Maryland Board of Pharmacy Public Board Meeting

<u>Agenda</u> May 15, 2019

Nai	me	Title	Present	Absent
Ashby, D.		Commissioner		
Bouyoukas, E		Commissioner		
Evans, K.		Commissioner		
Garmer, G.		Commissioner		
Hardesty, J.		Commissioner/Treasurer		
Laws Jr, A.		Commissioner		
Leikach, N.		Commissioner		
Morgan, K.		Commissioner/President		
Oliver, B		Commissioner		
Rusinko, K.		Commissioner		
Toney, R.		Commissioner/Secretary		
Yankellow, E.		Commissioner		
Bethman, L.		Board Counsel		
Felter, B.		Staff Attorney		
Speights-Napata,	D.	Executive Director		
Fields, E.		Deputy Director /Operations		
Goldberg, D.		Pharmacist Investigator Supervisor		
Clark, B.		Legislative liaison		
Chew, C.		Management Associate		
I. Executive	A.) K. Morgan,	Members of the Board with a conflict of interest relating to an	v item	1
Committee	Board	on the agenda are advised to notify the Board at this time or w		
Report(s)	President	the issue is addressed in the agenda.		

	Responsible		Action Due Date
Subject	Party	Discussion	(Assigned To)

		1. Call to (Order			
		0	on sign-in s	n and of mee heet if you are	0	,
		3. Distribu	tion of Age	nda and pack	et materials	
	B.) R. Toney, Secretary	4. Review	and approv	e April 2019	Public Meeti	ng Minutes
II. A. Executive Director Report	D. Speights- Napata, Executive Director	b) Boa	fing Update	s sed: May 27th mittee Proces		ау
		2. Meeting d) NAE	s Update P Annual M	leeting		
B. Operations	E. Fields, Deputy Director/			Budget Update inancial State		
	Operations			mation Syster omation Enha		
C. Licensing	E. Bouyoukas, Commissioner	1. Unit Upd 2. Monthly S				
		License Type	New	Renewed	Reinstated	Total
		Distributor	7	261	0	1,338
		Pharmacy	20	0	0	2,057

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		Pharmacist	49	487	0	12,093	
		Vaccination	21	68	0	4,702	
		Pharmacy Intern - Graduate	1	0	0	46	
		Pharmacy Intern - Student	23	17	0	843	
		Pharmacy Technician	108	248	2	9,856	
		Pharmacy Technician- Student	0	0	0	42	
		TOTAL	230	1,081	2	31,059	
D. Compliance	D. Goldberg, Pharmacist Investigator Supervisor	1. Unit Up 2. Monthly Complaints & In	v Statistics				
		New Complaints	- 34				
		 Employe Disciplin Sexual H Expired/ Consent Licensin Inspecti 	Harassmen Invalid CP	e - 1 in another Juri t - 1 R - 3 - 4	sdiction- 10		

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		Refusal to Fill - 1	
		 Unprofessional Conduct - 2 	
		Criminal Charges - 1	
		 Dispensing/Medication Error - 3 	
		 Closed without notifying the Board - 1 	
		Resolved (Including Carryover) – 59 Actions within Goal – 44/59 Final disciplinary actions taken – 19 Summary Actions Taken – 2 Average days to complete - 87	
		Inspections:	
		Total - 188	
		Annual Inspections - 164	
		Opening Inspections - 8	
		Closing Inspections - 7 Releasting (Change of Opperation 2	
		Relocation/Change of Ownership Inspections - 2	
		Board Special Investigation Inspections – 7	
E. Legislation &	B. Clark,	Regulations	
Regulations	Legislative	COMAR 10.34.05.05 Security Responsibilities	
	Liaison		
		COMAR 10.34.30 Applications	
		COMAD 10 24 00 Exce	
		<u>COMAR 10.34.09 Fees</u>	
		<u>COMAR 10.19.03.08C</u>	
		Logislation	
		Legislation	
		Age change for vaccination	

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III. Committee Reports A. Practice Committee	Evans, K. Commissioner	Mary H. Miller: The MD BOP regulations state that "at least 15 days before prescribing contraceptives, a pharmacist shall submit to the Board a notification form, which includes an attestation of completion of a Board-approved training program." Do you have an example of this notification form? We will beginning our program with 10 stores in the state and would like to have all the required pieces in place before the pharmacists begin their training.	
		Proposed response: The Board is currently in the process of developing and approving a notification form. Until the form has been approved, the Board is accepting the electronic certificate of completion that trainees receive as proof of completion of a Board approved training program.	
		John Jurchak: My name is John Jurchak. My wife and I are retired teachers and we depend on our pharmacy for needed prescriptions. It has come to our attention that our Pharmacists do not have breaks from their work during their shifts of filling prescriptions. This greatly concerns us. Our pharmacy is a very busy venue with staff constantly working to fill their client's prescriptive needs. Our pharmacists have a huge responsibility to get every prescription exactly correct. We don't understand how these people can work accurately without regular work breaks from their exacting work. It was coincidence that shortly before we found this out, we were visiting our son in North Carolina. He picked up a prescription there and noticed that the dosage on a very strong medication was filled out at twice the amount that the doctor prescribed! We don't want this to happen to us.	
		 Please explain to us why pharmacists in Maryland are not mandated to take regular breaks in their vital work of filling our much needed medications. Proposed response: In general, it is the professional responsibility of individual pharmacists to ensure that they are practicing in a safe manner. (CITE COMAR) Additionally, HG 12-403(c)(7) requires permit holders to support their professional staff and not interfere with their professional judgment. 	
		Jacob Tyler: I'm writing to inquire on the Maryland Board of Pharmacy's position/regulation with CBD Oil/tincture/products.	

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Froposed response: Because industrial nemp is not covered by the Maryland Pharmacy Act, the Board of Pharmacy does not have a position on this issue. For further information on the legal status of CBD products derived from industrial hemp in Maryland, please reach out to the Office of Controlled Substances Administration (OCSA) at 410-767-6500 or 1-877- 463-3464. Jennifer Hardesty: Our Pharmacy is a waiver closed-door institutional pharmacy, servicing SNFs, ALFs and CCRCs. One of our CCRCs would like to have a method of medication disposal for their independent living residents- a 'drop off' location for unused or discontinued medications. However, there is no actual 'pharmacy counter' for the residents to take their medications physically to- and it looks like the 10.34.33.05 'drop-off location' regulations are only for donated medications- not for disposal purposes. Is there a way to accommodate this situation? Can (non-CDS) medications be collected on the CCRC campus by a health care provider in lieu of a pharmacy counter, then sent via pharmacy delivery driver to the pharmacy for ultimate disposal?	On December 12 th , the United State Congress voted to pass the Agriculture Improvement Act of 2018. This is more commonly referred to as the Farm Bill. As well as including important policy extensions for certain areas in agriculture and nutritional policy for the next 5 years, the bill also confirms the legalization of hemp. Hemp is the term given to cannabis containing less the 0.3% tetrahydrocannabinol or (THC). *The passing of the "Farm Bill" removed the prohibition on Hemp, effectively removing it from the list of Schedule 1 substances. (Section 12619 of the Farm Bill)* My pharmacy and (many others in Maryland) would like to offer CBD products in our OTC inventory. We believe that this product (which does not produce a high) can be used to benefit patient's health. However, if this is going to cause problems with the Board of Pharmacy, we would like to be aware.	
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		1. Register with DEA for mail-in bags	
		2. Register as repository with the State	
		Neil Leikach: Will the board change their standing on CBD products made from hemp since Congress passed the farm bill in December 2018?	
		Proposed response: Because industrial hemp is not covered by the	
		Maryland Pharmacy Act, the Board of Pharmacy does not have a position on this issue. For further information on the legal status of CBD products	
		derived from industrial hemp in Maryland, please reach out to the Office of	
		Controlled Substances Administration (OCSA) at 410-767-6500 or 1-877- 463-3464.	
		Lauren Linkenaugher: I am reaching out for clarification on how to	
		handle device expiration specifically for Medicare Part B patients receiving Glucose Monitors. Based on MD BOP regulation we would label with an	
		expiration date of one year (most common scenario). The concern is	
		Medicare Part B only covers one meter every 5 years. If we label one year	
		and the patient discards then the device is not re-billable to MPB for a replacement.	
		Stacey Evans: My understanding is that CBD oil from hemp with less than	
		.3 THC has not been a controlled substance in Maryland since hemp was	
		legalized in Maryland and determined not to be a controlled substance several years ago.	
		Maryland law provides that any part of the plant Cannabis sativa L. (which	
		is what hemp is made from) with a less than .3 THC is not a controlled substance in Maryland. MD. Code. Criminal Law 5-101 $(r)(2)(vi)$. See	

Is that the Maryland Board of Pharmacy's understanding? See below.

below.

(i) All parts of any plant of the genius Cannabis, whether or not the plant is growing;
(ii) The seeds of the plant;

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	(iii) The resin extracted from the plant; and
	(iv) Each compound, manufactured product, salt, derivative,
	mixture, or preparation of the plant, its seeds, or its resin.
(2	2) " Marijuana" does not include:
	(i) The mature stalks of the plant;
	(ii) Fiber produced from the mature stalks;
	(iii) Oil or cake made from the seeds of the plant;
	(iv) Except for resin, any other compound, manufactured product,
	salt, derivative, mixture, or preparation of the mature stalks,
	fiber, oil, or cake;
	(v) The sterilized seed of the plant that is incapable of
	germination; or
	•
	(vi) The plant Cannabis sativa L. and any part of such plant,
	whether growing or not, with a delta-9-tetrahydrocannabinol
	concentration that does not exceed 0.3% on a dry weight basis.
М	Id Code, Criminal Law 5-101 (r)(2)(vi).
	egislative history also states that hemp products with less than .3 were not
	tended to be controlled substances in Maryland. See p. 3 and 4 of
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	04f5d2a0c46fd59b7d719cd09f9067a937dc716/Downloads/hb0698fiscalpo
	cy%20(1).pdf
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46	53-3464.
G	riffin Sauvageau: I'm a pharmacy student at the University of Maryland
	chool of Pharmacy and I'm involved in the National Community
	harmacists business plan competition this year. We are designing a

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company that delivers prescriptions to an automated locker system at people's place of work.	
Our lockers are designed to have QR code activating doors, screens for consultation as well as temperature controlled storage for refrigerated prescriptions.	
If you could comment on the potential legality of this pharmacy design we would greatly appreciate it.	
Proposed response: This method of prescription delivery is not permissible in Maryland, as the facility that you have described would be considered a depot under Maryland regulations. COMAR 10.34.25.02B(2)(a) defines a depot as "a location where filled prescriptions are stored before delivery to the intended patient or the intended patient's authorized agent." Under COMAR	
Adam McIntosh: I am preparing to become licensed in Maryland via reciprocity. I have been preparing for the MPJE and I have a question of sorts. I was hoping you might provide me an answer.	
I understand that a patient has 120 days from the written date to present to a pharmacy for the pharmacy to fill that prescription. I interpret that to mean if a patient has a prescription dated 11/20/2018 presented to me today, 04/01/2019 I would not fill that prescription. However, what if the same prescription dated 11/20/2018 was presented to me in January 2019 and it was placed on hold at that time and never filled. If the patient calls and requests the prescription to be filled, could it be filled on 04/01/2019?	
Without consulting the Board of Pharmacy, my instinct would be to "play if safe" and NOT fill the prescription. Rather I would call the prescriber for a new prescription. I hope this scenario makes sense. I also hope my instincts are correct, as I have a tendency to overthink things like this.	
Proposed response: The 120 day time limit begins to run on the date of the prescription. Therefore, if a prescription is dated 11/20/2018, as in your example, then the 120 day period begins running on 11/20/2018, regardless of whether the patient retains control of the prescription or if it is held at the	

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 pharmacy. Once 120 days have passed since the date of the prescription, the patient will need to visit their provider and obtain a new prescription in order for the prescription to be filled. Jacob A Smith: We are reaching out to seek guidance from the Board of Pharmacy regarding a request from the Baltimore City Fire Department to install automated medication dispensing technologies in our hospital's emergency department. The full text of the original request is in the email attached to this message. Essentially, the BCFD would like to install an automated dispensing system for restocking "units' (ambulances) in our ED. They've asked for a secure indoor location away from patients' area. The BCFD would be responsible for monitoring, maintaining, and restocking the unit. Does the Board have and guidance or concerns with this request? We (JHH) would still need to think through logistics of how/where to implement such a machine, but before we got too deep into that discussion we wanted to reach out to the BoP first. Proposed notice: If the machine that is contemplated is not related to the hospital pharmacy does not have jurisdiction. Please reach out to the Maryland Office of Healthcare Quality (OHCQ) at 410-402-8015 or the Maryland Institute for Emergency Medical Services (MIEMSS) at 1-800-762-7157 for more information. 	
762-7157 for more information.	

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B. Licensing Committee	D. Ashby, Chair	 1. Review of Pharmacist Applications: a. #116746- The applicant is requesting that the Board grant her an extension of the MDBOP application, which is due to expire on April 27, 2019. She had to travel to Africa (Cameroon) for some family issues concerning her father. Committee's Recommendation: Approve 	
		b. #19030 - The licensee is requesting that the Board waive the requirement of the MPJE exam.	
		His license has been expired over two years, but less than five years. He has been out of work since April of last year. He has been battling medical issues.	
		He was sent an email on 4/22/2019, requesting medical documents/notes from his doctor's office. He was advised to submit a detailed letter, documentation, and doctor's notes. (Any important information). He only sent in a detailed letter addressing the Board. The Licensing Unit sent an email and is still awaiting a response. All of his phone numbers in MLO are not in working order. (He has not submitted a reinstatement application) <u>Committee's Recommendation: Must take and pass</u> <u>MPJE, include the two year timeline in letter.</u>	
		 #116813- The applicant MDBOP application is due to expire on May 1, 2019. He is requesting that the Board extended his MDBOP application beyond May 1, 2019, to allow him time to retake the MPOJE exam. He has been diagnosed with Major Depressive Disorder secondary to Multiple Sclerosis, both which have affected my cognitive functions (impaired memory and slow processing) 	

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		<u>Committee's Recommendation: 6 month MDBOP</u> extension from 05/01/2019	
		 d. #117006- The applicant is due to expire on May 10, 2019. The applicant is requesting that their MDBOP application be extended, due to unforeseen circumstances. The Licensing Unit has made several attempts to contact the applicant via emails and awaited responses from the applicant on 5/21/2018, 4/2/2019, and 4/5/2019. The applicant submitted to the Board a request in writing on April 20, 2019 Committee's Recommendation: 6 month MDBOP application extension 	
		 2. Review of Pharmacy Intern Applications: a. Ms. NA- Request: I'm sending this email as a written request to ask for a review of her intern graduate registration. Ms. NA is a foreign graduate pharmacy graduate who became registered with the Board in February 2019 and would have expired 02/2020. Ms. NA applied for a technician registration in 03/2019 which will expire in 03/2020. She indicated she was un-ware that a licensee is unable to hold two different types of license Maryland. 	
		Ms. NA is required to complete 1560 hours of internship in order to sit for the NAPLEX and MPJE exam. She is now ready to start the process to complete the hours. Ms. NA is requesting to renew her Intern registration for another term <u>Committee's Recommendation: Deactivate</u> <u>Technician registration, reactivate Intern</u> <u>registration.</u>	

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		 Review of Pharmacy Technician Applications: Review of Distributor Applications: Review of Pharmacy Applications: Review of Pharmacy Technicians Training Programs: New Business:
C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update:
D. Disciplinary	J. Hardesty, Chair	Disciplinary Committee Update
E. Emergency Preparedness Task Force	N. Leikach, Chair	Emergency Preparedness Task Force Update
IV. Other Business & FYI	K. Morgan, President	
V. Adjournment	K. Morgan, President	 A. The Public Meeting was adjourned. B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications. C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.

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D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.	