Maryland Board of Pharmacy
Public Board Meeting

Agenda
June 12, 2019

Name	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.	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.) R. Toney, 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 May 2019 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**1. Rehabilitation Services Presentation-Robert K. White, LCPC, Director, Behavioral Health, University of Maryland Faculty Physicians, Inc.** **2. PDMP Advisory Board Meeting Report--Dan and Linda** **3. Technician Survey--Dan**	
B. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: May 2019 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: Systems Automation Letters & Notifications** **b: Systems Automation CE Audit**	
C. Licensing	**E. Bouyoukas, Commissioner**	**1. Unit Updates** **2. Monthly Statistics** **License Type** | **New** | **Renewed** | **Reinstated** | **Total**	

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<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>
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<tr><td>Distributor</td><td>59</td><td>588</td><td>0</td><td>1,375</td></tr>
<tr><td>Pharmacy</td><td>13</td><td>0</td><td>1</td><td>2,035</td></tr>
<tr><td>Pharmacist</td><td>49</td><td>513</td><td>0</td><td>12,110</td></tr>
<tr><td>Vaccination</td><td>15</td><td>113</td><td>0</td><td>4,698</td></tr>
<tr><td>Pharmacy Intern - Graduate</td><td>3</td><td>0</td><td>0</td><td>46</td></tr>
<tr><td>Pharmacy Intern - Student</td><td>43</td><td>11</td><td>0</td><td>858</td></tr>
<tr><td>Pharmacy Technician</td><td>111</td><td>266</td><td>2</td><td>9,876</td></tr>
<tr><td>Pharmacy Technician-Student</td><td>3</td><td>0</td><td>0</td><td>40</td></tr>
<tr><td>TOTAL</td><td>296</td><td>1,491</td><td>3</td><td>31,125</td></tr>
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<tr><td>D. Compliance</td><td>T. Leak, Compliance Director</td><td>
1. Unit Updates
2. Monthly Statistics
Complaints & Investigations:

New Complaints - 19
• Customer Service - 1
• Employee Pilferage - 3
• Disciplinary Action in Another State - 4
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		• Refusal to Fill - 1 • Unprofessional Conduct - 1 • Fraud - 3 • Missing Required CEs - 1 • Unsanitary Conditions - 1 • Dispensing Error - 1 • Invalid CPR - 1 • Criminal Charges - 1 • Billing Discrepancies - 1 Resolved (Including Carryover) – 40 Actions within Goal – 29/40 Final disciplinary actions taken – 11 Summary Actions Taken – 1 Average days to complete – 100 **Inspections:** Total - 226 Annual Inspections - 186 Opening Inspections - 6 Closing Inspections - 28 Relocation/Change of Ownership Inspections - 3 Board Special Investigation Inspections – 3	
E. Legislation & Regulations	**B. Clark, Legislative Liaison**	**<u>Regulations</u>** **<u>Legislation</u>**	

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III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	**Santos Camilo:** My name is Santos Camilo and I work at a non-resident pharmacy, Dunn Meadow Pharmacy, in Fort Lee, NJ. We are interested in providing naloxone to patients that live in Maryland that we mail prescriptions to. Since we are located in New Jersey, do our pharmacists have any Maryland-specific requirements/steps to take in order to do so? Or should we follow the New Jersey standing order protocol for naloxone, since we are located there? **Proposed Response:** A nonresident pharmacy may dispense naloxone to a Maryland patient provided that the dispensing complies with 1) Maryland laws and regulations, including Maryland's standing order on dispensing naloxone (*see* COMAR 10.34.37.04), and 2) all applicable New Jersey laws, including New Jersey's standing order (*see* Md. Code Ann., Health Occ. § 12-403(g)). **James Balestrino Jr.:** Can a multi-dose vaccine, such as the Vivotif typhoid vaccine, be part of a vaccine protocol between a physician and a pharmacy? **Proposed response:** Providing a patient with doses of a vaccine to take at home is considered dispensing—not administering—and therefore cannot be done pursuant to a vaccine protocol. There are therefore two potential options in the situation described: 1) the pharmacy may have a vaccine protocol for Vivotif if all doses are administered by the pharmacist directly to the patient (i.e. the patient would need to come back to the pharmacy for each dose); or 2) the pharmacist may dispense the vaccine to the patient in response to a prescription written by an authorized prescriber. **John (Jay) School:** I am e-mailing to find out about the regulations considering breaking insulin boxes (of pens). For example, if we have a prescription for Lantus Solostar, inject 10 units daily, but insurance only covers a 30 day supply…should we be opening the box and sending one pen? All of the insulin pen boxes states for SINGLE PATIENT USE only. Additionally, there is only one package insert per box.	

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		Proposed response: The single-use labeling refers to use of an individual pen, not to the entire box. A pharmacist may dispense one pen from a box to a patient. **Angela Morris:** We are a specialty pharmacy located in Gaithersburg, MD and we are wanting to do in-office prescription dispensing through an automated dispensing machine. Could you provide some guidance on how we could make a case to the board to allow such dispensing? Some information on what we are hoping to achieve: 1. This would be for an injectable controlled substance requiring administration by a physician. 2. The drug would be distributed to our specialty pharmacy direct from the manufacturer. The pharmacy would ship the drug to the physician's office and stock in an automated dispensing machine. 3. The physician would write a prescription and the pharmacist would complete a DUR and verify the prescription via integrated software. 4. A pharmacy technician employee of the pharmacy would fill and label the prescription at the physician's office which would be verified and counseling provided by a pharmacist via video-link prior to dispensing. Our goal is to help patients get their medication administered quickly at the point of care. **Proposed response:** This practice is not permissible. A remote automated medication system such as the one that you have described may only be located in a hospital or related institution as defined in Md. Code Ann., Health Gen. § 19-301, or in a medical facility owned and operated by a group model health maintenance organization as defined in Md. Code Ann., Health Gen. § 19-713.6 (*see* COMAR 10.34.28.02B(7) and COMAR 10.34.28.02B(5). Because the doctor's office that you have described does not appear to meet these requirements, an automated medication system may not be placed in that office. **Rick Irby:** Can a licensed pharmacist (who is not licensed in Maryland), who works at a non-resident pharmacy (central fill/processing or mail order pharmacy) licensed by the Maryland Board of Pharmacy, with a Pharmacist	

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		in Charge (PIC) who is also licensed by the Maryland Board of Pharmacy, conduct a comprehensive medication review (CRM) remotely with a patient located in Maryland? If the answer is no, what is required by the Board for pharmacists at a non-resident pharmacy, licensed by the Maryland Board, with a PIC also licensed by the Maryland Board, to conduct CMR's? **Proposed response:** A licensed pharmacist that is not licensed in Maryland may conduct a comprehensive medication review, as you have described. However, it should be noted that the Board will hold the Maryland pharmacist on staff responsible for the review pursuant to COMAR 10.34.37.04B (2). **Beth Arnold:** I am the project manager for Costco Pharmacy and we are considering adding travel medicine services to our locations in MD. I have a question about the training requirements to administer travel vaccines. If pharmacist is already registered with the MD BOP to administer vaccines, are we able to use an internal training program to add travel vaccines? If not, which training programs are approved by the BOP to administer travel vaccines? **Proposed response:** As long as there is a protocol in place for each new vaccine that is to be offered, the pharmacists that are registered with the Board to administer vaccinations are not required to complete an additional training program to administer such vaccines. *See* COMAR 10.34.32.03. **Rob Geddes:** With the recent release of several authorized generic drugs in the market, we conducted a review of state laws and regulations. During the review it was determined the laws or regulations in your state were unclear as to whether an authorized generic may be substituted for the brand name medication without calling the prescriber for authorization to change the medication. In many cases the authorized generic is much more cost effective than the labeled brand name medication. An authorized generic does not need to submit an Abbreviated New Drug Application (ANDA) or prove bioequivalence. An authorized generic is	

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		marketed under the brand name drug's New Drug Application (NDA). As a result, an authorized generic is not rated in the FDA's Orange Book for therapeutic equivalence evaluations. According to the FDA, "An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug." In light of this information, will you please confirm whether or not your state allows substitution of an authorized generic for its brand name medication without first contacting the prescriber for permission? **Proposed response:** Provided that the drug is on the FDA's list of authorized generic drugs, the drug may be substituted for a brand name drug without contacting the authorized prescriber, pursuant to Md. Code Ann., Health Occ. 12-504. **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:** The Board understands your concerns and has referred this issue to committee to examine possible solutions. In general, it is the professional responsibility of individual pharmacists to ensure that they are practicing in a safe manner. (COMAR 10.34.10.01B) Additionally, HG 12-403(c)(7) requires permit holders to support their professional staff and not interfere with their professional judgment.	

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		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? **Proposed response:** If the pharmacy wishes to dispose of only non-controlled substances, then the pharmacy may register as a prescription drug repository pursuant to COMAR 10.34.33.07, and the CCRC may deliver the returned drugs for disposal to the pharmacy. In this case, a pharmacist must accept the return—as this is a non-delegable act—to ensure that there are no controlled substances in the return, and then place the returned drugs in a secured, one-way container in the pharmacy. If the pharmacy plans to dispose of controlled substances, then the pharmacy may order mail-in bags that comply with the DEA's drug disposal guidelines and register with the State of Maryland as a prescription drug repository, pursuant to COMAR 10.34.33.06. **Griffin Sauvageau:** I'm a pharmacy student at the University of Maryland School of Pharmacy and I'm involved in the National Community Pharmacists business plan competition this year. We are designing a company that delivers prescriptions to an automated locker system at peoples' 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.	

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		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 10.34.25.04, a pharmacy "may not knowingly deliver prescription medications to a depot, or establish or cooperate in the establishment of a depot." **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 below. Is that the Maryland Board of Pharmacy's understanding? See below. (i) All parts of any plant of the genius Cannabis, whether or not the plant is growing; (ii) The seeds of the plant; (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) " 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;	

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		(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. Md Code, Criminal Law 5-101 (r)(2)(vi). Legislative history also states that hemp products with less than .3 were not intended to be controlled substances in Maryland. See p. 3 and 4 of file:///home/chronos/u-804f5d2a0c46fd59b7d719cd09f9067a937dc716/Downloads/hb0698fiscalpolicy%20(1).pdf *note: Link above is broken. **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.	

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B. Licensing Committee	**D. Ashby, Chair**	**1. Review of Pharmacist Applications:** **a. #121331-** The applicant is requesting MDBOP grant her an extension of her MPJE score report, which expired on 4/16/2019. She passed the NAPLEX exam on 4/10/2019. ***Committee' s Recommendation: Approve*** **b. #120022-** The applicant is requesting ADA Testing Accommodations for the MPJE and NAPLEX exams. The applicant has been recently diagnosed with Generalized Anxiety Disorder. Please grant more test time on exams. ***Committee' s Recommendation: Approve*** **c. #121757-** The applicant is requesting ADA Testing accommodations for the NABPLEX and MPJE exams. He would like the MDBOP to grant him permission to use chromogenic glasses, due to black and white graphs and pictures on exams and presentations. His diagnoses is Colorblindness-Red/Green spectrum. ***Committee' s Recommendation: Approve*** **d. #121334-** The applicant is requesting ADA Testing accommodations for the NABPLEX and MPJE exams. The applicant is requesting 1.5x on all exams, take in a separate and quiet environment. Provide a physical copy of all digital exams so that problems could be worked on paper prior to entering answer into exam software. The applicant has been diagnosed with ADHD. ***Committee' s Recommendation: Approve***	

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		e. **#116899-** The applicant is requesting the Board to grant him an extension of his MDBOP application, which expired on 05/07/2019 and his MPJE ATT eligibility with NABP; which expired on 05/14/2019. ***Committee' s Recommendation: Approve*** **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications:** **a.** **#111859-** Registrant is requesting a refund of the reinstatement fee. Registrant was not provided the appropriate information as to what would satisfy as proof when her CE's were requested. ***Committee' s Recommendation: Approve refund*** **4. Review of Distributor Applications:** **a.** **MM #97379**- Company is requesting an extension for the submission of the renewal application to approximately 06/24/2019. ***Committee' s Recommendation: Need to submit an application with designated representative and then file for an extension. No reinstatement fee required.*** **5. Review of Pharmacy Applications: NONE**	

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		6. Review of Pharmacy Technicians Training Programs: NONE **7. New Business:** **a. Immediate Supervisor (Discussion) -** Do companies need to petition the Board for an exemption to for the Immediate Supervisor of the Designated Representative? ***Committee' s Recommendation: On next renewal send notification in writing along with renewal indicating if small company with one representative.*** **b. Distributor Permit Renewal Extension (Discussion) -** Confirmation of an extension for substantially completed applications to continue operations after the expiration date. The expiration date will not change, however, the status will remain Active. ***Committee' s Recommendation: Approve, extend until Sept 1st.*** ***c.*** **Identifying Manufacture applications-** Changing permit number to DM0000 ***Committee' s Recommendation: Approve, change permit number to #DS0000…. For (Distributor Short form) beginning September 1st.*** ***The change is to identify the difference from the wholesale long form to the distributor short form.*** ***d.*** **Auditing of Pharmacist-** The Board is inquiring as to the capability of the NABP CE Monitor System to	

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		record Non-ACPE approved continuing education credits. ***<u>Committee' s Recommendation: Approve,motion to start with auditing 10% of pharmacist and technicians CE credits until the we determine the scope of reporting for the NABP CE Monitor System.</u>*** ***e.*** **Birth Control- Pharmacist-** Broad discussion ***f.*** **Pharmacist Contraceptive Training Notification Form-** Discussion for approval	
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.	