Maryland Board of Pharmacy
Public Meeting
Minutes
Date: March 16, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner	X		7	2
Chason, D.	Commissioner	X		8	1
Finke, H.	Commissioner	X		9	0
Gavgani, M. Z.	Commissioner	X		6	1
Handelman, M.	Commissioner	X		8	1
Israbian-Jamgochian, L.	Commissioner/Treasurer	X		9	0
Matens, R.	Commissioner	X		9	0
Souranis, M.	Commissioner//President	X		9	0
St. Cyr, II, Z. W.	Commissioner	X		7	2
Taylor, D.	Commissioner	X		8	1
Taylor, R.	Commissioner/Secretary	X		8	1
Zimmer, R.	Commissioner	X		8	1
Bethman, L.	Board Counsel	X		9	0
Banks, T.	MIS Manager	X		9	0
Wu, YuZon	Compliance Manager	X		2	0
Daniels, Demetrius	Licensing Manager	X		9	0
Gaither, P.	Administration and Public Support Manager	X		1	0
Jeffers, A.	Legislation/Regulations Manager	X		8	1
Naesea, L.	Executive Director	X		9	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 9:43 A.M. 2. M. Souranis requested all meeting attendees to introduce themselves and to remember to sign the guests list before leaving the meeting. M. Souranis asked guests to (Please indicate on sign-in sheet if you are 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 leave the meeting M. Souranis. 4. Review & Approval of Minutes of February 16, 2011.	D. Chason made a motion to approve minutes as amended. Motion: D. Taylor Seconded: R. Matens	Board Action: The Board voted to approve the motion
II. Staff Operations Report (s)	A. L. Naesea, Executive	1 Operations Updates: L. Naesea provided the following operational updates: The Board now		

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	Director	**has a full set of managers. She introduced the new Licensing Manager Demetrius Daniels. L. Naesea congratulated and acknowledged P. Gaither for filling most of the Board vacancies expeditiously. The Board will be hosting a new University of MD Pharmacy intern starting March 21, 2011. The student will be with the Board for five weeks.** **2. <u>Meeting Updates:</u>** **L. Naesea and T. Banks attended the audit exit meeting. L. Naesea noted that there were two audit findings: 1) Staff did not document that licensing stock monitored routinely; and 2) staff did not routinely reconcile checks issued licensing with fees paid. Board staff had been performing that task routinely, but the vacancy in the licensing unit caused negligence in performing it on a regular basis. L. Naesea accepted responsibility for not assuring that this process continued while she was the acting Licensing Manager. There is also a natural a lag time, as explained to previous auditors, between when the license application is received and the time the money is received. A license application may be pending for up to a year.** **L. Naesea attended the House and Senate budget hearings to oppose the transfer of approximately $237,000 from the Board of Pharmacy's 2012 fund balance (indicated in the Governor's Budget and Reconciliation Finance Act (BRFA) proposal). That she followed up with a letter explaining that the Board has a need for that money to support the initiated MIS project. The Board could not receive advance approval for its budget deficit request to pay for the project until the Legislature was in session to approve it. If the Governor's BRFA proposal is approved, the Board's 2012 fund balance will fall below 11% of its total appropriation. DBM has encouraged all Boards to maintain a fund of at least 20% in each Fiscal year to meet unanticipated spending requirements.** **The ACPE evaluation of University of Maryland Eastern Shore will be performed between April 6 – 8, 2011. M. Souranis and L. Israbian-Jamgochian will observe the evaluation.** **The Medication Therapy Management conference was on March 5, 2011. L. Israbian-Jamgochian and R. Taylor attended this conference.** **NABP National Meeting is scheduled in May L. Israbian-Jamgochian is the Board's delegate representative and she will received a NABP grant to attend.**		

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	B. P. Gaither, APS Manager	P. Gaither reported the following staffing/personnel updates: 1. Vacancies and Recruitments: The Executive Secretary position remains vacant. Recruitment letters were issued and responses are due March 16, 2011. Vanessa Thomas-Gray has been hired as the new Compliance Investigator and her vacated position is open. A freeze exemption has been requested for that position. The Board requested a freeze exemption to hire a 50% pharmacist to share with the Pharmacist Inspector, Emory Lin, who is now a .50 FTE. The Board request was denied and will be appealed. 2. Contracts: A new contract has been signed with Realistic Computing to provide help desk support. The new contract will end October 31, 2011. The Board's temporary employee in the Licensing Unit will end June 7, 2011. The NABP Inspection contract has been signed completed and inspections should begin soon. 3. The APS Manager applied for the NABP travel grant for L. Israbian Jangochian and has arranged to travel for the ACPE Evaluation observations on the Eastern Shore.		
	C. D. Daniels, Licensing Manager	D. Daniels reported on the following for the month of February: The Board had a total of 18,383 licensees. The number of pharmacist licensee was 8,716. The number of establishments was 1,729. The number of distributors was 640 The number of pharmacy technicians was 7,298.		
	D. T. Banks, MIS Manager	T. Banks reported the following: The licensing portion of the new database has been completed and work has begun on the compliance section. This section is scheduled for completion on March 17, 2011. The Board has ordered required hardware and will create an implementation plan. MIS staff must insure that disaster recovery is in place and this process will involve helpdesk personnel from Realistic Computing. M. Hsu has been moving data out of the current system into the new system. The next two major steps will be the installation of what has been created so far. Then the online		

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		system will be set up.		
	E. Y. Wu, Compliance Manager	**Y. Wu reported on the following:** **1. Inspection Program - A total of 82 inspections were completed in February: 67 annual, 9 openings, 2 relocations, and 4 others (generally related to investigation).** **2. Compliance Unit Updates- The Board received 19 complaints in the month of February.** **PEAC Update – Tony Tommasello reported that PEAC has 17 cases. There was one new case for the month of February. 39 drug tests were ordered for the month of February with one positive.**		
	F. A. Jeffers,Legs & Regs Manager	**1. Status of Proposed Regulations** **a. 10.34.03 Inpatient Institutional Pharmacy** Re-submitted for publication on January 31, 2011. **b. 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities** Published in the Maryland Register January 3, 2011. Notice of Final Action ready for sign-off – Does the Board want a specific date? c. **10.34.25 Delivery of Prescriptions** Submitted for publication on August 4, 2010. d. **10.34.28 Automated Medication Systems** Re-proposal published in the Maryland Register January 14, 2011. Comments to be received through February 14, 2011. One comment received from Kaiser Permanente.		

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		COMAR 10.34.28_automated medication systems_Kaiser Perman To be discussed at the March Practice Committee Meeting. e. **10.34.35 Home Infusion Pharmacy Services** **Final version approved at February 16, 2011 Board Meeting. To be submitted.** f. **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. Regulatory Proposal on a related matter: **14.09.03 012811 publication - WCC - fees** **14.09.03 Notice of Hearing** **2. Legislation - Letters and Position Papers for Ratification:** a. HB 3/SB 577 Pharmacies – Taking Back and Disposing of Unused Drugs – SWA **HB 3 Pharmacies - Taking Back&Disposing of UsedDrugs 022111** **SB 577** Pharmacies - Taking Back&Disposing of UsedDrugs 030111 **hb0003f**	**Motion: R. Matens made a motion to bundle as a group and to ratify** **Seconded : D. Chason**	**Board Action: The Board voted to approve motion**

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		The Board understands the intent of SB 577 and applauds the effort to address proper disposal of unused medications in Maryland. However, the Board had concerns about this legislation as written because it would require all pharmacies to take back and dispose of not only prescription, but nonprescription items. Since this legislation has been introduced the Board has been working with the Attorney General's Office to reconcile the Attorney General's Office future pilot disposal program with the Board's existing Prescription Drug Repository Program. The Board and the Attorney General's Office have agreed that the two programs would be able to co-exist. A disposing pharmacy would be required to be registered with one of these programs. Additionally, for inspection and regulatory purposes, the Board would receive a list of pharmacies twice a year that are registered with the Attorney General's office. Under the Attorney General's pilot program prescription and non-prescription medications would be collected in a locked one-way box that would be sent to a reverse distributor or law enforcement for disposal in accordance with State and federal law. Those pharmacies that choose to participate in the Prescription Drug Repository Program for disposal purposes would still register with the Board and dispose in accordance with State and federal law. The Board asks for a favorable report for SB 577 Pharmacies – Taking Back and Disposing of Unused Drugs with the following amendments to conform to HB 3. **The Board ratified the position paper to Support with Amendments.** b. SB 237/HB 359 Criminal Law – Selling a CDS to a Minor Causing Death - SWA **SB 237 Crim Law - Selling a CDS to a minor 021011** **sb0237f** The Board of Pharmacy (the "Board") **Supports with Amendment** SB 237. The Board recognizes the importance of making the criminal law more comprehensive by making it a felony for a person 18 years of age or older that sells to a minor a CDS, the use of which causes the death of the minor. The Board has concerns, however; with the use of the word "sell." Pharmacists "sell" CDS to minors on a routine basis under valid prescriptions, and under this law, they may be prosecuted for legitimately filling a CDS prescription which causes the death of a minor. The Board requests that an amendment be added to exclude pharmacists and		

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		other health care providers. The Board does not believe that criminally prosecuting health care providers was the intent of the legislation. The Board is established pursuant to the Health Occupations Article, 12-201, Annotated Code of Maryland, and is an independent body comprised of twelve Board members. The opinion of the Board expressed in this position paper does not necessarily reflect that of the Department of Health and Mental Hygiene. The Board requests the amendment below be added to SB 237. **The Board ratified the position paper to Support with Amendments.** c. HB 291/ SB 308 Public Health – Medical Marijuana - SWA **HB 291 Public Health MedicalMarijuana 022811[1]** **DHMH Testimony on 291_3 022811** **hb0291f** The Board of Pharmacy (the "Board") **Supports with Amendment** HB 291 Public Health – Medical Marijuana. The Board supports the concept of allowing medical marijuana to be prescribed and dispensed in Maryland. The Board recognizes the national trend toward making medical marijuana available to chronically or terminally ill patients where no other pain or nausea medications have been effective. The Board acknowledges that this is the only legislation in the country that has included pharmacies and pharmacists in the dispensing process and applauds the sponsors' recognition of the need to involve pharmacists in the dispensing of this medication. Pharmacists are professionally trained to understand the effects of all controlled dangerous substances in the treatment of chronically or terminally ill patients, including indications, proper dosing, and potential side effects of medical marijuana. They are also experts in record keeping, patient counseling, and dispensing in conformance with state and federal requirements. The Board requests that one amendment be added to the legislation that would to require each dispensing center to employ a consulting pharmacist. A consulting pharmacist would perform routine patient record reviews, respond to patient and dispensing center questions, and also guide the dispensing center in handling and dispensing the prescription medical marijuana. The guidance of a pharmacist would further ensure that proper policies and procedures are followed.		

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		The Board requests the amendment below be added to HB 291 **The Board ratified the position paper to Support with Amendments.** d. SB 560/HB 1100 Health Occupations – State Board of Naturopathic Medicine – Oppose **SB 560 Hlth Occs - Naturopathic Medicine – 030111** **sb0560f** The Maryland Board of Pharmacy **OPPOSES** HB 1100 Health Occupations – State Board of Naturopathic Medicine. The Board believes that naturopathic physicians' scope of practice overlaps existing health occupations without strong educational and clinical medical training. It is of particular concern to the Board that naturopathic physicians under this legislation would be authorized to "dispense" prescription drugs on a formulary determined by a Naturopathic Formulary Council if the naturopathic licensee is authorized by the Board of Naturopathic Medicine. The Board of Pharmacy maintains that dispensing prescription drugs and prescription medical devices is the primary function of pharmacists. Pharmacists are highly trained and regulated to dispense, store, maintain prescription records, and counsel patients on the best uses of prescription drugs and prescription medical supplies. Pharmacists often have the only complete record of a patient's prescriptions and can easily notify any of the patient's prescribers if a counter indication occurs. The Board believes that naturopathic physicians should not be authorized to practice or claim to practice as a pharmacist unless they are operating under a specific permit that requires them to meet all the State and federal dispensing requirements. The Board asks for an unfavorable report for HB 1100 Health Occupations – State Board of Naturopathic Medicine. **The Board ratified the position paper to Oppose.** e. HB 460/SB 770 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies – SWA		

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		SB 770 RxDrugRepProg-Disposal of RxDrugs&Med Supplies 022811[1] **sb0770f** The Maryland Board of Pharmacy **Supports with Amendments** SB 770 Prescription Drug Repository Program - Disposal of Prescription Drugs and Medical Supplies. The Board initiated this legislation to provide accountability for disposing pharmacies; to prevent potential hazards to children and young adults; to protect the environment; and to compliment recently strengthened federal requirements under the Secure and Responsible Drug Disposal Act of 2010. The application process is simple and there is no fee to apply. More and more pharmacies are participating in programs such as "DisposeMyMeds" and "Take Away." These programs lack accountability for what is donated for disposal. Expansion of the Prescription Drug Repository Program to include disposal would provide accountability and increase awareness of the original purpose of the program. Some pharmacies proactively collect unwanted, unused or expired prescription medications through various disposal programs, which accommodate customers while also protecting the environment. The Board is concerned that the true outcome of drugs returned to pharmacies is not known and Maryland law does not specifically address record keeping requirements for the receipt or returned unwanted or expired medications for disposal. Thus, the Board believes that the increase in the number of Maryland pharmacies that receive returned medications and the potential harm to the environment if they are not properly disposed, warrants greater State regulatory oversight. Required enrollment in this program would assure proper handling and accountability for donated and returned prescription drugs and devices; may provide support to customers who may otherwise be unable to pay for certain medications; and further supports the pharmacies efforts to dispose of medications. The Board is aware of the compelling public safety and environmental issues relating to the disposal of unwanted medications. Many consumers have numerous unused or outdated prescriptions in their homes. Many family members are left with a bounty of unused prescription medications when loved ones die. The Board is also cognizant of the serious potential hazards to children and teenagers who may pull discarded medications from the trash, or medicine cabinets and ingest them. Expanding the purpose of the repository program would also compliment the recently signed federal legislation to amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances. The Board would address disposal in a separate regulation within the COMAR chapter 10.34.33, once the federal regulations have been promulgated. Additionally, the Board would address in regulations any medications that are required by federal law to meet special handling requirements or may have specific restrictions under the U.S. Food and Drug Administration.		

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		Since this legislation has been introduced the Board has been working with the Attorney General's Office to reconcile their pilot disposal program with the Board's Prescription Drug Repository Program. The Board and the Attorney General's Office have agreed that the two programs would be able to co-exist. A disposing pharmacy would be required to be registered with one of these programs. Additionally, for inspection and regulatory purposes, the Board would receive a list of pharmacies twice a year that are registered with the Attorney General's office. Under the Attorney General's pilot program prescription and non-prescription medications would be collected in a locked one-way box that would be sent to a reverse distributor or law enforcement for disposal in accordance with State and federal law. Those pharmacies that choose to participate in the Prescription Drug Repository Program for disposal purposes would still register with the Board and dispose in accordance with State and federal law. The Board asks for a favorable report for SB 770 Prescription Drug Repository Program - Disposal of Prescription Drugs and Medical Supplies. **The Board ratified the position paper to Support with Amendments.** f. SB 698/HB 1144 Pharmacy Benefit Managers – Specialty Drugs – SWA **SB 698 PBMs-Specialty Drugs 030211** **sb0698f** The Maryland Board of Pharmacy **Supports with Amendments** HB 1144 Pharmacy Benefit Managers – Specialty Drugs. The Board maintains that it is the appropriate entity to approve specialty drugs because of its expertise in prescription drugs, their indications and interactions. The Board seeks one amendment to exempt prescription drugs that are part of programs mandated by the U.S. Food and Drug Administration (FDA) or have additional requirements under 21 CFR § 314.520 because of documented risk to patients. The other amendment clarifies that the Board designate a list of specialty drugs and publish that list twice a year in the Maryland Register. The Board asks for a favorable report for HB 1144 Pharmacy Benefit Managers – Specialty Drugs with the amendments below. **Amendment 1:** On page 1, in line 16, before the word "IF" insert (A). On page 1, after line 19, insert: (B) PROGRAMS THAT ARE MANDATED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR HAVE ADDITIONAL REQUIREMENTS UNDER 21		

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		CFR § 314.520 BECAUSE OF DOCUMENTED RISK TO PATIENTS, ARE EXEMPT FROM OBTAINING BOARD APPROVAL FOR SPECIALTY DESIGNATION. (C) THE STATE BOARD OF PHARMACY SHALL: (1) DESIGNATE A LIST OF SPECIALTY DRUGS; AND (2) PUBLISH THE LIST OF SPECIALTY DRUGS BI-ANNUALLY IN THE MARYLAND REGISTER. **Rationale 1:** This amendment is offered to exempt prescription medications that have been designated as specialty drugs and are part of programs that are mandated by the U.S. Food and Drug Administration (FDA) or have additional requirements under 21 CFR § 314.520 because of documented risk to patients. This amendment also clarifies that the Board of Pharmacy will be required to designate a list of specialty drugs and publish that list in the Maryland Register twice a year. **The Board ratified the position paper to Support with Amendments.** g. SB 700/HB 1149 Pharmacies – Delivery of CDS – Letter of Support **SB 700 - Pharmacies - Delivery of CDS - LoS – 030711** **sb0700f** The Board supports this legislation because it provides a safe guard to ensure that prescriptions for Schedule II controlled dangerous substances are delivered directly to the patient and signed for by the patient. If the patient is not at home, then only another adult may sign for the prescription. This legislation will prevent the theft of Schedule II controlled dangerous substances from mailboxes or interception by minors living in the home. It has been found that teenagers often obtain Schedule II controlled dangerous substances from their parents' homes or their friends' parents' homes. Requiring an adult to sign for the medications will help keep them out of the hands of teenagers and perhaps prevent a tragic overdose. The legislation is good public policy and the Board wholeheartedly supports it. The Board requests a favorable report on HB 1149. **The Board ratified the Letter of Support.**		

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		h. SB 701/HB 888 Health Insurance – Prescription Eye Drops – Refills – Letter of Support **HB888 Hlth Ins-RxEyeDrops- Refills LoS 022811[1]** **sb0701f_1** The Board supports this legislation because pharmacists see first hand the need of patients, especially elderly patients, for additional eye drops before the schedule time to refill their prescriptions. It is difficult to determine at the time of prescribing exactly how much eye drops would be appropriate for each patient. Some patients need more eye drops than others. Oftentimes patients are required to wait up to a week for eye drops that are critical for them to be able to see. The pharmacists are put in a difficult position because they see the need, but the patient's insurance will not cover the additional necessary eye drops. Therefore, the Board requests a favorable report on HB 888. **The Board ratified the Letter of Support.** i. SB 713 Pharmacists – Administration of Vaccines – Regulations – Support **SB 713 Pharm-Admin of Vaccines-Regulations 030311** **sb0713f** The Maryland Board of Pharmacy **Supports** SB 713 Pharmacists – Administration of Vaccines – Regulations. This statute change would simplify the promulgation process for adding vaccinations that are in the best interests of the community to the list of vaccinations that pharmacists may administer in Maryland. Pharmacists in Maryland have been safely administering influenza vaccinations since 2005 and herpes zoster and pneumococcal pneumonia vaccines since 2009 with no adverse reactions. Although the SB 713 does not require agreement with the Board of Physicians and the Board of Nursing, the Board of Pharmacy would still be required to consult with the two other boards prior to proposing any regulations concerning the administration of vaccinations by qualified pharmacists. This change of requiring the Board to consult with the other entities rather than obtaining agreement is in keeping with the precedence established by similar Maryland laws. See Health Occupations Article, 12-6C-03.1, Annotated Code of Maryland. This change would continue to provide the Board of Physicians and the Board of Nursing an opportunity to provide constructive comments to the Board before the		

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		formal regulatory promulgation process, while insuring that appropriate additions to the list of vaccines that pharmacists could be allowed to administer are not stalled during deliberations. The Board asks for a favorable report for SB 713 Pharmacists – Administration of Vaccines – Regulations. **The Board ratified the position paper to Support.** j. SB 769/HB 549 State Board of Pharmacy – Pharmacists – Practice of Pharmacy and Licensure – Support **HB 549 Bd of Pharm - Practice of Pharm&Licensure 022111** **hb0549f** The Maryland Board of Pharmacy **Supports** HB 549 State Board of Pharmacy – Pharmacists – Practice of Pharmacy and Licensure. The Board initiated this legislation for three reasons: 1) to provide recourse for Maryland consumers who are subjected to medication errors and/or other serious acts by out-of-state pharmacists who dispense into Maryland; 2) to ensure that pharmacists dispensing into Maryland or practicing pharmaceutical care in Maryland meet Maryland standards; and 3) to ensure compatibility with other occupational and other States' requirements. **Recourse for Maryland Consumers** Currently there is no conduit for a Maryland patient except to file a complaint with the state board where the pharmacist is licensed when a problem arises. In such cases, it is also virtually impossible for the Maryland Board to investigate a complaint against an out-of-state pharmacist or impose any type of sanction. This concerns the Board because it has begun to view more in more applications from out-of-state pharmacists, who want to transfer their out-of-state licenses to Maryland that had the following kinds of issues tied to their out of state licenses: • Histories of addiction, whether it is alcohol or controlled dangerous substances; • High medication misfill rates; • Pilfering of narcotics; • Forged prescriptions; • Convictions for Medicare/Medicaid Fraud; • Stolen identity of the a practicing pharmacist for use in reciprocating into Maryland; • Submission of fictitious documents to obtain licensure from out-of-state; and/or		

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		• Employment with internet pharmacies that have not been accredited by the NABP's Verified Internet Pharmacy Practice Sites program (VIPPS). Cases or complaints in other states may be evaluated using different criteria than that used in the Maryland Board's disciplinary review process. The Board would like to provide Marylanders a right to resolve dispensing disputes through their Maryland Board. **Meeting Maryland's pharmacist standards** Since the practice of pharmacy affects the lives of most people in this state, requiring all pharmacists who practice in Maryland to be licensed will protect Marylanders by requiring the same standards of qualification, education, and experience to be met by every pharmacist who provides patient care in the State. Maryland Health Occupations Section 12-301(a) states that: Except as otherwise provided in this title, an individual shall be licensed by the Board before the individual may practice pharmacy in this State. According to Board counsel interpretation, this standard does not apply to non-resident pharmacists working for non-resident pharmacies; therefore, it is vital and paramount to the Board to incorporate this into statute. **Compatibility with other Occupational and States' Requirements** Pharmacy is one of the few professions that allow practitioners in other states to practice in Maryland. Most other health occupations and professional occupations do not allow it, or if they do, under limited conditions. The Maryland Department of Labor, Licensing, and Regulation (DLLR) assure that in-state and out-of-state Maryland licensees under its jurisdiction meet a standard of competence in their chosen profession. Thus, no non-resident attorney, physician, dentist, certified public accountant, master electrician, plumber, or even a real estate broker can practice in Maryland without a Maryland license. Eight other states require the Pharmacist in Charge (PIC) at a non-resident pharmacy to be licensed in their state. The Board proposes that all pharmacists that practice pharmacy as defined in Health Occupations Article, 12-101, Annotated Code of Maryland, be licensed in Maryland. The Board asks for a favorable report for HB 549 State Board of Pharmacy – Pharmacists – Practice of Pharmacy and Licensure. **The Board ratified the position paper to Support.** k. HB 986 Pharmacists – Administration of Vaccines – Children – SWA **HB 986 Pharm-Admin of Vaccines-Children 022711[1]** **hb0986f**		

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		The Maryland Board of Pharmacy **Supports** HB 986 Pharmacists – Administration of Vaccines – Children. During the 2009/2010 H1N1 flu season, the Secretary of the Department of Health and Mental Hygiene (DHMH) issued an Executive Order authorizing licensed, certified pharmacists to administer the H1N1 vaccine to individuals 13 years old and older. This Executive Order was in effect from December 11, 2009 through February 7, 2010. During this time pharmacists were able to administer vaccines to parents and their children 13 years old and older. The results were positive and no adverse reactions or injuries were reported. This Executive Order made it possible for many more individuals to be vaccinated with the H1N1 vaccine. The Board supports lowering the age to at least 7 years old so that entire families may be vaccinated at one time. This would be a great convenience and incentive for families to obtain vaccinations. Other states have lowered the age for pharmacist administration of vaccinations to children and the results have been positive. The Board has learned that HB 986 will be amended to conform to SB 845 Health Occupations – Pharmacists – Administration of Vaccinations, Epinephrine, and Diphenhydramine. The Board embraces the more comprehensive revisions to Health Occupations Article, 12-508, Annotated Code of Maryland, which allows pharmacist administration of vaccinations in Maryland. The more comprehensive revisions allow for the administration of all vaccinations listed in the Centers for Disease Control and Prevention (CDC) Recommended Immunization Schedule or CDC's Health Information for International Travel, without a prescription. It lowers the age to at least 7 years old, as in HB 986, and only requires the pharmacist to make a reasonable effort to inform the patient's primary care physician that the vaccination has been administered. The Board asks for a favorable report for HB 986 Pharmacists – Administration of Vaccines – Children as amended to conform to SB 845 Health Occupations – Pharmacists – Administration of Vaccinations, Epinephrine, and Diphenhydramine. **The Board ratified the position paper to Support with Amendments** l. HB 1051 Freestanding Pain Management Clinics – Regulation – Letter of Support **HB 1051 Freestanding Pain Management Clinics - Regs LoS 030411** **hb1051f** The Maryland Board of Pharmacy (the "Board") submits this **Letter of**		

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		Support regarding HB 1051 Freestanding Pain Management Clinics - Regulation HB 1051 requires a freestanding pain management clinic to be licensed by the Department of Health and Mental Hygiene (the "Department") who will adopt regulations for that purpose. The regulations will include procedures and practice standards; qualifications of health care practitioners and support personnel; licensing and renewal requirements; requirements for inspections and complaint investigations; and any other requirements that the Secretary of the Department considers necessary for quality of care and patient safety. HB 1051 includes restrictions on who may operate a freestanding pain management clinic so that those with prior disciplinary actions or criminal convictions will be precluded from operating a clinic. The legislation requires that the owner or operator of a freestanding pain management clinic be on site at least 33% of the total operating hours of the clinic. The owner or operator would also be required to review for appropriateness of care at least 33% of the total number of patient files, including clinic employees, or contractors who have been delegated authority for patient care. The Board supports this legislation because pharmacists are well aware of the large number of patients utilizing "freestanding pain management clinics" and the large number of prescriptions that are being written by "pain management" physicians. Although many "freestanding pain management clinics" provide a valuable service to those patients in chronic pain, a few appear to be sources for pain medication that is then diverted and sold on the street. The Board believes that regulation of "freestanding pain management clinics" would weed out the bad apples and provide the responsible "freestanding pain management clinics" with standards and regulations to follow. Left unregulated, some "freestanding pain management clinics" will continue to move frequently and write unnecessary controlled dangerous substance prescriptions. Therefore, the Board requests a favorable report on HB 1051. **The Board ratified the Letter of Support.** m. SB 845 Health Occupations - Pharmacists - Administration of Vaccinations, Epinephrine, and Diphenhydramine – SWA **SB 845 Hlth Occs - Pharm - Admin of Vacc, Epine, Diphen 030111** **sb0845f** The Maryland Board of Pharmacy **Supports with Amendments** SB 845		

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		Health Occupations – Pharmacists – Administration of Vaccinations, Epinephrine, and Diphenhydramine. The Board embraces the comprehensive revisions to Health Occupations Article, 12-508, Annotated Code of Maryland, which allows a pharmacist to administer vaccinations in Maryland. During the 2009/2010 H1N1 flu season, the Secretary of the Department of Health and Mental Hygiene (DHMH) issued an Executive Order authorizing licensed, certified pharmacists to administer the H1N1 vaccine to individuals 13 years old and older. This Executive Order was in effect from December 11, 2009 through February 7, 2010. During this time pharmacists were able to administer vaccines to parents and their children 13 years old and older. The results were positive and no adverse reactions or injuries were reported. This Executive Order made it possible for many more individuals to be vaccinated with the H1N1 vaccine. The Board supports lowering the age to at least 7 years old so that entire families may be vaccinated at one time. This would be a great convenience and incentive for families to obtain vaccinations. Other states have lowered the age for pharmacist administration of vaccinations to children and the results have been positive. This legislation would also simplify the promulgation process for adding vaccinations that are in the best interests of the community to the list of vaccinations that pharmacists may administer in Maryland. Pharmacists in Maryland have been safely administering influenza vaccinations since 2005 and herpes zoster and pneumococcal pneumonia vaccines since 2009 with no adverse reactions. Although the SB 845 does not require agreement with the Board of Physicians and the Board of Nursing, the Board of Pharmacy would still consult with the two other boards prior to submission of any regulations concerning the administration of vaccinations. Additionally, both boards would have the opportunity to provide formal comments to the Board during the regulatory promulgation process. The Board offers one amendment that revises a section of the statute regarding the Board of Pharmacy, Board of Physicians and the Board of Nursing meeting annually to jointly develop, adopt, and review regulations to provide for patient safety. The Board's amendment, would revise this section so that the three boards would still meet annually, but to review regulations. This would be consistent with SB 845 removing the agreement of the three boards to select vaccinations to be in the best health interests of the community. The Board notes that the administration of epinephrine and diphenhydramine is currently allowed under COMAR 10.34.32 Pharmacist Administration of Vaccinations. In COMAR 10.34.32.04 pharmacists are currently trained to respond to an emergency situation as a result of the administration of a vaccination, which would be when epinephrine and diphenhydramine would be administered by a pharmacist. That ability of the pharmacist to administer		

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		these medications in emergency situations remains, and should remain, whether or not this legislation is successful. The Board asks for a favorable report for SB 845 Health Occupations – Pharmacists – Administration of Vaccinations, Epinephrine, and Diphenhydramine, with the Board's amendments. **Amendment 1:** On page 2, in line 25, after "(c)" insert "(1) THE BOARD SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SECTION. On page 2, in line 25 and line 28, strike "(1)" and "(2)", respectively, and substitute "(2)" and "(3)", respectively. **Rationale 1:** This amendment revises this section so that the three boards would still meet annually, but to review regulations. This would be consistent with SB 845 removing the agreement of the three boards to select vaccinations that would be administered by pharmacists. **Amendment 2:** On page 2, in line 26, strike "jointly develop, adopt, and". On page 2, in line 26, after "regulations", strike "to provide for patient safety and to implement this section" and substitute "ADOPTED BY THE BOARD UNDER PARAGRAPH (1) OF THIS SUBSECTION" **Rationale 2:** This amendment revises this section so that the three boards would still meet annually, but to review regulations. This would be consistent with SB 845 removing the agreement of the three boards to select vaccinations that would be administered by pharmacists. **The Board ratified the position paper in Support with Amendments.** n. SB 884/HB 1268 Prescription Drugs – Dispensing Permits – SWA **Board of Pharmacy amendments for SB 884 030411** **sb0884f- text** **sb0884f** The Maryland Board of Pharmacy **Supports with Amendments** SB 884		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		Prescription Drugs – Dispensing Permits. The Board of Pharmacy has been concerned with the arbitrary manner by which prescribers are allowed to dispense medications to patients (not samples) because of the risk it poses to Maryland patients. In 2007, the Board of Pharmacy was assigned under the State Regulatory Review and Evaluation Process to review COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee. Recognizing that the original intent of the regulations was to allow physicians, podiatrists, veterinarians and dentists to dispense to patients (in the public interest) when a pharmacy was not "conveniently available," the Board of Pharmacy reviewed the criteria by which dispensing permits were issued. In essence, the Board of Pharmacy learned that dispensing permits were issued upon request as long as the prescriber was in good standing with their respective Boards. Upon further review, the Board of Pharmacy learned that there were as many permits issued to physicians in Maryland by the Board of Physicians (alone) as there were pharmacy permits issued to pharmacies (more than 900). Currently, State and federal inspections of dispensing offices is minimal. The Division of Drug Control (DDC) began monitoring these dispensing offices in 2008, only after the Board of Pharmacy relieved it from acting as its agent in inspecting pharmacies. Prior to 2008, the only inspections performed at these offices were related to federal investigation of criminal activities. A DDC inspector brought to the attention of the Board of Pharmacy that serious violations of the existing HO 12-102 and COMAR 10.13.01 had been observed. Specifically, the drugs were not stored properly, they were dispensed without proper labeling by individuals not authorized to dispense the medication without a final check by the prescriber, some of the medications dispensed were expired, and patient records were not properly maintained. Based on the facts that there has been limited oversight of authorized dispensers and, other than being in good standing, there is not specific criteria required in order to obtain a dispensing permit, the Board of Pharmacy recommend in its response pursuant to the Regulatory Review and Evaluation Act assignment that authorized dispensers' offices be inspected prior to initial application and then annually thereafter to ensure compliance with state and federal laws. The Board of Pharmacy also recommended that the terms "public interest" and "conveniently available" be defined. The Board of Pharmacy suggested that the term "public interest" should defined to require prescribing dispensers to meet the same storage, labeling, dispensing, packaging and security standards as pharmacies and pharmacists are required to meet. It also suggested defining "conveniently available" as issuing a permit only to a prescribing dispenser that is located more than 15 miles of the dispenser's location (*this later changed to 10 miles, which is compatible with the State Medical Assistance Provider Reimbursement laws*).		

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		The recommended changes were not enacted because the governing Boards for the dispensing prescribers opposed them. The Board of Pharmacy has attempted to work out the areas of disagreement with its sister boards (Dentist, Podiatry and Physicians) with the assistance of the Department of Health and Mental Hygiene (DHMH), however; several meetings over the past two years have yielded little change in the respective Boards' positions. The Board of Pharmacy obtained inspection reports for dispensing licensees from DDC in December 2010 and upon review had a number of concerns. An initial concern was the number of wholesale distributors not licensed by the Board of Pharmacy that have been selling/distributing prescription drugs to dispensing licensees and ultimately dispensed to Maryland consumers. This is a concern to the Board of Pharmacy because it has worked diligently to strengthen wholesale distributor licensing requirements in Maryland and was surprised that dispensing licensees would be purchasing from unlicensed wholesale distributors. The inspection reports also revealed that out of approximately 1100 dispensing licensees, DDC had only inspected approximately 450 of them. About half of the dispensing licensees did not actually dispense prescription medications. Of the other half that dispense, the Board of Pharmacy counted a total of 712 violations that consisted of: • incomplete and inaccurate recordkeeping for all prescriptions, but in particular, controlled dangerous substances; • no evidence of a final check by the dispensing licensee before delivery to the patient; • no determination that a pharmacy was not conveniently available to the patient; • dispensing expired medications. • misbranding or insufficient labeling; • unsecured storage areas; • purchasing from unlicensed wholesale distributors; • advertising as a pharmacy; • dispensing in non-child proof containers; and • licensee dispensing without a permit in a practice with a permitted dispensing licensee. In August 2010, the Board of Pharmacy received a letter from the IWIF Workers' Compensation Insurance group indicating that it has some of the same concerns expressed by the Board of Pharmacy. IWIF expressed concerns regarding its observations of irregular dispensing practices, poor patient medical records documentation, and the unnecessary need for the number of dispensing permits to be issued to prescribers since patients		

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		needed to go to pharmacies in order to fill prescriptions issued by the same authorized prescribers who dispensed other prescription medications. Further, a recent study by the Workers Compensation Research Institute found that "for several common physician-dispensed drugs, workers [in Maryland] received more prescriptions and pills than in other states where physician dispensing was not common. For these medications, physician-dispensers [in Maryland] were paid nearly double or triple the price paid to a pharmacy for the same prescription." Workers Compensation Research Institute, Prescription Benchmarks for Maryland, at 11 (March 2010). "Maryland physicians were paid an average of $2.59 per pill when they dispensed, while retail pharmacies were paid $0.67 per pill." Id., at 14. In response to this finding, IWIF published revised regulations in the Maryland Register, 38:3 Md. R. 207 – 210, (January 28, 2011), to establish a uniform pricing schedule for reimbursing prescription drugs required to treat an injured covered employee irrespective of the identity of the person or entity that dispenses the prescription drug. The new pharmaceutical fee schedule is designed to eliminate the existing disparity in reimbursement rates between physician-dispensed and pharmacy-dispensed prescriptions by establishing a single reimbursement rate tied to the average wholesale price ("AWP") for brand drugs and to the generic equivalent average price ("GEAP") for generic drugs. A public hearing has been scheduled for this regulatory proposal for April 14, 2011. This legislation would mostly impact those permitted prescribers who are located within 10 miles of a pharmacy. All offices still allowed to dispense would be required to be inspected annually, which may require them to change many of their existing dispensing practices. Many of the patients that would be affected by this legislation already receive their medications from the same pharmacies that would likely fill their prescriptions for them. Thus, they would not be inconvenienced by the changes in requirements. Any revenue gained by a pharmacy would be negligible and certainly not an incentive for the passage of SB 884. For more than twenty years, the active policy of the Council on Ethical and Judicial Affairs (CEJA) of the American Medical Association has provided guidelines on conflict of interest with respect to pharmaceuticals and has stated that: "Although there are circumstances in which physicians may ethically engage in the dispensing of drugs, devices, or other products, physicians are urged to avoid regular dispensing and retail sale of drugs, devices or other products when the needs of patients can be adequately met by local ethical pharmacies… **In-office sales transactions risk exploiting the**		

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		inherent imbalance of power in the patient-physician relationship. Patients often enter this relationship vulnerable and dependent on the doctor's expertise. In many cases, patients lack the expertise and independent judgment to make a proper determination about their need for the product and have no alternative reliable source of information. This asymmetry of knowledge means that patients may enter into transactions on the basis of subliminal fears or misjudgments about the necessity of making the purchase. Patients mistakenly may feel that purchasing a physician –recommended health –related product is medically necessary. They may feel more inclined or even compelled to buy an item because they wish to secure the doctor's favor, or in the case of a health related product, because they have placed implicit trust in their doctor's judgment and believe that he or she is acting in their best interest. Indeed, it is often because of these circumstances that manufactures and distributors are interested in using physicians' offices as sales sites." [Bold added for emphasis] The Board of Pharmacy strongly supports the proposed changes in requirements in the interest of patient safety and asks that the Committee also consider the overview provided above in terms of patient safety. It has been demonstrated that some prescribers dispense prescription medications without following proper storage, labeling and record keeping procedures and that there is no routine monitoring of these sites by State or federal officials. <u>To fix these concerns, the Board of Pharmacy asks for a favorable report for SB 884 Prescription Drugs – Dispensing Permits.</u> The Board of Pharmacy has reviewed SB 884 in detail and offers the following amendments for consistency with the existing Maryland Pharmacy Act. **<u>Amendment 1:</u>** On page 1, in lines 12 and 13, strike "authorizing certain individuals to dispense starter dosages of prescription drugs under certain circumstances;" **<u>Rationale:</u>** This amendment revises the purpose paragraph by deleting the reference to starter dosages because the section on starter doses was deleted from the bill because of duplicity in the title.		

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		Amendment 2: On page 1, in line 22, after the word "Section" insert "12-102.". **Rationale:** This amendment adds Health Occupations, 12-102, Annotated Code of Maryland to the function paragraphs because that section was added to the bill and amendments have been made to that section. **Amendment 3:** On page 2, after line 4 insert: §12–102. (a) (4) "CONVENIENTLY AVAILABLE" MEANS THE AVAILABILITY OF PHARMACY SERVICES TO A PATIENT WITHIN A 10-MILE RADIUS OF THE PERMIT HOLDER. (b) This title does not limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article. (c) This title does not prohibit: (1) A licensed veterinarian from personally preparing and dispensing the veterinarian's prescriptions; (2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when: (i) The dentist, physician, or podiatrist: 1. Has applied to the [board of licensure in this State which licensed the dentist, physician, or podiatrist] BOARD FOR A DISPENSING PERMIT UNDER §12-6D-02 OF THIS TITLE; 2. Has demonstrated to the satisfaction of [that board] THE BOARD that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest; 3. Has received a written permit from		

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		[that board] THE BOARD to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and 4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed; (ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist; (iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and (iv) The dentist, physician, or podiatrist: 1. Complies with the labeling requirements of § 12–505 of this title; 2. Records the dispensing of the prescription drug or device on the patient's chart; 3. Allows the **[**Division of Drug Control**]** BOARD OR ITS AGENT to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours; 4. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12–403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions; 5. Does not direct patients to a single pharmacist or pharmacy in accordance with § 12–403(b)(8) of this title; **[**and**]** 6. Does not receive remuneration for referring patients to a pharmacist or pharmacy; **[**or**]** AND 7. COMPLIES WITH THE REQUIREMENTS OF SUBTITLE 12-6D OF THIS TITLE; OR (3) A hospital–based clinic from dispensing prescriptions		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		to its patients. **Rationale:** The amendment was added for consistency purposes with the new subtitle 12-6D. **Amendment 4:** On page 3, in line 26 down through line 27, strike "HOME OF THE PATIENT" and substitute "PERMIT HOLDER". **Rationale:** This amendment revises the definition of conveniently available to mean with a 10-mile radius of the permit holder, not the patient's home. **Amendment 5:** On page 4, in line 11, strike "OFFICE" and substitute "LOCATION". On page 4, in line 11, strike "WILL BE" and substitute ":". On page 4, after line 11, insert: "(1) DOES NOT HAVE PHARMACY SERVICES CONVENIENTLY AVAILABLE TO THE PATIENTS OF THE PERMIT HOLDER; AND (2) WILL BE **Rationale:** This amendment clarifies the qualifications for a permit holder to obtain a permit to dispense from the Board. **Amendment 6:** On page 4, strike beginning with "AN OFFICE" in line 15 down through "SUBTITLE" in line 16 and substitute "THE PERMIT HOLDER" **Rationale:** This amendment clarifies that the permit holder to responsible for the requirements in § 12-6D-04. **Amendment 7:** On page 4, in line 17, strike "BE OPERATED" and substitute "OPERATE".		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		Rationale: This amendment was made for grammatical purposes. **Amendment 8:** On page 4, strike beginning with "RESTRICTIONS" in line 27 down through "DRUGS" in line 28 and substitute "LABELING REQUIREMENTS UNDER § 12-505 OF THIS TITLE". **Rationale:** This amendment removes the requirement for compliance with restrictions for repackaging of prescription drugs and substitutes compliance with labeling requirements of this title because of the importance of proper labeling no matter who is dispensing prescription medications. **Amendment 9:** On page 6, strike beginning with "A PERMIT" in line 5 down through "SECTION" in line 6 and insert: "(A) (1) A PERMIT EXPIRES ON THE DATE SET BY THE BOARD UNLESS IT IS RENEWED FOR AN ADDITIONAL TERM AS PROVIDED IN THIS SECTION: (2) A PERMIT MAY NOT BE RENEWED FOR A TERM LONGER THAN 2 YEARS." **Rationale:** This amendment is added for consistency with current renewal statutes for other entities licensed by the Board. **Amendment 10:** On page 6, in line 8 strike "ON OR BEFORE OCTOBER 1 OF THE YEAR THE PERMIT EXPIRES," On page 6, in line 9, after the word "HOLDER" insert ", AT LEAST 1 MONTH BEFORE THE PERMIT EXPIRES,". On page 6, in lines 15 and 17, in each instance, strike "MAIL" and substitute "MEANS". On page 6, in line 30, strike "5-YEAR". On page 6, in line 30, after "TERM" insert "SET BY THE BOARD IN ITS REGULATIONS" **Rationale:**		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		This amendment is added for consistency with current renewal statutes for other entities licensed by the Board. **Amendment 11:** On page 7, in line 5, after the words "PERMIT OF" insert "AND ISSUE A RENEWAL CERTIFICATE TO" **Rationale:** This amendment is added for consistency with current renewal statutes for other entities licensed by the Board. **Amendment 12:** On page 7, strike beginning with "(E) IF APPLICATION" in line 7 down through "BOARD" in line 13. **Rationale:** This amendment is added for consistency with current renewal statutes for other entities licensed by the Board. **Amendment 13:** On page 7, after line 23 insert "(B) THE PERMIT HOLDER SHALL SUBMIT TO AN ANNUAL INSPECTION BY THE BOARD OR ITS AGENT." On page 7, in lines 24 and 27, strike "(B)" and "(C)", respectively, and substitute "(C)" and "(D)", respectively. On page 8, in lines 1 and 5, strike "(D)" and "(E)", respectively, and substitute "(E)" and "(F)". **Rationale:** This amendment sets forth the requirement that the permit holder be inspected annually by the Board or its agent. Inspections are important to maintain safety in dispensing of prescriptions drugs. **Amendment 14:** On page 8, strike beginning with "12-6D-11" in line 7 down through "PHARMACY" on page 9, in line 27. **Rationale:**		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		This amendment strikes the entire existing § 12-6D-11 because it is duplicative of §12-102. **Amendment 15:** On page 9, in line 28, strike "12-6D-12" and substitute "12-6D-11". **Rationale:** This amendment renumbers § 12-6D-12 since 12-6D-11 was stricken from the bill. **The Board ratified the position paper in Support with Amendments** o. SB 883/HB 1229 Prescription Drug Monitoring Program **sb0883f** **The Board ratified taking no position.** p. HB 1338/SB 974 Health Insurance – Pharmacy Benefit Managers – Contracts, Disclosures, and Audits **sb0974f** **The Board ratified the position to submit a Letter of Support.**		
III. Committee Reports	**A. H. Finke, Chair, Practice Committee**	**1. Board approval was requested to create a pdf brochure to be sent to pharmacy permit holders explaining the Prescription Drug Repository Program, which had been suggested by Chairman Hammen of the House Health and Government Operations Committee. The brochure could be copied by each permit holder for customer.** **2.. Letters for Board Approval** **a.** Jency T., PharmaCare Discount Pharmacy **Electronic Signature Prescriptions** **David Sharp's response on FAXING RE e-prescribing question 011211** **David Sharp - e-prescribing by FAX 021011**	**Assigned to the Public Relations Committee for follow-up.** **2. A. Motion: Practice Committee** **Seconded: R. Zimmer**	**2.A. Board Action: The Board voted to approve motion**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		DRAFT – electronic signature prescriptions Thank you for contacting the Maryland Board of Pharmacy concerning whether a prescription is valid if it is noted on the prescription "Prescription/ Order signed electronically by Dr. John Doe, MD (record available upon request)." 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. The DEA has recently described procedures for prescribers to follow if they want to prescribe controlled dangerous substances (CDS) electronically. Below is an excerpt from a Board of Pharmacy Newsletter article: "On March 31, 2010, the Drug Enforcement Agency (DEA) published an Interim Final Rule (IFR) that allows for the electronic transmission of controlled substance prescriptions. The DEA accepted public comments on the IFR until May 31, 2010 and it became effective June 1, 2010. The IFR allows prescribers the option of electronic prescribing for controlled drugs prescriptions. It also outlines procedures for pharmacies to receive, dispense and store these prescriptions. The revised regulations address system and process requirements and appropriate access to electronic prescription applications. Before any pharmacy computer system can be used for electronic prescribing of controlled substances, it must be audited or certified by a third party and found to be in compliance with DEA requirements for recording, signing, storing and transmitting information. There are currently no third parties approved to perform such certification. In addition, there are also major processes and system changes that must be in place before prescriber and pharmacy applications can be used for electronic prescribing of controlled substances. These include: • Requiring two-factor authentication at signing (e.g., password and either use of a token or fingerprint verification); • Developing signature and record keeping protocols; • Enhancing reporting and auditing functionality;		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		• "Identity proofing," whereby providers must be authorized by a federally approved credentialing body to electronically prescribe controlled substances; • Developing policies and procedures to address data entry, access control and other aspects of the IFR requirements. Most prescribers and pharmacies in the United States are not positioned to currently meet the intricate requirements of the IFR. Pharmacies should begin reviewing their current and planned systems and software applications with the anticipation of the IFR full implementation. More details on the IFR can be found on the DEA Diversion Control website at http://www.deadiversion.usdoj.gov/ ." For you 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 **b.** Robert Healey, Great Western Veterinary **Veterinary PDMA Pedigrees** **DRAFT – Veterinary PDMA Pedigrees** Thank you for contacting the Maryland Board of Pharmacy concerning whether veterinary prescription drugs require a pedigree in Maryland. Please be advised that Health Occupations Article, Subtitle 6C, Annotated Code of Maryland does not exempt veterinary prescription drugs. If a prescription drug leaves, or has ever left, the normal distribution channel, then it is required to have a pedigree in Maryland. See Health Occupations Article, 12-6C-10, Annotated Code of Maryland. **c.** Derek Post, Walgreens Pharmacy **Butalbital issue** **DRAFT – Butalbital** Thank you for contacting the Maryland Board of Pharmacy concerning the classification of Butalbital as a controlled dangerous substance in Maryland even though compounds including acetaminophen and butalbital are not controlled by federal law.	**2.B. Motion: Practice Committee to ratify** **Seconded: M. Gavgani** **2.C. Motion: Practice Committee** **Seconded: D. Taylor**	**2.B. Board Action: The Board voted to approve** **2.C. Board Action: The Board voted to approve**

Field Code Changed

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		Maryland classifies all derivatives of barbituric acid as Schedule III medications. There are no exemptions in Maryland for combination products. Therefore, any product containing butalbital (includes Fioricet) is classified as a Schedule III controlled dangerous substance in Maryland. See Criminal Law Article, 5-404(d)(1), Annotated Code of Maryland. You may access the Annotated Code of Maryland through our website link at www.dhmh.maryland.gov/pharmacyboard. Click on Laws, Regulations, Legislation and Reports on the left menu. Scroll down and click on Pharmacy Statute Text, then click on [Another Article] at the top. Enter the article and section in the drop down boxes provided. Please feel free to forward this letter for informational purposes to any individual who may not be aware of the law. **d.** Larry Siegel, Carroll Hospital Center **CPOE - discharge w meds - Carroll Hospital Center** **DRAFT – CPOE – discharge w meds – Carroll Hospital Center** Thank you for contacting the Maryland Board of Pharmacy concerning whether a hospital pharmacy may fill a discharge prescription from a screen without the usual prescription information or an actual prescription for dispensing upon discharge. The hospital pharmacy is required to have a readily retrievable and complete document in electronic or paper form to dispense prescriptions upon discharge. In the scenario described in your inquiry, the hospital pharmacy would have neither. The pharmacist should manually transfer all required information to a written, retrievable prescription format. For controlled dangerous substances the pharmacist is required to verify the information with the prescriber. No part of this process would be acceptable for a Schedule II controlled dangerous substance prescription. Schedule II prescriptions should be in the proper format and signed by the prescriber. **e.** Mike Chubre **PMP in Florida** **DRAFT – PMP in MD**	**2.D. Motion: Practice Committee to ratify** **Seconded: D. Taylor** **2.E. Motion: Practice Committee to ratify** **Seconded: R. Zimmer**	**2.D. Board Action: The Board voted to approve motion** **2.E. Board Action: The Board voted to approve motion**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		Thank you for contacting the Maryland Board of Pharmacy concerning prescription drug databases to monitor the prescribing of controlled dangerous substances. Please be advised that currently no prescription monitoring program exists in Maryland to monitor or report prescriptions of controlled substances. HB 525, Advisory Council on Prescription Drug Monitoring - Study, passed in the Maryland 2008 Legislative Session. This legislation established an Advisory Council on Prescription Drug Monitoring in the Department of Health and Mental Hygiene. It required the Council to study the establishment of a prescription drug monitoring program and to make recommendations to the Secretary of Health and Mental Hygiene for establishing a prescription drug monitoring program that electronically collects and stores data concerning monitored prescription drugs. The Advisory Council completed their work and House Bill 918 was introduced in the 2010 Legislation Session. It did not pass. During the current legislation session, SB 883/HB 1229 Prescription Drug Monitoring Program has been introduced. Please see http://mlis.state.md.us/2011rs/billfile/SB0883.htm for further information and to view the bill. The session ends on April 11, 2011 and you may access the above link to determine if the legislation has passed.		
III. Committee Reports	**B.D. Chason, Chair, Licensing Committee**	**Mahbub Khundkar- Pharmacist request waiver of reinstatement fee** **Better Bodies by Chemistry- Designated Representative/Owner has criminal charges** **F. Gibbs asked that the Board address the issue of reviewing applications from New Jersey and Georgia that have been previously approved prior to the recognition that these states do not conduct inspections that are essentially equivalent to the Maryland requirements. Recommendation is to conduct a review of New Jersey and Georgia applications and require that previously approved licensees obtain VAWD accreditation. Licensees would be required to demonstrate that application had been made for accreditation within 60 days of notification.**	**Motion: Licensing Committee recommend approval** **Seconded R. Zimmer** **Licensing Committee recommend Administrative denial** **Motion: Licensing Committee recommend approval to conduct a review of New Jersey and Georgia applications.** **Seconded: H. Finke**	**Board Action: The Board voted to approve motion** **Board Action: The Board voted to approve motion**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
		FYI- R. Taylor reported that he has received applications for approval of CE for on-line programs from community colleges. The programs are being offered for technicians to complete for re-registration. Committee recommendation is for the Secretary to continue reviewing the programs and to request additional support as needed from members of the licensing Committee.		
	C. L. Bradley-Baker, Chair, Public Relations Committee	**L. Bradley-Baker reported the following: The winter newsletter has been sent out. She apologized for not reflecting that the Public Board Meeting time was not changed from 9:00 am to 9:30 am in the newsletter.** **The next big Board event that is coming up is the Annual Flower Mart that will be held Friday May 6, 2011. The Board is looking for pharmacist volunteers and Board Commissioners to support this annual event.**		
	D. L. Israbian-Jamgochian, Chair Disciplinary Committee	**No additional report**		
	E. D. Taylor Emergency Preparedness Task Force	**D. Taylor reported the following Task Force Updates:** **As a part of Emergency Preparedness Task Force on-going task D. Taylor has been trying to get DHMH and other state officials to include Pharmacy in their planning, so we at least have some say in things that are being planned in the future. The Board has had two requests. The first is from DHMH Infectious Disease and Environmental Health Administrations who has invited the Board to participate as a stakeholder in a work group that is staring this month meeting three times. D. Taylor will be sitting in with this group.** **The second request is from Anne Arundel County who has form a group of three or four counties who are going to be talking about purchasing medication caches with rotation options for those three or four counties. They have invited a member of the Board of Pharmacy to sit in on that group as far as planning, security, storage, and so forth.**	**Motion:** **D. Taylor made a recommendation to have a Board member to sit on that task force.** **Seconded: H. Finke**	**Board Action: The Board voted to approve motion**
IV. Other Business	**A. M. Souranis**			

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
	B. Drug Therapy Management		**Motion:** **R.Taylor made a recommendation to send out letters to all applicant informing them that the Board of Pharmacy approved protocols in December 2010.** **Seconded: D. Taylor**	**Board Action:** **The Board voted to approve motion**
	C. FYI	**M. Handelman reported the following: The University of Maryland School of Pharmacy will be hosting a program on Wednesday, February 17, 2011 on Elder Care**		
V. Adjournment	**M. Souranis, Board President**	**The Public Meeting was adjourned at 11:21 a.m.** **B. At 11:37 a.m. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.** **C. The Closed Public Session was adjourned at 12:03 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.**