Maryland Board of Pharmacy
Public Board Meeting

Agenda
October 21, 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 September 2020 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**Executive Director Report:** **1. Staffing Update** **2. COVID 19 testing Update** **3. Maryland Medical Assistance Program Pharmacy Provider Guidance on Vaccine Administration and Reporting to Immunet**	
B. New Business	**K. Morgan, Board President**	**1. NCDQS Presentation**	
C. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: September 2020 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: None**	
D. Licensing	**E. Bouyoukas, Commissioner**	**1. Unit Updates** **2. Monthly Statistics**	

<table>
<tr><th>Subject</th><th>Responsible Party</th><th>Discussion</th><th>Action Due Date (Assigned To)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>License Type</th><th>New</th><th>Renewed</th><th>Reinstated</th><th>Total</th></tr>
<tr><td>Distributor</td><td>16</td><td>0</td><td>0</td><td>1,432</td></tr>
<tr><td>Pharmacy</td><td>12</td><td>1</td><td>0</td><td>2,086</td></tr>
<tr><td>Pharmacist</td><td>77</td><td>510</td><td>0</td><td>12,901</td></tr>
<tr><td>Vaccination</td><td>66</td><td>162</td><td>0</td><td>4,969</td></tr>
<tr><td>Pharmacy Intern - Graduate</td><td>3</td><td>0</td><td>0</td><td>63</td></tr>
<tr><td>Pharmacy Intern - Student</td><td>12</td><td>9</td><td>0</td><td>758</td></tr>
<tr><td>Pharmacy Technician</td><td>104</td><td>304</td><td>2</td><td>10,620</td></tr>
<tr><td>Pharmacy Technician-Student</td><td>3</td><td>0</td><td>0</td><td>36</td></tr>
<tr><td>TOTAL</td><td>293</td><td>986</td><td>2</td><td>32,865</td></tr>
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</td><td></td></tr>
<tr><td>E. Compliance</td><td>T. Leak, Compliance Director</td><td>1. Unit Updates
2. Monthly Statistics
Complaints & Investigations:

New Complaints – 26</td><td></td></tr>
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		• Customer Service – 3 • Disciplinary Action in Another State – 3 • Refusal to fill - 3 • Unprofessional Conduct - 3 • Fraud – 2 • Medication Error – 2 • VPP Inspection issues – 4 • Inspection Issues – 4 • Pharmacy Operating without a pharmacist - 1 • Labeling issue – 1 Resolved (Including Carryover) – 27 Actions within Goal – 21/27 Final disciplinary actions taken – 1 Summary Actions Taken – 0 Average days to complete – 0 **Inspections:** Total - 201 Annual Inspections - 126 annual and 59 Narcotic Audits (follow-Up) Opening Inspections - 7 Closing Inspections - 8 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>**	

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		None	
III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	**Jeffrey Ingalls, PharmD** - Recently the labeling requirements of birth control packs has come into question at my pharmacy. MD HO 12-505 reads: *a) Label required - Except for a drug or device dispensed to an inpatient in a hospital or related institution, **each container** of a drug or device dispensed shall be labeled in accordance with this section.* My question refers to the part of the statement regarding ***each container***. As you're well aware, birth controls come in monthly packs. The debate we're having around labeling is this: Does each individual monthly pack need a label, or can you place multiple packs into one container (such as a plastic bag or the manufacturer box the packs are contained in) and simply label the bag/box? By combining the packs into a bag/box is that considered "the container" or are the individual packs considered all separate containers and each pack must be labeled separately. Many birth control packs are small in size and difficult to label. In recent months, lots of manufacturers have even changed the packages to more flimsy cardboard packets in lieu of the previously used plastic containers, which are even more difficult to label. Lastly, labeling each pack also requires additional time, supplies, and to sometimes remove outer plastic wrapping which some patients then complain about anyways. If you have to label the outer plastic wrap, the patient will just remove it upon opening the package and discard the label, thus defeating the point of labeling each pack to begin with. In summary, in the board's opinion, is it acceptable when dispensing a multiple month supply of birth control medication, that the packages be placed in one container (i.e. re-sealable plastic baggie or sold in the manufacturer box) and only one label placed on the outer container in lieu of labeling each individual monthly pack of medication?	

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		Proposed Response: The law that you have cited does require that each container be labeled as stated. However, the dispensing pharmacist may use professional judgment in determining, in a case such as you have described, the appropriate labeling that ensures the patient receives all necessary information, whether it is by labeling each individual package or providing a single label for the entire amount dispensed. **Matthew Weeman, Bayside Bovine Veterinary Services LLC -** I am a veterinarian practicing within the state of Maryland who also serves on the legislative committee for the Maryland Veterinary Medical Association. The board of the association has been receiving inquiries from veterinarians within our state who are concerned that numerous pharmacies have been refusing to prescribe non-controlled medications without providing a DEA number. As this board is well aware veterinarians don't fit the definition of "healthcare providers" and are therefore not able to receive a National Provider Identifier. Veterinarians consistently report that, generally large chain pharmacies, insist that a DEA or NPI number be provided to fulfill a prescription request. Reportedly they have no way of filling the prescription without these numbers. The DEA has offered explicit guidance in its request for pharmacies not to require or request a DEA number from prescribers that are not requesting controlled substances. I am requesting the Board of Pharmacy provide guidance to this board and to responsible veterinarians who wish to comply with DEA guidelines while protecting their DEA number when fulfilling the prescription requests of their veterinary patients. I have heard that some states allow veterinarians to enter 000-000-000-9 (or other similar formats) to these pharmacies to fulfill non controlled prescription requests. Is there a comparable work around within the state of Maryland? **Proposed Response:** The Board understands that some pharmacies may have internal policies requiring a DEA number to verify a prescriber; however, this is not a legal requirement of the Board of Pharmacy. The Board thus encourages you to	

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		continue discussions with the pharmacies in question to find a mutually agreeable solution. **Joie Damico, Adventist HealthCare** - Our Rehab hospital currently has a glove box and does minimal sterile compounding. Our larger facility that is on the same campus can handle the sterile compounding workload from Rehab and we would like to prepare the medications at the larger site. Jered told me this is fine and I can simply let the BOP know that Rehab will no longer perform sterile compounding. However, he advised me to reach out to the board to see if a dispensing agreement is needed between the two facilities. Would you be able to forward my question on to whoever could answer for us? **Additional questions from Board Council and the responses:** 1) Are you intending to distribute sterile compounds made at one facility to another facility at the same campus? Yes, the facilities are on the same campus and part of our organization, We will use the drugs from the facility to make the compounds. 2) How far are the two facilities? Within 50 ft. or less. 3) What volume do you anticipate? Most would be estimated at 10 per day; often we don't have any to make at all 4) What type of permit does the larger facility hold? Both facilities are licensed as hospital pharmacies. **Proposed Response:** The Board generally follows FDA guidance on sterile compounding matters. The FDA has issued draft guidance on this issue; however, it has not yet issued Final Guidance. For further information and advice, you may wish to consult with a private attorney. For your reference, the draft FDA guidance can be accessed at: https://www.fda.gov/media/97353/download	

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B. Licensing Committee	**D. Ashby, Chair**	**1. Review of Pharmacist Applications:** **a. Applicant #123610 -** Foreign Pharmacist Graduate is requesting approval of her Intern hours obtained as an Associate Researcher to be used towards the Intern hours' requirement for the Pharmacist license. Intern registration was issued 11/01/2019 and expires 11/30/2021. ***Committee recommendation: Approve*** **b. Applicant# 123365 -** Applicant is requesting a 30-day extension of his Board's application to retake the MPJE. ***Committee recommendation: Approve*** **c. Applicant# 123063 -** Applicant is requesting an extension of his Board's application for one month so that he may take the MPJE. ***Committee recommendation: Approve*** **d. Applicant# 121489 -** Applicant is requesting reconsideration of the denial of her request for an extension of her ATT approval. Due to COVID 19 she did not have the full 12-month timeframe to test. Her original request was presented at the August 2020 Committee and Board meetings. ***Committee recommendation: Approve extension of ATT and Board applications for 6 months*** **e. Applicant# 123344 -** Applicant is requesting an extension of her Board application (30 days) to allow for rescheduling of her test date. Due to COVID 19 and the cancellations and relocation she has been unable to sit for the MPJE. ***Committee recommendation: Approve***	

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		f. Applicant# 124817 - Applicant is requesting an extension of his NAPLEX exam score, which expired 07/24/2020. Due to testing sites being closed he was unable to take the MPJE prior to the expiration of his NAPLEX score. ***Committee recommendation: Approve*** **g. Applicant# 121754 -** Applicant is requesting an extension of his Board's application. Exam was scheduled on 03/18/2020 but Pearson cancelled it due to closing of testing sites because of COVID. ***Committee recommendation: Approve extension until February 2021*** **h. Applicant# 123541 -** Applicant is requesting the Board waive the 45-day wait time to retake the NAPLEX. ***Committee recommendation: Approve*** **i. ZU -** Pharmacist is requesting a waiver of the reinstatement fee of $527 and the requirement to take the MPJE. She has been going through a financial hardship. ***Committee recommendation: Deny*** **j. NF -** Pharmacist is requesting reconsideration of the Board's denial of her request for a waiver of the MPJE. Her original request was presented at the July 2020 Committee and Board meetings. ***Committee recommendation: Deny*** **2. Review of Pharmacy Intern Applications:**	

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		a. AE - Foreign Graduate Intern is requesting an extension of her registration. She was placed on strict bed rest during her 3rd trimester, once she was able to return to work COVID 19 occurred, which required her to remove her child from daycare and decrease her working hours. ***Committee recommendation: Extend until 01/31/2021.*** **b. TC -** Registrant is requesting an extension of her expiration until she takes her MPJE in November. She has previously renewed. ***Committee recommendation: Approve extension until 04/30/2021*** **3. Review of Pharmacy Technician Applications: NONE** **4. Review of Distributor Applications: NONE** **5. Review of Pharmacy Applications:** **a.** Eminent Services Corp, Eminent Services Corp Historic File, Eminent Services Corp 2020 Renewal - At the September 2020 Compliance Committee meeting it was recommended to discuss approval status of the Waiver permit application. ***Committee recommendation: Request Pharmacy submit a Waiver application, waive application fee.*** **6. Review of Pharmacy Technicians Training Programs:** **a.** (PharmaSeer) NHA ExCPT-New Training Module (Online) ***Committee recommendation: Approve***	

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		b. Whitesell Pharmacy ***Committee recommendation: Approve*** **c.** Heartland Pharmacy of Maryland ***Committee recommendation: Approve*** **d. Top Knowledge** ***Committee recommendation: We appreciate them providing an update and approve the changes.*** **7. Continuing Education Requests:** **a. AZO Pharmaceutical Fraternity: AZO Antiretroviral, AZO Antiretroviral II (2 hours)** ***Committee recommendation: Approve*** **b. AZO Pharmaceutical Fraternity: AZO Kappa 1, AZO Kappa 2, AZO Kappa 3(2 hours)** ***Committee recommendation: Approve*** **8. New Business:** **a. Crystal Tubbs** - Crystal Tubbs, the director of pharmacy at The Ohio State University Wexner Medical Center in Columbus OH is requesting guidance on possessing and/or distributing prostaglandin to send it to Star Teams, and then they will send that drug with the on call surgeons to perform the organ harvest on our behalf using the drug provided. ***Committee recommendation: Outside the scope of the Board's definition of a prescription drug.***	

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		b. National Coalition for Drug Quality and Security (NCDQS) - National Coalition for Drug Quality & Security (NCDQS). NCDQS recently introduced two new programs for companies in the pharmaceutical supply chain - the Quality and Security (QAS) Accreditation program and the QAS Inspection program. NCDQS is requesting approval to become a Board approved accrediting body.	
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.	