Maryland Board of Pharmacy Public Board Meeting Minutes

Date: July 17, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	Commissioner		✓	0	1
Chason, D.	Commissioner	✓		1	0
Finke, H.	Commissioner/Secretary	✓		1	0
Gavgani, M. Z.	Commissioner/Treasurer	✓		1	0
Israbian-Jamgochian, L.	Commissioner/President	✓		1	0
Jones, David H.	Commissioner	✓		1	0
Smith, J.	Commissioner		✓	0	1
Souranis, M.	Commissioner	✓		1	0
St. Cyr, II, Z. W.	Commissioner	✓		1	0
Taylor, R.	Commissioner	✓		1	0
Board Counsel					
Bethman, L.	Board Counsel	✓		1	0
Felter, B.	Staff Attorney	✓		1	0
Board Staff					
Naesea, L.	Executive Director	✓		1	0
Wu, Y.	Compliance Manager	✓		0	1
Waddell, L.	Licensing Manager	✓		1	0
Gaither, P.	Administration and Public Support	✓		1	0
	Manager				
Jeffers, A.	Legislation/Regulations Manager	✓		1	0
Johnson, J	MIS Manager	✓		1	0

Subject	Responsible	D: .	Action Due Date	Results
	Party	Discussion	(Assigned To)	
I. Executive	A. L. Israbian-	Members of the Board with a conflict of interest relating to any		
Committee	Jamgochian,	item on the agenda are advised to notify the Board at this time or		
Report(s)	Board	when the issue is addressed in the agenda.		
	President			
		1. L. Israbian-Jamgochian called the Public Meeting to order		
		at 9:40 a.m.		
		2. L. Israbian-Jamgochian requested all meeting attendees to		
		introduce themselves, to sign the guest log and to indicate		
		whether they would like continuing education credits.		
		3. Members of the Board with any conflict of interests		
		relating to any item on the agenda were advised to notify		
		the Board.		
		the Board.		
		4. L. Israbian-Jamgochian reported that all handouts were to		
		be returned by attendees when they leave the meeting.		
		To returned by antenders when they read the meeting.		
		5. Review and approval of June 19, 2013 public board	Motion by R.	Motion was approved.
		meeting minutes. Approval of June 19, 2013 public board	Taylor to approve	
		meeting minutes were approved as submitted.	the June 19, 2013,	
			public board	
			meeting minutes	
			as presented.	
			Motion was	
			seconded by M.	
			Souranis.	
II. Executive	A. Executive	1. Operations Updates –		
Director's Report	Director, L.	Michael Baier, Coordinator of the Prescription Drug		
	Naesea	Monitoring Program (PDMP) presented a PowerPoint		
		presentation which highlighted the issues which concern		
		both Maryland and the entire US concerning prescription		
		drug overdose, misused and what the objectives of the		
		PDMP are. A copy of the PowerPoint presentation is		

Party Discussion (Assigned To) attached to these minutes and incorporated herein and marked as Attachment No. 1. 2. Meeting Updates -	Subject	Responsible		Action Due Date	Results
attached to these minutes and incorporated herein and marked as Attachment No. 1.		Party	Discussion	(Assigned To)	
marked as Attachment No. 1.			attached to these minutes and incorporated herein and		
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2. Meeting Updates -					
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2	Party	Discussion	(Assigned To)	
B. Administration & Public Support	Administration & Public Support Manager, P. Gaither	 Personnel Updates Recruitment has begun for the Licensing Secretary position, the Board has received the freeze exemption and recruitment closes on June 27, 2013, after which interviews will begin. The Pharmacist III position (50% Inspector Position) applications have been received and have been forwarded to the Board's Compliance Manager, YuZon Wu, for review. Kerrie Weigley pharmacy technician inspector began employment on June 3, 2013. Paperwork has been filed to get 5 temporary employees to assist with scanning project and other office duties, as assigned, and the Board is waiting for final approval. Contracts and Procurement PEAC and State archives contracts has been completed, effective 07/01/2013. Contract for scanning project is still in process. 	(Abbigned 16)	
C. Management Information Systems	MIS Manager, John Johnson	J. Johnson informed the Board of configuration changes in MyLicenseOffice to reflect change of pharmacist renewal fee based on new Healthcare Commission fees and change of password for secured website.		
D. Licensing	L. Waddell, Licensing Manager	Monthly Statistics for June, 2013. Pharmacists: New Applications – 70 Renewals – 373 Total Licensed – 9470 Pharmacists Administer Vaccinations: New Applications – 30 Renewals – 0 Total Certified - 3158 Technicians:		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
	Party	 New Applications – 70 Renewals – 253 Total Registered –8639 Student Technicians New Applications – 51 Renewals – 0 Total Registered – 757 Pharmacies: New Applications – 48 Renewals – 0 Total Pharmacies- 1905 Distributors: New Applications – 23 Renewals – 194 Total – 1065 	(Assigned To)	
E. Compliance	C. Jackson, Compliance Secretary	1. Monthly Statistics for June, 2013 Complaints & Investigations: New Complaints- 19 Resolved (Including Carryover) – 37 Final disciplinary actions taken – 4 Reversal – 0 Summary Actions Taken – 1 Inspections: 102 Annual Inspections- 92 Opening Inspections- 5 Closing Inspections - 0 Relocation Inspections- 2 Board Special Investigation Inspections – 3		

	Party Gil Cohen, PEAC	Discussion Total Pharmacist Rehabilitation Committee Clients – 18 Pharmacist Clients – 17	(Assigned To)	
		 Technician Clients – 0 Pharmacy Student Clients – 0 Clients Monitored by Board Req. PEAC Assistance – 1 Drug Testing Results – 27 Number of Positive Results – 1 (Client with neck surgery prescribed benzodiazepines and opioids). 		
Regulations I	A. Jeffers, Legislation & Regulations Manager	REGULATIONS: 10.34.03 – Inpatient Institutional Pharmacies Published June 28, 2013. Comments will be considered at the August 28, 2013 Practice Committee Meeting. 10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder. Effective July 8, 2013. 10.34.19 Sterile Pharmaceutical Compounding (Emergency) Board approved draft revisions at May 15, 2013 Board Meeting. Revised proposal sent to the Secretary for initial comment May 23, 2013. Secretary attended June 19, 2013 Board Meeting. Public Notice for initial comments posted July 11, 2013. Comments to be reviewed at the July 30, 2013 Sterile Compounding Subcommittee Meeting. 10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors (Emergency) 2013 May NACDS Cmts Wholesaler Background Checks		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
	Faity	Board approval requested for:	(Assigned 10)	
		Board approval requested for.		
		Draft Bd Response – NACDS – 10.34.22 Comment from	Motioned by M.	Motion was approved
		041913 Publication	Gavgani to	
			approve the Board	
		The Board approved the following response to NACDS:	response to	
		Thenk you for submitting a comment concerning the proposed Code of	NACDS. Motion	
		Thank you for submitting a comment concerning the proposed Code of Maryland Regulations (COMAR) 10.34.22 Licensing of Wholesale	was seconded by D. Jones.	
		Prescription Drug or Device Distributors, as published in 40:8 Md. R.	D. Jones.	
		742 - 745 (April 19, 2013). Below you will find the Board's response to		
		your concerns.		
		The Board agrees with the National Association of Chain Drug Stores		
		(NACDS) that the practices for dissemination of criminal background		
		check reports varies among the states and realizes that it may not be possible for out-of-state applicants to follow the process for submitting		
		criminal background check results as set forth in the April 19, 2013		
		published proposal. Therefore, the Board will revise the proposal as		
		follows:		
		B-1. Criminal Background Check Requirements		
		for an Applicant Located Outside this State.		
		(1) The Board shall require the designated		
		representative and the immediate supervisor of the		
		designated representative at the applicant's place of		
		business as part of the application for a permit to		
		submit to a criminal history records check by the		
		applicant's state of residence, in accordance with		
		the laws of the applicant's state of residence.		
		(2) The criminal history records check shall		
		consist of:		
		(a) A state criminal history records check for the applicant's state of residence; and		
		(b) A national criminal history records check.		
		(3) The designated representative and the		
		(5) The designated representative and the		l

Subject	Responsible		Action Due Date	Results
	Party	Discussion	(Assigned To)	
		immediate supervisor of the designated representative of an applicant shall request the appropriate entity in the applicant's state of residence to forward the results of the criminal history records check to the Board and the applicant. (4) If the appropriate entity in the applicant's state of residence is unable to forward the results of the criminal history records check, then the designated representative and the immediate supervisor of the designated representative of an applicant shall ensure that the results of the criminal history records check are forwarded to the Board in a manner approved by the Board.		
		Board approval requested for: Proposed 10.34.22 - Wholesale Distribution - July 17th Bd Mtg	Motioned by M. Gavgani to	Motion was approved.
		The Board approved submitting the proposal for COMAR 10.34.22,	approve submitting proposal for COMAR	
		10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities Published May 31, 2013. 30 day comment period to follow. No Comments. Notice of Final Action forthcoming.	10.34.22. Motion was seconded by D. Jones.	
		10.34.32 Pharmacist Administration of Vaccinations Meeting scheduled for July 16 th with Infectious Disease Program.		
		Protocol criteria to be discussed at the July 24, 2013 Practice Committee Meeting.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		 10.34.33 Prescription Drug Repository Program Proposal submitted May 22, 2013. In the DHMH sign-off process. Revisions to comply with federal law and regulations to be considered at the July Practice Committee Meeting. 10.13.01 Dispensing of Prescription Drugs by a Licensee Meeting with Dr. Herrera scheduled for July 29th at the Board Offices. 		
		LEGISLATION: 1) Consumer Board Members Board approval requested for: Draft Bill - Bd of Pharm - Consumer Bd Members 070213		
		Anna Jeffers presented two versions of the draft bill. One that allowed any member of the Board to run for election as a Board Officer. This is consistent with the other Health Occupation Boards. The other draft allowed any member of the Board to run for election of a Board Officer, except for Board President. Ms. Jeffers indicated that MPhA preferred the second version as have some members of the Board. After discussion and input from the consumer member of the Board, the Board voted to submit the first version that allows any member of the Board to run for an officer position.	Motioned by D. Jones to approve first version of Draft Bill on Consumer Board Members. Motion was seconded by M. Souranis.	Motion was approved.
		2) Pharmacy Interns Draft bill concerning pharmacy interns to be discussed at July Practice Committee Meeting.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		3) Naturopathic Medicine	(22 6 2 2 2 7	
		Meetings organized by Board of Physicians - First meeting was June 27 th . Participants of the Naturopathic Medicine Task Force were asked to look at the 2013 SB 783 to determine if there were any new issues concerning the Board of Pharmacy. The Practice Committee will make recommendations at the August 21, 2013 Board Meeting. It was also suggested by David Jones to look at the prescribing and formulary section.		
III. Committee Reports	H. Finke, Chair,	Inquiries: 1) Soumi Saha, Kaiser Permanente		
A. Practice Committee		 KP - COMAR 10.34.28 AMS returns Draft Bd Response - KP - AMS returns to AMS Soumi Saha mentioned to the Board the huge amount of waste that is caused by not being able to put medications back into the system. The Board asked her to submit additional information concerning the types of medications and the functionality of the system. 	Motion by H. Finke to approve draft board response to Soumin. Saha of Kaiser Permanente. Motion was seconded by M. Souranis.	Motion was approved.
		The Board approved the following response:		
		Thank you for contacting the Maryland Board of Pharmacy requesting clarification regarding what is required under COMAR 10.34.28.08(C) which states "Unused medications dispensed from a centralized automate medication system stocked with bulk medications may not be returned to the system."		
		The intent of this regulation is to prohibit putting medications back into the automated medication systems (AMS) once removed. A pharmacy may re-dispense what has been removed from an AMS, but once remove from the AMS, medications may not be placed back into the AMS.	d	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		If an AMS is opened for cleaning and maintenance, in that instance, a pharmacy may return the medications that were removed for that purpose 2) Louis G. Depaola, Chief of Clinical Operations, School of Dentistry Request from the School of Dentistry Draft Bd Response – School of Dentistry The Board approved the following response: Thank you for contacting the Maryland Board of Pharmacy concerning the use of the University of Maryland School of Dentistry's Facility DEA number and Facility NPI number by the school's clinicians and faculty for its Dental School patients. Although the Code of Maryland Regulations (COMAR) 10.19.03.07 doe allow the use of a facilities registration number by certain practitioners, health insurance companies and pharmacy benefit managers will often no process claims without the DEA and NPI numbers of the specific prescriber. Dental School clinicians and faculty should obtain their own NPI and DEA numbers to avoid confusion. Another option would be for clinicians and faculty to use the attending or supervising dentist's NPI and DEA numbers.	Motion by H. Finke to approve draft board response to the leUniversity of Maryland School of Dentistry. Motion was seconded by M. Souranis.	Motion was approved.
		3) Sam Georgiou Office use compounding Sam Georgiou Draft Bd Response – Office Use Compounding The Board approved the following response: Thank you for contacting the Maryland Board of Pharmacy	Motion by H. Finke to approve draft board response to Sam Georgiou. Motion was seconded by D. Jones.	Motion was approved.

Subject	Responsible		Action Due Date	Results
	Party	Discussion	(Assigned To)	
	Party	concerning office use compounding and your request for an exception, waiver, or clarification by the Board, so that pharmacists may be on solid ground to compound medications used in the office. The Board may not consider granting an exception or waiver under the new statute until the implementing regulations have been adopted. The Board's Sterile Compounding Subcommittee will be meeting throughout this year to draft regulations to implement HB 986 State Board of Pharmacy - Sterile Compounding – Permits, Chapter 397, 2013. Its first priority is to address criteria for the waiver provision. Office use compounding is an issue that the subcommittee will include in discussion of waiver criteria. Again, please be advised that until related regulations are adopted, the law in Maryland is clear that all compounding must be performed pursuant to a patient specific prescription. Health Occupations Article, 12-101, Annotated Code of Maryland. The Board and the Department of Health and Mental Hygien (DHMH) have posted a solicitation for comments and ideas for the proposed regulations to implement HB 986 on the DHMH website: http://dhmh.maryland.gov/SitePages/BOP%20public%20comment%20compounding.aspx Your previously submitted emails will be included in the comments received. Feel free to submit any additional concerns by July 25, 2013. Please be aware that no permit will be required for non-sterile compounding, as any compounding in Maryland, requires a patient specific prescription.	(Assigned To) nt	

Subject Responsi		Action Due Date	Results
Subject Responsi Party	4) Laura Downes, Md State Bd of Veterinary Medical Examine KurtzPharmBdLtr062413 The Case for Office Use 061213 0 ListCompoundedMeds Draft Bd Response – Bd of Vet Med Examiners Dr. Kurtz inquired about the timeline for the regulations. It was mentioned to Dr. Kurtz that the veterinarians could have legisla introduced to exempt veterinarian prescriptions from the law. The Board approved the following response: Thank you for contacting the Maryland Board of Pharmac requesting a waiver from HB 986 State Board of Pharmac Sterile Compounding – Permits, Chapter 397, 2013, for no human use. The Board may not consider granting a waiver non-human use under the new statute until the implementi regulations have been adopted. One alternative, during the interim, is for the veterinarians to compound and dispense sterile products in accordance with applicable standards of practice. Veterinarians may also compound a limited quan of a particular medication in anticipation of immediate fut need, as based on previously documented prescriptions filled for that medication. Veterinarians who wish to engage in sterile compounding after the implementation of the new Maryland law will be required to apply for a sterile compounding permit from the Board of Pharmacy and comply with certain minimum	Motion by H. Finke to approve draft board response to Dr. Kurtz, MD State Board of Veterinary Examiners. Motion was seconded by D. tion Jones.	Results Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		compounding of sterile products, they may also request a Board waiver under the conditions established in the newly adopted regulations. Veterinarians who compound non-steri products do not require an additional permit from the Board since HB 986 only applies to sterile compounding. However non-sterile compounding, as with any compounding in Maryland, requires a patient specific prescription. The Board's Sterile Compounding Subcommittee will be meeting throughout this year to draft regulations to impleme HB 986 State Board of Pharmacy - Sterile Compounding – Permits, Chapter 397, 2013. Its first priority is to address criteria for the waiver provision. Office use compounding and non-human use compounding are issues that the subcommittee will include in discussion of waiver criteria. Again, please be advised that until related regulations are adopted, the law in Maryland is clear that all compounding must be performed pursuant to a patient specific prescription Health Occupations Article, 12-101, Annotated Code of Maryland.	nt	
		The Board and the Department of Health and Mental Hygien (DHMH) have posted a solicitation for comments and ideas for the proposed regulations to implement HB 986 on the DHMH website: http://dhmh.maryland.gov/SitePages/BOP%20public%20comment%20compounding.aspx Your letter of June 24, 2013 will be included in the comments received. Feel free to submit any additional concerns by July 25, 2013.		

Subject	Responsible		Action Due Date	Results
Subject	Party	Discussion	(Assigned To)	resures
B. Licensing Committee	D. Chason Chair,	Larynette Ndah - Applicant answered yes to question 3 regarding surrendering or failing to renew registration. Explanation: Obtained CNA/GNA license but never used it. Licensing Committee recommendation is to approve.	Motioned by Licensing Committee to approve application of Larynette Ndah. Motion was seconded by D. Jones.	Motion was approved.
		• Denise Schuhart - Applicant answered yes to question 3 regarding surrendering or failing to renew registration. Explanation: Obtained a radiology license from MD more than 15 years ago but didn't renew it when left that field. Licensing Committee recommendation is to approve. 2. New Business:	Motioned by Licensing Committee to approve application of Denise Schuhart. Motion was seconded by M. Gavgani.	Motion was approved.
		• Steven's Pharmacy Since they have not met requirement to have MD licensed pharmacist on staff and states that nothing was disclosed to them at the time of application, they would like the \$700 fee prorated for the months that they will lose for permit. They are asking for a refund of \$408. Recommendation is to deny request. It's an administrative fee.	Motioned by Licensing Committee to deny request of Steven's Pharmacy Motion was seconded by R. Taylor.	Motion was approved.

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	Party	Discussion	(Assigned To)	
		McGuff Compounding Pharmacy Services, Inc.	Motioned by	
		<u>McGuir Compounding</u> I narmacy services, Inc.	Licensing	Motion was approved
		Requesting waiver of HB 986 requirement. Recommendation	Committee to	
		is to inform company that regulations have not been drafted	inform McGuff	
		so no waivers are available.	Compounding	
			Pharmacy	
			Services, Inc.,	
			that regulations	
			have not been	
			drafted so no	
			waivers are	
			available. Motion	
			was seconded by M. Gavgani.	
		Vogan Chaon	M. Gavgaiii.	
		• <u>Yaser Chaar</u>		
		Requesting a refund of the \$300 application fee as he chooses to withdraw his application. Recommendation is to send pharmacist a letter informing him that he owes us \$300.	Motion by Licensing Committee to send Yaser Chaar a	Motion was Board approved.
			letter informing him that he owes the Board \$300. Motion was seconded by	
			by D. Jones	
C. Public Relations Committee	Z. St. Cyr, II	 Public Relations Committee Update: Z. St. Cyr II reported that David Jones was now on Committee. Spring/Summer Newsletter is ready and will be sent out soon. FY2012 report was taken to conference and FY2013 will be done by November. 		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
D. Disciplinary	L. Israbian- Jamgochian, Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	L. Bradley- Baker, Acting Chair	Emergency Preparedness Task Force Update: No updates. Meeting wasn't held in July 2013.		
IV. Other Business & FYI	L. Israbian- Jamgochian, President	There was no other business presented.		
V. Adjournment	L. Israbian- Jamgochian, President	The Public Meeting was adjourned at 12:05 P.M. At 12:44 P.M. L. Israbian-Jamgochian convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 2:10 P.M. Immediately thereafter, L. Israbian-Jamgochian 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.	Motion by L. Israbian- Jamgochian to adjourn the Public Board meeting pursuant to State Government Article 10- 508(a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding	Motion was approved.

Subject	Responsible		Action Due Date	Results
	Party	Discussion	(Assigned To)	
			confidential	
			matters in	
			applications	
			Meeting. The	
			motion was	
			seconded by M.	
			Souranis	

Attachment No. 1 PDMP Board of Pharmacy 071713