Maryland Board of Pharmacy
Public Meeting
Minutes

Date: June 15, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner			10	2
Chason, D.	Commissioner			11	1
Finke, H.	Commissioner			12	0
Gavgani, M. Z.	Commissioner			9	1
Handelman, M.	Commissioner		X	10	2
Israbian-Jamgochian, L.	Commissioner/Treasurer			12	0
Matens, R.	Commissioner			12	0
Souranis, M.	Commissioner//President			12	0
St. Cyr, II, Z. W.	Commissioner			10	2
Taylor, D.	Commissioner			11	1
Taylor, R.	Commissioner/Secretary			11	1
Zimmer, R.	Commissioner			11	1
Bethman, L.	Board Counsel			12	0
Banks, T.	MIS Manager			12	0
Wu, Y.	Compliance Manager			5	0
Daniels, D	Licensing Manager			12	0
Gaither, P.	Administration and Public Support Manager		X	10	2
Jeffers, A.	Legislation/Regulations Manager		X	10	2
Naesea, L.	Executive Director			12	0

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
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 9:42 A.M. 2. M. Souranis requested all meeting attendees to introduce themselves and to remember to sign the guest list before leaving the meeting. M. Souranis asked guests to indicate on the sign-in sheet if they were requesting CE Units for attendance. 3. M. Souranis reported that guests will be given packets of materials so that they can follow meeting discussions. He requested that all guests return their draft packets before they left the meeting. 4. Review & Approval of Minutes of May 18, 2011.	4. Motion: D. Taylor Seconded: Z. St. Cyr, II	Board Action: The Board voted to approve

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II. Staff Operations Report (s)	**A. L. Naesea, Executive Director**	**1. Operations Updates** **L. Naesea reported on the following staff updates. The Board's Administrative Specialist position has been filled by N. Dupye as of June 3, 2011. The office Secretary II position in the Compliance Unit is in the recruitment process and hopefully OHR have the position posted by June 20, 2011. As for the .50 pharmacist II position we are still waiting for the freeze exempt. The original request was sent in May and P. Gaither sent a follow-up on June 14, 2011. The final decision can take six to eight weeks. F. Yorkman our Administrative Specialist in the Licensing Unit has resigned effective June 28, 2011. The Help Desk position will be ending October 31, 2011 and we have put in to renew contract. We will need him to help with the new database** **2. Meeting Updates – The following meetings were participated in by Board or staff members since the May 2011 meeting:** **- DHMH Sec. Joshua Sharfstein met with L. Naesea and all Health Occupations (HO) Board Directors to introduce himself and announce his initial priorities in working with the Board. They include 1)improving Consumer Services, 2) resolving Scope of Practice conflicts between various boards, and 3) addressing procedures for use of emergency suspensions disciplinary actions for HO practitioners who .** **3. Correspondence MedChi**		
	B. P. Gaither, APS Manager	**1. P. Gaither reported on the following Staffing Updates:**		
	C. D. Daniels, Licensing Manager			
	D. T. Banks, MIS Manager			

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	E. Y. Wu, Compliance Officer	**1. Inspection Program Report** **2. Comprehensive Care Pharmacy Inspection Form** **3. PEAC Update- Tony Tommasello**		
	F. A. Jeffers, Regs/Legs. Manager	**1. Status of Proposed Regulations** **10.34.03 Inpatient Institutional Pharmacy** Published June 3, 2011 with comment period through July 5, 2011 **10.34.33 Prescription Drug Repository Programs** A Board Subcommittee is continuing to work on wording and waiting for the promulgation of the federal regulations this summer. Meeting to be scheduled with the Attorney General's Office in the near future. **10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment** Proposal submitted to OHCQ and the Department April 26, 2011. One comment received during DHMH internal review: **infusion 10.34.35_1 Board of Physicians** **DRAFT Bd Response to Bd of Physicians 10.34.35 Infusion 061511** **The Board approved the response to the Board of Physicians with 3 minor revisions bolded below:**		

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		Dear Mr. Pinder: Thank you for submitting inquiries concerning the Maryland Board of Pharmacy's draft proposed regulations for COMAR 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment. The Board would also like to thank the Board of Physicians staff for participation in the Home Infusion Task Force from September 2009 through July 2010 to assist in drafting the proposed regulations and reviewing the final draft of the proposed regulations that was sent for informal comment on October 26, 2010. Below you will find the Board's responses to your new concerns. 1. How does the Board of Pharmacy know which pharmacies are "infusion pharmacies"? Is there some requirement that the physician (or patient) find such a place and use it? Does an "alternate site care setting" refer to an "infusion pharmacy" or does "alternate site care setting" mean anywhere besides an inpatient hospital as explained in the definitions? Could an "alternate site care setting" mean an individual's home? A pharmacy "that provides pharmaceutical care to patients receiving parenteral therapy in an alternate site care environment" is usually licensed as a "waiver pharmacy" because it is not usually full service. The Board has a database of all licensed pharmacies in Maryland, full service and waiver. The type of service a waiver pharmacy provides is indicated on their permit application. Board inspectors also inspect all Maryland pharmacies: first at the opening of the pharmacy; once a year; and have inspection reports indicating the type of practice of each pharmacy **yearly**. Not all pharmacies provide pharmaceutical care to patients that receive parenteral therapy in an alternate site care environment. For example, this type of therapy might be IV pain management therapy for hospice patients. Hospice is a type of care, not a location, and may occur in a patient's home. Infusion Pharmacies not only provide the prescription medication, but also provide the equipment and supplies (such as tubing) for administration of the pain medication for hospice patients. Most Infusion Pharmacy pharmacists are on-call 24/7 for patient support and to triage patients' needs. The pharmacists hired by Infusion Pharmacies are trained to manage the parenteral medication therapy. They also must pass competencies for clinical knowledge as well as aseptic techniques. Since only a limited number of pharmacies provide this service, discharge planners in the hospital or the ordering prescriber who is providing the medical care, directs patients to the Infusion Pharmacies. The third party insurance companies may influence the selection of the infusion provider due to contracts that are in effect.		

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		"Alternate site care environment" or "setting" means the location where the patient is receiving infusion therapy other than an inpatient hospital setting. It is usually in the patient's home **or a caregiver's home**. 2. It is unclear how and when the pharmacy/pharmacist would become involved, beyond supplying prescription medications or supplies. What triggers the involvement with patient assessment and care? When an Infusion Pharmacy receives an order for parenteral therapy, it triggers the pharmacy to obtain patient information for the patient's medical records. Patient information as well as caregiver ability and availability are a vital part of the assessment as to the patient being suitable for infusion therapy. The list of medications is reviewed to assure that the new therapy will not interfere with the current medications that are being used. Since the patient and the patient's caregiver are often new to infusion therapy, the patient and/or caregiver often have a myriad of questions. They routinely call the pharmacy. The infusion pharmacists have found that patients' medical records assist them in better meeting patients' needs. Infusion pharmacists play an integral role in communicating patients' responses to treatment to the prescriber of record. There are regular interactions between the infusion pharmacist and the nurse who is visiting the patient. As a multidisciplinary team, nurses and pharmacists evaluate patients' responses to treatment and provide feedback to the prescriber. Some of the factors that are considered in this evaluation include environmental/social circumstances, caregiver support, patient's age and independence with the therapy, patient's response to therapy and adverse reactions, if any. 3. The pharmacist is responsible for developing a patient care plan and maintaining a detailed record on the patient. Regulation .04 seems to envision a role for the pharmacist that is beyond the practice of pharmacy. For instance, why does the pharmacist retrieve and assess lab values and other monitoring parameters? The pharmacist retrieves and assesses lab values and other monitoring parameters to determine if the dosage is correct and if there are any drug interactions. A consistent practice is taking vancomycin and aminoglycoside peak and trough levels and not sending the next scheduled supply until the results are within the acceptable range. In parenteral nutrition the same type of guidelines exist for patient safety. <u>When any untoward results of a therapy are recorded during a patient consult, the pharmacist contacts the prescriber of record immediately. If a change in the order appears to be warranted, the pharmacist contacts the physician for direction.</u> The pharmacy is often given a standing order for this type of therapy, and in the interest of patient safety, retrieves and assesses lab		

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		values and other monitoring parameters to ensure that the patient's order is still appropriate. This practice is common at the existing pharmacies that provide infusion therapy. During the course of infusion therapy, the patient may not be evaluated by the prescriber for **a** period of several weeks. In these cases, the prescriber relies on the on-going communication from the infusion pharmacist who is managing the infusion therapy for an accurate account of patient's response to the therapy including a review of the labs and maintaining a record. 4. Most of the record keeping is duplicative of what the physician would already have. Why does the pharmacist need all of this information? How does this fit with the role of home health care agencies? This practice is common at the existing pharmacies that provide infusion therapy. The information requested by the pharmacy when receiving an order for infusion therapy assists the pharmacy in providing safe and effective infusion therapy. For example, the type of device and equipment varies by the age of patient, dexterity level, support system and availability of a caregiver. The pharmacy has to schedule the delivery of the infusion therapy and would need to know addresses, phone numbers and to whom the infusion therapy should be delivered. Home Health Care Agencies do not dispense prescription medications required for infusion therapy. Additionally, some patients and caregivers do not utilize Home Health Care Agencies because they are independent or it is not a covered service by patient's insurance. 5. Would a patient ever go to an Infusion Pharmacy for infusion by an RN or an infusion nurse? No. Infusion pharmacies are licensed as waiver pharmacies and are not open to the public or to those patients that it provides medications for. The infusion medications are delivered to the alternate site such as the patient's home or caregiver's home. The Board would like to thank you again for your thorough reading of, and inquiries concerning, the recently submitted COMAR 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment. The Board hopes that this letter has answered the Board of Physician's questions. **10.13.01 Dispensing of Prescription Drugs by a Licensee** A meeting was held with representatives from the stakeholder Boards per direction from Wendy Kronmiller on September 30, 2010.		

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		DDC PIA request for Inspection Reports – DDC requested an extension until December 17th – Received December 16, 2010. Legislation was introduced, but did not pass. The Senate Education, Health and Environmental Affairs Committee, Health Subcommittee will meet in June to determine the summer schedule to assist the Boards in resolving the dispensing of prescription drugs by licensees. Anna Jeffers is monitoring the Committee's schedule. **2. Proposed Legislation for the 2012 Legislative Session** **Board approval requested for:** a. Propose legislation for Uniform Standard for dispensing prescribers. This proposed legislation will be pursued if COMAR 10.13.01 has not been resolved so that dispensing prescribers are following the same standards as pharmacists when dispensing into Maryland. b. Propose legislation that requires non-resident pharmacies to comply with the laws of Maryland if dispensing into Maryland. If there is a conflict between Maryland law and the laws of the state in which the non-resident is located, the non-resident pharmacy shall follow the laws of the state in which it is located. c. .Propose legislation adding to 12-403(b)(17) that non-resident pharmacies shall provide a specific written notice in each shipment of a prescription drug that provides information to the patient concerning how to file a complaint with the Board.	**2a. _____ moved to approve** **_____ _seconded the motion to approve** **2b. _____ moved to approve** **_____seconded the motion to approve** **2c _____ moved to address this issue in regulations.** **_____seconded the motion**	**2a. The legislation was approved for the 2012 Legislative Session if necessary.** **2b. The legislation was approved for the 2012 Legislative Session.** **2c. The legislation was not approved for the 2012 Legislative Session.** **2d. The legislation was approved for the 2012 Legislative Session.** **10.34.14 The Board voted to return the draft to**

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		d. Propose legislation that establishes different licensing criteria for "virtual" wholesale distributors and revises criminal background checks for out of state designated representatives and supervising designated representatives to be only from the state where they reside. **3. Review of Draft Regulations** **10.34.14 Opening and Closing of Pharmacies** Board approval requested for revisions to COMAR 10.34.14 adding opening requirements and inspections to be performed within 30 days of the closing inspection to ensure that the pharmacy is permanently closed. **DRAFT proposed- COMAR 10.34.14 052511** **Discussion ensued regarding the use of the word "expire" and the Board recommended returning the draft revisions to the July Practice Committee Meeting.** **10.34.25 Delivery of Prescriptions** Submitted for publication August 4, 2010. Board approval requested for revisions to COMAR 10.34.25 that remove temperature sensing devices from the proposal. **Final for submission 10.34.25 052511** **10.34.28 Automated Medication Systems**	**2d. _____ moved to approve** **_____seconded the motion to approve** **10.34.14 Opening and Closing of Pharmacies: _____moved to return the draft to the July Practice Committee Meeting.** **_____seconded the motion to approve** **10.34.25 Delivery of Prescriptions** **_____ moved to approve the draft regulations without the temperature sensing device.** **_____seconded the motion to approve** **10.34.28**	**the July Practice Committee Meeting** **10.34.25 The Board voted to approve the draft regulations without the temperature sensing device.** **10.34.28 The**

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		Practice recommends breaking 10.34.28.05B. into two parts: 1) review within 24 hours; OR 2) the prescriber reviews the patient medical history prior to dispensing the dose to the patient. Board approval requested to release the proposal for informal comment: **proposed-7-10 COMAR 10.34.28 Auto Med Systems 052511** **10.34.32 Pharmacist Administration of Vaccinations** (to be promulgated in consultation with the Department pursuant to SB 845) Board approval requested for the Practice recommendation to revise the draft regulations with 3 requirements when administering to individuals 9 years and older: 1) Provide the patient with the VIS from; 2) Obtain a signed consent form; and 3) "The pharmacist should observe the patient for a period of time after administration of the vaccine." **DRAFT proposed-COMAR 10.34.32 052511**	**Automated Medication Systems** **_____ moved to release the draft regulations for informal comment.** **_____ _seconded the motion to release.** **10.34.32 _____moved to approve draft regulations for review by the Department.** **_____ seconded the motion to approve.**	**Board voted to release the draft regulations for informal comment.** **10.34.32 The Board voted to submit the draft regulations for review by the Department**
III. Committee Reports	**A. H. Finke, Chair, Practice Committee**	**1. Letters for Board Approval** a. Dr. Geoffrey Buff **Suboxone for pain** **FW Katayama questions on suboxone prescribing** **DRAFT Bd Response – Suboxone for pain** Thank you for contacting the Maryland Board of Pharmacy concerning whether it is legal to dispense Buprenorphine for the use of pain management to be used on an outpatient basis.	**1a. _____moved to approve the letter.** **_____ _seconded the motion to approve.**	**1a. The Board voted to approve the letter as written.**

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		A pharmacist may, in the pharmacist's professional judgment, dispense Buprenorphine with a valid prescription for pain management so long as the prescriber is SAMSA certified. The prescriber is ultimately responsible for prescribing the appropriate pain medication. b. Stephen Wienner, Mt. Vernon Pharmacy **Proposed COMAR 10.34.20 Format of Rx Transmission-Release for Comments** **DRAFT Bd Response – Faxing and E-prescribing** **One typographical error was corrected as bolded below.** Thank you for contacting the Maryland Board of Pharmacy concerning COMAR 10.34.20.02 and the receiving of prescriptions in the pharmacy by fax machine. The recently revised 10.34.20 allows for electronic prescribing to be received in the pharmacy by fax. COMAR 10.34.20.02A(2)(b). That is a different process from when the prescriber faxes a prescription directly to the pharmacy from the prescriber's fax machine or computer. In true electronic prescribing the issue is how the prescription arrives at the pharmacy. In electronic prescribing the prescription moves from the prescriber's office through an electronic intermediary to the pharmacy. A valid electronic prescription would not arrive at the pharmacy directly from the physician's office. To determine whether or not a faxed electronic prescription has been sent through an electronic intermediary, verify that the fax number on the prescription matches the fax number of the electronic intermediary. The strip containing the transmission information must be maintained intact and filed as a part of the hard copy prescription. A prescriber, however; may still fax a prescription directly to the pharmacy so long as it contains all the information required to be a valid prescription in the professional judgment of the pharmacist responsible for filling the prescription. Faxed prescriptions from the physician's office, that do not go through an electronic intermediary, like traditional hard copy prescriptions, should contain a handwritten, pen-to-paper signature of the prescriber. COMAR	**1b.** **_____** **____moved to approve the letter with one correction.** **_____** **_seconded the motion to approve.**	**1b. The Board voted to approve the letter as corrected.**

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		10.34.20.02A(1) and (2)(a). See also COMAR 10.19.03.09A(1). For **your** information I have attached FAQs concerning electronic prescribing that are also available on the Board's website. http://dhmh.maryland.gov/pharmacyboard/legislation/FAQs%20for%20Electronic%20Prescriptions.doc **c.** Frank Fazio, Esq. Porzio, Bromberg & Newman, P.C. **Wholesale Dist - virtual manufacturers** **DRAFT Bd Response – virtual manufacturers** **Three typographical errors was corrected as bolded below.** Thank you for contacting the Maryland Board of Pharmacy concerning the licensing of virtual manufacturers in Maryland. Maryland requires manufacturers to hold a wholesale distributor permit if they are acting as a distributor. If a manufacturer is distributing into Maryland directly, or through an agent, then it would be considered a distributor. Maryland does reference the federal definition of manufacturers in its FAQs, but the Maryland Pharmacy Act only allows an exemption from certain Board requirements under the Wholesale Distributor Permitting and Prescription Drug Integrity Act, beyond that required by federal law, for a manufacturer who **distributes** its own prescription drugs approved by the U.S. Food and Drug Administration. The Board has generally interpreted this to mean that an FDA manufacturer that physically manufactures the product and then distributes its own product into, out of, or within Maryland may complete an abbreviated form. Given the various models employed by the pharmaceutical industry in the manufacturing of prescription drugs, the Board finds that Health Occupations Article Sec. 12-6C-03 may include entities (*e.g.,* virtual manufacturers, own-label manufacturers, private label manufacturers) that engage contract manufacturers **(CMO)** to do the actual manufacturing. However, in order to ascertain whether these entities qualify under 12-6C-03, they must provide the Board with: (1) documentation that they own the NDC number for the prescription drug; **and** (2) a copy of the CMO contract. In addition, please be advised that the CMO that is actually manufacturing the drug must also have a wholesale distributor's permit in Maryland if it is shipping the drugs into, out of, or within Maryland. The CMO would not qualify for the abbreviated distributor application under Sec. 12-6C-03, unless it could verify that it is	**1c. _____ moved to approve the letter with three corrections.** **_____seconded the motion to approve.**	**1c. The Board voted to approve the letter as corrected.**

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		manufacturing prescription drugs for solely one entity. **2. FYI:** Adam Christophe, PharmD, CDE, APhA Diabetes Care Specialist Giant Eagle, Inc. **immunizations in MD** **DRAFT Bd Response – Needle free injection systems** Thank you for contacting the Maryland Board of Pharmacy concerning whether the utilization of PharmaJet's needle-free injection system for flu shots would present any conflict with Maryland's pharmacist immunization laws. A needle-free injection system for flu shots would comply with the Code of Maryland Regulations (COMAR) 10.34.32.04 which requires training in the administration of intramuscular and subcutaneous injections and intranasal vaccinations.	**2. _____moved to approve the letter as written.** **_____ seconded the motion to approve.**	
	B.D. Chason, Chair, Licensing Committee	**1. Ms. Mearg Gebremedhin Tareke- Gondar University, Ethiopia (FYI) - Graduated in 4 yrs. rather than 5 due to an accelerated program in Ethiopia; however, FPGEC program requires 5 yrs – she asks if this can be waived.** **2. Smith, Richard- United States Air Force Applicant (military is always reviewed by Licensing Committee) has taken and passed PTCB** **3. Mitchell, Nicole- Applicant is requesting a refund for $30 payment for duplicate registration card.**	**1. NABP standards are upheld and applicant must have Doctorate, not Bachelors degree. Provided as FYI.** **2. Licensing Committee recommend approval** **3. Licensing Committee recommend to deny refund, did not notify Board of address change.**	

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		4. Mercer Medical (Distributor)- Request of refund of Renewal fee **5. Advanced Medical Sales, Inc- (Distributor)- Request for refund, was informed CA was a 'deemed' state, insists would not have applied if correctly informed**	**4. Licensing Committee recommend Issuing a Letter of Intent to Deny** **Licensing Committee recommend refund as Board changed status after accepting them as a deemed state.**	
	C. L. Bradley-Baker, Chair, Public Relations Committee	**L. Bradley-Baker reported the following:** 1. Annual report for the board is completed and was available to attendees during the trade show this past Sunday at the Maryland Pharmacists Association. 2. Spring newsletter was sent to the printer earlier this week---should be mailed out by late June. 3. Annual CE Training Breakfast Proposed Topic for October 2011 "Emergency Preparedness: The Role of the Pharmacist before, during, and after a Disaster" was approved by the board.		
	D. D. Taylor, Chair, Emergency Preparedness Task Force	**Committee Updates:** **Task Force Updates:** D. Taylor reported that DHMH has hired Michael Mannozi an the new Emergency Preparedness Coordinator. M. Mannozi's previous position as the SNS Coordinator for DHMH is temporarily being filled by Kim Eshleman, who also serves as the CRI Coordinator for the State.		
	E. L. Israbian-Jamgochian, Chair Disciplinary Committee	**No Additional Report**		
IV. Other Business	**A. M. Souranis**			

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	B. Drug Therapy Management			
	C. FYI			
V. Adjournment	**M. Souranis, Board President**	**The Public Meeting was adjourned at 11:10 a.m.** **B. At 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 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.**	**Mmade a motion to close the Public Meeting and open a Closed Public Meeting.** **D. Taylor seconded the motion.**	**Board Action: The Board voted to approve the motion.**