

**Maryland Board of Pharmacy
Public Board Meeting**

**Meeting Minutes
November 21, 2018**

Name	Title	Present	Absent
Ashby, D.	Commissioner	X	
Bouyoukas, S.	Commissioner	X	
Evans, K.	Commissioner	X	
Hardesty, J.	Commissioner/Treasurer	X	
Laws Jr, A.	Commissioner	X	
Leikach, N.	Commissioner	X	
Morgan, K.	Commissioner/President	X	
Oliver, B.	Commissioner	X	
Peters, R.	Commissioner	X	
Rusinko, K.	Commissioner	X	
Toney, R.	Commissioner/Secretary	X	
Yankellow, E.	Commissioner	X	
Bethman, L.	Board Counsel	X	
Felter, B.	Staff Attorney	X	X
Speights-Napata, D.	Executive Director		X
Fields, E.	Deputy Director of Operations	X	
Brand, E.	Licensing, Legislative and Regulation Manager	X	
Evans, T.	Compliance Director	X	
Chew, C.	Management Associate	X	

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
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I. Executive Committee Report(s)	<p>A.) K. Morgan, Board President</p> <p>B.) R. Toney, Secretary</p>	<p><i>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.</i></p> <ol style="list-style-type: none"> 1. Call to Order 9:31 am 2. Sign-in Introduction and of meeting attendees – <i>(Please indicate on sign-in sheet if you are requesting CE Units for attendance)</i> 3. Distribution of Agenda and packet materials 4. Review and approve November 2018 Public Meeting Minutes 	<p>President, K. Morgan, introduced K. Rusinko as the new commissioner for home infusion.</p> <p>Motion by D. Ashby to approve the November 2018 Public Meeting minutes; 2nd K. Evans.</p>	<p>4. The Board voted to approve this motion.</p>
II. A. Executive Director Report	D. Speights-Napata, Executive Director	<ol style="list-style-type: none"> 1. Operations Updates 2. Meetings Update <ul style="list-style-type: none"> • MD Health Care Commission Electronic Submission Workgroup-Commissioner J. Hardesty • American Society for Pharmacy Law Meeting-Staff Attorney L. Bethman 	<p>2a) Commissioner, J. Hardesty, provided an overview of the meeting. Additional information can be located on MHCC website.</p> <p>Staff Attorney L. Bethman provided a recap of the meeting</p>	

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		<ul style="list-style-type: none"> <li data-bbox="651 334 1219 396">• Notre Dame School of Pharmacy Licensing meeting-Etzion Brand <li data-bbox="651 537 1119 566">• Contraception Forms-Etzion Brand 	<p data-bbox="1272 232 1676 293">and presentations held November 1st-4th in Hilton Head, SC.</p> <p data-bbox="1272 334 1661 496">2b) E. Brand provided a brief update of the Board's presentation on the licensing requirements at the Notre Dame School of Pharmacy.</p> <p data-bbox="1272 537 1576 599">2e) E. Brand provided an introduction of the forms</p> <p data-bbox="1272 639 1672 834">2g) D. Speights-Napata will accompany a representative from the University of Maryland Rehabilitation Services Contract for a brief presentation for 1st year pharmacy students.</p> <p data-bbox="1272 875 1647 997">2h) APhA-ASP will be hosting their international student segment at the Radisson on November 3rd.</p> <p data-bbox="1272 1037 1630 1135">2i) The November 21st and December 19th meetings will take place in room 110.</p>	
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B. Operations Report	E. Fields, Deputy Director/ Operations	1. Procurement and Budget Updates a) October 2018 Financial Statements b) UMAB Survey c) System Automation Enhanced Services 2. Management Information Systems (MIS) Unit Updates None	1a. A report on board revenue for October was provided. 1b. The survey by UMAB was approved for payment. 1c. System automation upgrades and cloud based environment conversion will take place over the next few months.																															
C. Licensing	E. Brand/ Licensing Regulations Manager	1. Unit Updates 2. Monthly Statistics <table border="1" data-bbox="651 883 1257 1406"> <thead> <tr> <th>License Type</th> <th>New</th> <th>Renewed</th> <th>Reinstated</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Distributor</td> <td>21</td> <td>0</td> <td>0</td> <td>1,310</td> </tr> <tr> <td>Pharmacy</td> <td>13</td> <td>0</td> <td>0</td> <td>2,105</td> </tr> <tr> <td>Pharmacist</td> <td>104</td> <td>473</td> <td>0</td> <td>12,001</td> </tr> <tr> <td>Vaccination</td> <td>63</td> <td>28</td> <td>0</td> <td>4,669</td> </tr> <tr> <td>Pharmacy Intern - Graduates</td> <td>1</td> <td>0</td> <td>0</td> <td>44</td> </tr> </tbody> </table>	License Type	New	Renewed	Reinstated	Total	Distributor	21	0	0	1,310	Pharmacy	13	0	0	2,105	Pharmacist	104	473	0	12,001	Vaccination	63	28	0	4,669	Pharmacy Intern - Graduates	1	0	0	44		
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		<table border="1"> <tbody> <tr> <td data-bbox="651 228 795 334">Pharmacy Intern - Students</td> <td data-bbox="795 228 900 334">14</td> <td data-bbox="900 228 1023 334">17</td> <td data-bbox="1023 228 1161 334">0</td> <td data-bbox="1161 228 1268 334">911</td> </tr> <tr> <td data-bbox="651 334 795 412">Pharmacy Technician</td> <td data-bbox="795 334 900 412">103</td> <td data-bbox="900 334 1023 412">288</td> <td data-bbox="1023 334 1161 412">5</td> <td data-bbox="1161 334 1268 412">9,800</td> </tr> <tr> <td data-bbox="651 412 795 526">Pharmacy Technician Student</td> <td data-bbox="795 412 900 526">3</td> <td data-bbox="900 412 1023 526">0</td> <td data-bbox="1023 412 1161 526">0</td> <td data-bbox="1161 412 1268 526">13</td> </tr> <tr> <td data-bbox="651 526 795 604">TOTAL</td> <td data-bbox="795 526 900 604">322</td> <td data-bbox="900 526 1023 604">806</td> <td data-bbox="1023 526 1161 604">5</td> <td data-bbox="1161 526 1268 604">30,853</td> </tr> </tbody> </table>	Pharmacy Intern - Students	14	17	0	911	Pharmacy Technician	103	288	5	9,800	Pharmacy Technician Student	3	0	0	13	TOTAL	322	806	5	30,853		
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D. Compliance	T. Evans Compliance Director	<p>1. Unit Updates</p> <p>2. Monthly Statistics</p> <p>Complaints & Investigations: New Complaints –47 Child Support –2 Disciplinary Actions in Another State – 6 Medication Error – 3 Billing Error – 1 Reimbursement complaint – 1 Inspection Issues – 27 Refusal to Fill – 2 Customer Service – 1 Unprofessional Conduct -2</p> <p>Resolved (Including Carryover) –50 Actions within Goal – 19/50 Final disciplinary actions taken – 7 Summary Actions Taken – 0</p>	<p>1. A new inspector will be hired by the 1st or 2nd week in December.</p> <p>2. T. Evans provided an overview of the complaints and investigations from the previous month.</p>																					

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		<p>Inspections:</p> <p>Total – 129 Annual Inspections – 111 Opening Inspections - 7 Closing Inspections – 4 Relocation/Change of Ownership Inspections – 2 Board Special Investigation Inspections – 5</p>		
<p>E. Legislation & Regulations</p>	<p>E. Brand Licensing, Legislation and Regulations Manager</p>	<ol style="list-style-type: none"> 1. <u>COMAR 10.34.32.03 D Requirements to Administer Vaccinations</u> 2. <u>Proposed COMAR 10.34.05.05 Security Responsibilities</u> 3. <u>COMAR 10.34.30 Applications</u> 4. <u>Proposed COMAR 10.34.09 Fees</u> 	<ol style="list-style-type: none"> 1. This regulation requires a CPR card be readily available. The regulation is currently awaiting approval from the Office of Regulation. 2. Approved by the Governor’s office, signed by the Secretary and will be published in the Maryland Register December 21st with a comment period ending Jan 22nd. 3. This regulation will allow the Board to withdraw applications after one year, submitted to the Office of Regulation October 12th and is awaiting approval from the Office of Regulation. 4. This regulation will eliminate fees for technician programs previously 	

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		<p style="text-align: center;">5. <u>Contraceptive Prescription Forms</u></p> <p><u>Legislation</u></p> <p><u>Generic Substitution Revision 12-504</u></p>	<p>approved by the Board and will be published in the Maryland Register December 21st with a comment period ending January 22nd.</p> <p>5a) Motion to refer back to the practice committee to adopt suggestions from the stakeholders and make additional changes, D. Ashby; 2nd by S. Boyoukas.</p> <p>The revised proposal will not move forward.</p>	<p>The Board voted to approve this motion.</p>
<p>III. Committee Reports</p> <p>A. Practice Committee</p>	<p>R. Peters, Chair</p>	<p><u>A. Opeoluwa Fagbemi</u></p> <p>I am a licensed pharmacist in Maryland. I am interested in engaging my local community church and nursing homes to offer flu shots. I would like to know what the board requires for me to maintain compliance. For example, I want to independently purchase flu shots, store them appropriately, and immunize my local church and engage local nursing homes. Since I do not own a pharmacy, and so do not have an NPI# or contract with the insurance/a processing software for claims, I wanted to know what steps, if possible, and/or compliance I would need in order to serve my community while education them on the importance of getting immunized.</p>	<p>a) Motion by D. Ashby to approve draft response; 2nd by S. Boyoukas.</p>	<p>The Board voted to approve this motion.</p>

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		<p>Proposed response:</p> <p>You may administer vaccines off-site under the authority of your pharmacist's license. However, you must comply with the regulations for registration to administer, and the reporting, recordkeeping and protocol requirements of COMAR 10.34.32.</p> <p><u>B. Rotimi Fagbemi</u></p> <p>My name is Rotimi Olawale Fagbemi, holder of Maryland Pharmacist license #23198. I have the desire to operate an online pharmacy based in the state of Maryland but specifically designed for patients outside of the United State of America.</p> <p>The main purpose of this is to serve patients with valid prescriptions from hospitals and health institutions from their countries of residence while in need of pharmaceutical products from the United States of America. For example, I practice pharmacy for about two decades in Nigeria before coming to United States of America and I noticed that many patients are sometimes in need of pharmaceutical produce from America without knowing how to go about it.</p> <p>I hereby require from your board what you will want me to do in order to meet the compliance as to obtain this noble and special license. Should I be given the opportunity, I promise to professionally and dutifully follow the compliance accordingly.</p> <p>Proposed response:</p>	<p>b) Amended motion by committee; 2nd by R. Toney.</p>	<p>The Board voted to approve this motion.</p>
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		<p>The Maryland state law does not authorize pharmacist to fill prescriptions written by prescribers outside the United States.</p> <p><u>C. Jered Pasay</u></p> <p>During a follow-up inspection it was observed that a pharmacy is filling prescriptions and all refills of sterile compounded Avastin for ophthalmic use at once, per doctor's requests. As per the Pharmacy PIC regarding prescription dispensing and refills: "Pharmacy gets an order pursuant to a prescription and dispenses prescription to the doctor for patient administration at the administration site (at Doctors Office). In ONLY THESE INSTANCES as per Doctors request a new prescription and refills will be requested all at once and dispensed accordingly."</p> <p>In accordance with HO §12-403(22) A pharmacy:</p> <p>"(ii) May provide to an ophthalmologist for office use, without a patient-specific prescription:</p> <ol style="list-style-type: none"> 1. Compound antibiotics for the emergency treatment of bacterial endophthalmitic or viral retinitis; and 2. Compound antivasular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema; and <p>(ii) Shall require the ophthalmologist to inform the pharmacy of the identity of any patient to whom the drugs are administered."</p> <p>Avastin is used, off label, by Ophthalmologists in the treatment of macular degeneration by blocking the growth of new abnormal blood vessels in the macula</p>	<p>c) Motion to approve recommendation by committee; 2nd by A. Laws, Jr.</p>	<p>The Board voted to approve this motion.</p>

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		<p>of the eye. Treatment is repeated as needed at 4 to 6 week intervals.</p> <p>Is filling prescriptions and refills all at once an appropriate pharmacy practice? Is it appropriate for this type of medication? Is this practice even required for this medication given the allowances provided in HO §12-403(22)? Would dispensing prescriptions and refills all at once lead to doctors misusing prescription medication as office use?</p> <p>Proposed responses:</p> <p>A compounding pharmacy may provide to an ophthalmologist for office use, without a patient-specific prescription: Compounded antivascular endothelial growth factors agents for emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema. The pharmacist does not need to have a prescription with multiple refills under the office use provision. The process under office use supplied drug is to have the ophthalmologist place an order for the drug for office use. The ophthalmologist shall inform the pharmacy of the identity of any patient to whom the drug is administered.</p> <p><u>D. Bob Gadani</u></p> <p>We at the pharmacy level are getting increasing queries as to if we carry and sell CBD products. Quarterfinal Pharmacy is contemplating ordering the product from our wholesaler and concurrently doing its own research on the compliance of selling CBD products as it relates to the Pharmacy laws in the state of Maryland and compliance with Controlled Substance ACT. What we have found is the following:</p>	<p>d) Motion to approve response with a link to the DEA guidance by committee; 2nd by R. Toney.</p> <p>After a brief discussion, motion to refer back to practice committee for guidance by K. Morgan; 2nd by A. Laws, Jr.</p>	<p>The Board voted to approve this motion.</p>

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		<p>1. Maryland House Bill 803 which dealt with the agriculture, criminal and legalization of Industrial Hemp was Approved by Governor Hogan in May 2015.</p> <p>2. In a Senate hearing on June 24, 2015, it was mentioned that “CBD derived from cannabis plant is controlled under schedule 1 of the CSA” (see attached). The CBD products that our wholesaler is carrying is from the Hemp plant, which was legalized in Maryland by the previous mention Bill. On the DEA website it does not have the classification of CBD derived from the HEMP plant.</p> <p>3. We could not find any guidance as to Cannabidiol products in COMAR 10.62</p> <p>4. A law firm has done research on the legality of CBD as it relates to the Controlled Substance Act, on behalf of the company whose CBD products our wholesaler will carry. (Please see attached).</p> <p>5. Certificate of Essay showing lack of and detectable THC is available on any CBD products carried by our wholesaler.</p> <p>6. Pain clinic physician are actively promoting CBD as an alternative option to opioids.</p> <p>7. Maryland residents can freely get CBD online or from non-pharmacy</p> <p>8. Our Wholesaler, Value Drug, is asking for a retail pharmacy agreement signed by the pharmacy before any CBD products can be ordered (see attached)</p> <p>Based on the above Quarterfield Pharmacy is asking for guidance from the Maryland Board of Pharmacy on being able to order and sell CBD products at the retail pharmacy level.</p> <p>Proposed response:</p>		
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		<p>CBD is listed as a Schedule I substance under federal law. The DEA's position is to treat it as a Schedule I substance regardless of conflicting state law.</p> <p><u>E. Governor Hogan's office</u></p> <p>Would you please take up legislation to lower the State mandated age that pharmacists can give vaccines? Many other states are already doing this and Maryland is behind the curve. With many children disproportionately sick from diseases in server flu seasons, for example, this will save lives. There is no medical reason a pharmacist should not be able to give a vaccine. There are trained to do so. This would also help to decrease the burden on the health care system and make it easier on parents and caregivers.</p> <p><u>F. Thomas Evans</u></p> <p>The practice committee recommended that the draft of the MOU should go before the full Board and the public for discussion and comment before 12/10/2018, the close of public comment.</p> <p>Proposed comment:</p> <p>The requirement for the state board of pharmacy to report adverse events and interstate distribution (dispensing) of 50% or greater should be limited to sterile compounded products only for 503A facilities. The potential safety issues associated with Non-sterile compounded products does not rise to the same level as sterile compounded products and the collection and reporting of these</p>	<p>Motion by N. Leikach to refer to practice committee; 2nd by K. Evans.</p> <p>f) Motion to approve recommendation by committee to place comments; 2nd by J. Hardesty.</p>	<p>The Board voted to approve this motion.</p> <p>The Board voted to approve this motion.</p>

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		statistics would be burdensome to both pharmacies and boards of pharmacy.		
B. Licensing Committee	D. Ashby, Chair	<p>1. Review of Pharmacist Applications: NONE</p> <p>2. Review of Pharmacy Intern Applications: NONE</p> <p>3. Review of Pharmacy Technician Applications: NONE</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications: a. HHI Infusion Services LLC- Company is requesting the Board reconsider its prior denial</p> <p>6. Review of Pharmacy Technicians Training Programs: NONE</p> <p>7. New Business: a. L.M.-Registrant is requesting that the Board send the hours earned working as a Technician to the DC Board of Pharmacy as Intern hours. <u>Licensing Committee's Recommendation: Deny</u></p> <p>b. Maria Eng- Requests approval of CE's <u>Licensing Committee's Recommendation: Deny</u></p>	<p>5a) Recommendation by committee to deny; 2nd by E. Yankellow.</p> <p>7a) Recommendation by committee to deny; 2nd by D. Ashby.</p> <p>7b) Recommendation by committee to approve; 2nd by J. Hardesty.</p>	<p>The Board voted to approve this motion.</p> <p>The Board voted to approve this motion.</p> <p>The Board voted to approve this motion.</p>

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C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update: <ul style="list-style-type: none"> • The committee met October 24th. The CE Breakfast was one of the topics discussed. The breakfast was well received. • There were 300 in person participants and 200 webinar registrants. • There will be an upcoming article describing the CE Breakfast in the newsletter. • The newsletter will include an article on error prevention, and how to integrate a root cause analysis into a quality assurance program. 		
D. Disciplinary	J. Hardesty Chair	Disciplinary Committee Update: <ul style="list-style-type: none"> • Committee met November 7th • A confidential discussion will be held in the Board's Closed Public Session. 		
E. Emergency Preparedness Task Force	N. Leikach, Chair	Emergency Preparedness Task Force Update: <ul style="list-style-type: none"> • Point of Dispensing drill was held at Notre Dame on November 8th. There were 40 students, five taskforce members, and three employees from Baltimore City Health Department assisting with the six hour drill. • Maryland Responds was able to register 15 volunteers during the drill. 		

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IV. Other Business & FYI	K. Morgan, President	<ul style="list-style-type: none"> • President K. Morgan acknowledged Secretary Neall's participation during the CE Breakfast. 		
V. Adjournment	K. Morgan, President	<p>A. The Public Meeting was adjourned at 11:15 am</p> <p>B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</p> <p>C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan, convened an Administrative Session for purposes of discussing confidential disciplinary cases.</p> <p>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.</p>	Motion to close the Public Board Meeting by D. Ashby; 2 nd by B. Oliver.	The Board voted to approve this motion.

**PRESIDING OFFICER'S WRITTEN STATEMENT FOR CLOSING A MEETING ("CLOSING STATEMENT")
UNDER THE OPEN MEETINGS ACT (General Provisions Article § 3-305)**

This form has two sides. Complete items 1 – 4:

1. Recorded vote to close the meeting: Date: 11/21/18; Time: 11¹⁵ AM; Location: 4201 Patterson Ave Baltimore
Motion to close meeting made by: D Ashby Seconded by B Oliver;
Members in favor: All; Opposed: none;
Abstaining: none; Absent: none.

2. Statutory authority to close session (check all provisions that apply):

This meeting will be closed under General Provisions Art. § 3-305(b) only:

(1)___ "To discuss the appointment, employment, assignment, promotion, discipline, demotion, compensation, removal, resignation, or performance evaluation of appointees, employees, or officials over whom this public body has jurisdiction; any other personnel matter that affects one or more specific individuals"; (2)___ "To protect the privacy or reputation of individuals concerning a matter not related to public business"; (3)___ "To consider the acquisition of real property for a public purpose and matters directly related thereto"; (4)___ "To consider a matter that concerns the proposal for a business or industrial organization to locate, expand, or remain in the State"; (5)___ "To consider the investment of public funds"; (6)___ "To consider the marketing of public securities"; (7) "To consult with counsel to obtain legal advice"; (8)___ "To consult with staff, consultants, or other individuals about pending or potential litigation"; (9)___ "To conduct collective bargaining negotiations or consider matters that relate to the negotiations"; (10)___ "To discuss public security, if the public body determines that public discussion would constitute a risk to the public or to public security, including: (i) the deployment of fire and police services and staff; and (ii) the development and implementation of emergency plans"; (11)___ "To prepare, administer, or grade a scholastic, licensing, or qualifying examination"; (12)___ "To conduct or discuss an investigative proceeding on actual or possible criminal conduct"; (13) "To comply with a specific constitutional, statutory, or judicially imposed requirement that prevents public disclosures about a particular proceeding or matter"; (14)___ "Before a contract is awarded or bids are opened, to discuss a matter directly related to a negotiating strategy or the contents of a bid or proposal, if public discussion or disclosure would adversely impact the ability of the public body to participate in the competitive bidding or proposal process."

Continued →

3. For each provision checked above, disclosure of the topic to be discussed and the public body's reason for discussing that topic in closed session.

Citation (insert # from above)	Topic	Reason for closed-session discussion of topic
§3-305(b) () 13	Applications for registrations, licenses and permits	To engage in medical review committee deliberations regarding confidential matters in applications
§3-305(b) ()		
§3-305(b) ()		
§3-305(b) ()		
§3-305(b) ()		

4. This statement is made by K. M. Morgan, Presiding Officer.
Kevin Morgan, President

WORKSHEET FOR OPTIONAL USE IN CLOSED SESSION: INFORMATION THAT MUST BE DISCLOSED IN THE MINUTES OF THE NEXT OPEN MEETING

Time of closed session: 11:15 AM Place: 4201 Patterson Ave Baltimore
 Purpose(s): To engage in medical review committee deliberations
 Members who voted to meet in closed session: unanimous
 Persons attending closed session: all members present at open session
 Authority under § 3-305 for the closed session: § 3-305 (a) (7) and (13)
 Topics actually discussed: confidential matters in applications
 Actions taken: process each application accordingly Each recorded vote: Unanimous
except for Applicant PLOD588

For a meeting recessed to perform an administrative function (§ 3-104): Time: 12:12 PM
 Place: 4201 Patterson Ave Persons present: all present in open closed unless recessed
 discussed: case investigation