MARYLAND BOARD OF PHARMACY
Board Meeting Minutes
September 21, 2005

Attendance:

Officers: John Balch, President, Mark Levi, Treasurer; Jeanne Furman, Secretary

Commissioners: Donald Yee, Donald Taylor, Mayer Handelman, Margie Anne Bonnett, David Chason and Michael Souranis, Joseph DeMino and Rodney Taylor

Staff: LaVerne Naesea; Executive Director; Linda Bethman; Board Counsel; Christina M. Harvin; Legislative/Regulations Manager, Anna Jeffers; Legislative/Regulations Officer, Linda Prince-Garrison; Compliance Specialist; Colin Eversley; Compliance Investigator.

Guest: Gary Wirth, Giant of Maryland. LLC

REGULATIONS/LEGISLATION IN PROCESS

A. COMAR 10.34.32 Pharmacists Administration of Influenza Vaccinations

Christina M. Harvin reported on the meeting with the Board of Physicians to seek final approval of the draft influenza regulations. Dr. Farah of the Maryland Board of Physicians expressed concerns regarding the definition of the term certification, the process for tracking vaccines performed by pharmacists and the practical training that pharmacists would receive.

During a conference call between Dr. Farah and Ms. Naesea, as well as Ms. Harvin and staff of the MD Board of Physicians, it was explained that the definition of certification denoted actual actions taken by the Board. Specifically, pharmacist applicants will only be allowed to register with the Board if (among other criteria) the Board can verify that they have participated in a recognized influenza vaccine certification program that includes the Centers for Disease Control and Prevention (CDC) and the American Pharmacists Association's (APhA) current guidelines and recommendations.
Dr. Farah agreed that it would be acceptable if the Board registered rather than actually certified qualified pharmacists.

Regarding tracking patient records that received influenza vaccines from registered pharmacists, following clarification, Dr. Farah agreed that the language in the draft regulations that addressed Record Keeping and Reporting Requirements was adequate to resolve his concern. Dr. Farah was also concerned that registered pharmacists should receive classroom/book training, as well as 'hands-on' clinical training in actual vaccine administration methods. Ms. Naesea noted that the Required Training section of the

regulations specified not only course work, but also actual vaccine administration training in a clinical setting. Dr. Farah indicated that that section of the regulation was acceptable if it was intended to mean 'hands-on' practical training.

Finally, Dr. Farah wanted assurance that the Board would develop a method to distinguish pharmacists who are registered to perform influenza vaccines on publicly accessible listings of pharmacists; specifically the on-line listing. He was assured that a system for designating registered pharmacists would be developed and utilized. A letter was sent to Dr. Farah and the Board of Physicians to confirm the items discussed during the conference call.

The Board of Nursing representatives accepted the language of the draft regulations, which were on their September 27, 2005 agenda for approval by the full Board of Nursing membership. The full membership of the Board of Physicians is slated to approve the draft regulation on September 28, 2005. The regulations are planned to be process as emergency regulations immediately following the approval by respective Boards.

Board Decision: Unanimous Vote of Approval

B. Maryland Board of Pharmacy's position on methamphetamine production and use in the State of Maryland

Christina Harvin updated the Board on the status of the position paper and regulations adding that Michele Phinney made some clarification changes to the definition of Pseudoephedrine in the proposed regulations.

Christina Harvin indicated that Senator Gladden is developing legislation regarding pseudoephedrine utilizing Oklahoma and surrounding states laws. Mark Levi indicated at the hearing in Annapolis that the Board of Pharmacy could only enact regulations that effect pharmacy. Removing or limiting pseudoephedrine in convenience stores will have to be done through legislation.

C. Registration of Pharmacy Technician Legislation

Don Taylor had a question regarding § 12-304 from last year's version that appears to have been totally omitted from this year's bill. Linda Bethman indicated that § 12-304 is existing law and it is not needed to be included in this legislation since it will not be changed.

Don Taylor's main concern is on page 25, § 12-6B-02. Christina Harvin explained to the Committee that the August 18th version provided reflects the third reader and final amendments at the end of the 2005 session. The August 31st version reflects changes that Linda Bethman suggested.

Don's concern regarded the language "Pharmacy Technician training program approved by the Board within 6 months immediately before registration." The word "immediately" caused him concern because if someone wants to be registered who took the technician training more than 6 months ago, then they would be required to take the course again. Don says it was not in the original bill. There was discussion regarding when and who made this amendment.

"Immediately" is the problem and discussion ensued regarding the various versions of the bill since last fall. Mark Levi indicated that the August 31st version is the version streamlined by Linda Bethman, but no requirements have changed. Mark Levi reads that first, the exam is approved by the Board, and second, need 160 hours of training. Linda Bethman asked about the 6-month requirement. Do they have to have it completed in 6 months or does it have to be immediately prior to registration? If immediately prior to registration, then some individuals will have to retake the course. That is Don Taylor's issue.

Don Taylor believes that the pharmacy technicians may take the training program at any time, not necessarily 6-months before registration. Linda Bethman indicated that Chains who have previously trained their pharmacy technicians might request, once the bill passes, that their training program be approved. The Chains will ask for retroactive approval of their training program. Don Taylor says that it should not be retroactive.

Mark Levi and Linda Bethman asked if Don Taylor would like a grandfathering clause for the training programs taken more than 6 months before registration is required. Linda Bethman said it would not be applied retroactively.

Don Taylor asked that, therefore, the word "immediately" should be removed. Discussion ensued regarding the time limit. It was then clarified that the word "immediately" is not in the final August 31st version and Don Taylor's issue was resolved.

Discussion ensued regarding what was meant by "completing a pharmacy technician training program approved by the Board within 6-months." Mark Levi summarized that everyone agreed that they did not want someone taking more that 6 months to be trained. Mark Levi indicated that the issue of retraining is problematic for the Chains. Mark Levi would like to add language that allows any technician that was trained within the last "X number of years" to be registered. Do we want to leave this up to the interpretation of the Board?

Can this be addressed in a legal way or do we address it as an interpretation? Linda Bethman needs to know what they mean by "6-months." Mark Levi and the Committee agreed that they would like the program to be taken within a 6-month time period and will include the 160 hours of work experience.

Don Taylor would like a statement in the bill that says, "Pass a pharmacy technician training program approved by the Board." Linda Bethman suggested including the 160

hours. So Linda Bethman suggested taking out the "6-months" altogether because it is confusing.

Christina Harvin indicated that Mark Levi, Don Taylor, Delegate Rudolf and MHA originally put the "6-months" language in the bill. Discussion ensued regarding the "6-month" language and its origination.

Linda Bethman said that the current language means that they would have to complete the training program within 6-months of registration. It doesn't mean that the training program is 6 months long. Rodney Taylor clarified that everyone who completed a training program more than 6 months before the effective date of the bill will not qualify to register. The Chains will not like having to retrain everyone.

Linda Bethman clarified that what the Board was concerned about was having someone in a training program for three years or an extended period of time. Do the chains have a problem with limiting the length of a program? Don Taylor indicated no. They care when you took the program.

Mark Levi wants to limit the actual length of the program and Don Taylor is in agreement with that. They would like to change the language to reflect this.

John Balch asked Christina Harvin if the changes concerned her. Christina Harvin indicated that the bill had been reviewed, line-by-line, at the March Board meeting and she wanted to know why they were making changes at this time. Linda Bethman indicated that the changes were due to misunderstandings by several people.

Linda Bethman suggested a subsection under § 12-6B-02(B)(4)(II): "Complete a pharmacy technician training program approved by the Board that:

(a) includes 160 hours of work experience; and
(b) is no longer that 6 months in duration.

The Committee approved the above language.

Don Taylor wanted to discuss the grandfathering date. Mark Levi indicated that it will be changed to 2004.

Don Taylor also was concerned because he did not see in the bill where registered pharmacy technicians were required to report suspected theft by other technicians or by pharmacists. Linda Bethman indicated that pharmacy technicians would be amended into current the Code of Conduct Regulations, which address this issue.

John Balch would like Don Taylor to let the Board know if he hears of any more misunderstandings on the part of the Chains or any other concerns that they may have regarding the bill.

Board Decision: Unanimous Vote of Approval

COMMITTEE REPORTS

A. Practice Committee

a. PEAC participant inquires whether a pharmacist may dispense all the refills to a patient at one time or does the physician need to stipulate that all the refills may be dispensed at once rather than monthly.

Mark Levi responded yes, call the physician up, ask for his authorization and do it. The prescriber has to authorize a years supply to be given out at once.

b. Inquiry concerning dispensing prescriptions to a family member of a patient who has moved out-of-state, knowing that the family member will mail the prescription to the out- of-state patient.

If a waiver pharmacy, the dispensing of medications is restricted to what's on the waiver application. A full pharmacy license would allow the pharmacy to do any of these things. Her concern was that the prescription was going to be mailed out of state by the daughter. That is irrelevant since it depends what is on the waiver application.

3. OLD BUSINESS

a. Official written request from Ahold USA, Inc. for a waiver of State laws and regulations for utilization of the Script Center prescription pick-up device.

Discussion ensued regarding this request. The question was asked what is the compelling reason to approve this? It involves after hours pick-up of prescriptions at an automated machine. Linda Bethman asked if the Board wants to waive the regulatory requirement that a pharmacist be in the pharmacy at all times during operation? The Practice Committee did not want to open up waivers to this requirement and recommended denying the request. Linda Bethman suggested: "It's not feasible to waive a uniform requirement in this fashion, however, any change in practice needs a regulatory revision, not a waiver."

b. Drug-Dispensing Machines/Automated Pharmacy Machines – Wall Street Journal Article - FYI

4. NEW BUSINESS

b. Don Yee inquires of the Practice Committee if a MD hospital, with a patient with a highly specialized pump for pain relief, could obtain medications from the patient's Virginia physician to use in the mixing of

the medication for the pump. Patient specific medication can be brought into a hospital in Maryland.

c. Director of Pharmacy at Frederick Memorial Hospital – Question regarding nature of pharmacy permit and whether their permit allows them to compound home infusion products for their home health and hospice patients.

Linda Bethman reminded the Practice Committee that Frederick Memorial Hospital is allowed to do this because they have a general license. Linda Bethman indicated that Chandra Mouli had sent a response. Christina Harvin will follow-up with Chandra Mouli.

d. NationalRx Security asks the Board if the attached prescription meets Maryland's requirements for pre-printed prescriptions.

The form should be revised to reflect "Date of Birth" instead of "Age." They also need the area code with the fax number. The written response presented is fine.

e. Lynn Weiland, Health Facility Surveyor for the Department of Health and Human Services in Montgomery County asks whether prescription labels may be translated into languages other than English and what other restrictions apply to labels in languages other than English.

Discussion ensued regarding English labels for non-English speaking people. Mark Levi suggests that a layperson may translate the labels, but they should put it on a separate piece of paper. The first response should be that a layperson would be allowed to translate the label and may attach it to the bottle so long as it does not obliterate the original label. Delete the last sentence from the first response. The second response that Maryland law does not limit prescription labeling to English is correct. The third response should be modified to reflect that retail pharmacies may print, in addition to the original label in English, a label in another language. It should also be added that the pharmacist must have the capability to translate the labels into other languages.