D.	Commissioner		X	2	1
Bouyoukas, S.	Commissioner	X		3	
Gavgani, M. Z.	Commissioner/President	X		2	1
Jones, David H.	Commissioner/Secretary	X		3	
Peters, R.	Commissioner		X	2	1
Robinson, T.	Commissioner	X		2	1
Rochester, C.	Commissioner		X	2	1
Roy, S.	Commissioner	X		3	
Smith, J.	Commissioner/Treasurer	X		3	
St. Cyr, II, Z. W.	Commissioner	X		3	
Yankellow, E.	Commissioner		X	2	1
Zagnit, B.	Commissioner	X		3	
Board Counsel					
Bethman, L.	Board Counsel	X			
Felter, B.	Staff Attorney		X		
Board Staff					
Speights-Napata, D.	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	X			
Neville, K	Legislation/Regulations Liaison	X			
Johnson, J.	MIS Manager	X			

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results										
		<p>Reviewed NABP notification regarding MPJE changes</p> <p>2. Meetings Update</p> <p>NABP 2016 Annual Conference NABP Correspondence</p>												
B. Operations Report	S. Ennels, Deputy Director of Operations	<p>1. APS Unit Updates</p> <p>Fiscal Audit updates Anticipated “go live” date for the new lockbox process to begin is 03/28. It will be a soft implementation. Stephanie prepared an article for the newsletter, training has been held for staff and administrators, and testing will be done on 03/18 for a small batch of incoming mail.</p> <p>Personnel updates- <i>L. Waddell</i></p> <p>2. Data Integrity Unit Updates</p> <p>3. MIS Unit Updates- <i>J. Johnson</i></p> <p>Online pharmacy renewals began 03/16. TORFP will be developed for the new licensing system. Business Analyst, J. Towles will be returning for a second 6 month contract.</p>												
C. Licensing	Y. Wu, Compliance Manager	<p>1. Unit Updates</p> <p>2. Monthly Statistics</p> <table border="1"> <tr> <td>License Type</td><td>New</td><td>Renewed</td><td>Reinstated</td><td>Total</td></tr> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td></tr> </table>	License Type	New	Renewed	Reinstated	Total							
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			Distributor	10	19	0	1066	
			Pharmacy	20	1	0	2089	
			Pharmacist	30	375	0	10909	
			Vaccination	16	55	0	4166	
			Pharmacy Intern - Graduates	3	0	0	32	
			Pharmacy Intern - Students	36	0	0	583	
			Pharmacy Technician	78	322	2	9195	
D. Compliance	Y. Wu, Compliance Manager	1. Unit Updates Nothing to note 2. Monthly Statistics Complaints & Investigations: New Complaints - 38 Resolved (Including Carryover) – 21 Final disciplinary actions taken – 0 Reversals – 0 Summary Actions Taken – 2						

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		<p>Inspections:</p> <p>Total - 150 Annual Inspections - 136 Opening Inspections - 8 Closing Inspections - 1 Relocation Inspections - 2 Board Special Investigation Inspections – 3 Division of Drug Control Closing Inspections – 1</p>		
E. Legislation & Regulations	K. Neville	<p><u>Legislation</u></p> <p>SB 1083</p> <p><i>Presented by Kristen Neville</i></p> <p>PDMP There has been discussion on the bill but no decision at this point.</p> <p>Open Meetings Act No decisions have been made at this point.</p> <p>HB56 Withdrawn from the House, Senate bill has not been withdrawn.</p> <p>Right to Die Act Bill has been withdrawn from the Senate, House bill still active.</p> <p>HB 1632 Bill was voted unfavorable by the Judiciary committee, the Senate bill is still alive.</p>		

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		<p>Naturopathic Formulary This bill has passed by Senate and crossed over to the House for a hearing.</p> <p>English Oral Competency The final amendments have been made, a hearing has not yet been scheduled.</p> <p>HB 1418 A position paper has been drafted by K. Neville. Motion from committee to ratify letter, 2nd by J Smith, approved</p> <p>HB 752 A hearing will be scheduled for the House version of this bill.</p> <p>Vet compounding amendments, new draft updated Board concerns about conflict with existing federal law (FDA). Proposed amendments have contradictions. The bill may need to be rewritten to avoid the contradictions and be more specific.</p>	<p>HB 1418 Motion to ratify position paper, 2nd by J. Smith.</p>	<p>HB 1418 The Board voted to approve this motion.</p>
<p>III. Committee Reports A. Practice Committee</p>	<p>D. Jones, Chair</p>	<p>Legislation Review</p> <ul style="list-style-type: none"> 10.34.33 Prescription Drug Repository Program <p>Comments received and responses approved at Feb. 17th Board Meeting.</p> <p>Newsletter summary to be published.</p>		

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		<ul style="list-style-type: none"> 10.34.37 Chapter 37 Pharmacy Permit Holder: <i>Requirements — Wholesale Distribution and Non-Resident Pharmacy Operations</i> <p>Released for Informal Comment</p> <ul style="list-style-type: none"> 10.34.39 Pharmacist Administration of Self-Administered Drugs <p>Published December 28th. Board approved response to the only comment Feb. 17, 2016. Sent to Michele Phinney 2/19/16.</p> <p>Review of other regulations</p> <ul style="list-style-type: none"> <u>Regulatory Review and Evaluation</u> <u>Act: 10.34.02, .04, .16, .24, .26, .27, and .31</u> <p>Work Plan approved by the Board on 012016. Submitted</p> <p>Returning Questions to the Committee:</p> <p>Daniel F. Luce, Walgreens regarding a “Remote AMS”. The inquiry presents a description of a remote automated medication system pursuant to COMAR 10.34.28 to be deployed in the ED of GBMC.</p> <p>Response: This is not a remote system. GBMC has a pharmacy on site. Remote is for facilities that do not have a pharmacy. The definition does not allow this. There are many ways to do this by GBMC – dispensing docs in ER for example. DEA won’t allow CDS in a machine unless registered as a DEA facility.</p> <p>New Questions to the Committee:</p>	<p>Letter will be written by L. Bethman. S. Bouyoukas recused.</p>	

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		<ul style="list-style-type: none"> <div data-bbox="619 261 667 293" style="background-color: #cccccc; width: 20px; height: 15px; display: inline-block; margin-right: 5px;"></div> Mollie Roark, University of Illinois College of Pharmacy at Rockford. Looking for information on distributing an investigational drug that is IND exempt to Maryland. <p>Response: We do not regulate the distribution of IND drugs under an IRB. We only regulate the distribution of prescription drugs. The IRB does define the chain of custody. Patient-specific requirement may not be applicable if double-blinded.</p> <ul style="list-style-type: none"> Sean Brennan PhD, VP, Regulatory Affairs, UPM Pharmaceuticals. UPM Pharmaceuticals is a drug contract manufacturing and development organization in Bristol Tennessee that produces finished drug products for other pharmaceutical companies. Is UPM required to register with the Maryland Board of Pharmacy? <p>Response: Yes – they need to have a wholesale distributor permit. It's NOT the short form.</p> <ul style="list-style-type: none"> Lanham, Mary Lynn. Transitional Care Center-part of the Hospital and is outpatient-opened a month ago. Can they dispense from main pharmacy to Transitional Care Center - 	<p>Response will be reviewed by Practice Committee with new information provided by Y. Wu from an email sent by UPM Pharmaceuticals.</p>	

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		<p>what are their limitations - more than 72 hour supply?</p> <p>Response: If full service – no problem. If a waiver – need to become a full services.</p> <p>Committee/ Work Group Updates</p> <ul style="list-style-type: none"> Working Conditions Survey <p>A Newsletter article has been drafted, reviewed, and submitted for publication. A copy will be provided separately.</p>	Response will be reviewed further with new information provided by Y. Wu from an email sent by M. Lanham.	
B. Licensing Committee	J. Smith, Chair	<p>1. Review of Pharmacist Applications:</p> <p>a. S. Essuman – Applicant is requesting to take the NAPLEX. He has failed the NAPLEX a few times. <u>Licensing Committee's recommendations:</u> May retake the NAPLEX.</p> <p>2. Review of Pharmacy Intern Applications: <i>NONE</i></p> <p>3. Review of Pharmacy Technician Applications: <i>NONE</i></p> <p>4. Review of Distributor Applications:</p> <p>a. Intersurgical Inc. (K. Etori) – Permit holder is requesting the Board to pro-rate the relocation fee as the company moved around December 2015 and the renewal fee is not until 2017.</p>	<p>1a. Motion to approve by committee, 2nd by T. Robinson.</p> <p>4a. Motion by committee to deny, 2nd by T. Robinson.</p>	<p>1a. The Board voted to approve this motion.</p> <p>4a. The Board voted to approve this motion.</p>

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		<p><u>Licensing Committee's recommendations:</u> Deny the request. Must submit fee.</p> <p>5. Review of Pharmacy Applications:</p> <p>a. F. Zaidi - Pharmacist would like to open a pharmacy inside an office building (Suite G) where her husband's medical practice (Suite E) is located</p> <p><u>Licensing Committee's recommendations:</u> May open a pharmacy in the same building as her husband and must abide by Maryland Pharmacy Regulations including HO 12-313(b)(14) and HO 14-404(a)(30).</p> <p>6. Review of Pharmacy Technicians Training Programs: NONE</p> <p>7. New Business:</p> <p>a. First Year Pharmacy Students Pharmacy Intern – First year Pharmacy Students are being offered position of the summer and have not actually completed their first year of school but will before they begin. Logistically, the Board does not let them apply. How can this be handled? 1st year Students in MD finish on 06/17/16 (UMES), 05/13/16 (UMD), and 05/10/16 (Notre Dame); in other</p>	<p>5a. Motion by committee to approve, 2nd by B. Zagnit.</p> <p>7a. Motion by committee, 2nd by B. Zagnit.</p>	<p>5a. The Board voted to approve this motion.</p> <p>7a. The Board voted to approve this motion.</p>

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		<p>states the range is between mid-April to mid-August.</p> <p><u>Licensing Committee's Recommendations:</u></p> <ul style="list-style-type: none"> • 1st year students should obtain a technician registration to be enrolled in a technician training program • Can accept applications anytime, however, should not be processed until May 15. • On the Pharmacy School Enrollment Affidavit, have the school write the last day that students finish 1st year <p>b. University of Kentucky College of Pharmacy Immunization training program – Applicant C. McDonald is requesting approval for the Vaccine Certification Course received at the University of Kentucky.</p> <p><u>Licensing Committee's Recommendations:</u> Approve immunization training program from University of Kentucky.</p>	<p>7b. Motion by committee to approve, 2nd by S. Bouyoukas.</p>	<p>7b. The Board voted to approve this motion.</p>
C. Public Relations Committee	B. Zagnit, Chair	<p>Public Relations Committee Update</p> <p>The latest edition of the Newsletter is set to be printed.</p>	<p>S. Roy suggests that the Newsletter be sent to NABP for publication on their website.</p>	
D. Disciplinary	T. Robinson, Chair	<p>Disciplinary Committee Update</p> <p><i>None at this time</i></p>		

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E. Emergency Preparedness Task Force	S. Roy, Chair	<p>Emergency Preparedness Task Force Update</p> <p>The funds granted from the Board of Pharmacy to the Office of Preparedness and Response have been used.</p> <p>The Office of Preparedness and Response does not have a stockpile of medication available for an actual disaster. The Rx warehouse is nearly empty.</p> <p>An emergency exercise drill will be held in April.</p>	Motion by S. Roy to resend the letter sent previously to the Governor's Office requesting funds be made available for a medication stockpile, 2 nd by D Jones.	The Board voted to approve this motion.
IV. Other Business & FYI	M. Gavgani, President			
V. Adjournment	M. Gavgani, President	<p>M. Gavgani asked for a motion to close the Public Meeting at 11:01 AM and open 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>At 11:15 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 12:05 AM and 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>	Motion by J. Smith to close March Public Board Meeting, 2 nd by D. Jones.	The Board voted to approve this motion.