WINTER 2008-2009

Maryland Board of Pharmacy news

In This Issue:

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists, registering technicians and issuing permits to pharmacies, and distributors, setting standards for the practice of pharmacy through regulations and legislation, educating consumers, and receiving and resolving complaints from the public regarding pharmacists, pharmacies, and distributors.

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Official Notification

2009 Acute Care Hospital, Independent and At Large Pharmacist Board Representatives Nominations Being Accepted

Maryland law requires Board notification to all licensed pharmacists and other interested parties of record in Maryland of anticipated member Board vacancies in order to solicit nominations to fill the vacancies and to provide information for contacting representatives of the groups that submit nomination lists for new appointments to the Governor. This newsletter article serves as that notification.

The Board of Pharmacy is comprised of ten (10) pharmacist members and two (2) consumer members. A Commissioner may serve a total of two consecutive four-year terms. The Commissioners' terms are staggered. The full text of the statute is found in Health Occupations Section 12-202. The terms for the Commissioners serving in the Acute Care Hospital Representative, Independent Representative and At Large Representative seats will expire April 30, 2009. The three Commissioners currently filling those seats are eligible for reappointment.

Maryland law designates specific categories of representation for the 12 Board seats: Two (2) non-pharmacist, consumer members are appointed by the Governor to the Board with the advice of the Secretary and the consent of the Senate. Ten (10) pharmacist members are appointed by the Governor with the advice of the Secretary of the Department of Health and Mental Hygiene, from lists submitted by the appropriate Association as noted below:

Acute Care Hospital (Two seats): The Maryland Society of Health-System Pharmacists submits three (3) pharmacists' names, who at the time of appointment practice primarily in an acute care hospital for each open seat;

Independent (Two seats): The Maryland Pharmacists Association and the Maryland Pharmaceutical Society jointly submit three (3) pharmacists' names, who at the time of appointment, practice primarily in independent pharmacy for each open seat;

Chain Store (Two seats): The Maryland Association of Chain Drug Stores submits three (3) pharmacists' names, who at the time of appointment, practice primarily in chain store pharmacy for each open seat;

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From The Executive Director's Desk

LaVerne G. Naesea

Happy 2009! The Board has been so involved over the past year that I thought it good to reflect in this issue on what the Board has been working on over the past twelve months. In January, the Board engaged in a one-day planning retreat. Specifically, the Board and Staff developed short and longer-term objectives in the areas of communication, compliance, staffing, public awareness and political relationships. The meeting set the tone for the numerous successful outcomes during the year, including: development of an easier to use law book; Board-sponsored CEU training on medication safety; expansion of the scope of practice allowed under the administration of vaccines statute; and development of new technician review processes and pharmacy and wholesale distributor inspection procedures.

February began with the Board's Disaster Recovery Plan being approved with flying colors by State auditors. Also in February, the initial receipt of technician programs and individual applications were received by the Board. To date more than 20 technician programs and 4000 technician applications have been submitted for Board review. The following month, the Board's Public Relations Committee was reconvened. Its first initiatives included developing plans to update the Board's public web site. The regulations for the Licensing of Wholesale Prescription Drug or Device Distributors were also adopted in March.

The Board's new slogan, *Setting Standards for Consumer Safety*, was adopted in April, which was most appropriate in light of the announcement of key pharmacy-related legislative statutes passed during the 2008 session including: the appointment of an Advisory Council on Prescription Drug Monitoring Study (the Board of Pharmacy is represented on the Council); expanded authority for pharmacists to administer Pneumococcal pneumonia and/or herpes zoster vaccines in addition to influenza vaccines; the Board's required review and revision of regulations related to remote automated medication systems; and a Task Force assigned to study the Discipline of Health Care Professionals and Improved Patient Care.

In May, the Board co-hosted the National Association of Boards of Pharmacy (NABP) Annual Meeting in Baltimore. The event's success was due in part to the roles that Board and staff members played. The Board also won first prize in May at the Flowermart for its booth staffed by Board Commissioners and staff, Pharmacy Coalition participants and University of Maryland School of Pharmacy student representatives. The Board joined other organizations in June in support of the on-going DELMARVA-sponsored Patient Safety Initiative to reduce inappropriate prescribing of medications to the elderly. Also in June, the Board conducted an extensive survey of wholesale distributors and pharmacies on behalf of the Wholesale Distributor Workgroup convened to recommend a date to the Legislature for the State to begin requiring electronic pedigrees for prescription medications and devices. The month of June ended with the completion of training for three new contractual technician inspectors in preparation for the Board's assumption of annual pharmacy and distributor inspection responsibilities.

July and August were somewhat less active due to the summer vacation period; unless of course one notes the 1384 new and 672 renewal licenses, registrations and permit applications that were processed and approved, the 149 pharmacy inspections performed and the 23 on-going complaint investigations in which the Board was involved over those two months.

Two permanent staff positions were secured in September to support the revamped Board Compliance Unit. The unit's contractual Secretary and the first hired contractual Pharmacy Technician Inspector positions became permanent. Also during September, the Board completed design of the new application to allow distributors to apply for a new permit under the Wholesale Prescription or Drug Device Distributor Permit revised regulations in time for the October open-renewal period.

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Licensing Corner

Shirley Costley

For each employee performing delegated pharmacy acts under the supervision of a pharmacist, there must be documentation that:

A) Shows in the permit holder's personnel file the date of entry into a Board-approved pharmacy technician training program; the length of the training program must not exceed 6 months;

B) Demonstrates in the permit holder's personnel file that the employee or individual is a Board-exempted pharmacy student; OR

C) There is a posted pharmacy technician registration from the Maryland Board of Pharmacy.

A list of Board approved pharmacy technician training programs is available on the Board's web site www.mdbop.verifications.

Current Wholesale Distributor Permit Holders

The Maryland Board of Pharmacy approved at its January 20, 2009, Public Meeting, a 90 day extension for the approval of incomplete applications received for permits under the Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act. This decision was made in order to provide applicants sufficient time to meet new surety bond and other important new requirements. All submitted supplemental materials must be received by the Board in sufficient time for the Board to review and make a determination by March 31, 2009. A minimum of two weeks is required to process and determine the adequacy of supplemental materials. Therefore, applicants should consider submitting materials no later than March 16, 2009.

New Wholesale Distributors

The Wholesale Distribution Permitting and Prescription Drug Integrity Act is now in effect. All Wholesale Prescription Drug or Device provisions of the new Distribution Permitting and Distributors that apply to operate in Maryland in 2009 are required to demonstrate that they can meet the Prescription Drug Integrity Act and revised COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors regulations.

To assist in completing the new wholesale distributor application, here are some frequently asked questions and answers.

Q. Who is required to apply for a permit as a Maryland wholesale distributor?

A. Any person or business entity that meets the definition for a Wholesale Distributor as defined in HO, 12-6C-O1(v), Annotated Code of Maryland, that does business in Maryland is required to apply for a permit to operate as a wholesale Distributor in Maryland, using an application provided by the Maryland Board of Pharmacy.

Q. Does a manufacturer need to apply for a permit under these rules?

A. Yes. A manufacturer that distributes products in addition to its own products needs to apply for a Maryland distributor permit under HO, 12-6C-O3, Annotated Code of Maryland using an application form provided by the Maryland Board of Pharmacy.

Q. Is an entity (in-state or out-of-state) that "directs or controls" the distribution of prescription medications in Maryland required to hold a Maryland Distributor permit?

A. Yes. An entity must be licensed as a wholesale distributor in Maryland if it "directs or controls" the distribution of prescription medications in Maryland, even if it does not take actual physical possession of the prescription medications. (See Health Occupations Article, 12-6C-01(g) and (v), Annotated Code of Maryland, which lists entities required to be licensed in Maryland.)

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*****ERRATUM*****

Please note that the Board is revising the article "Guidelines for Unauthorized Refills" that appeared in the "Winter 2007-2008 Newsletter." The article stated that "The pharmacist may not however, refill a prescription for controlled dangerous substances (Schedule II). The statute is specific, however, that no controlled dangerous substance may be refilled without a prescription, no matter what the schedule. Thank you to Judge Fader for alerting the Board to this necessary clarification. □

COMAR Reminder—Providing Information Concerning Medication Errors

Since Patient Safety Improvement regulations were effected in October 2003, pharmacy permit holders have been required to have an ongoing Quality Assurance Program. Please be reminded that pharmacy permit holders are also required by the regulations to establish methods to provide patients with information regarding the patient's role and responsibility in preventing medication errors. This should be done in a manner that is reasonably likely to convey the information to the patient and is in addition to any other patient counseling or information required to be given by other laws and regulations.

Conveying the information to the patient may be accomplished in any reasonable manner such as by: 1) posting a conspicuous sign at the dispensing location; 2) placing a leaflet in the bag with the prescription medication; or 3) printing the information on the actual bag containing the prescription medication.

It is important that the information be provided to the patient before or at the time the drug or device is presented to the patient. The information is required to include:

- A patient's rights when receiving a medication or a prescription;
- The patient's role and responsibility in preventing a medication error;
- The procedures to follow when reporting a suspected medication error to the pharmacy permit holder, pharmacist, health care facility, or other healthcare provider; and
- How to report a suspected medication error to the Board.

For more information please refer to the Patient Safety Improvement regulations, COMAR 10.34.26.01 - .04. ☐

From The Executive Director's Desk...continued from page 2

The Board engaged in several forms of information sharing with constituents, licensees and others in October, including: meeting with the intended Deans of two probable new pharmacy schools, Dr. Anne Lin, of the College of Notre Dame School of Pharmacy, and Dean Nicholas R. Blanchard, of the University of Maryland, Eastern Shore; hosting nearly 200 licensees at a successful continuing education session on patient safety; and holding discussions with Del. Rudolph about possible incentives to encourage pharmacies to participate in the Prescription Drug Repository program. (Please visit the web site if interested in becoming a repository or a drop-off site.)

November and December will be most remembered for the hundreds of inquiries fielded by Board and staff members related to the new Wholesale Prescription or Drug Device Distributor Permit application process. The new and more detailed requirements under the revised law led to many permit holders' needing to ascertain whether (and how) certain provisions were applicable to their respective companies. The process, although very challenging, proved to be a great exercise for the Board staff in learning how to enhance its performance as a team in creating a seamless process from receipt of inquiries to the final review and processing of applications – including the development of required inspection processes.

To say that the Board was busy in 2008 may possibly be an understatement. Better to say, the Board and its staff members worked faithfully, diligently and without wavering in 2008 to meet its mandates and mission to protect Maryland consumers and promote quality health care in the field of pharmacy. Thanks to all of those who supported the Board's efforts. May you each have a very successful year in 2009! ☐

Licensing Corner...continued from page 3

Q. Is a FDA-approved manufacturer who distributes its own drugs and devices required to maintain a wholesale distributor license to distribute its product in the State of Maryland?

A. Yes. Manufacturers that are engaged in wholesale distribution only of their own prescription drugs approved by the U.S. Food and Drug Administration are not exempted and must hold a permit issued by the Board if they are distributing directly into Maryland. However, manufacturers that meet this criterion will not be required to meet all of the criteria set forth for other types of distributors and will need only to demonstrate to the Board that they have met federal requirements by submitting the following to the Board:

1) A completed condensed application form provided by the Maryland Board of Pharmacy;

2) Documentation of FDA registration as an establishment approved to distribute the list of prescription drugs or a FDA Site Registration Form(s) 2656;

3) The Name(s) Title(s) and Position(s) all of Owners, Partners and Officers; and

4) An application fee in the amount of $1,000.00 (payable to the Maryland Board of Pharmacy).

Q. Does an out-of-state manufacturer who distributes to an out-of-state third party logistics provider need to obtain a Maryland distributor permit?

A. No. An out of state manufacturer who distributes to an out of state third party logistics provider does not need to be licensed in Maryland.

Q. Are distributors and manufacturers of non-prescription medical devices and/or of over-the-counter drugs and cosmetics used by health care professionals for institutional purposes, required to obtain a distributor permit?

A. No. A wholesale distributor is defined as a person that is engaged in the wholesale distribution of prescription drugs or prescription devices. See Health Occupations Article, 12-6C-01 and 12-6C-03, Annotated Code of Maryland.

Q. Why is a surety bond or an irrevocable letter of credit required from distributors?

A. The purpose of the $100,000 surety bond is to secure payment of any fines or penalties imposed by the Board and any fees and costs incurred by the State relating to the permit that:

- Are authorized under State law; and
- Are not paid by the permit holder within 30 days after the fines, penalties, fees, or costs become final. (HO §12-6C-05(f), Annotated Code of Maryland). The State may make a claim against the surety bond or other security up until 2 years after the permit holder's permit ceases to be valid.

Q. When should the bond requirement be made effective?

A. The bond should be made effective January 1, 2009 through at least December 31, 2010 (or for the period that the permit will be effective).

Q. If a distributor has more than one facility in Maryland, which permit number should be placed on the surety bond?

A. All of the permit numbers for all of facilities located in Maryland should be placed on one surety bond. Then, a copy of that surety bond must be attached to each distributor application. ¨ □

Official Notification...continued from page 1

Home Care Infusion (One seat): The Maryland Society of Health-System Pharmacists submits three (3) pharmacists' names, who at the time of appointment, practice primarily in a pharmacy that specializes in the provision of home infusion/home care services for the open seat;

Long Term Care (One seat): The Maryland Society of Consultant Pharmacists submits three (3) pharmacists' names, who practice primarily in a pharmacy that provides services to a long-term care facility, for the open seat, and

At Large (Two seats): The Maryland Pharmacists Association submits a list of all interested pharmacists that have submitted their names to MPhA for each open seat.

The eligibility requirements for appointment to the Board are as follows:

PHARMACIST APPOINTEES (10)	CONSUMER APPOINTEES (2)
- Maryland Resident	- Maryland Resident
- Licensed Maryland pharmacist	- May not have been a pharmacist
- In good standing with the Board	- May not have a pharmacist in the household
- Skilled and competent pharmacist	- May not have participated in pharmacy field
- Possesses at least five years of professional experience	- May not have had a substantial financial interest in a person regulated by the Board within two years prior to the appointment.

Applications must be received by April 1, 2009. All appointments take place after April 30, 2006, concurrent with the expiration dates of the incumbents' terms. Commissioners' whose terms have expired serve until a replacement is sworn in.

Eligible licensed pharmacists who wish to be considered for the **2009 Acute Care Hospital Representative** appointment can obtain an application form and a description of Board member duties at:

Maryland Society of Health System Pharmacists
8480-M Baltimore National Pike, #252
Ellicott City, MD 21042
Phone: 410.465.9975
Fax: 410.465.7073 fax
E-mail: mshp@rxassociationmgt.com

Eligible licensed pharmacists who wish to be considered for the 2009 **At Large Representative** should contact the Maryland Pharmacists Association (MPhA) at:

Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, Maryland 21201
Phone: 410-727-0746
Fax: 410-727-2253

Those interested in the **Independent Representative** appointments can obtain an application form and a description of Board member duties at:

Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, Maryland 21201
Phone 410-727-0746
Fax 410-727-2253

Maryland Pharmaceutical Society
4501 West Forest Park Avenue
Baltimore, MD 21207
E-mail: rxlottier@aol.com □

FDA Request -Heparin Recall

The Food and Drug Administration has recently requested health professionals and institutions to continue their efforts to prevent heparin from being used. Please help FDA spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the last heparin recall announcement January 1, 2007. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm).

We ask that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin. To read this update, and to learn how to report these problems to FDA, please go to: http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html.

Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, please contact the Division of Drug Information at: 301-796-3400 or Ethan Moore with HFAM at: 410-290-5132 x103 or EMoore@hfam.org. ☐

Disciplinary Cases
Dorcas Ann Taylor

11/19/08 Jerome Berger - 6065 – Reprimand; fine of $1500.

11/19/08 State Pharmacy - P00771 - Probation for one year; fine of $1,500.

11/19/08 Devon Schlieper - 17864 - Suspension for one year, all of which is stayed; Probation for 1 year.

11/25/08 Raymond Jackson - 10050 - Surrender of Pharmacist License. ☐

Enhance Your Practice With Drug Therapy Management

Many pharmacists are not aware of the advantages of participating in Drug Therapy Management (DTM). Participation in this program allows pharmacists and physicians to enter into time-limited agreements to treat specific disease states using approved protocols. DTM allows pharmacists to work directly with patients monitoring their medications and assisting them in achieving the best results from their drug therapy. Not all states allow DTM, so participating Maryland pharmacists are in the forefront of pharmacy practice nationwide. Please go to http://mdbop.org/acrobat/dtmprocess.pdf for an explanation of the process. You will find all the forms you need at www.mdbop.org Click on Forms on the Homepage and then scroll down and click on Drug Therapy Management Forms. ☐

Maryland Board of Pharmacy

How are we doing?

Please e-mail the Board staff your questions and comments.

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Address or Employment Change: Submit the *Pharmacist Change of Information form* on our website. Go to **www.mdbop.org** and click on *Forms & Publications*.

Special Notice: The Maryland Board of Pharmacy Newsletter is considered an official method of notification to pharmacists and pharmacies**.** These Newsletters may be used in administrative hearings as proof of notification. Please read them carefully and keep them in the back of the Maryland Pharmacy Law Book for future reference.

Editorial Committee: Summar J. Goodman, LaVerne G. Naesea,

Donald Taylor, Lynette Bradley-Baker and Linda Bethman, (Board Counsel).

Newsletter Layout and Design: Summar J. Goodman

***E-mail Event Notices or Story Ideas to sjgoodman@dhmh.state.md.us.**

Meetings

The Pharmacy Board meetings are open to the public from 9:00 a.m.—12 noon at 4201 Patterson Avenue, Baltimore, Maryland 21215. The Board encourages all interested parties to attend. Dates are:

February 18, 2009 **April 15, 2009**

March 18, 2009 **May 20, 2009**

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