Maryland Board of Pharmacy
Public Board Meeting
Minutes

Date: June 19, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	**Commissioner/Treasurer**	✓		**10**	**2**
Chason, D.	**Commissioner**	✓		**11**	**1**
Finke, H.	**Commissioner**	✓		**12**	**0**
Gavgani, M. Z.	**Commissioner**	✓		**11**	**1**
Israbian-Jamgochian, L.	**Commissioner**	✓		**11**	**1**
Jones, David H.	**Commissioner**	✓		**2**	**0**
Smith, J.	**Commissioner**	✓		**3**	**0**
Souranis, M.	**Commissioner/President**	✓		**11**	**1**
St. Cyr, II, Z. W.	**Commissioner**	✓		**12**	**0**
Taylor, R.	**Commissioner/Secretary**	✓		**9**	**3**
Board Counsel					
Bethman, L.	**Board Counsel**	✓		**12**	**0**
Felter, B.	**Staff Attorney**	✓		**11**	**1**
Board Staff					
Naesea, L.	**Executive Director**	✓		**12**	**0**
Wu, Y.	**Compliance Manager**	✓		**10**	**2**
Waddell, L.	**Licensing Manager**	✓		**6**	**0**
Gaither, P.	**Administration and Public Support Manager**	✓		**9**	**3**
Jeffers, A.	**Legislation/Regulations Manager**	✓		**12**	**0**
Johnson, J	**MIS Manager**	✓		**8**	**0**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. M. Souranis, Board President	*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. M. Souranis called the Public Meeting to order at 9:45 a.m. 2. M. Souranis requested all meeting attendees to introduce themselves, to sign the guest log and to indicate whether they would like continuing education credits. 3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. 4. M. Souranis reported that all handouts were to be returned by attendees when they leave the meeting. 5. Review and approval of May 15, 2013 public board meeting minutes. The May 15, 2013 minutes were amended as follows: • Page 16, III. Committee Reports. B. Licensing Committee. 2) IV Solutions – Replace Action column with the following:: "2. IV Solutions – Motion by Licensing Committee to inform IV Solutions of the regulations on posting of pharmacy hours (COMAR 10.34.05.03B) and clarify to IV Solutions that this means the pharmacy must post hours open to the public, if, and only if the pharmacy/prescription area has different hours than the establishment it is located in..	Motion by M. Gavgani to approve the May 15, 2013, public board meeting minutes as amended and shown in these minutes. Motion was seconded L. Israbian-Jamgochian.	Motion was approved.
II. Executive Director's Report	A. Executive Director, L.	**1. Operations Updates –** L. Naesea noted that in addition to the Executive		

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	Naesea	Director's report she will also be giving the report of Patricia Gaither, Administration and Public Support Manager who out of the office. • Recruitment has begun for the Licensing Secretary position, the Board has received the freeze exemption and recruitment closes on June 27, 2013, after which interviews will begin. The Pharmacist III position (50% Inspector Position) applications have been received and have been forwarded to the Board's Compliance Manager, YuZon Wu, for review. Kerrie Weigley pharmacy technician inspector began employment on June 3, 2013 . • The State Legislative auditors will be with the Board much of the summer, which will allow the Board to look at its new automated licensing system to insure they are up to date and in-line with Board business rules. • The Board is negotiating with NABP to perform out of state inspections for Wholesale Distributors that do not fit into Board categories that would allow them to otherwise undergo a Board required inspection . • NABP has some strategic retreat funding for state boards. Ms. Naesea suggested that the Board to start thinking about a strategic retreat date and Ms. Naesea will get further information from NAPB on funding assistance. • LaVerne Naesea introduced Justin Ortique, pharmacy student intern from the University of Maryland Eastern Shore School of Pharmacy. Mr. Ortique will be with the Board until June 21, 2013. **2. Meeting Updates** - • L. Naesea and J. Johnson met with Systems Automation on June 18, 2013. SA indicated that it is actively working to address the remaining issues/problems with the automated system.		

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		• Staff and Board representatives met with Deputy Secretary Laura Herrera concerning dispensing practitioners. A copy of meeting notes is in the Board packet. • L. Israbian-Jamgochian attended the MPHA and will report on the deliberations. • The NABP Annual Meeting was held May 17 through 21, 2013 in St. Louis, MO. L. Naesea, Harry Finke, L. Isranbian-Jamgochian, and Lynette Bradely-Baker attended. L. Israbian-Jamgochian will report on the meeting and resolutions adopted. • Michael Baier, Director of the Prescription Drug Monitoring Program (PDMP) of the Alcohol and Drug Abuse Administration requested to present at the Board's July, 2013 Public meeting. Mr. Baer will address questions the Board may have related to the initiation of the PDMP. Currently, Pharmacy waiver requirements do not apply to non-resident pharmacies. Mr. Baer asked if the Board wants those non-resident pharmacies that would be eligible for a waiver if they were applicable, to be waived from meeting the PDMP requirements. • L. Israbian-Jamgochian reported that the MPHA 130th Annual Convention was held in Ocean City, MD June 9 through 12, 2013. Approximately 150 persons attended. Four resolutions were discussed, 2 were defeated, 1 passed and one resolution was sent back to Committee. Board of Pharmacy attendees were H. Finke, L. Bradley-Baker and L. Israbian-Jamgochian. • L. Israbian-Jamgochian also reported on the NABP Annual Meeting held in St. Louis. 8 resolutions were passed at the meeting. The resolutions are incorporated herein by reference and attached as Exhibit No. 1.	The Board referred Michael Baier's question to the Practice Committee.	
B. Administration &	Administration	See II A, Executive Director's report above.		

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Public Support	& Public Support Manager, P. Gaither			
C. Management Information Systems	MIS Manager, John Johnson	• J. Johnson reported that as a result of working with OPASS and MD Works recently the Board has identified at least one vendor that could meet all of the Boards' scanning project criteria. The vendor submitted a bid of ($288,000.00). Patricia Gaither is checking with other state agencies to see if this bid is high or in line with similar projects around the state of Maryland. Mr. Johnson has asked MD Works to check with the vendor to see if the bid was high as a result of the Board indicating it needed to have the scanning project done quickly. The Board is also looking at retentions record schedules to see if some of the documents in the Board's possession need to be scanned. Some of the Board's documents may not need to be retained due to being outside if the retention dates in the State's retention of records schedule. • J. Johnson and L. Naesea spoke with SA about on-going problems. SA agreed to send a representative on-site to review the issues the Board is still having with the SA software. After the review SA was made aware that many of the issues are a direct result of problems with SA's software. MIS and SA came up with a plan for SA to do additional work, at no		

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		additional cost to the Board, that includes upgrading SA software. This is hoped to eliminate most of the problems that still exist. • The Sunset legislations requires the Board's MIS Unit to report on the progress and status of the conversion to new automated computer licensing system. MIS is in the process of preparing this report and will be pointing out both the positive and negative features of SA's software		
D. Licensing	L. Waddell, Licensing Manager	Monthly Statistics for May, 2013. Pharmacists: • New Applications – 43 • Renewals – 248 • Total Licensed – 9394 Pharmacists Administer Vaccinations: • New Applications – 18 • Renewals – 0 • Total Certified - 3131 Technicians: • New Applications – 145 • Renewals – 164 • Total Registered –8548 Student Technicians • New Applications – 61 • Renewals – 5 • Total Registered – 705		

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		Pharmacies: • New Applications – 9 • Renewals – 0 • Total Pharmacies- 1861 Distributors: • New Applications – 40 • Renewals – 317 • Total – 1051 Jermaine Smith asked the Board to consider establishing a licensing category for pharmacy students who have graduated from pharmacy school and have not yet taken the exam. Pharmacy students who possess student exemptions may continue to work until the exemption is required to be renewed by October 1st. Additionally, pharmacy school graduates are allowed to work under a Board approved pharmacy technician training program for up to 6 months. However, if it takes longer for these students to become licensed as pharmacists in Maryland, there may be a gap between the exemption and trainee periods and the former students' are licensed and they would be restricted from working under a pharmacist's supervision in any capacity. The Board approved introducing legislation that would set up an "internship" level of licensure for graduate pharmacy students, which would also include foreign pharmacists who need to earn 1560 hours. This internship level would expire after 1 year from issuance.	Take legislative concept to the June Practice Committee Meeting.	
E. Compliance	C. Jackson, Compliance Secretary	1. Monthly Statistics for May, 2013 <u>Complaints & Investigations</u>: New Complaints- 42 Resolved (Including Carryover) – 35 Final disciplinary actions taken – 4 Reversal – 0		

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	Gil Cohen, PEAC	Summary Actions Taken – 2 <u>Inspections:</u> 107 Annual Inspections- 94 Opening Inspections- 4 Closing Inspections - 0 Relocation Inspections- 4 Board Special Investigation Inspections – 5 • Total Pharmacist Rehabilitation Committee Clients – 18 • Pharmacist Clients – 17 • Technician Clients – 0 • Pharmacy Student Clients – 0 • Clients Monitored by Board Req. PEAC Assistance – 1 • Drug Testing Results – 28 • Number of Positive Results - 0		
F. Legislation & Regulations	A. Jeffers, Legislation & Regulations Manager	**<u>REGULATIONS:</u>** **10.34.03 – Inpatient Institutional Pharmacies** Anticipated to be published June 28, 2013. **10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.** Notice of Final Action anticipated to be published either June 28th or July 12th.with effective date 10 days later. **10.34.19 Sterile Pharmaceutical Compounding (Emergency)** Board approved revisions at May 15, 2013 Board Meeting. Revised proposal sent to the Secretary for initial comment May 23, 2013. **Secretary Joshua Sharfstein, Department of Health and Mental Hygiene, made a presentation to encourage the Board to seek outside stakeholder input and buy-in on the proposed**		

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		regulations. **He noted the three categories in the HB 986 that need to be addressed by Board regulations: 1) fully licensed FDA manufacturer; 2) pharmacies and other traditional compounders that will be required to obtain a sterile compounding permit; and 3) bulk compounders for which the FDA is working on rules that would place them under the federal authority.** **Bulk compounders pose greater risks, but were acknowledged as being are critical for hospital care. Under this group the Secretary anticipates the Board establishing a list of products that are critically needed with input from stakeholders in Maryland. The Board would then have authority under the law to grant waivers to facilities that meet requirements under Board regulations. This list would be posted on the Board's website.** **The Secretary designated David Blythe to as liaison between the Department and the Board. He asked the Board to seek community input and develop a process to select the list of drugs.** **The Secretary then responded to comments and questions from the Board and the audience.** **Dr. Kurtz, State Board of Veterinary Medical Examiners, expressed concern with the unintended consequences of the bill for veterinarians. He provided an example of a pet with an emergency in the middle of the night and the possible inability of a veterinarian to treat the pet because a specific compounded prescription could not be prepared when most pharmacies are closed. He was asked to put his concerns in writing to the Board.**		

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		Soumi Saha, Kaiser Permanente, wanted the Board to open the Sterile Compounding subcommittee to the public. The Board advised that because of time constraints this would not be likely, although stakeholders will have an opportunity for input before the regulations are promulgated. **Kristen Webb, Johns Hopkins, commented that some drug manufacturers would be able to obtain a waiver under the bill and noted her understanding, that non-sterile compounding would not be affected by the sterile compounding legislation.** **Secretary Sharfstein emphasized need for input from stakeholders. He asked that the Board solicit written comments before completing the draft regulations.** **The Board acknowledged its intent to release the draft regulations for informal comment.** **Dr. Kurtz asked if there was a way to exempt veterinarians from this legislation. and asked the Board to include veterinarians in the list of stakeholders.** **Soumi Saha asked that the Gastointestinal physicians and ophthalmologists also be included as stakeholders.** **Maryland Veterinary Medical Association inquiry** **Veterinarian Office Use Compounding** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy with your additional comments and request to publish the information provided in my email in the Maryland Veterinary Medical Association Newsletter.		

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		Please feel free to publish the Board's previous response and note that it intended to address only the specific facts and questions that were provided in your inquiry. The Board's response was not intended to be legal advice. Although references to current laws and regulations may be included in this and previous Board responses, state laws and/or regulations may be changed at any time. Further, all information provided by the Board is based on state pharmacy laws and regulations that are in effect at the time it is provided. Thus, until the new sterile compounding laws become effective (both State and federal), veterinarians may continue to compound and dispense sterile products in accordance with applicable standards of practice. Veterinarians may also compound a limited quantity of a particular medication in anticipation of immediate future need as based on previously documented prescriptions filled for that medication. Veterinarians who wish to engage in sterile compounding after the implementation of the new Maryland law must obtain an additional permit from the Board of Pharmacy and comply with certain minimum standards. Veterinarians who compound non-sterile products do not require an additional permit from the Board. If using a pharmacy, a pharmacy would have the ability to compound in anticipation of receipt of a patient specific prescription. Any compounded prescription that is dispensed must be pursuant to a patient specific prescription. See COMAR 10.34.19.08. The veterinarian should work with the pharmacy to arrange availability in an emergency situation. Please be advised, however, that the law has not changed regarding compounding pursuant to a patient specific prescription. Maryland law has always required a prescription in order for a pharmacy to dispense a compounded medication. Legally, the prescription requirement is one of the main	Motion by Legislative Committee to ratify the letter to the Maryland Veterinary Medical Association, as stated in these minutes. Motion to ratify was seconded by D. Chason.	Motion to ratify the letter to the Maryland Veterinary Medical Association was approved.

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		distinguishing factors in determining whether a pharmacy is engaged in traditional pharmacy practice, as opposed to manufacturing, which would be regulated by federal law. The Board hopes to consider your concerns as the implementation of HB 986 unfolds. Please continue to send comments or concerns to the Board and include any specific drugs that you believe should be on the "waiver list" as described in HB 986. **10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors (Emergency)** Published April 19, 2013. 30 day comment period to follow. Emergency was withdrawn on April 25, 2013.AELR putting this proposal on hold so it will not become effective until SB 595 becomes effective on October 1, 2013. Practice Committee to consider the revised proposal and comment received regarding the April 19th proposal. **Board approval requested** for the "Reporting Form" for pharmacies that wholesale distribute to wholesale distributors: **DRAFT Board of Pharm Reporting Form 060513ln** **The Board approved the Reporting Form for pharmacies that wholesale distribute to other pharmacies.** **10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities** Published May 31, 2013. 30 day comment period to follow. Comments to be considered at July 24th Practice Committee Meeting. **10.34.32 Pharmacist Administration of Vaccinations** Draft revisions to be considered at June 26th Practice Committee Meeting. Infectious Disease Unit working on criteria for the	Motion by Legislation Committee to approve the Reporting Form for pharmacies that wholesale	Motion was approved.

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		protocol. **10.34.33 Prescription Drug Repository Program** Proposal submitted May 22, 2013. In the DHMH sign-off process. **10.13.01 Dispensing of Prescription Drugs by a Licensee** Mike Souranis, Rodney Taylor, Lenna Israbian-Jamgochian, Harry Finke, LaVerne Naesea, Anna Jeffers, and Justin Ortique (pharmacy school student) met with Dr. Laura Herrera on June 5, 2013 to discuss her comments and the fiscal impact of inspections. Dr. Herrera plans to follow-up with the Board within 2 months. **Dr. Laura Herrera June 13, 2013 Letter** **The Board ratified the following letter:** On behalf of the Board of Pharmacy, I am writing to thank you for meeting with representatives on June 5, 2013 to discuss proposed language for the revised dispensing practitioner regulations. The Board was pleased to have an opportunity to discuss our mutual goal of safe medication dispensing and understands that Department funding to meet this goal was based on inspecting one practice site for each issued dispensing permit rather than inspecting all practice sites that dispense under each dispensing permit. Board representatives provided a history of its involvement with this issue and described findings that: IWIF (Workman's Comp Insurers) reported that some practitioners dispensed medications and also provided prescriptions to the same patients during the same office visits; some practitioners have ordered drugs from wholesale distributors who were not licensed to operate in	distribute to wholesale distributors. Motion was seconded by D. Chason. Motion by Legislation Committee to ratify the draft letter to Dr. Laura Herrera, as stated in these minutes, Motion to ratify was seconded by M. Gavgani.	Motion to ratify letter to Dr. Laura Herrera was approved.

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		Maryland; and most importantly, that many practitioners do not adhere to the same mandated patient safety dispensing requirements as do experienced pharmacists who are annually monitored. The latter concern was evidenced in 2011/2012 inspection reports that revealed a large majority of inspected sites had not properly stored, labeled and/or dispensed medications; nor were appropriate patient dispensing records maintained. Following the Board's discussion of its attempts to address problems, you acknowledged the need to inspect all sites and agreed to review alternatives to support this goal. Board representatives agreed to defer promulgation of the dispensing practitioner regulations for a couple of months and suggested that you explore the following: 1) Revisit the notion of defining "conveniently available" to meet the original intent of allowing practitioners to dispense to patients that have limited access to pharmacies. This would significantly reduce the number of permits issued – ergo the number of required inspections. (See COMAR 10.09.03.07 in State Medical Assistance regulations, upon which the Board based its 10 mile location definition); 2) Reassign inspection responsibilities to allow Board of Pharmacy inspectors to perform all routine CDS inspections (concurrent with annual pharmacy inspection) and refer identified problems to the Division of Drug Control (DDC) for investigation. This will allow the DDC to better monitor dispensers of prescriptions drugs and CDS prescribers, while also help reduce duplication of effort; and 3) Increase the dispensing permit fee in order to generate sufficient revenue resources to fund additional DDC inspectors. On a final note, you relayed concern that the outline for the proposed sterile compounding regulations did not mirror the authorizing statute. The Board agreed to revise the proposed		

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		regulations to the extent possible, to better follow the format of the statute. Once again the Board appreciates your taking time from your busy schedule to meet on these important issues. We look forward to hearing from you in the near future. **LEGISLATION:** **Naturopath Meetings organized by Board of Physicians - First meeting is tentatively June 27th and then on Tuesdays.** **Harry Finke and Anna Jeffers will be attending the Naturopath Meetings. (Note: Meeting was actually attended by Anna Jeffers and Dave Jones, not Harry Finke).** **Proposal ideas for 2014.** **The Board approved in concept the following proposed legislation:** **1) Graduate interns, as discussed in the licensing section;** **2) Revise the statute so that consumer members could hold Board Officer positions.** **Both to be discussed at the June Practice Committee Meeting.** **Other Matters** **Board comment requested for US HB 1919** **Email about OGA comment request on US HB1919** **Pharmaceutical paper inserts Gov Legislative Week June 3 2013 -- This Week on the House Floor (1)** **Pharmaceutical paper inserts Gov W ENGEL**		

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		Referred to the Practice Committee.		
III. Committee Reports A. Practice Committee	H. Finke, Chair,	**Inquiries:** 1) Sam Georgiou, Professional Arts Pharmacy **Non sterile Compounding** **Compounded office use products** **Draft Bd Response - compounding for office use** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy concerning office use compounding. Please be advised that the law in Maryland is clear. Health Occupations Article, 12-101, Annotated Code of Maryland. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device: (i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or (ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device. "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns. The definition of compounding does not differentiate between	1. Motion by Practice Committee to approve response to Sam Georgiou, Professional Arts Pharmacy as stated in these minutes. Motion was seconded by Mitra Gavgani.	1. Motion was approved.

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		sterile and non-sterile. If you continue to perform patient specific compounding, you will be required to obtain a sterile compounding permit once the new law, HB 986 State Board of Pharmacy – Sterile Compounding – Permits, is implemented. HB 986 allows for a phase-in of this program by April 1, 2014. If you choose to manufacture sterile drug products without a patient specific prescription as defined in the bill, then you would have to be licensed by the FDA as a manufacturer and obtain a wholesale distributor permit from the Board, or request a waiver from the Board. 2) Kathy Wille, C2R Global Manufacturing Inc. - Producer of "Drug Buster" **Drug Buster** **Another Drug Buster inquiry** **Article with Inventor of the Drug Buster** **DEA-316_UPDATED_ChemicalDrugDestruction** **Drug Buster description, claims and research** **Drug Buster_DEA_patent** **Fwd DEA 316** **msds_drug buster_RevA** **Draft Bd Response - Drug Buster**	2. Motion by Practice Committee to approve response to Kathy Wille, as stated in these minutes. Motion was seconded by M. Gavgani.	2. Motion was approved.

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		The Board approved the following response: Thank you for contacting the Maryland Board of Pharmacy concerning the disposal method "Drug Buster." If the U.S. Drug Enforcement Administration (DEA) includes "Drug Buster" as an acceptable part of a DEA disposal method in its regulations, then the Maryland Board of Pharmacy has no further requirements. I have attached the proposed federal regulations for your review. 3) Eric Hartkopf, PAAS National **LTC - signatures on orders** **Draft Bd Response - LTC - signing dr orders** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy concerning whether a prescriber is required to sign each page of a multiple page long-term care (LTC) physician order or simply the last page. It is not necessary for the prescriber to sign each page of a physician order. The Board recommends that the prescriber clearly delineate how many pages are included in the physician order on the page where the prescriber signs the order. For controlled dangerous substances, please refer to the U.S. Drug Enforcement Administration (DEA). 4) Chandra Mouli, DDC **DDC - approval of non pharmacy sites** **Draft Bd Response – approval of non pharmacy sites**	3. Motion by Practice Committee to approve response to Eric Hartkopf, PAAS National as stated in these minutes. Motion was seconded by M. Gavgani. 4. Motion by Practice Committee to approve	3. Motion was approved. 4. Motion was approved.

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		The Board approved the following response: Thank you for contacting the Maryland Board of Pharmacy concerning a pharmacist dispensing prescriptions to a patient in a setting other than a pharmacy. Below are responses to your specific questions: 1. There is a physician(s) practice where the physicians(s) have a dispensing permit, but would like to engage the services of a Maryland licensed pharmacist to do the final check, counsel and dispense to the patient. Can a pharmacist also engage in Drug Therapy Management in such a clinic setting? See COMAR 10.34.31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit, where a pharmacist may request Board approval to dispense or distribute at a setting that does not possess a pharmacy permit if: (1) The dispensing or distribution occurs while the pharmacist is providing drug therapy management services in: (a) The office of a licensed physician; (b) A clinic; or (c) A medical facility; or (2) The setting is: (a) Operated or funded by a public health authority of the State; (b) A medical facility or clinic that is operated on a nonprofit basis and is not otherwise required to possess a pharmacy permit; or	response to Chandra Mouli, Maryland Division of Drug Control as stated in these minutes. Motion was seconded by M. Gavgani.	

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		(c) A health center that operates on a campus of an institution of higher education. B. If the drug therapy management services referred to in §A(1)(a) of this regulation include the dispensing or distribution of controlled dangerous substances, the request may be approved by the Board if the physician possesses a dispensing permit issued by the Board of Physicians. C. If a pharmacist seeks to obtain Board approval to dispense or distribute at a setting that is not set forth in §A of this regulation, the pharmacist shall apply to the Board for a waiver permit under COMAR 10.34.17. For additional requirements please review COMAR 10.34.31.02 - .08. http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.34.31.* 2. In research facility conducting clinical trial can a pharmacist fill or compound and dispense to the patient? Please also see COMAR 10.34.31.01 - .08. 3. May a pharmacist also engage in "administering" by injection or other means (HO 12-102(e)(2)). The pharmacist would be working under the supervision of "Individual Practitioner." Health Occupations Article, 12-102(e)(2), Annotated Code of Maryland, applies to dentists, physicians and podiatrists. At the present time, pharmacists are only allowed to administer vaccinations under Health Occupations Article, 12-508, Annotated Code of Maryland.		

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B. Licensing Committee	D. Chason Chair, Reported by L. Bradley-Baker	**1. New Business:** • **CSM-Clinical Supplies Management** - Licensing Committee recommendation is to inform CSM that under MD law, medications must be sent directly to patients and be patient specific. The pharmacy has to be MD licensed and has to have at least one MD licensed pharmacist on staff.	Motion by Licensing Committee to inform CSM that under MD law, medications must be sent directly to patients and be patient specific. The pharmacy has to be MD licensed and has to have at least one MD licensed pharmacist on staff. Motion was seconded by M. Gavgani.	Motion was approved.
C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update: • The Board participated in the Maryland Pharmacists Annual Meeting in Ocean City, MD last weekend, June 15 and 16, 2013. The Board will also be participating in the Maryland chapter of the American Society of Consulting Pharmacists on Soloman's Island, MD in August, 2013. • The Public Relations Committee was unable to get a commitment from Rear Admiral Giberson to speak at the Board's annual continuing education breakfast. In order to prepare for CE processing purposes the Committee needs to look at other topics and at the Committee's meeting this morning the topic of prescription drug monitoring was discussed. The PDMP (Prescription Drug Monitoring Program) is being implemented in Maryland and the local schools of pharmacies are looking at various initiatives to assist pharmacists in preparation for the PDMP. The Board would invite one of the professors at		

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		the University of Maryland School of Pharmacy who is working in this area to give an overview of the problems Maryland, and the entire country, face with controlled dangerous substances.. In addition the Board would invite Michael Bair who is Director of the Maryland Prescription Drug Monitoring Program to speak as well. The date that the Board is looking at tentatively is Sunday, October 6, 2013 at the Radisson Cross Keys Hotel. As soon as the Committee can confirm this date, location and speakers more information will be provided to the Board and to the public.. • L. Bradley-Baker reminded all that the September public board meeting will be held off-site on Friday, September 20, 2013 at the University of Maryland Eastern Shore School of Pharmacy. The Board members will be receiving an e-mail from either Janet Seeds of Patricia Gaither giving them information on hotels and asking the each Board member confirm whether they will be attending or not.. The hotel the Board is looking at is in Fruitland, MD approximately 12 miles from the campus.		
D. Disciplinary	L. Israbian-Jamgochian, Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	L. Bradley-Baker, Acting Chair	Emergency Preparedness Task Force Update : • Don Taylor, Reid Zimmer and L. Bradley-Baker, all members of the EPTF presented to emergency preparedness representatives of all of the Maryland health departments on May 22, 2013 as to the function of the EPTF and how the task force can assist the local health departments, such as disseminating information and assisting in drills. The		

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		presentation was very well received by the local health department representatives. • Lastly, the BOP participated in a POD (Point of Distribution) drill on June 3, 2013 at the University of Maryland Eastern Shore School of Pharmacy. The second year pharmacy class participated and spent time rotating between being a staff member that would distribute medications during an actual emergency and also being a patient in the drill. Emergency preparedness officials from Worcester, Wicomico and Somerset counties attended as did DHMH officials. There was very positive feedback from all who participated and who were present. UMES School of Pharmacy is looking to document all of the information from the drill in order to enhance these drills in the future for their students and to pass it along to other schools of pharmacy.		
IV. Other Business & FYI	M. Souranis, President	There was no other business presented.		
V. Adjournment	M. Souranis, President	The Public Meeting was adjourned at 12:02 P.M. At 12:44 P.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 2:10 P.M. Immediately thereafter, M. Souranis 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.	Motion by L. Israbian-Jamgochian to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(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 Z. St. Cyr, II.	Motion was approved.

EXHIBIT NO. 1

RESOLUTION NO: 1

TITLE: Pharmacy Compounding of Sterile Products

SUBMITTED BY: Districts 1, 2 and 4 COMMITTEE RECOMMENDATION: PASS

WHEREAS, the patient need for compounded medications has increased and pharmacists compounding safe and effective medications of the required quality for their patients is necessary; and

WHEREAS, shortages of critical, lifesaving prescription medication have resulted in the increased demand for compounded medications by pharmacists; and

WHEREAS, in many states, pharmacies engaging in sterile compounding must meet or exceed the applicable quality standards contained in the most current edition of the United States Pharmacopeia (USP) , including but not limited to Chapter <797>; and

WHEREAS, pharmacies engaging in high risk sterile compounding require additional oversight; and

WHEREAS, protecting the public health is the primary mission of the state boards of pharmacy and the National Association of Boards of Pharmacy (NABP);

THEREFORE BE IT RESOLVED that NABP encourage boards of pharmacy to reference sterile compounding quality standards, including but not limited to those contained in USP Chapter <797> , as the standard for sterile compounding in their state; and

BE IT FURTHER RESOLVED that NABP encourage that all boards of pharmacy conduct qualified surveys or inspections of pharmacies engaged in sterile compounding or use and recognize qualified surveys or inspections conducted by a nationally recognized body; and

BE IT FURTHER RESOLVED that NABP review and, if necessary, propose amendments to the Model State Pharmacy Act and Model Rules of the National Association of Board-.; of Pharmacy to address appropriate regulation and require inspection of pharmacies engaged in sterile compounding.

RESOLUTION NO: 2

TITLE: Prescription Medication Distribution - The Five Percent Rule for Resale

SUBMITTED BY: District 2 COMMITTEE RECOMMENDATION: PASS

WHEREAS, state and federal safeguards, statutes, and regulations for the United States distribution system for prescription drugs secure against adulterated, misbranded, and counterfeit drugs;

WHEREAS, despite the systems in place to secure the drug distribution system from such adulterated, misbranded, and counterfeit drugs there are problems that exist; and

WHEREAS, state provisions that allow pharmacies to distribute to other pharmacies and to practitioners a specified quantity of prescription medications based upon determined ratios (often times five percent) have been exploited and resulted in diversion; and

WHEREAS, properly constructed laws and regulations allow the distribution of medications between pharmacies in the event of emergency situations and special patient circumstances;

THEREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy (NABP) urge its member boards of pharmacy to revise their "five percent" rules to only allow the transfer, distribution, or sale of prescription drugs between pharmacies, or from pharmacies to practitioners, for the purpose of dispensing or administration, but not for resale, and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale; and

BE IT FURTHER RESOLVED that NABP urge its member boards to allow for the pharmacy transfer of medications only for emergency medical reasons, including a public health emergency declaration by federal or state officials and individual patient needs.

RESOLUTION NO: 3

TITLE: Review and Revision of the Model State Pharmacy Act and Model R11les of the National Association of Boards of Pharmacy Regarding Pharmacy Benefit Managers

SUBMITTED BY: District 3 COMMITTEE RECOMMENDATION: PASS

WHEREAS, the member boards of the National Associations of Boards of Pharmacy (NABP)

adopted Resolution 108-6-12 at the l081

Annual Meeting, acknowledging the need for state

regulations of pharmacy benefit managers (PBM) engaged in the practice of pharmacy using the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) as a standard for states to develop and implement regulations for PBMs; and

WHEREAS, state boards of pharmacy are charged with protecting the public health as it relates to patient safety, patient health, and patient services provided by pharmacies and pharmacists; and

WHEREAS, the policies and practices of PB Ms that engage in the practice of pharmacy directly affect patient safety, patient health, and patient services; and

WHEREAS, the regulation of PBMs extends beyond individual state jurisdictions and requires communication and cooperation among the state boards of pharmacy; and

WHEREAS, there is a need to determine the status of PBM regulations in the states to provide a cohesive strategy for revising and reviewing the Model Act;

THEREFORE BE IT RESOLVED that NABP convene a task force to review the status of PBM regulations in the states, determine the level of cooperation and collaboration among the states in regard to regulating PBMs, and review and propose recommendations to the Model Act language pertaining to PBMs to provide a cohesive and current guideline for states to utilize in developing regulations.

RESOLUTION NO: 4

TITLE: Alternate Patient Medication Information Delivery

SUBMITTED BY: District 8

COMMITTEE RECOMMENDATION: PASS

WHEREAS, it has been observed that the provision of patient information using paper leaflets or attachments to prescription containers and bags may not be read by patients and is often discarded in trash receptacles upon leaving the pharmacy; and

WHEREAS, electronic delivery of patient information is an acceptable, and perhaps more beneficial alternative to paper; and

WHEREAS, it has been noted that patients often request and state a preference to receive patient medication information (PMI) via electronic means;

THEREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy engage in discussions with the United States Food and Drug Administration and state boards of pharmacy the feasibility of allowing patients to choose to access mandatory PMI through electronic means.

RESOLUTION NO: 5

TITLE: Definition of Pharmacy Compounding

SUBMITTED BY: District 7

COMMITTEE RECOMMENDATION: PASS

WHEREAS, pharmacy compounding is regulated by the state boards of pharmacy as a part of the practice of pharmacy; and

WHEREAS, pharmaceutical manufacturing is regulated by the United States Food and Drug Administration (FDA); and

WHEREAS, a regulatory void in the definitions of and the distinctions between pharmacy compounding and pharmaceutical manufacturing exists that has allowed manufacturing to occur under the guise of pharmacy compounding with tragic consequences;

THEREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy (NABP) and the state boards of pharmacy work with FDA and other interested parties to establish mutually agreeable definitions for pham1acy compounding and pharmaceutical manufacturing; and

BE IT FURTHER RESOLVED that NABP revise the Model State Pharmacy Act and Model Rules /'the National Association /'Boards l Pharmacy to reflect the new definitions.

RESOLUTION NO: 6

Compounding and Reconstituting Drugs for Infusion in Establishments Other Than Pharmacies

SUBMITTED BY: District 7 COMMITTEE RECOMMENDATION: PASS

WHEREAS, recent tragic events involving contaminated, adulterated, or misbranded products that were compounded and reconstituted for infusion have demonstrated that significant risks exist when drugs are not properly compounded and reconstituted for infusion; and

WHEREAS, it has been brought to the attention of many boards of pharmacy that a variety of medical practices, including but not limited to, oncology, rheumatology and gastroenterology practices, employ nurses and registered or unregistered pharmacy technicians to compound and reconstitute sterile products for infusion to patients in their clinics; and

WHEREAS, these compounded and reconstituted products often involve complicated calculations and the final product may not be checked by the prescriber prior to administering or dispensing to the patient; and

WHEREAS, it is uncertain as to whether these individuals and clinics fully comply with United States Pharmacopeia (USP) guidelines for the preparation of sterile products for infusion, potentially leading to unsafe conditions and unnecessary risk to patients; and

WHEREAS, it may be in the best interest of protecting the public to require that the compounding and reconstituting of sterile products for infusion be overseen by a pharmacist and in compliance with applicable standards, including but not limited to Chapter <797>, of the most current edition of the USP;

TH EREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy collaborate with the Federation of State Medical Boards and the National Council of State Boards of Nursing to assess the impact on patient safety of the compounding and reconstitution of sterile products for infusion in establishments other than pharmacies and without pharmacists' oversight.

RESOLUTION NO: 7

TITLE: Performance Metrics and Quotas in the Practice of Pharmacy

SUBMITTED BY: District 7 COMMITTEE RECOMMENDATION: PASS

WHEREAS, a survey conducted by the Institute for Safe Medicine Practices (ISMP) of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor; and

WHEREAS, performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment; and

WHEREAS, the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy;

THEREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy (NABP) assist the state boards of pharmacy to regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians; and

BE IT FURTHER RESOLVED that NABP review and propose amendments to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to address the regulation, restriction, or prohibition of the application of performance metrics and quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians.

RESOLUTION NO: 8

TITLE: Recognition Resolution

WHEREAS, the individuals listed here have made significant contributions to the National Association of Boards of Pharmacy (NABP), the protection of the public health, and the practice of pharmacy:

Howard Bolton (LA) Robert E. Duncan (KS) Larry C. Froelich (KS) Lester Hackner (MN) Gene Martin (FL)
Martin Forrest Parmley (TN) Martin "Marty" Nie (KY)

WHEREAS, NABP and its member boards of pharmacy are saddened by the death of these individuals;

THEREFORE BE IT RESOLVED that NABP and its members formally acknowledge the leadership and contributions made by these individuals; and

BE IT FURTHER RESOLVED that NABP and the boards of pharmacy extend their sincere sympathies to the family and friends of these members.