

**Maryland Board of Pharmacy
Public Board Meeting**

**Agenda
July 21, 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) | A.) J. Hardesty, 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 2021 Public Meeting Minutes | | | | | | | | | | | | | | | | | | | | | | | | | |
| II. A. Executive Director Report | D. Speights-Napata, Executive Director | 1. Meetings 2. Reminders | | | | | | | | | | | | | | | | | | | | | | | | | |
| B. New Business | J. Hardesty, Board President | 1. None | | | | | | | | | | | | | | | | | | | | | | | | | |
| C. Operations | E. Fields, Deputy Director/ Operations | 1. Procurement and Budget Updates a: June 2021 Financial Statements 2. Management Information Systems (MIS) Unit Updates a: | | | | | | | | | | | | | | | | | | | | | | | | | |
| D. Licensing | E. Bouyoukas, Commissioner | <table><tr><td colspan="5">1. Unit Updates</td></tr><tr><td colspan="5">2. Monthly Statistics</td></tr><tr><td>License Type</td><td>New</td><td>Renewed</td><td>Reinstated</td><td>Total</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table> | | | | | 1. Unit Updates | | | | | 2. Monthly Statistics | | | | | License Type | New | Renewed | Reinstated | Total | | | | | | |
| 1. Unit Updates | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. Monthly Statistics | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| License Type | New | Renewed | Reinstated | Total | | | | | | | | | | | | | | | | | | | | | | | |
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| Subject | Responsible Party | Discussion | Action Due Date (Assigned To) |
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| | | <ul style="list-style-type: none"> • Unprofessional Conduct – 5 • Dispensing Error – 1 • Refusal to Fill – 4 • Customer Service – 3 • Unlicensed Personnel – 1 • FDA Warning Letter, USP 797 - 1 • Inspection Issues – 11 <p>Resolved (Including Carryover) – 26 Actions within Goal – 14/26 Final disciplinary actions taken – 1 Summary Actions Taken – 0 Average days to complete – N/A</p> <p>Total - 195</p> <p>Annual Regulatory Inspections - 27 COVID Administration Site Inspections - 112 Narcotic Audit Follow Ups - 32</p> <p>Opening Inspections - 17 Closing Inspections - 3 Relocation/Change of Ownership Inspections - 3 Board Special Investigation Inspections – 1</p> | |
| F. Legislation & Regulations | J. Reed, Legislative Liaison | <u>Regulations</u> COMAR 10.19.03.08C – proposed regulatory change to align with Federal provision <u>Legislation</u> None | F. Legislation & Regulations |

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| III. Committee Reports A. Practice Committee | Evans, K. Commissioner | <p>Varsha Gaitonde: QuVa Pharma is a 503B registered outsourcing facility and is registered with the Maryland Pharmaceutical Control Division as a distributor- D05728. We currently ship compounded sterile preparations directly to hospitals in Maryland. 503B preparations are required by the FDA to be labeled- For Institutional or Office Use only, Not for Resale.</p> <p>One of our customers which is a large hospital system, MedStar, has stated: we feel we can facilitate this process by setting up an account at our extenCARE pharmacy operation in Elkridge, MD. They can be the ordering pharmacy which can then send the product to MedStar's urgent care sites.</p> <p>Question: Is it okay for QuVa Pharma to ship our products to this facility for further distribution to their urgent care sites? The license numbers of the extenCARE pharmacy is: PW0039 with Board of Pharmacy, NRX1901466 with the Pharmaceutical Control Division.</p> <p>Proposed Response (K. Evans was recused): Under the federal Drug Quality and Safety Act (DQSA), a recipient of compounded sterile preparations purchased from a 503B outsourcing facility may not further distribute the products. Please contact the FDA for further guidance and interpretation.</p> <p>Tony Brocato: We have gotten inquiries from some local Dermatologists and Veterinarians about compounding for office use. When searching the Maryland Pharmacy law book, it is hard to determine what is allowed.</p> <p>Dermatologists often use numbing creams for procedures in their offices. Are they required to use a 530B outsourcing facility or are pharmacies allowed to compound? Veterinarians also inquire about Compounds they may need to treat patients in their office when commercial products will not due. Can you please give us some</p> | |
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| Subject | Responsible Party | Discussion | Action Due Date (Assigned To) |
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| | | <p>clarification on what is currently allowed. We look forward to your reply.</p> <p>Proposed Response: Generally, a pharmacy may only compound sterile products that are patient-specific. Therefore, dermatologists must order office stock compounds from a 503B outsourcing facility.</p> <p>However, a pharmacy that complies with specific compounding rules and does not provide an amount that would be greater than 10% of total pharmacy drug sales, may provide compounded preparations to a licensed veterinarian without a patient-specific prescription to a licensed veterinarian. See Md. Code Ann., Health Occ., § 12-510. Please note, however, that the federal law does not contain a similar exception to the prescription requirement for veterinarians.</p> <p>Robert Kent: With all due respect I feel your Pharmacy Board needs to address the issue of background checks being needed for license renewal. We are licensed in 25 states and have accreditation with VAWD/NABP. None of the others states or VAWD require background checks upon renewal. It is a very expensive and time consuming activity that is redundant especially with the all-encompassing VAWD inspections and renewal process. Please forward this email to your Executive Secretary for consideration.</p> <p>Proposed Response: The Maryland Board of Pharmacy (Board) provides a 2-year renewal term for a pharmacy permit. Md. Code Ann., Health Occ., § 12-407. The Board requires a background check of the designated representative and immediate supervisor of a wholesale distributor to ensure that appropriate personnel are overseeing the wholesale distribution of prescription drugs, including controlled substances. The Board is not currently considering changing the requirements for a distributor's permit.</p> | |

| Subject | Responsible Party | Discussion | Action Due Date (Assigned To) |
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| | | <p>Vishal Thaker – I have a question around shared services (specifically processing) between two pharmacies.</p> <p>Pharmacy A: Located within Maryland and licensed as a retail pharmacy.</p> <p>Pharmacy B: Located outside Maryland, licensed in its home state as a retail pharmacy and holds a non-resident Maryland permit.</p> <p>Pharmacy B would process (prescription intake, data entry, patient counseling) prescriptions for Pharmacy A.</p> <p>Pharmacy A would print the label, fill the prescriptions, and perform a final check on the prescription.</p> <ul style="list-style-type: none"> • Is this type of practice allowed? • Would the pharmacist in charge of pharmacy B need to be licensed as a pharmacist in Maryland? • Do staff pharmacists and/or pharmacy technicians in pharmacy B performing processing for pharmacy A need to be licensed in Maryland? <p>Is there a special approval needed to conduct this type of service?</p> <p>Proposed Response:</p> <p>The Maryland Pharmacy Act does not prohibit this type of shared service model provided that all licensure, recordkeeping, and practice standards and laws are met. The nonresident pharmacy must staff a pharmacist licensed by the Board. Md. Code Ann., Health Occ., § 12-403(e). The nonresident pharmacy must designate the pharmacist licensed by the Board as the pharmacist responsible for providing pharmaceutical services to patients located in Maryland. Md. Code Ann., Health Occ., § 12-403(e).</p> <p>The Board does not require additional staff members, including pharmacy technicians, located in the nonresident pharmacy to register with the Board. Special approval is not required.</p> | |

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| | | <p>Vaishali Khushalani: I am reaching out with a question that has come up regarding labeling of some ophthalmic eye drops that get sent home. Our current label was previously approved by the Board of Pharmacy.</p> <p>[SEE EMAIL FOR EXAMPLE LABEL.]</p> <p>Is it permissible to have a Sig: “Use as directed in discharge instructions” instead of exact number of drops? That way, it refers the patient to their written instructions which will have all the instructions. This will help prevent confusion for some complex or tapering instructions.</p> <p>Proposed Response: The indicated labeling is permitted.</p> <p>Marybeth McLaverty: I am reaching out with a few questions regarding operating pharmacy services in two different states. Currently our main network resides in Delaware with multiple locations, all able to access the same electronic medical record (EMR). Recently, the company expanded acquiring a new inpatient facility in Maryland. I am looking into the different requirements and limitations my team will face with this transition.</p> <p>I am looking for information regarding: Will pharmacists still be able to access the EMR and perform tasks such as verify orders etc. at either location if they are only licensed in one? Will training be impacted? Meaning will a pharmacist working at the Delaware location be able to train in Maryland if needed? (again with one license) For certified pharmacy technicians, are there different capabilities legally between Delaware and Maryland, in terms of roles or responsibilities?</p> | |
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| | | <p>Proposed Response: Unless a pharmacist is practicing within a Maryland permitted non-resident pharmacy, the pharmacist must be licensed by the Maryland Board of Pharmacy to engage in remote order processing of a prescription for a Maryland patient.</p> <p>If an out-of state pharmacy provides pharmaceutical services to an individual located in Maryland, the out-of-state pharmacy must obtain a nonresident permit which requires that at least one pharmacist on staff be licensed in Maryland and be responsible for pharmaceutical services delivered to an individual located in Maryland. Md. Code Ann., Health Occ., § 12-403(e).</p> <p>A pharmacist licensed in Delaware may attend or provide orientation in Maryland, but may not engage in clinical or dispensing functions. Md. Code Ann., Health Occ., §§ 12-301, 12-307.</p> <p>Pharmacy technicians must comply with the guidelines issued by the state in which they are registered.</p> <p>Jeffery Sinko: Please see attached three page letter. Topic: prescription order outsourcing regulation. COMAR 10.34.04.06.</p> <p>Proposed Response: If the out-of-state pharmacy is not dispensing to an individual located in Maryland, the Maryland Board of Pharmacy does not require that the out-of-state pharmacy obtain a nonresident permit. Md. Code Ann., Health Occ., § 12-401.</p> | |
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| | | <p>Jessica Adams: The project/model combines two unique services into one offering: central fill and customized patient medication packaging. In the model, the Cardinal Health pharmacy located in Texas will fill the prescriptions into patient specific medpacks at the request of the independent pharmacy located in Maryland. From our review, central fill meets the requirements for outsourcing a prescription order as defined in COMAR 10.34.04.02 and outlined in 10.34.04.06. The customized medication packages meet USP requirements and label requirements as discussed in § 12-505 and COMAR 10.34.04.06.</p> <p>Prescription Order Outsourcing PowerPoint</p> <p>Proposed Response: If the out-of-state pharmacy provides pharmaceutical services to an individual located in the state of Maryland, the out-of-state pharmacy must obtain a nonresident pharmacy permit and staff a pharmacist licensed by the Maryland Board of Pharmacy. Md. Code Ann., Health Occ., §§ 12-401, 12-403(e). In addition, since the proposed practice model constitutes outsourcing, the primary pharmacy in Maryland and the secondary pharmacy in Texas must comply with outsourcing regulations. COMAR 10.34.04. Lastly, the use of automated devices must comply with the Board's automation regulations. COMAR 10.34.28.</p> | |
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| B. Licensing Committee | E. Bouyoukas, Commissioner | <p>1. Review of Pharmacist Applications:</p> <p>a. Applicant# 123213 - Applicant is requesting approval to retake the NAPLEX. He was unable to take the exam on the scheduled date as he contracted COVID 19. <i>Committee recommendation: Approve eligibility extension for 6 months. Applicant must reapply.</i></p> <p>b. Applicant# 129630 - Reciprocity applicant is requesting a waiver of the MPJE citing the Health Occ 12-305 clause. Her argument includes that she meets the requirements of the citation and there is no telehealth specific pharmacist license. <i>Committee recommendation: Deny. Inform applicant the reciprocity process waives the NAPLEX exam requirement. The state specific MPJE exam must be taken.</i></p> <p>c. Applicant# 124583 - Applicant is requesting a waiver of the application fee for the Pharmacist initial licensure application. She was not aware of the expiration date of her Board application. All exams have been passed. <i>Committee recommendation: Deny, must pay application fee.</i></p> <p>d. Applicant# 129865 - Applicant is requesting an extension of her MPJE score. Due to deaths in her family, she was not able to take the NAPLEX exam. MPJE score expires 07/11/21. Original application submitted expired 04/26/2021. <i>Committee recommendation: Extend MPJE score for 6 months.</i></p> <p>e. Applicant# 125188 - Applicant is requesting an extension of her NAPLEX score until 01/2022 to complete the licensure requirements. Original application submitted expired 09/04/2019.</p> | |
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| | | <p><i>Committee recommendation: Extend eligibility for 6 months, must reapply.</i></p> <p>f. Applicant# 125546 - Applicant is requesting an extension of his MPJE score which expired 06/11/21, he plans to take the NAPLEX in July 2021. <i>Committee recommendation: Extend MPJE score for 6 months, must reapply.</i></p> <p>g. RO - Expected Reciprocity applicant is requesting a letter from the Board to be sent to NABP approving his school change from a foreign pharmacy school to a US pharmacy school. <i>Committee recommendation: Approve. Send letter to NABP accepting the US school's information.</i></p> <p>1. Review of Pharmacy Intern Applications:</p> <p>a. MM - Registrant is requesting an extension of the expiration date of his Intern registration while he prepares for the licensing exams. As a foreign graduate he cannot renew. <i>Committee recommendation: Approve extension until 10/31/2021.</i> JAVIER VAZQUEZ RECUSED</p> <p>b. CG - Registrant is requesting an extension of her Intern registration. <i>Committee recommendation: Deny, unable to extend.</i></p> <p>2. Review of Pharmacy Technician Applications:</p> <p>a. AB - The applicant is currently working to complete her application for Pharmacy Technician Registration. During the last two-years, Ms. Battle has completed a pharmacy technician training program and has passed the</p> | |

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| | | <p>state exam. Due to COVID-19 and her inability to complete the 160 hours, Ms. Battle is now requesting for the 160 hours to be waived and to become registered without having to redo the entire training program again. Committee recommendation: Deny waiving 160 hours. Applicant should contact training program for another site placement.</p> <p>b. LCOH - LCOH was receiving funds from unemployment and it recently ended. She states that she does not have the money, which stopped on June 1st to renew her technician registration. She was one of the people kicked off the program on June 1st. Due to financial difficulties, she, is requesting for an extension to renew her pharmacy Technician registration that will expired on 06/30/2021. Committee recommendation: Approve. Due to COVID 19 related financial hardship, a waiver of the renewal fee for one time. Must submit the renewal application.</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications:</p> <p>a. Janet Adeyemi - Permit holder is requesting a refund of the application fee paid for a new pharmacy permit. The new application initially submitted expired 04/30/2021. Committee recommendation: Deny, fee paid is an administrative fee.</p> <p>6. Review of Pharmacy Technicians Training Programs:</p> <p>a. Meritus Medical Center Inpatient Pharmacy Committee recommendation – Approve</p> | |

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| | | <p>7. New Business:</p> <p>a. Nick Shelly - Inquirer is requesting clarification regarding the requirements of the CPR requirements. His company provides training to include BLS through the American Red Cross. He has been informed by pharmacists that the CPR course must indicate “American Heart Association” on the card, is that true?</p> <p>1. This course has to include an in person training portion with an instructor. The course that we offer is a blended learning course where half the course is online instruction and the other half is in person and hands-on practice with skills assessments for each module. Some potential customers have stated they could not take this course because it was not 100% in person and therefore would not be accepted by the board. The representative on the phone has already told me that as long as there is an in person portion the course qualifies. Could you verify that for me?</p> <p>2. It has been expressed to me by these pharmacists that they are under the impression that their American Red Cross Certification card has to have a mention of American Heart Association somewhere on the card. I do not believe this is true, and, as of this month the ARC and AHA programs have merged to be the same program. So long as the training is provided by a certified instructor of a qualifying organization, the training is valid, correct? Does ARC qualify as a training organization for BLS?</p> <p>3. Is there a list of approved certifying trainers that your pharmacists can reference in order to obtain their BLS or CPRO training certification? If so, how does one get onto that list?</p> <p>4. Could you please provide documentation detailing your training requirements?</p> <p>Committee recommendation:</p> <p>1. <i>Yes, “blended” courses are acceptable.</i></p> | |
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| | | <p>2. <i>The training is valid if provided by a certified instructor of a qualifying organization. ARC is an acceptable provider</i></p> <p>3. <i>There is no reference list of providers</i></p> <p>4. <i>Refer to requirements.</i></p> <p>b. Trieu Bao - Inquirer has the following question: Is a pharmacist graduate allowed to administer Covid vaccines without the presence of a pharmacist at an offsite vaccination clinic? The pharmacist graduate had done his clinical rotations at M&T Bank stadium and had also attended vaccination clinics offsite with a supervising pharmacist the past 2 months. <i>Committee recommendation: No. Pharmacy graduates may not administer COVID vaccinations without pharmacist supervision.</i></p> <p>c. BA- Expected applicant is requesting the Board allow him to reciprocate to Maryland without completing the FPGECE. <i>Committee recommendation: Deny.</i></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> | |