

**Maryland Board of Pharmacy  
Public Board Meeting  
Minutes**

Date: January 15, 2014

| Name                    | Title                                     | Present | Absent | Present | Absent |
|-------------------------|-------------------------------------------|---------|--------|---------|--------|
| <b>Board Committee</b>  |                                           |         |        |         |        |
| Bradley-Baker, L.       | Commissioner                              | ✓       |        | 6       | 1      |
| Finke, H.               | Commissioner/Secretary                    | ✓       |        | 7       | 0      |
| Gavgani, M. Z.          | Commissioner/Treasurer                    | ✓       |        | 7       | 0      |
| Israbian-Jamgochian, L. | Commissioner/President                    | ✓       |        | 6       | 1      |
| Jones, David H.         | Commissioner                              | ✓       |        | 6       | 1      |
| Robinson, T.            | Commissioner                              | ✓       |        | 3       | 0      |
| Rochester, C.           | Commissioner                              | ✓       |        | 5       | 0      |
| Roy, S.                 | Commissioner                              | ✓       |        | 6       | 0      |
| Smith, J.               | Commissioner                              | ✓       |        | 5       | 2      |
| St. Cyr, II, Z. W.      | Commissioner                              | ✓       |        | 7       | 0      |
| Zagnit, B.              | Commissioner                              | ✓       |        | 2       | 0      |
|                         |                                           |         |        |         |        |
| <b>Board Counsel</b>    |                                           |         |        |         |        |
| Bethman, L.             | Board Counsel                             | ✓       |        | 7       | 0      |
| Felter, B.              | Staff Attorney                            | ✓       |        | 7       | 0      |
|                         |                                           |         |        |         |        |
| <b>Board Staff</b>      |                                           |         |        |         |        |
| Naesea, L.              | Executive Director                        | ✓       |        | 6       | 1      |
| Wu, Y.                  | Compliance Manager                        | ✓       |        | 5       | 2      |
| Waddell, L.             | Licensing Manager                         | ✓       |        | 6       | 1      |
| Gaither, P.             | Administration and Public Support Manager | ✓       |        | 6       | 0      |
| Jeffers, A.             | Legislation/Regulations Manager           | ✓       |        | 7       | 0      |
| Johnson, J              | MIS Manager                               | ✓       |        | 7       | 0      |



| Subject                            | Responsible Party                          | Discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Action Due Date (Assigned To) | Results |
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|                                    |                                            | reporting further on the recruitment of these positions. L. Naesea welcomed the Board's newest interns, Perry Shafner from the University of Maryland School of Pharmacy and also Sih Nanga Ndumo from the University of Maryland Eastern Shore School of Pharmacy. Both interns began Monday, January 13, 2014 and will be with the Board for five weeks.                                                                                                                                                                                                                                                                                                                                                                                                                                          |                               |         |
| B. Administration & Public Support | P. Gaither, Admin.& Public Support Manager | <p><b>Personnel Updates</b> – P. Gaither noted that last month she reported that the Board was fully staffed. The Board is now down one inspector and recruitment will begin shortly to fill that position. P. Gaither confirmed that the Board is actively recruiting for the three temporary positions for the Compliance Unit.</p> <p><b>Contract Updates</b> – The Board will be meeting with PEAC at the end of January, 2014 to discuss the renewal of its contract with PEAC. The NABP contract for inspections is in the process of being finalized. The scanning contract has been revised and sent to OPASS yesterday with the hope it will be placed on the Board of Public Works' February, 2014 agenda. The Board anticipates a March 1, 2014 start date for the scanning project.</p> |                               |         |
| C. Management Information Systems  | John Johnson, MIS Manager                  | <ul style="list-style-type: none"> <li>• Renewals for pharmacies are due by May 31, 2014. Changes the Board made to the application related to regulatory updates and language revisions, limit the time required to configure the on-line renewal system to reflect them in the applications. Thus, the Board's vendor, System Automation, will be creating a Web Form application for renewing pharmacies to complete on-line. The Web Form will look similar to the paper renewal application and pharmacies can complete the form, upload required documents and pay on-line.</li> <li>• A change is being made to the MLO application to allow the Board's Licensing staff to record and track decentralized</li> </ul>                                                                        |                               |         |

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|              |                                  | <p>pharmacies within an institution.</p> <ul style="list-style-type: none"> <li>Monthly board meeting WiFi access is now being broadcasted to make access easier for the board commissioners. Changes are also being made to the board's secure website which will make it easier for the Board's MIS staff to reset the password if someone is locked out due to entering an incorrect password.</li> <li>The Phase II Contract with System Automation has not begun and will begin in approximately 6-8 months. J, Johnson reported that he is developing a scope of work for inclusion in a separate vendor contract to develop/install inspection software that bridges with the database created by Systems Automation, for use by Board compliance inspectors when they are in the field.</li> </ul> |                               |         |
| D. Licensing | L. Waddell,<br>Licensing Manager | <p>Monthly Statistics for December, 2013.</p> <p>Pharmacists:</p> <ul style="list-style-type: none"> <li>New Applications – 42</li> <li>Renewals – 377</li> <li>Total Licensed – 9825</li> </ul> <p>Pharmacists Administer Vaccinations:</p> <ul style="list-style-type: none"> <li>New Applications – 22</li> <li>Renewals – 33</li> <li>Total Certified - 3480</li> </ul> <p>Technicians:</p> <ul style="list-style-type: none"> <li>New Applications – 105</li> <li>Renewals – 271</li> <li>Total Registered –8632</li> </ul> <p>Student Technicians</p> <ul style="list-style-type: none"> <li>New Applications – 32</li> <li>Renewals – 30</li> <li>Total Registered – 581</li> </ul>                                                                                                                 |                               |         |



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| F. Legislation & Regulations | A. Jeffers, Legislation & Regulations Manager | <p><b><u>REGULATIONS:</u></b></p> <p><b><u>10.34.09 Fees and 10.34.19 Sterile Compounding Preparations and Sterile Drug Product</u></b></p> <p>Anticipated to be published January 24, 2014.</p> <p><b><u>10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors</u></b></p> <p>Anticipated to be published January 24, 2014.</p> <p><b><u>10.34.32 Pharmacist Administration of Vaccinations.</u></b></p> <p>Published December 27, 2013.</p> <p><b><u>10.13.01 Dispensing of Prescription Drugs by a Licensee</u></b></p> <p>Submitted to DHMH for sign-off December 23, 2013.</p> <p><b><u>MEETINGS:</u></b></p> <p>Meeting with Chairman Pete Hammen – January 7, 2014</p> <p>Anna Jeffers provided a summary of the meeting with Chairman Hammen. He was in favor of the Board Member bill and the Registered Pharmacy Intern Bill. He was in agreement to ask Delegate Murphy to sponsor the Board Member bill and suggested Delegate Cullison to sponsor the Intern Bill.</p> <p>He was not in favor of introducing a bill that would restrict a prescribing dispenser from dispensing when a pharmacy is available within a ten mile</p> |                               |         |

| Subject | Responsible Party | Discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Action Due Date (Assigned To) | Results |
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|         |                   | <p>radius of the physician's office. He asked the Board to obtain support from DHMH before pursuing.</p> <p>Discussion ensued regarding whether the Board should seek this legislation in 2013. It was suggested to work with the other Boards to resolve this issue. It was also suggested to strongly pursue. Anna Jeffers was directed to send a PIA request to the Division of Drug Control to obtain inspection reports since the last reports the Board requested.</p> <p>The political ramifications of pursuing this legislation was discussed, as the Chairs of both EHE and HGO are not in favor of this legislation.</p> <p><b><u>LEGISLATION:</u></b></p> <p>1) Board of Pharmacy – Registration of Pharmacy Interns</p> <p><b><u>DRAFT INTERN BILL 011014 Under Direct Supervision</u></b></p> <p>This draft allows the intern to practice pharmacy under the direct supervision of the pharmacist. This gives the intern more opportunity to experience the work of a pharmacist and does not restrict what the intern may do.</p> <p>Discussion ensued regarding out of state pharmacy students who have recently graduated and want to obtain a Maryland pharmacist license. Those individuals would have to apply to a registration and a pharmacist license at the same time.</p> <p>The ration issue was also discussed and the Board concluded that a 1 to 2 ratio would assure protection of the public by not overburdening a pharmacist with too many interns to supervise.</p> <p><b><u>The Board approved the draft legislation.</u></b></p> <p>2) DME Task Force – Draft Legislation</p> |                               |         |

| Subject | Responsible Party | Discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Action Due Date (Assigned To) | Results |
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|         |                   | <p>Ann Horton, Maryland-National Capital Homecare Association, had sent the Board a draft bill that removed “device” from the Maryland Pharmacy Act. <b>The Board voted to</b>, instead, <b>approve the language below</b> as exempting device only dispensers, but not removing the regulation of devices dispensed by pharmacists or distributed by wholesale distributors.</p> <p>§12–401.1.</p> <p>THIS SUBTITLE DOES NOT AFFECT ANY PERSON WHILE DISPENSING ONLY PRESCRIPTION DEVICES IN WHICH NO PRESCRIPTION DRUGS ARE CONTAINED, OR DURABLE MEDICAL EQUIPMENT.</p> <p><b><u>3) BILLS as of January 10th:</u></b><br/> SB 106 Senior Prescription Drug Assistance Program - Sunset Extension</p> <p>Ratification of Letter of Support – <b>Board ratified</b> the Letter of Support below.</p> <p><b><u>hb0106F</u></b></p> <p><b><u>SB 106 Sr Rx Drug Assist. Prog - LoS</u></b></p> <p><b><u>OTHER MATTERS:</u></b></p> <p><b>Briefing on January 22, 2014 regarding the implementation of the HB 986 State Board of Pharmacy – Sterile Compounding Permits</b></p> <p>Mitra Gavgani, LaVerne Naesea and Anna Jeffers will present at the briefing.</p> <p><b>The Board approved a recommended revision to Subtitle 4A, Sterile Compounding Permits</b> as set forth below. This revision would clarify the immediate use exemption and would also allow hospitals and other entities that perform “immediate use” to be exempt from Maryland’s</p> |                               |         |



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|         |                   | <p>sterile compounding permit.</p> <p>(B) THE BOARD MAY APPROVE AN EXEMPTION FROM THE PERMIT REQUIREMENT ABOVE TO A STERILE COMPOUNDING FACILITY THAT ONLY PERFORMS STERILE COMPOUNDING IN THE STATE FOR IMMEDIATE USE AS DEFINED BY USP 797 PROVIDED THAT:</p> <p>(1) THE STERILE COMPOUNDING FACILITY REQUESTS AN EXEMPTION FROM THE BOARD ON A FORM THE BOARD REQUIRES;</p> <p>(2) THE STERILE COMPOUNDING FACILITY ATTESTS TO COMPLIANCE WITH USP 797 STANDARDS FOR IMMEDIATE USE, INCLUDING BUT NOT LIMITED TO:</p> <p>(I) USE OF ASEPTIC TECHNIQUES;</p> <p>(II) QUALITY ASSURANCE MEASURES;</p> <p>(III) TRAINING OF PERSONNEL; AND</p> <p>(IV) APPROPRIATE GARBING;</p> <p>(3) THE STERILE COMPOUNDING FACILITY PAYS A FEE ADOPTED BY THE BOARD FOR REVIEW OF THE REQUEST;</p> <p>(4) THE STERILE COMPOUNDING FACILITY IS SUBJECT TO INSPECTION BY THE BOARD;</p> |                                  |         |

| Subject | Responsible Party | Discussion                                                                                                                                                                                                                                                                                                                                                  | Action Due Date<br>(Assigned To) | Results |
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|         |                   | <p>(5) THE BOARD MAY WITHDRAW ITS APPROVAL OF AN EXEMPTION IF THE STERILE COMPOUNDING FACILITY FAILS TO COMPLY WITH USP 797 OR FAILS TO COOPERATE WITH A BOARD INSPECTION; AND</p> <p>(6) IF THE STERILE COMPOUNDING FACILITY FAILS TO COMPLY WITH USP 797, THE STERILE COMPOUNDING FACILITY IS SUBJECT TO DISCIPLINARY ACTION BY ITS RESPECTIVE BOARD.</p> |                                  |         |

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| III. Committee Reports<br>A. Practice Committee | H. Finke, Chair   | <b><u>Inquiries:</u> NONE</b> |                               |         |
|                                                 |                   |                               |                               |         |

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| B. Licensing Committee        | L. Bradley-Baker, Chair, | <p><b>1. Review of Pharmacist Applications: None for January, 2014.</b></p> <p><b>2. Review of Pharmacy Tech. Applications: None for Jan., 2014.</b></p> <p><b>3. Review of Distributor Applications: None for January, 2014.</b></p> <p><b>4. Review of Pharmacy Applications: None for January, 2014.</b></p> <p><b>5. Review of Pharmacy Tech. Training Programs:</b></p> <ul style="list-style-type: none"> <li><b>Pharmacy Technician University from Pharmacist Letter/Wal-Mart Pharmacy Technician Training Program - Licensing Committee recommendation is to approve.</b></li> </ul> <p><b>6. New Business:</b></p> <ul style="list-style-type: none"> <li><b><u>Deborah Sturpe</u> - Would like two week extension of expiration of license. Licensing Committee recommendation is to deny request and inform her that she cannot practice as a pharmacist once her license expires. C. Rochester is recused.</b></li> </ul> | <p>5. Motion by Licensing Committee to approve Wal-Mart Pharmacy Technician Training program. Motion was seconded by J. Smith.</p> <p>6. Motion by Licensing Committee to deny request of Deborah Sturpe for two week extension for expiration of license. Motion was seconded by D. Jones. Commissioner C. Rochester recused herself from voting on this matter.</p> | <p>5. Motion was approved.</p> <p>6. Motion was approved.</p> |
| C. Public Relations Committee | D. Jones, Chair          | <p><b>Public Relations Committee Update:</b></p> <ul style="list-style-type: none"> <li>D. Jones reported that the Public Relations committee met this morning and noted that the committee will be publishing a formal calendar which will detail all of the Board's activities for the year.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                       |                                                               |

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|                 |                   | <ul style="list-style-type: none"> <li>• The committee will adding a meeting mid-year to allow all four associations and the pharmacy schools to attend at one time</li> <li>• The committee is working on a questionnaire to hand out at events of frequently asked questions so that the Board can educate the public and pharmacists and technicians on exactly what the Board does.</li> <li>• D. Jones reported that the committee is looking to add a link to the Board's website as to legislation that the Board is involved with or may be taking a position on, to the extent allowed.</li> <li>• D, Jones reported the committee is looking to hold a Board meeting at all of the schools of pharmacy in Maryland with the next one being held at the Shady Grove campus of Maryland sometime this Spring, April or May. The exact date has not yet been confirmed.</li> </ul> |                               |         |
| D. Disciplinary | M. Gavgani, Chair | <p><b>Disciplinary Committee Update –</b></p> <ul style="list-style-type: none"> <li>• M. Gavgani reported that the Disciplinary Committee is looking to streamline the process of closing pharmacy inspections. M. Gavgani noted that herself, L. Naesea and Y. Wu are meeting with the Division of Drug Control to streamline the process so permit holders do not need to notify two State Units for the closing inspection.</li> <li>• M. Gavgani reported that the Disciplinary Committee is identifying administrative decisions that could be made by the Compliance manager to speed up the decision making process of investigations to reduce time before a decision can be made.</li> </ul>                                                                                                                                                                                    |                               |         |

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| E. Emergency Preparedness Task Force | S. Roy, Chair                            | <b>Emergency Preparedness Task Force Update:</b> <ul style="list-style-type: none"> <li>S. Roy noted that as a result of last quarter's state exercise the Board of Pharmacy has become a major player in emergency preparedness in Maryland. As a result the EPTF is asking the Board to send a letter to all the pharmacy schools asking for volunteers and also for participation on the EPTF.</li> </ul>                                                                                                                                                                  |                                                                                                                                                                                                                                                                                         |                      |
| <b>IV. Other Business &amp; FYI</b>  | <b>L. Israbian-Jamgochian, President</b> | <ul style="list-style-type: none"> <li>L. Naesea reported that the Board's Management Associate, Stephen Holmes, last day of employment with the Board will be February 12, 2014. Mr. Holmes has accepted a position with the Child Support Administration with the Department of Human Resources. L. Naesea thanked Mr. Holmes for his service with the Board and stated that he will be missed.</li> </ul>                                                                                                                                                                  |                                                                                                                                                                                                                                                                                         |                      |
| V. Adjournment                       | L. Israbian-Jamgochian, President        | <p>The Public Meeting was adjourned at <u>11:41 A.M.</u></p> <p>At <u>12:05 P.M.</u> L. Israbian-Jamgochian convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>C. The Closed Public Session was adjourned at 2:00 P.M. Immediately thereafter, L. Israbian-Jamgochian convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.</p> | Motion by S. Roy to adjourn the Public Board meeting pursuant to State Government Article 10-508a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by J. Smith. | Motion was approved. |

