Maryland Board of Pharmacy
Public Meeting
Minutes

Date: January 19, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner	X		6	1
Chason, D.	Commissioner	X		6	1
Finke, H.	Commissioner	X		7	0
Gavgani, M. Z.	Commissioner	X		4	1
Handelman, M.	Commissioner	X		7	0
Israbian-Jamgochian, L.	Commissioner/Treasurer	X		7	0
Matens, R.	Commissioner	X		7	0
Souranis, M.	Commissioner//President	X		7	0
St. Cyr, II, Z. W.	Commissioner	X		6	1
Taylor, D.	Commissioner	X		6	1
Taylor, R.	Commissioner/Secretary	X		6	1
Zimmer, R.	Commissioner	X		6	1
Bethman, L.	Board Counsel	X		7	0
Gibbs, F.	Board Counsel	X		7	0
Banks, T.	MIS Manager	X		7	0
Gaither, P.	Administration and Public Support Manager	X		7	0
Jeffers, A.	Legislation/Regulations Manager	X		6	1
Naesea, L.	Executive Director	X		7	0

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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 9:40 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 guest to (Please indicate on sign-in sheet if you are requesting CE Units for attendance). 3. M. Souranis reported that guest will be given packets of materials so that they can follow meeting discussions. He requested that all guest return their draft packets before they leave the meeting M. Souranis 4. Review & Approval of Minutes of December 15, 2010. Minutes was not posted will review in February Board meeting. 5. Drug Therapy Management Meeting- M. Souranis had a meeting with Dr Paul Elder chair of the physicians Board. They discussed the issues that affect Drug Therapy Management processing. This involved the approval process and basically everything that has been hampering the progress of these protocols. Dr P. Elder has set up a date of February 9, 2011 at 1:00 pm. M. Souranis did hand Dr P. Elder the eleven protocols that the Board approved at our meeting. M. Souranis did stress in his meeting with Dr. P. Elder, that no staff member of the	.	

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		Physicians Board can make any recommendations of any approval of any protocols. Only members of the two joint committees. It was a good meeting and Dr. P. Elder understood our position and willing to move forward.		
II. Staff Operations Report (s)	**A. L. Naesea, Executive Director**	**1. L. Naesea reported on the following Operations Updates:** **First started by introducing our new intern student Courtney King.** **a. D. Chason and L. Naesea did complete interviews for the Licensing Manager position on January 18, 2011. The Board did make a selection for the Inspector position. The licensing unit is still struggling without a lead person.** **2. <u>Meeting Updates since last Public Board meeting:</u>** **a. . The Board is still continuing to go through with the audit. The Board will hear more about this as we proceed.** **3. Licensing Unit Updates:** **The Board has a total of 18,124 for the month of December. The number of pharmacist licensee is 8,680. The number of establishments is 1,739. The number of distributor is 561 currently. There are quite a few distributors that are still not licensed yet. This is because they may have submitted their application after the deadline. We also have applications that were submitted in the time frame that are still being processed. The Board has only one person processing these applications we have issued them an extension to continue to practice. The numbers of pharmacy technicians are 7,144.** **4. Inspection Program Report:** **The Board has a total of 65 inspections completed. There were 56 for retail community pharmacies, 5 for long care term pharmacies, 2 for hospital pharmacies, and 2 others generally related to investigation or other types of review.** **5. Compliance Unit Updates:** **Year to date PEAC is tracking 12 self referred pharmacists and two board cases representing a total of 14. There are no new cases for the month of December. There have been 34 drug test order for the month of December.** **6. PEAC Update- Tony Tommasello: Not presented**		
	B. P. Gaither, APS	**<u>Staffing Updates</u>** **a. The Board is awaiting freeze exempt approval to begin recruitment for**		

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	Manager	**the Board Secretary position.** **b. Selection was made for the Pharmacist Compliance Officer and is awaiting approval from Budget Management for January 26, 2011 appointment date. .** **c. The Board Inspector position has been offered and accepted awaiting approval for appointment date.** **d. The Board is awaiting freeze exempt approval for Pharmacist II position. E. Lin is now a 50% employee and pin needs to be split.** **e. Interviews have been completed for the Licensing Manager and now waiting for an appointment letter. The contract for the Help Desk was extended.** **f. The Board has filled the Office Secretary Temp position with a TE employee.** **Contracts:** **a. The Help Desk contract has been extended until February 4, 2011 new contract in progress.** **<u>Public Relations (PR) Committee Report</u>** **a. The next meeting of the PR Committee will be held on Wednesday January 26, 2011.** **b. The Public Information Officer, Janet Seeds, is still currently working on collecting and inputting the email addresses for pharmacist and technicians to put into our database.** **c. Reminder for staff the newletter articles is due today January 19, 2011 please give J. Seeds your article.** **<u>Emergency Preparedness Task Force Update-Report by D. Taylor</u>** **D.Taylor reported that he attended the CEC FAD meeting on January 19, 2011 that was held downtown. There were representative from all 50 states including Canada, Puerto Rico, and some of the outline areas. The meeting was talking about emergency preparedness and the supplies of drug during an emergency. The main discussion was rather or not the state could use the SLUT program. On February 16, 2011 CDC will be coming to Maryland to do their annual review of emergency preparedness for the state of Maryland this will be held downtown. Every agency will have to provide their emergency plan; D. Taylor will be present for the Maryland Board of Pharmacy. We are prepared, we do have a new SNS coordinator this will be his first time going through a review will be a learning experience. The first of May there will be a statewide exercise believes the base will be an influenza scenario, and no other details given yet.**		

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	C. T. Banks, MIS Manager	**T. Banks reported the following:** **T. banks reported database team is working on an ambitious schedule. We need to modify the schedule to meet certain conditions. The ending period that Systems Automation has is for October, which is the beginning of our next renewal period. The schedule will have to accommodate Board meetings and State holidays; we will have this schedule from draft form to final form this week. The next step for the database is to set up questionnaires and get the answers on our entire licensee once complete we will set up training and we are on our way. On the Board website we have a link to NABP for candidates can view a preliminary score.**		
	F. A. Jeffers,Legs & Regs Manager	**1. Status of Proposed Regulations** **a. 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities** Published in the Maryland Register January 3, 2011. Comments to be received until February 2, 2011. b. **10.34.25 Delivery of Prescriptions** Submitted for publication on August 4, 2010. c. **10.34.28 Automated Medication Systems** Re-proposal anticipated to be published in the Maryland Register January 14, 2011. d.. **10.34.35 Home Infusion Pharmacy Services** The Practice Committee's recommended responses to the informal comments sent to the Home Infusion Task Force for review with response deadline of 01/12/11. **DRAFT 10.34.35 HomeInfusion for Informal Release 102610** **Cindy's response to Inf comnts & Bd responses - HI proposed regs 011011** 1. **Bruce Krug II 102610**	**1.Motion: Practice Committee** **Seconded: M.**	**Board Action: The Board voted to approve the response as**

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		Bd response to informal cmmts - 10.34.35 - Omnicare -KRUG 112310 Omnicare indicated that the title of the chapter appears misleading because it implies that infusion therapy would only occur in the home. Upon further consideration the Board agrees. Although in the definitions "Home Infusion Pharmacy" and "Alternate Site Care Environment" indicate that the location where the patient is receiving infusion therapy would include locations other than an inpatient hospital setting, the title of the chapter implies home therapy. Therefore, the Board will be changing the title of the chapter to: "Infusion Pharmacy Services in an Alternate Site Care Environment." 2. **Dr. Nay 111710** **Bd response to informal cmmts - 10.34.35 - Dr. Nay 112310** You had requested that "and functional limitations" be added to .04B(2)(n). Although medical and social factors should include functional limitations, stating "and functional limitations" stresses the importance of the individual's function. The Board agrees. The new subsection would read: (n) Documented applicable medical and social factors and functional limitations which may affect home infusion therapy including but not limited to: (i) Language; (ii) Sight; (iii) Hearing; (iv) History of IV drug abuse; (v) History of drug or alcohol abuse; or (vi) Other physical or mental limitations; and Another revision that has been suggested is to add "and or caregiver" after the word "patient" where appropriate. That revision will appear in the published proposal.	**Gavgani** **M. Gavgani made a motion to amend title** **Seconded: R Matens** **2. Motion: Practice Committee** **Seconded: D. Chason**	**amended.** **Board Action: The Board voted to approve the response**

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		3. **Jeff Seabolt 102710** **Bd response to informal cmmts - 10.34.35 - Seabolt 112310** You indicated that although medication reconciliation at the conclusion of therapy was becoming the normal practice, requiring home infusion pharmacies to forward the discharge medication list to the patient and primary care provider might cause some home infusion pharmacies to be out of compliance. Please be advised that it is important for patient care that the primary care provider has a copy of the patient's medications and be informed of the status of their patient. Those home infusion pharmacies that do not currently provide this information to the primary care provider will have to adjust their policies and procedures to comply with this important patient safety requirement. 4. **Kaiser Permanente - 111710** **Bd response to informal cmmts - 10.34.35 - Kaiser -Friedman 112310** Kaiser requested that the required review of policies and procedures in 10.34.35.02 Permit Holder Responsibilities, be performed at least every 2 years, rather than annually. Kaiser's request is based on the unnecessary burden on Kaiser's pharmacists, especially given all the other regulatory mandates that pharmacies must conform to. The Board will not be changing the requirement for an annual review. Under the proposed regulations the policies and procedures would not be required to be changed or revised every year, just reviewed. The Board believes that it is good pharmacy practice to review policies and procedures annually. Kaiser also requested should this regulation become effective, that the Board of Pharmacy provide an effective date that would allow ample time to prepare. The final effective date of the regulations will be determined at a Public Board Meeting before the Notice of Final Action is published. It would be impossible to predict at this point when the regulations would be effective since it has not been submitted to the Department for sign-off yet. Please submit a suggested effective date during the official comment period.	**3. Motion:** **Seconded: R. Zimmer** **D. Taylor made a motion to amend letter** **Seconded: H. Finke** **4. Motion: Practice Committee** **Seconded: D. Taylor**	**Board Action: The Board voted to approve the amended response** **Board Action: The Board voted to approve the response** **Board Action: The Board voted to**

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		The Board voted to submit the regulations to DHMH for sign-off and publication with the revisions discussed in the responses above. e. **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. Wendy will schedule another meeting in the future. DDC PIA request for Inspection Reports – DDC requested an extension until December 17th – Received December 16, 2010. Database of information created. **2. Status of Proposed Legislation** a. Meeting with Senator Carter-Conway and Senator Montgomery – January 13th – both will sponsor the Disposal Bill and Licensure of Pharmacists Bill. b. Legislation for Board Consideration: HB 3 – Pharmacies – Taking Back and Disposing of Unused Drugs **hb0003f – Bill has been withdrawn.**	**Motion: Legislation Committee made recommendation** **Seconded: D. Taylor**	**approve the regulations for publication with revisions as discussed today.** **Board Action: The Board voted to approve the regulations for publication with revisions as discussed today.**
III. Committee Reports	**A. H. Finke, Chair, Practice Committee**	**1. Regulations:** **10.34.03 Inpatient Institutional Pharmacy** Submitted for publication on October 4, 2010. Corrected and re-submitted December 8, 2010 Chandra Mouli submitted questions to the Dept. Substantive changes recommended pursuant to Chandra's inquiry. **COMAR 10.34.03 - 121310 email from Dept** **Board Response to DDC COMAR 10.34.03** Thank you for contacting the Maryland Board of Pharmacy with your	**Motion: Practice Committee** **Seconded: D. Taylor**	**Board Action: The Board voted to approve motion**

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		comments concerning the proposed COMAR 10.34.03 Inpatient Institutional Pharmacy. Below you will find responses to your concerns. **10.34.03.06D(7)(c) Security.** *(c) Federal and other State law enforcement officials.* The Division of Drug Control (DDC) asked if it is included under "other State law enforcement official" and suggested that the proposal be revised to read "State regulatory and law enforcement official." You indicated that DDC inspectors are not State law enforcement officials. Since it could be argued that DDC is not a State law enforcement official, the Board voted at the January 19, 2011 Board meeting to revise COMAR 10.34.03.06D(7)(c) to read "Federal and State regulatory and law enforcement official." **10.34.03.13A(1)(e) Controlled Dangerous Substances.** *A. Drug Accountability.* *(1)* The director *of pharmacy* is responsible for **[**the establishment of effective**]** *establishing* procedures and **[**the maintenance of**]** *maintaining* adequate *written or electronic* records regarding **[**use**]** *dispensing* and accountability of **[**Schedule II**]** controlled dangerous substances which specify at least the following: *(e) Patient name with second identifier;* DDC asked for a definition of "second identifier" In hospitals a "second identifier" is a second form of identification for the patient. Normally the primary identifier is the bar code on the hospital identification bracelet. An example of a second identifier could be a date of birth. For clarification purposes the Board voted at the January 19, 2011 Board meeting to add the following definition of "second identifier." *(15) "Second identifier" means a reliable method to:* *(a) Identify a patient for whom service or treatment is intended; and*		

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		(b) Match the service or treatment intended to the patient. **10.34.03.13A(4) Controlled Dangerous Substances.** *A. Drug Accountability.* *(4) The director of pharmacy or [the director's pharmacist] designee shall [specify that these] establish procedures to ensure that controlled dangerous substance records include the handwritten or electronic signature of the individual authorized:* DDC indicated that there are specific requirements for electronic signatures for controlled dangerous substances (CDS). DDC suggested that this section read: "handwritten or electronic signature of the individual authorized, in accordance with applicable federal and state regulations." Please be advised that the Board will not be spelling out specific requirements for electronic signatures for CDS. The specific requirements would be spelled out in the procedures. Adding "in accordance with applicable federal and state regulations" does not add specific requirements to the proposed regulations and any procedures would have to comply with applicable federal and state regulations. **10.34.03toV1 11109 1 120910 revote 011911** **The Board voted to submit the regulations to DHMH for sign-off and publication with the revisions discussed in the responses above.** **2. Letters for Board Approval** **a. Jack McNamara, Southern Md Hospital Center** **Anethesia Techs handling of Medications** **DRAFT Bd Response – Anethesia Techs handling meds**	**Motion:** **Seconded: D. Chason** **2.A. Motion: Practice Committee**	**Board Action: The Board voted to approve the regulations for publication with revisions as discussed today.**

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		Please be advised that the Board finds the use of a medication closet not to be a best practice. The medication closet you described is not maintained by the pharmacy department and is not a controlled environment. Therefore, the Board feels that there are security risks to the use of "medication closets", as well as the potential for placing patients at risk due to missed doses or diluted medications. **b. Chandra Mouli, DDC** **DDC - automatic refills billed but not picked up** **DRAFT Bd Response – automatic refills billed but not picked up** Although not specifically addressed in the Maryland Pharmacy Act or regulations, please be advised that if the patient gives consent in advance, a pharmacy may automatically refill a patient's prescription. No actual consent form is required. A pharmacy may not, however; automatically refill a PRN prescription because the pharmacy would have no way of knowing if the patient would continue to need the medication. **c. Chandra Mouli, DDC** **DDC - Questions on 10.34.23 published proposal & reproposal** **Md. R. June 4, 2010 COMAR 10.34.23** **Md R 010311 reproposal publication** **10.34.23v6 to_10909_1_1 120610** **DRAFT Bd Response – DDC inquiry - COMAR 10.34.23** COMAR 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities was initially published in the Maryland Register on June 4, 2010. A 30 day official comment period followed. A re-proposal of COMAR 10.34.23 was published in the Maryland Register on January 3, 2011. There is another official comment period until February 2, 2011. Since you	**Seconded: R.Zimmer** **2.B. Motion: Practice Committee** **Seconded: D. Taylor** **2.C. Motion: Practice Committee** **Seconded: D. Taylor**	**Board Action: D. Taylor made a motion to amend. The Board voted to approve motion as amended** **Board Action: The Board voted to approve motion** **Board Action: The Board voted to approve motion**

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		submitted your inquiry on December 15, 2010 the Board will respond to your specific questions at this time. 1. 10.34.23.07.C(1) - 12 months from the date of repackaging Comment - In order to be in compliance (COMAR 10.34.23.07A(2)(d)) with FDA regulations the expiration date should not be more than six months from the date of repackaging without conducting stability studies. Please be advised that the expiration date for medication is the lesser of 12 months from the date of packaging under the FDA and USP. 2. 10.34.23.09A(3) - Drugs classified as Schedule II, Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy. Comment - CDS should not be returned to the pharmacy and should be destroyed at the facility COMAR 10.19.03.10D(3)(d). All Comprehensive Care Facilities are required to have a CDS registration Please be advised that if the inventory is in unit dose packages and billed after administration, it would still belong to the pharmacy and may be returned to the pharmacy. 3. 10.34.23.09B. Medications may be accepted for return if: (1) The returned medication is properly labeled and properly sealed in the manufacturer's package or an individually labeled unit dose of a drug or a device; Comment - are blister packages included in individually labeled unit dose of a drug or device? If by using the term "blister packages" you are referring to "bingo cards" then the blister packs/bingo cards may be returned to the pharmacy if properly labeled. 4. 10.34.09C. Discontinued Medications — Controlled Dangerous Substances. (1) Except as provided in §§B(2) and C(2) of this regulations, drugs classified as Schedule II, Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy. (2) Schedule III, Schedule IV, and Schedule V medications may be returned to inventory of a pharmacy when the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the patient.		

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		Comment - This adds to more confusion. Does this refer to CDS that have been discontinued and NOT left the pharmacy? If not, no CDS may be received by the pharmacy and returned to stock including Schedule III through V. Again, if the inventory is in unit dose packages and billed after administration, it would still belong to the pharmacy and may be returned to the pharmacy.		
III. Committee Reports	**B.D. Chason, Chair, Licensing Committee**	**No additional report**		
	C. L. Bradley-Baker, Chair, Public Relations Committee	**L. Bradley-Baker reported the following:** **No additional report**		
	D. L. Israbian-Jamgochian, Chair Disciplinary Committee	**L. Israbian- Jamgochian reported the following:**		
IV. Other Business	**A. M. Souranis**			
IV. Other Business	**BB. Drug Therapy Management**			
	C. Staff Member Updates t			

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	D. 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.**	**Motion:** **D. Chason made a motion to close the Public Meeting.** **Seconded the motion: D. Taylor**	**Board Action:** **The Board voted to approve the motion.**