

**Maryland Board of Pharmacy
Public Board Meeting**

**Agenda
September 15, 2021**

Name	Title	Present	Absent
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Fink, K.	Commissioner		
Hardesty, J.	Commissioner/President		
Geigher, P.	Commissioner		
Leikach, N.	Commissioner/Treasurer		
Morgan, K.	Commissioner		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner/Secretary		
Singal, S.	Commissioner		
Vasquez, J.	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		
Reed, J.	Legislative Liaison		
Chew, C.	Enforcement Compliance Auditor		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
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I. Executive Committee Report(s)	<p>A.) J. Hardesty, Board President</p> <p>B.)K. Rusinko, 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 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 August 2021 Public Meeting Minutes 											
II. A. Executive Director Report	D. Speights-Napata, Executive Director	<ol style="list-style-type: none"> 1. Staffing update 2. Meetings update 											
B. New Business	J. Hardesty, Board President	<ol style="list-style-type: none"> 1. None 											
C. Operations	E. Fields, Deputy Director/ Operations	<ol style="list-style-type: none"> 1. Procurement and Budget Updates <ol style="list-style-type: none"> a: August 2021 Financial Statements 2. Management Information Systems (MIS) Unit Updates <ol style="list-style-type: none"> a: None 											
D. Licensing	E. Bouyoukas, Commissioner	<ol style="list-style-type: none"> 1. Unit Updates 2. Monthly Statistics <table border="1" data-bbox="751 1263 1367 1344"> <thead> <tr> <th data-bbox="751 1263 905 1292">License Type</th> <th data-bbox="905 1263 1058 1292">New</th> <th data-bbox="1058 1263 1211 1292">Renewed</th> <th data-bbox="1211 1263 1367 1292">Reinstated</th> <th data-bbox="1367 1263 1467 1292">Total</th> </tr> </thead> <tbody> <tr> <td data-bbox="751 1292 905 1344"></td> <td data-bbox="905 1292 1058 1344"></td> <td data-bbox="1058 1292 1211 1344"></td> <td data-bbox="1211 1292 1367 1344"></td> <td data-bbox="1367 1292 1467 1344"></td> </tr> </tbody> </table>	License Type	New	Renewed	Reinstated	Total						
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E. Compliance	T. Leak, Compliance Director	<p>1. Unit Updates</p> <p>2. Monthly Statistics</p> <p>Complaints & Investigations:</p> <p>New Complaints – 24</p> <ul style="list-style-type: none"> • Medication Error - 3 • Employee Pilferage – 2 																																														

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		<ul style="list-style-type: none"> • Disciplinary Action in Another State – 1 • Failure to Report Adverse Event – 2 • Dispensing Error – 1 • Refusal to Fill – 3 • Customer Service - 2 • Inspection Issues – 9 • NABP VPP Compounding Issues – 1 <p>Resolved (Including Carryover) – 27 Actions within Goal – 20/27 Final disciplinary actions taken – 3 Summary Actions Taken – 1 Average days to complete – 22</p> <p>Inspections: Total - 122</p> <p>Annual Regulatory Inspections - 61 COVID Administration Site Inspections - 18 Narcotic Audit Follow Ups - 1</p> <p>Opening Inspections - 10 Closing Inspections - 0 Relocation/Change of Ownership Inspections - 1 Board Special Investigation Inspection - 0 VPP Review - 31</p>	
F. Legislation & Regulations	J. Reed, Legislative Liaison	<u>Regulations</u> None	F. Legislation & Regulations

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		<p><u>Legislation</u> None</p>	
<p>III. Committee Reports</p> <p>A. Practice Committee</p>	<p>Evans, K. Commissioner</p>	<p><u>DTM Applications</u></p> <p>1. <u>Kaiser Permanente – Part 1 & Part 2</u></p> <p><u>Questions</u></p> <p>1. S. Gaulkin – I have a question related to an out-of-state company (the “Company”) that provides prescription drug destruction and disposal services for customers, such as pharmacies, that collect prescription drug products from consumers – like a drug take-back program (like a reverse distributor).</p> <ul style="list-style-type: none"> • The Company’s customers would include pharmacies and other entities that would like to help consumers dispose of their excess prescription medications, which may include controlled substances. • The customers currently maintain kiosks at their sites (per the customers’ existing DEA and state licenses), where patients can drop off excess prescription drugs for disposal. • The Company will arrange for the pick-up of the kiosk contents on a routine basis (e.g., monthly) by a common carrier, that will then ship the contents to company’s facility (located out of state) for destruction. <ul style="list-style-type: none"> ○ The Company will send a representative to help the customer’s personnel box up the drugs for shipment before the common carrier arrives. However, the customer remains responsible for all security and storage until the common carrier arrives. ○ The Company’s facility is properly registered in its home state and also with DEA for its Rx drug destruction activities. 	

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		<ul style="list-style-type: none"> • The Company itself will <u>not</u> perform the physical shipment of the Rx drugs and will <u>not</u> hold title to the Rx drugs when they cross state lines. The customer holds title until the drugs are received at the company's facility. • The Company will <u>not</u> be shipping anything to any customer within Maryland. Rather, the drugs will only be shipped out of the state – i.e., from the customer's location within the state to the company's facility outside the state. • The company is only receiving Rx drugs from customers for destruction - <u>not</u> for further distribution or resale. <p>Does Maryland require licensure for the Company for these activities?</p> <p>Proposed Response: No, the Company would not require a distributor's permit if the pharmacy holds title to the drugs and is responsible for transferring the returned drugs to the Company as a third party returns process. Md. Code Ann., Health Occ., § 12-6C-01(u)(2)(xi).</p> <p>2. N. Howell - [Q]uestion regarding the legality of emailed rx (not electronic scripts). The clinic I work in has CRNPs and MDs who prescribe travel medicine for deployments and our rx software (super old) does not have the capability of processing (sending and receiving) e-scripts, therefore our pharmacy dispense all rxs via hardcopy format. I am wondering if our prescribers within the clinic are allowed to scan then email the scripts for non-controlled meds via OUTLOOK to us even though the contents contain PII? It would be sent only through our classified network. It would also be emailed from alias to alias instead of our own personal email accounts.</p> <p>Proposed Response: If a pharmacy transmits prescriptions within an electronic system, the system must comply with the Health Insurance</p>	
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		<p>Portability and Accountability Act (HIPAA). <i>See</i> 45 C.F.R. §§160, 164.</p> <p>3. K. Gibson: I have a couple of questions regarding immunization CE requirements.</p> <p>Currently the immunization CE requirements are 4 hours of the 30 required CE hours every 2 years.</p> <ol style="list-style-type: none"> 1. How will the enactment of HB 1040 (Chapter 792) change that requirement from July 1, 2021 to June 30, 2023? 2. Will the Board of Pharmacy be promulgating regulations for the requirements in HB 1040? <p><u>Proposed Response:</u> Generally, the continuing education credit requirement to administer a vaccine will not change (4 hours). COMAR 10.34.32.03A(3)(a).</p> <p>From July 1, 2021 to June 30, 2023, a pharmacist that <i>only</i> administers an FDA-approved vaccine to a child aged 3 – 17 will be required to complete an ACPE-approved practical training program of at least 20 hours and 2 hours of ACPE-approved continuing education credits related to immunization.</p> <p>The Maryland Board of Pharmacy will not promulgate regulations.</p> <p>4. R. Ross: The local Fire Marshall has requested that our pharmacy, Heartland Pharmacy of Maryland, LLC, provide the fire department with a key or key card that they can place in the KNOX box for our industrial plaza. This key or key card would only be capable of being accessed and utilized by the fire department. I'm hoping to get</p>	

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		<p>clarification from the Board of Pharmacy as to whether or not that would be permitted by Maryland law.</p> <p>In section 10.34.05.03 B(2),(3) of the Maryland Pharmacy Laws book it states:</p> <p>The pharmacy permit holder shall:</p> <p>(2) Have sole possession of a means of access to the pharmacy, except in emergencies; and (3) Establish a means of access for use in an emergency when the pharmacist is not available to access the prescription area</p> <p>I'm assuming that the fire department access would fall under the "emergency" category, but I am looking for Board of Pharmacy interpretation.</p> <p>Proposed Response: The Maryland Board of Pharmacy supports the enforcement of municipal safety regulations. Storage of a key or key card in a KNOX box for emergency access would constitute an emergency exception to the requirement of a pharmacist to maintain sole possession of a means to access the pharmacy. COMAR 10.34.05.02B.</p> <p>5. M. Mazzenga: We are researching the possibility of opening an stand-alone ambulatory infusion suite run by a Nurse Practitioner. A pharmacy will provide patient specific medication to be infused at the suite. Would we need any license to store the medication until the patient came in for treatment?</p> <p>Proposed Response: A licensed healthcare facility or prescriber's office is not considered an illegal depot under COMAR 10.34.25.02B(2). Therefore, dispensed non-controlled dangerous substances may be delivered and stored without a pharmacy permit.</p>	
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		Please contact the Drug Enforcement Agency regarding federal regulations on the delivery of a controlled substance by a pharmacy to a practitioner. <i>See</i> 21 C.F.R. § 1306.07.	
B. Licensing Committee	K. Rusinko, Chair	<p><i>1. Review of Pharmacists Applications: NONE</i></p> <p><i>2. Review of Pharmacy Intern Applications: NONE</i></p> <p><i>3. Review of Pharmacy Technician Applications: NONE</i></p> <p><i>4. Review of Distributor Applications: NONE</i></p> <p><i>5. Review of Pharmacy Applications: NONE</i></p> <p><i>6. Review of Pharmacy Technician Training Programs: NONE</i></p> <p><i>7. CE Approval Request:</i></p> <p>a. Sovitj Pou - Recertification of Advanced Cardiovascular Life Support (ACLS) and Basic Life Support (BLS) <i>Committee recommendation: Deny</i></p> <p><i>8. New Business:</i></p> <p>a. Andelika Tutak - Mr. Andzelika Tutak, pharmacist of Med One Thurmont Pharmacy; would like further clarification about the re-enrollment process for a potential pharmacy technician candidate. The candidate recently took her pharmacy technician test for the second time and did not pass. Mr. Tutak would like to know; what are the requirements? Can the trainee be re-enrolled into the training program? (At this time, the Board has not received an application from trainee.)</p>	

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		<p><u>Committee recommendation: Can only work as a Technician in training for up to six months. Can take the training and exam as many times as necessary</u></p> <p>b. AB - Pre Technician applicant is requesting the Board reconsiders their denial of a waiver of the 160 experience hours. She has not been successful in finding a location to obtain her experience hours.</p> <p><u>Committee recommendation: Deny request for waiver of 160 hours, (Include COMAR 10.34.34.04). Inform her of the option to become Nationally Certified and her ability to attend another program.</u></p> <p>c. DD - Intern is requesting an extension to the expiration date of her registration until she becomes licensed as a Pharmacist. She expects to become licensed by October.</p> <p><u>Committee recommendation: Deny. Inform her she is welcome to apply as a pharmacy technician if she meets the requirements. The Intern registration cannot be extended any further.</u></p>	
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	J. Hardesty, President		
V. Adjournment	J. Hardesty, President	A. The Public Meeting was adjourned.	

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		<p>B. J. Hardesty 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>	