Maryland Board of Pharmacy
Public Board Meeting

<u>Agenda</u>
July 15, 2020

Name	Title	Present	Absent
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Fink, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Geigher, P.	Commissioner		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner/Secretary		
Singal, S.	Commissioner		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	**A.) K. Morgan, Board President** **B.)K. Rusinko, Secretary**	*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.* **1. Call to Order** **2. Sign-in Introduction and of meeting attendees** – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)* **3. Distribution of Agenda and packet materials** **4. Review and approve June 2020 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**1. Board Investigator Position** **2. Building COVID-19 Policy Update** **3. NABP District 1 and 2 meeting update**	
B. New Business	**K. Morgan, Board President**	**1. NONE**	
C. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: June 2020 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: None**	
D. Licensing	**E. Bouyoukas, Commissioner**	**1. Unit Updates** **2. Monthly Statistics**	

License Type	New	Renewed	Reinstated	Total
Distributor	7	1	0	1,404

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)

Pharmacy	7	37	0	2,073		
Pharmacist	83	503	0	12,578		
Vaccination	14	148	0	4,887		
Pharmacy Intern - Graduate	14	0	0	68		
Pharmacy Intern - Student	67	12	0	781		
Pharmacy Technician	116	342	3	10,267		
Pharmacy Technician- Student	2	0	0	37		
TOTAL	310	1,043	3	32,095		

E. Compliance	**T. Leak, Compliance Director**	**1. Unit Updates** **2. Monthly Statistics** **Complaints & Investigations:** New Complaints – 11 • HIPAA Violation – 11 • COVID-19 – 1 • Professional Misconduct – 1 • CPR Certification – 2	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		• Inspection Issues – 3 • Customer Service – 1 • Fraud – 1 • Shipping to MD without Permit – 1 Resolved (Including Carryover) – 45 Actions within Goal – 41/45 Final disciplinary actions taken – 5 Summary Actions Taken – 1 Average days to complete –79 **Inspections:** Total - 250 Annual Inspections - 240 Opening Inspections - 7 Closing Inspections - 2 Relocation/Change of Ownership Inspections - 1 Board Special Investigation Inspections – 0	
F. Legislation & Regulations	**B. Clark, Legislative Liaison**	**<u>Regulations</u>** None **<u>Legislation</u>** None	
III. Committee Reports			

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
A. Practice Committee	**Evans, K. Commissioner**	**Angela Morrow – Terrapin Pharmacy:** We currently fill prescriptions for detox/inpatient (30 -60 day) programs. Providers want to use preprinted scripts. I know that Maryland law HG 21-20 does not allow this for controlled dangerous substances. However, can the instructions/directions be preprinted? Also, would a provider initial by each drug, strength, and qty. allow the preprinted prescription to be used? **Proposed response:** It is the Board's understanding that no part of a prescription for a controlled substance may be preprinted; however, the law that you are referring to is not a part of the Maryland Pharmacy Act. For further information, please contact the Maryland Office of Controlled Substances Administration (OCSA) at maryland.ocsa@maryland.gov **Teresa Abraham – Anne Arundel Medical Center:** I would like to get some guidance on law regarding managing patients discharged on a medication that needs monitoring (warfarin management for 4 weeks post total hip/knee surgeries). Can pharmacists in the outpatient pharmacy clinic perform medication management under protocol without a clinical contract referral (CRC) from providers in a regulated space (hospital clinic)? We do see patients in our clinic for chronic Ac management under protocol and with clinical referral contract. There have been some new requests to manage these post-op warfarin patients for 4 weeks under protocol and I was wondering if they need clinical referral contract like the chronic management patients. This clinic is in a regulated space and no CDTM and CPA in place. **Proposed response**: Under Maryland law, there is an exemption allowing pharmacists providing inpatient treatment to participate in drug therapy management without an approved drug therapy management agreement. Absent this scenario, a pharmacist must be part of an approved DTM agreement. If your institution already has a DTM agreement for the given disease state, then the current agreement can be amended, rather than submitting a new agreement for approval. **Janet Petula-Grane Rx25:** We recently submitted a question to the Maryland State Board of Pharmacy regarding who may stock Interim Boxes (Omnicell Medication Storage	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Cabinets) onsite at nursing facilities in Maryland for emergency and first dose, supplying only non-patient specific unit dose packs in an individual locking bin (not open matrix). Does this system require a pharmacy technician to stock or can the nursing staff at the healthcare facility stock? The response that we received from Doris James, Licensing Program Manager, on March 18, 2020 was specific to pharmacy technicians only: *Thank you for contacting the Board. In response to your question, under COMAR 10.34.28.07* *A. A licensed pharmacist shall verify the accuracy of medications selected for stocking and replenishment of the automated medication system before medications are stocked in the system.* *B. A registered pharmacy technician may stock an automated medication system provided that:* *(1) The pharmacy technician's selection of medications is verified by a pharmacist; and* *(2) The system uses positive drug identification such as bar code technology.* Our question is specific to the Interim Box (Omnicell Medication Storage Cabinet) defined as follows: Sec. 10.34.28.02 Definitions "Interim box" means a tamper evident and secure container or secure electronic storage system holding minimal quantities of medications agreed on by the health care facility intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply. May nursing staff at the healthcare facilities stock an Interim Box as defined above? **Revised proposed response:** A pharmacist must do a final check of the medications from inventory selected for stocking the interim box; however, the pharmacist does not need to perform a final check of the medications once they have been loaded into the interim box.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		PRX Roshan Randeniyay, -CGS Pharmaacy LLC: I wanted to check on what the stance is on medications that are mailed out and get returned to the pharmacy by USPS without ever having reached the patient. Since we are a mail order pharmacy, there are instances when the mailed out box gets returned for incorrect address or some other undeliverable reason, where it never left the possession of USPS. If the package is visibly untampered with and in its original sealed box, are we able to reuse the solid form tablets and capsules for future dispensing or do these need to be discarded. Also, once the package has left the building we report any controlled medications to the PDMP, but if they then get returned several days later due to them being undeliverable, does the PMP need to be altered in some way to reflect this? **Proposed response:** Pursuant to Code of Maryland Regulations (COMAR) 10.34.10.07, "a pharmacists may accept the return of a properly labeled and properly sealed manufacturers package or individual unit dose of a drug or device that the pharmacist determines to have been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy." A pharmacy may *not* return to the pharmacy's stock or offer for sale a prescribed drug or device that has been previously sold and has left the pharmacy's possession except as provided above (COMAR 10.34.10.07B(1)).	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
B. Licensing Committee	**D. Ashby, Chair**	**1. Review of Pharmacist Applications:** **a. Applicant#: 118457 -** Applicant is requesting an extension of her ATT for the NAPLEX. She was unable to schedule the exam due to the COVID19 closures. Her NAPLEX eligibility expired 05/26/2020. ***Committee recommendation: Approve extension for one year, applicant must reapply with the Board.*** **b. Applicant# 122516 -** Applicant is requesting an extension of his MPJE ATT eligibility so that he may continue studying for the NAPLEX. His MPJE approval eligibility expires 08/19/2020. ***Committee recommendation: Approve extension for one year from the time the ATT expires, applicant must reapply with the Board.*** **c. Applicant# 119770 -** Applicant is requesting an extension of his MPJE ATT eligibility which expires 07/16/2020. Board application was received 12/10/2018. Board application fee was received 02/21/2019. Approval for the NAPLEX was granted 02/21/2019 and approval for the MPJE was granted 07/18/2019. ***Committee recommendation: Approve extension for one year, applicant must reapply with the Board.*** **d. Applicant# 122031-** Applicant is requesting an extension of her MPJE ATT eligibility which expires 06/22/2020. ***Committee recommendation: Approve extension for one year, applicant must reapply with the Board.***	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		e. **Applicant# 123061-** Applicant is requesting an extension of her NAPLEX ATT eligibility which expires 09/04/2020 ***Committee recommendation: Approve extension for one year, applicant must reapply with the Board.*** ***f.*** **Applicant# 120974-** Applicant is requesting an extension of her Board application which expired 04/10/2020. Applicant passed the MPJE on 05/27/2020 and has not passed the NAPLEX. ***Committee recommendation: Deny, must reapply*** **g.** **Applicant# 124659-** Notice received from NABP requesting approval for applicant to sit for the MPJE for a sixth time. ***Committee recommendation: Approve*** **h.** **Applicant# 121259-** Applicant is requesting an extension of his eligibility to schedule and take the NAPLEX exam. His ability to schedule the exam was hindered by the closures of the testing centers due to COVID19. ***Committee recommendation: Approve extension for one year, applicant must reapply with the Board.*** **i.** **ME -** Pharmacist M.E. is requesting waiver of the required 30 CE's. His license was reinstated December 2019 where 30 hours were submitted. ***Committee recommendation: Approve*** **j.** **NF -** Pharmacist is requesting the Board waives the requirement to retake the MPJE as a part of the	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		reinstatement process. If denied, she requests the Board refunds the application fee. ***Committee recommendation: Deny request for waiver of MPJE and refund.*** **2. Review of Pharmacy Intern Applications:** **a. SA -** Registrant is requesting an extension of her Intern-Foreign Graduate registration. She did not receive a full two years**.** ***Committee recommendation: Approve*** **b. SS -** Registrant is requesting an extension of her Pharmacy Intern-Student registration until 04/2022. ***Committee recommendation: Extend until 04/30/2021*** **3. Review of Pharmacy Technician Applications: NONE** **4. Review of Distributor Applications:** **a. Republic Pharmaceuticals -** Wholesale distributor located in Michigan is requesting issuance of the permit without the required background checks. Company is VAWD accredited and willing to sign attestations/affidavits confirming no previous criminal history for the Designated Representative and Supervisor. Tabled 06/03/2020: Ask if they have background results available dated within 6 months. Company's response: Federal background results are dated 01/08/2019. ***Committee recommendation: Will accept attestation and submitted results. Background checks must be completed within 6 months.***	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		b. PuraGraft- Company is requesting waiver of VAWD accreditation. Although they are in the process obtaining VAWD accreditation they do not expect issuance until December 2020. ***Committee recommendation: Deny*** **5. Review of Pharmacy Applications:** **a. eRemedy Rx Wellness Solutions -** Pharmacy is requesting a waiver of the relocation application fee. Operations of the Pharmacy were severely impacted by COVID19 ***Committee recommendation: Waive $500, permit holder must pay $200.*** **b. Tidewater Drug and Health Care -** Pharmacy is requesting a waiver of the Pharmacy permit renewal fee. Approval for the inspection was granted 10/24/2019, inspection was conducted and passed 03/19/2020. ***Committee recommendation: Deny*** **6. Review of Pharmacy Technicians Training Programs:** **a. Walgreens Technician Training Program** – ***Committee recommendation: Approve*** **STEVE BOUYOUKAS RECUSED** ***b.* Merritt Star Pharmacy-** Wise Pharmacy is closed and the owners would like to transfer the training program to their other pharmacy Merritt Star Pharmacy.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Committee recommendation: Submit Training Program application, confirming no changes. No fee. **7. New Business:** **a. Drug Repository Program Inspections** - Requiring DRP applicants to have an inspection prior to beginning operations. ***Committee recommendation: Approve*** **b. Intern Discussion-** Possible regulation/statute change to handle Interns who need additional time for their intern registration before they graduate. Look into the feasibility of interns expiring a full two years after issuance of registration. Amend the statute to allow for an additional renewal period for Intern Students. ***Committee recommendation: Initiate for 2022 legislative session.***	
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.**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		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.** **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.**	