## Maryland Board of Pharmacy Public Board Meeting

## Meeting Minutes Date: September 19, 2014

Name	Title	Present	Absent	Present	Absent
<b>Board Committee</b>	-				
Ashby, D.	Commissioner	X		8	1
Bradley-Baker, L.	Commissioner/Secretary	X		9	0
Gavgani, M. Z.	Commissioner/Treasurer	X		8	1
Israbian-Jamgochian, L.	Commissioner/President	X		8	1
Jones, David H.	Commissioner	X		9	0
Peters, Roderick	Commissioner	X		4	0
Robinson, T.	Commissioner	X		8	1
Rochester, C.	Commissioner	X		9	0
Roy, S.	Commissioner	X		8	1
Smith, J.	Commissioner	X		8	1
St. Cyr, II, Z. W.	Commissioner	X		9	0
Zagnit, B.	Commissioner	X		8	1
<b>Board Counsel</b>					
Bethman, L.	Board Counsel	X		9	
Felter, B.	Staff Attorney		X	8	1
Board Staff					
Naesea, L.	Executive Director	X		7	2(excused)
Wu, Y.	Compliance Manager	X		7	2(excused)
Waddell, L.	Licensing Manager	X		7	2(excused)
Gaither, P.	Administration and Public Support Manager	X		7	2(excused)
Jeffers, A.	Legislation/Regulations Manager	X		9	0
Johnson, J.	MIS Manager		X	7	2(excused)

Subject	Responsible Party	Discussion	on	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A.) L. Israbian- Jamgochian, Board President	Tembers of the Board with a celating to any item on the agence Board at this time or when agenda.	nda are advised to notify	The Meeting was hosted at the Western Maryland Health Systems Hospital Center.	
		<ol> <li>L. Israbian-Jamgo meeting to order at</li> <li>L. Israbian-Jamgoo guests to sign the guests to sign they would</li> </ol>	10:02 a.m.  chian reminded all lest log, indicating	1. L. Israbian-Jamgochian extended thanks to Western Maryland Health Systems, Barry Ronan, CEO WMHS, Nancy Adams, COO WMHS, and Board Commissioner Sajal Roy for providing meeting accommodations,	
		education credits.  3. L. Israbian-Jamgoo	chian requested that all	breakfast and lunch.  3. All Board commissioners, staff	
		and packet materia	the meeting agenda ls were available for l them that all packets	members, and audience members introduced themselves.	
	B.) L. Bradley Baker, Secretary	4. Review and approv Minutes	al of August 2014	4. Motion to approve August 2014 minutes with no corrections by J. smith, 2 <sup>nd</sup> by D. Ashby	4. The Board approved the motion.
II. A. Executive Director Report	L. Naesea, Executive Director	1. Operations Updates: L. Naesea reported that the floor is slated for Octo specific date will be requalike to move after the scan	ber, confirmation of a ested. The Board would		
		Call center update: There reduction since the inception pilot. The quality of the	otion of the call center		

Subject	Responsible	Discussion	Action Due Date (Assigned To)	Dogulto
Subject	Party	Discussion	(Assigned 10)	Results
		information being collected will be reviewed and reported at a later date.  L. Naesea presented the proposed reorganization plan to unit managers who supported the plan. The Department of Health and Mental Hygiene is receptive of the plan and will support it then when it is submitted to The Department of Budget and Management for final approval.  2. Meetings Updates:  None at this time.		
B. Administration and Public Support (APS)	B. P. Gaither, APS Manager	1. Personnel Updates DHMH is implementing a new automated personnel system that will reduce manual paperwork preparations and provide automated reports. The system will also be accessible to employees.  The Board Secretary has been re-classed to the APS assistant (Secretary II). The position of Office Secretary I is vacant as a consequence. Recruitment will begin for that position.		
		The new Licensing Secretary has been appointed and will begin on Wednesday, September 24, 2014.  The Contractual Office Clerk will be converted to a permanent employee.		
		Recruitment for the new Licensing Specialist		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	rarty	Discussion	(Assigned 10)	Results
		position, Database Specialist replacement, and 2 new permanent Health Occupation Specialists have begun. Recruitment for the contractual Lab Specialist position is still in progress.  There will be no recruitment activity from 10/15-11/15 because of DHMH implementation of the new personnel system.  2. Contracts and Procurement		
		The PEAC rehabilitation contract has been finalized.		
		The expert witness contracts for the Sterile compounding program have been approved.		
		A Request for Resumes (RFR) has been submitted to DHMHs Contract Unit (OPASS) for the Mobile inspection contract.		
		The Systems Automation MIS vendor maintenance contract is in progress and will be signed in October.		
C. MIS	J. Johnson, MIS Manager	1. MIS Update Presented by John Bozek in the absence of John Johnson		
		Over 970k images have been scanned by the scanning project vendor. The Licensing Unit has been completed. The entire project is about 2/3 complete.		
		The application for the new Sterile Compounding program has been completed		

Subject	Responsible Party	1	Discussi	on		Action Due Date (Assigned To)	Results
Subject	1 at ty		DISCUSSI	OII		(Assigned 10)	Results
		and the waiver updated into M  The new eFax two new fax nutrition The surveys for work condition available on Suthe Sterile Concollected.  The recruitment Specialist has been absence of the MIS team for the surveys for work condition available on Suthe Sterile Concollected.	system ambers in Pharmas are convey Mapounding the process of the	is complete, for the complete and vonkey. Informal surveys is some for the Data ozek for pression. M Gave willing to me	including liance unit. echnician's will be mation for s still being tabase		
D. Licensing	L. Waddell, Licensing Manager	work requiremand Monthly Statistics for August 2014 Data License Type:			Total		
		Pharmacists	142	347	10399		
		Pharmacy Technician	61	197	8832		
		Student	7	0	863		
		Pharmacy	18	0	1923		
		Distributor	11	0	1053		
		Vaccination	92	32	3638		

G.I.	Responsible	D	Action Due Date	D 1/
Subject	Party	Discussion	(Assigned To)	Results
E. Compliance	Y. Wu,	1. Monthly Statistics		
	Compliance Manager	Complaints & Investigations:		
		New Complaints - 10		
		Resolved (Including Carryover) – 32		
		Final disciplinary actions taken – 3		
		Reversals – 0		
		Summary Actions Taken – 0		
		Inspections:		
		Total - 96		
		Annual Inspections -91		
		Opening Inspections - 4		
		Closing Inspections - 0		
		Relocation Inspections - 1		
		Board Special Investigation Inspections – 0		
		Division of Drug Control Closing Inspections – 0		
		2. Pharmacist Rehabilitation (PEAC) Update		
		<b>Total Pharmacist Rehabilitation Clients – 19</b> Pharmacist – 16 Technician – 2		
		Pharmacy Student – 0		
		Clients Monitored by Board Req. PEAC Assistance –1		
		<b>Drug Test Results -</b> Number of Positive Results-0		
		Discharged Clients/Closed Cases-0		
F. Legislation & Regulations	A. Jeffers, Legislation &	REGULATIONS:		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	1 arty	Discussion	(Assigned 10)	Results
	Regulations Manager	10.34.19 Sterile Pharmaceutical Compounding and 10.34.09 Fees		
		Notice of Final Action published on June 27, 2014 with an Effective Date of January 1, 2015.		
		Sterile Compounding Committee continuing to meet regarding implementation – next meeting is September 29 <sup>th</sup> .		
		Sterile Compounding Survey went live on the website on July 21st. Blast email sent shortly thereafter with a September 1, 2014 deadline for responses. FAQs went on the website July 31, 2014.		
		Extended to October 1, 2014 to capture more people.		
		Emailed Christine, Eva and Laurie on September 3 <sup>rd</sup> asking them to link the survey on their websites. Christine Farrelly of Bd of Physician did post on their website.		
		Board approval requested to do a hard copy mailing to pharmacy permit holders to encourage participation in the survey.		
		Meeting with Dental Board representatives - August 27 <sup>th</sup> – Dental Board will provide the Sterile Compounding Committee with a list of products that they compound in their offices. Follow up email to be sent to Dr. Jee so that the Committee may consider at Sept. 29 <sup>th</sup> Meeting.		
		10.34.38 Pharmacy Interns Informal Comments:	Motion from the Practice Committee to allow interns to check in CDS, 2 <sup>nd</sup> by	Not approved, answer will be adjusted

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Domlta
Subject	Party	Discussion	(Assigned 10)	Results
		Don Taylor - Pharmacy Intern Draft 072214  Anne Lin - NDofMDSchool of Pharmacy 081814  Draft Board Responses:  Draft Board Response - Pharm Intern Regs - Dtaylor  Dear Mr. Taylor:  Thank you for offering informal comments to the Maryland Board of Pharmacy concerning the proposed COMAR 10.34.38 Pharmacy Interns. Below you will find the Board's response to your comments.  10.34.02.04: Is there a procedure for a foreign graduate already in a program to get credit for hours already completed prior to registration as a		The Board voted to approve.
		pharmacy intern?  Thank you for your insight. The Board would like to give a foreign graduate credit for hours completed before registration as a pharmacy intern. That chapter will be revised with the following addition:  10.34.02.04  C. An applicant may receive credit for any of the 1,560 hours earned up to 10 months before the effective date of this regulation.		The board voted to approve.  The Board voted to approve.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Dogulta
Subject	Party	Discussion	(Assigned 10)	Results
		10.34.38.03C I am certain this was discussed, but why would a registered pharmacy intern not be permitted to sign for incoming orders which may contain CDS? The registered pharmacy intern MUST be working under the direct supervision of a licensed pharmacist, so I don't know why this would be a prohibited act. I could understand Schedule II medications, but not all CDS.  Thank you for your insight. The Board agrees and has removed that prohibition from the proposed COMAR 10.34.38.03.  10.34.38.06D I don't see any requirement that the registered pharmacy intern must have the registration posted in place of employment or carried on person while working.  Although this is set forth in the statute, Health Occupations Article, 12-6D-10, Annotated Code of Maryland, the Board will add this requirement to the proposed regulations as follows:  .04 General Requirements.  A. Each registered pharmacy intern's registration in the office or place of business in which the pharmacy intern is practicing pharmacy under the direct supervision of a licensed pharmacist; or		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	Farty	Discussion	(Assigned 10)	Results
		also be adding a section regarding individuals that work in pharmacies in a volunteer capacity. This will be added to 10.34.38.01 Scope:  C. This chapter applies to individuals functioning as a pharmacy intern		
		regardless of whether they are paid.  Thank you again for your thorough reading of, and informal comments to, COMAR 10.34.38 Pharmacy Interns. The Board voted at the September 19, 2014 Public Board Meeting to submit the proposed regulations to the Department of Health and Mental Hygiene for publication with the revisions set forth above and those contained in the Board's letter to Dr. Anne Lin, Dean, Notre Dame of MD University School of Pharmacy. Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.		
		Draft Board Response – Pharm Intern Regs -ALin  Dear Dr. Lin:  Thank you for offering informal comments to the Maryland Board of Pharmacy concerning the proposed COMAR 10.34.38 Pharmacy Interns. Below you will find the Board's response to your comments.  1) Will there be a requirement for the intern		

Cook to a	Responsible	Diamenton	Action Due Date	D14
Subject	Party	Discussion	(Assigned 10)	Results
Subject	Party	registration card be displayed in the pharmacy?  Although this is set forth in the statute, Health Occupations Article, 12-6D-10, Annotated Code of Maryland, the Board will add this requirement to the proposed regulations as follows:  .04 General Requirements.  A. Each registered pharmacy intern shall:  (1) Display the pharmacy intern's registration in the office or place of business in which the pharmacy intern is practicing pharmacy under the direct supervision of a licensed pharmacist; or  (2) Have the registration on the pharmacy intern's person available for viewing.  (b) When practicing pharmacy under the direct supervision of a licensed pharmacy intern shall wear identification that conspicuously identifies the registered pharmacy intern.  2) In 10.34.38.04A – how will be the pharmacy intern be identified as such to the public?  The permit holder will determine how the	(Assigned To)	Results
		-		

G.11	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned To)	Results
		identification is implemented.		
		3) In 10.34.38.04C – what is the penalty should an intern not inform the Board of their enrollment status? Within what timeframe does the notification have to occur after the change in status? What happens to the registration period /status of the student depending on the change in status in school?  The .04C of the proposed regulations required the intern to "notify immediately." It is the responsibility of the employer to validate that the		
		intern is enrolled as a student. If the intern is not in school, they do not qualify for this registration.		
		4) In 10.34.38.05A – does this mean not physically at one time or does this mean that a pharmacist cannot have more than two registered pharmacy interns listing him/her as the supervising pharmacist?		
		The Board interprets this section to mean physically at one time.		
		5) In 10.34.11.4-1A – what is meant by physical or mental incompetence?		
		Physical or mental incompetence means mentally or physically unfit to practice, which is the same criteria for pharmacists or pharmacy technicians.		
		6) <b>In 10.34.34.05</b> – if the Board requires		

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Subject	Party	Discussion	(Assigned To)	Results
		students to submit proof of enrollment in good		
		standing once a year – should an intern be required		
		to do so as well?		
		COMAR 10.34.34.05B has been deleted from the		
		pharmacy technician chapter by the use of		
		brackets. The Board apologizes for the confusion.		
		Only 10.34.34.05A still exists.		
		7) <b>In 10.34.38.01 Scope</b> – I am not sure what is		
		meant that this chapter does not apply to pharmacy		
		students and only to interns.		
		Please see 10.34.38.01B which sets forth the		
		exemptions for registration of pharmacy interns.		
		Students would not have to register if part of an		
		experiential learning program or have registered as		
		a pharmacy technician performing delegated		
		pharmacy acts.		
		8) <b>In 10.34.38.07G</b> – this states that interns		
		cannot renew their registration (if I recall it is		
		good for a two year period. This is saying that they cannot renew if they have graduated from an		
		ACPE accredited school of pharmacy. What		
		happens to the student who graduates and perhaps		
		they do not pass the NAPLEX the first time then		
		they cannot renew registration? If at that point		
		they can only be a technician while studying for		
		the exam again, this limits what they can do.		
		Should that be the case or should they have		
		opportunities to continue to do more with the		
		intent of better preparation for the Boards?		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	1 arty	Discussion	(Assigned 10)	Results
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		The Board is aware that some students may not		
		pass their exams the first time. Therefore, the		
		Board has given students 2 years plus one renewal		
		to complete their licensure qualifications. The		
		Board cannot, however; allow an individual to be		
		an intern for an indefinite time period.		
		In addition to the revisions above, the Board will		
		also be adding a section regarding individuals that		
		work in pharmacies in a volunteer capacity. This		
		will be added to 10.34.38.01 Scope:		
		C. This chapter applies to individuals		
		functioning as a pharmacy intern		
		regardless of whether they are paid.		
		Thank you again for your thorough reading of, and		
		informal comments to, COMAR 10.34.38		
		Pharmacy Interns. The Board voted at the		
		September 19, 2014 Public Board Meeting to		
		submit the proposed regulations to the Department of Health and Montal Hygiana for publication with		
		of Health and Mental Hygiene for publication with the revisions set forth above and those contained		
		in the Board's letter to Don Taylor. Should you		
		have questions or additional concerns, please feel		
		free to contact Anna D. Jeffers, Legislation and		
		Regulations Manager at (410) 764-4794.		
		Board approval requested for revisions pursuant to		
		the comments:		
		REVISED DRAFT 10 34 38 Pharmacy Interns	Motion to approve regulations with	
		DAME TO COMMITTEE THE INC.	revisions J Smith 2 <sup>nd</sup> by D Jones.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
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		091914		
		10.13.01 Dispensing of Prescription Drugs by a Licensee  Proposal published May 30, 2014. Placed on HOLD by AELR (Del. Morhaim).  All required responses submitted to DHMH Regulations Office on July 17, 2014.  Bd of Physicians posted courses approved by the Secretary on their website September 10, 2014.  Update on communication with Del. Morhaim.	Anna Jeffers was directed to contact the Dental Board to see if their offered CE course would be available for physicians.	
		1) State Board of Pharmacy – Pharmacist Rehabilitation Committee – Membership		
		Waiting for sign-off from the Governor's Office.  2) EPT legislation:  LaVerne agreed with the changes to the bill that were recommended at Practice Committee and reviewed by Linda Bethman.  PHPA.EPT.bill Practice Revisions 082814  New version was disseminated to the Board.	Motion to accept by D Jones, 2 <sup>nd</sup> by R Peters.	
		3) Nurse Dispensing in LHD:  Nursing Board approved of the Board of Pharmacy revisions from August Board Meeting.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	Responsible Party	OTHER MATTERS:  Pharmacist working conditions:  Board approval requested for final Survey Questions to be run in October.  FINAL SURVEY REV 090214	Action Due Date (Assigned To)  Motion by committee, 2 <sup>nd</sup> by D Ashby to approve survey questions.	Results
III. Committee Reports A. Practice Committee	M. Gavgani, Chair	Inquiries:  Mario Richards, Miles & Stockbridge  Letter - Board of Pharmacy - Request for Guidance  Draft Board Response - physician substantial ownership  M Gavgani Sterile compounding/oncology meeting update  The physicians would like to use the safety standards from the CDC, MOSH and NIOSH for the basis of their recommendations for appropriate national safety standards for mixing, reconstituting, and other similar acts routinely performed by, or under the supervision of, an oncologist, a rheumatologist, or a hematologist who administers chemotherapy, biologic therapy,	Motion to approve from Practice Committee, 2 <sup>nd</sup> by D Jones.  Motion to table to go back to Practice Committee by C Rochester, 2 <sup>nd</sup> by Z. St.Cyr, II.	Table to go back to practice for revisions, give interim response.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	1 arty	Discussion	(Assigned 10)	Results
B. Licensing Committee	L. Bradley- Baker, Chair	supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition.  The physicians focus is on the "immediate use" exemption from USP 797 and exemption from the Board's Sterile Compounding regulations.  1. Review of Pharmacist Applications:		
		Kristle Green-Would like to extend her NAPLEX score due to several address changes. Licensing Committee recommendation is to approve her request.  2. Review of Pharmacy Technician Applications: None  3. Review of Distributor Applications: None  4. Review of Pharmacy Applications: None	1. Motion to approve applicant's request by committee, 2 <sup>nd</sup> by D. Ashby.	1. The Board voted to approve the motion.
		5. Review of Pharmacy Technicians Training Programs: None  6. New Business: Anthony Ortiz – Would like to know if a veterinary reference laboratory that formulates veterinary biological products need to be licensed in MD. Licensing Committee recommendation is to inform company that they don't have to be licensed in MD.	6. Motion to inform the company of no need for licensure, 2 <sup>nd</sup> by M. Gavgani.	6. The Board voted to approve the motion.
C. Public Relations	D. Jones, Chair	Public Relations Committee Update: D. Jones reported that enrollment for the Board	Discussion ensued regarding the high number of "no shows" at the CE	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Subject	Tarty	Discussion	(Assigned 10)	Acsuits
Committee		sponsored Annual CE Breakfast on October 19, is full.	breakfast that have occurred after people have registered in the past. The PR Committee is considering ways to address or reduce "no shows."	
		Acquiring vendor booths for the MPhA, ASCP, MPhA meetings next year are being scheduled.  The Baby Boomers Expo will be held October 22 and 23 and volunteers are needed at the Board's booth.  The PR Committee will collaborate with the Call Center to develop FAQs for the center.  The PR Committee would like the Board's recommendations regarding recognition of former Board Members whose terms have recently ended.  Commissioner Jones thanked the MIS Unit for preparing and posting several recent surveys.  Commissioner Jones has been appointed to serve on the Baltimore County grand jury, and will have limited availability on Mondays and Wednesdays in the morning for approximately 4 months.		
		Commissioner St. Cyr II encouraged all commissioners and staff members to attend the Annual Consumer Advocacy Coalition's conference that will be held in Baltimore this year on October 23 and 24. The event will be co-sponsored by the MD Department of Health and Mental Hygiene and include presentations from L. Bethman and Z. St. Cyr, II and other state officials.		
D. Disciplinary	L. Israbian- Jamgochian, Chair	Disciplinary Committee Update:  Water Bottles in Medication Refrigerators per CDC recommendation	The committee recommends that bottles are sealed and unopened if they are place in the refrigerator for use in	The Board approved the recommendation.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
Bubject	Tarty	Discussion	(Assigned 10)	Acsuits
			reconstituting medications.	
E. Emergency Preparedness Task Force	S. Roy, Chair	Emergency Preparedness Task Force Update:  The Emergency Preparedness Task Force recommends mirroring the Maryland Insurance Administration statute by allowing pharmacists to dispense up to 30 days' supply during an emergency versus the current 14 day, and to do so without a proclamation from the Governor.  The dispensing of medications would be under a pharmacist's professional judgment and based on previous prescription history.	Motion to change regulation to reflect 30 days from committee, 2 <sup>nd</sup> by D Ashby.  L. Bethman suggested that the Emergency Preparedness Task Force submit a bill to change the regulation. The Task Force will send the language to the Legislative Committee for preparation.	The Board voted in favor of the proposed actions.
IV. Other Business & FYI	L. Israbian- Jamgochian, Board President		An audience member asked about the survey posting dates. Commissioner Jones responded that the sterile compounding survey will be posted on October 1.  A Kaiser Permanente thanked the Board for considering comments they submitted regarding Pharmacy Technician Regulations.	
V. Adjournment	L. Israbian- Jamgochian, Board President	The Public Meeting was adjourned at 11:45 a.m.  At 12:00 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 12:20 P.M. Immediately thereafter, L. Israbian-Jamgochian convened an Administrative Session	Motion to close by D. Ashby, 2 <sup>nd</sup> by D. Jones.	The Board voted to close the public meeting at 11:45 a.m.  During closed session, the Board reviewed and approved the

Responsible		Action Due Date	
Subject Party Discuss	ion	(Assigned To)	Results
for purposes of discussing co	onfidential disciplinary		proposed
cases. With the exception of	cases requiring		reorganization plan.
recusals, the Board member	s present at the Public		-
Meeting continued to partici	pate in the		
Administrative Session.	•		