SUMMER 2006

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 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.

4201 Patterson Avenue
Baltimore, Maryland 21215
Tel: 410.764.4755
Fax: 410.358.6207
Toll Free: 800.542.4964
TTY: BALTO.383.7555

CHANGE! PATIENCE!

John Balch, Board President

Change comes very slowly at government agencies, often trying one's patience to reach the outcome. At the Board of Pharmacy, this summer, we have experienced the results of change and patience. After more than a year of meeting and planning, the Board has relocated its office to a more expansive and functional operation on the first floor of the Patterson Avenue office complex.

The relocation was necessary, in part, to prepare for the registration of pharmacy technicians, scheduled to begin in January of 2007. Change and patience were paramount in the passage of legislation to approve the registration of pharmacy technicians. More than three years were required for the legislature to establish the law. Numerous amendments and changes over the thirty-six months of debate produced the final bill. Change and patience — a worthwhile combination.

It is ironic that change and patience were also in play in the passage of legislation to allow pharmacists to provide immunization vaccines for the flu. A change in philosophy from the Board of Nursing, and the patience required to review proposed regulations with the Board of Physicians, gave Maryland pharmacists a long awaited clinical practice opportunity. The cooperation of these three professional boards has also been beneficial in reviewing Drug Therapy Management protocols and requests for changes to the dispensing formularies for mid-wife and local health clinic nurses.

Change has never been more evident than with the cooperation between the Board of Pharmacy and the Office of Health Care Quality (OHCQ). Through the efforts of the Long Term Care (LTC) Task Force, new regulations will be proposed to include requirements for a quarterly pharmacist review for assisted living residents and annual medical reviews by physicians or nurse practitioners. In addition, at the request of OHCQ, the LTC Task Force is recommending a number of bulk medications for approval in Skilled Nursing Facilities. These initiatives required more than two years of collaboration. Change and patience...winning again.

The Practice Committee, under Chair Mark Levi, is busy preparing regulations for the registration of pharmacy technicians. Those regulations should be completed by August and presented to the Board for adoption by its monthly September meeting. The Practice Committee continues to answer all inquiries by letter, after committee review and Board approval. In addition to Chairman Levi, the Practice Committee includes Jeanne Furman, Don Yee, David Chason, and Rodney Taylor.

Mayer Handelman chairs the Disciplinary Committee, which is charged with reviewing consumer complaints. The Committee meets at least monthly, and is responsible for all disciplinary cases presented to the Board. Chairman Handelman's Committee members include Rodney Taylor and Donald Taylor. A Board consumer member will also be assigned to the Committee once an appointment is made.

Continued on page 3

PRESCRIPTION DRUG REPOSITORY PROGRAM

Anna Jeffers, Acting Legislative Officer

Maryland's first Prescription Drug Repository Program became a reality with the passage of SB 1059—Prescription Drug Repository Program. The Prescription Drug Repository Task Force, chaired by Board member Donald Taylor, consisted of stakeholders representing the American Cancer Society, pharmacies, nursing homes, community health centers, the legislature, the pharmaceutical industry, the Office of Health Care Quality, University of Maryland - School of Pharmacy and the Maryland Medical Assistance Program. The members worked diligently to develop the recommendations included in the approved statute (SB 1059) and on draft regulations recently approved by the Board.

Based on the Task Force's recommendations Board of Pharmacy is proposing regulations that will impose the following requirements for Repositories and Drop-off sites:

Repository Requirements

Repositories, which must be pharmacies in good standing with the Board, will accept, inspect, store and dispense the donated prescription drugs or medical supplies. The Repository will dispose of donated items that are ineligible for the program. The types of drugs determined by the Task Force as ineligible addressed concerns related to potency, quality and the threat to public health. A designated pharmacist at the Repository site will obliterate patient specific information from the prescription labels of donated items. Repositories may not resell donated items or establish or maintain a waiting list. A Repository may charge a fee of not more than $10 per dispensed prescription.

Drop-Off Site Requirements

The Drop-off site may be a pharmacy or other health care facility that is in good standing with their respective licensing board. A pharmacist or other health care practitioner at the Drop-off site will place the donated items in a sealed bag with the signed donor form and store the bag in a secure area accessible only to those pharmacists or health care practitioners who have been assigned the responsibility of accepting donated items. The Drop-off site will then forward the sealed bags to a Repository at least every two weeks. The Drop-off site may not dispense donated items, resell them, or charge a fee for the donations

Federal and State Requirements

The standards and procedures for dispensing, shipping, disposing and safely storing donated items shall be in accordance with State and federal laws and regulations. Repositories shall maintain separate inventories for donated items; store donated items in a secure location; maintain separate prescription files for patients receiving donated items; and submit annual reports on its activities to the Board. All related documents will be reviewed during routine inspections.

Patient Eligibility

Patient eligibility will be determined by the patient's prescribing health care practitioner, based on the financial need of the patient and Maryland residency. Recipients will be required to sign a Board approved recipient form to confirm that the recipient understands the donated items have been donated and that entities involved in the program are immune from liability.

For more information about the Prescription Drug Repository Program or the status of the pending regulations, please e-mail Acting Legislative/Regulations Manager, Anna Jeffers at: adjeffer@dhmh.state.ms.us ■

FAST BYTES

DEA Form 106 Now Available Online !!

The DEA has announced that a secure, electronic version of their DEA Form 106 is now available on their website. The DEA Form 106 is required for theft or other significant loss of any controlled substances. Any losses must be reported to DEA within one business day from the time of discovery. If any investigation of loss requires more than 2 months, updates of the investigation must be provided to DEA. Pharmacists may either print the Form 106, fill it out by hand and mail it to DEA or complete the form online.

FDA Drug Safety and Quality Actions

The Food and Drug Administration (FDA) has stepped up their actions against unapproved drug products. The most recent drugs involved are carbinoxamine-containing products. The FDA estimates that there may be several hundred unapproved products currently on the market. To date, they have only approved 2 products, and they are encouraging companies to comply with the drug approval process for the other products on the market.

FDA says that it is committed to working with companies to facilitate the process of ensuring that their products are both safe and effective and meet appropriate manufacturing and labeling standards.

Drug Pedigree Deadline

The FDA has announced that they will NOT extend its current hold on an industry-wide drug pedigree requirement that is scheduled to expire in December of this year.

The drug pedigree is a document that records the chain of custody of drug products throughout the distribution system. This has been a large concern for members of the drug supply chain as it may increase the cost of doing business.

Even though current technology may not be adequate for total implementation of electronic pedigrees, the FDA has determined that it can no longer justify delaying implementation of the drug pedigree requirements.

An FDA Task Force is recommending that all stakeholders continue to work expeditiously toward making technology, such as RFID, a reality and that the products considered the most susceptible to counterfeiting and diversion be tagged initially.

This announcement was one part of a series of recommendations that the FDA is planning to adopt on the advice of its Counterfeit Drug Task Force in an attempt to limit America's potential exposure to counterfeit drugs.

Medicare's Doughnut Hole

When Congress created the Medicare prescription drug program, it adopted the so-called "doughnut hole" as a means of controlling the cost of the program. Once seniors reach a total of $2850 in total costs, they are then required to pay the entire cost of their medications until they reach a total of $5100. Once they reach that plateau, Medicare will then pay 95 percent of the remaining cost.

At this point, nearly 3 million seniors are at, or nearing, the "doughnut hole". Most people who are facing problems are middle class seniors with multiple chronic illnesses. Some are now reeling from the abrupt surge in prescription costs.

Most plans do not cover the "hole", and the few that do charge substantially higher premiums. More than 2 million seniors did pay extra for some level of gap coverage, but for most seniors the "doughnut hole" may soon be a reality.

DISCIPLINARY CASES

Disciplinary cases highlighted each quarter in the Board's newsletter reflect public orders that have been issued following a disciplinary investigation and formal proceeding involving the listed pharmacist, pharmacy or distributor. Many orders are the result of complaints received and investigated by the Board's Pharmacist Compliance Unit. The Unit's main function is to support the Board's mission to protect Maryland Consumers and to promote quality health care in the field of pharmacy by insuring compliance with State and federal pharmacy laws. The Unit initiates investigations when it is made aware of possible violations of those laws. Below is a list of definitions to provide a better understanding of the decisions issued by the Board.

Revoked – the license or permit is no longer valid. The licensee may not legally practice pharmacy or operate a pharmacy.

Voluntary Surrender – the licensee may no longer practice pharmacy and is in the same position as an unlicensed person. A pharmacist's license may only be surrendered by agreement with the Board. Surrenders are usually the result of a Board investigation and are issued in the form of a Letter of Surrender.

Suspension – usually a set period of time during which a licensee or permit holder may not legally practice pharmacy or operate a pharmacy. Satisfaction of specified conditions may be required for reinstatement of the license or permit.

Stayed – the Board's action is not enforced, in whole or in part.

Summary Suspension – the license or permit is suspended immediately when emergency action by the Board is necessary to protect public health and safety. This action may be taken prior to a hearing provided that the licensee or permit holder is given the opportunity for a hearing at a later date.

Probation – the license or permit remains in effect, however, restrictions or conditions are placed on the license or permit.

Reprimand – a public declaration indicating that the licensee violated the laws or standards governing pharmacy practice

Monetary Fine/Penalty – in addition to or instead of some of the above actions, the licensee or permit holder may be required to pay a monetary fine assessed by the Board. Monies collected from fines go into the State's general fund and not to the Board. ■

CHANGE! PATIENCE!*...continued from page 1*

The Licensing Committee, under the leadership of Chair Mike Souranis, is charged with the registration of pharmacy technicians. Implementing the new program will require hiring additional staff and unknown challenges. The Licensing Committee continues to monitor the online license renewal process, and reviews the renewal applications for continuing education credits. The Licensing Committee, with recommended changes forthcoming, is also scrutinizing the annual pharmacy inspection form. In addition, Jeanne Furman and Joseph DeMino head a sub-committee charged with reviewing and recommending amendments to the regulations for registering and inspecting distributors in the State of Maryland.

The leadership of Don Taylor has given the Emergency Preparedness Committee a prominent presence. The pharmacy profession is far better organized to respond to a disaster than many of the other professions in Maryland. As evidenced by the overwhelming response to Hurricane Katrina, this Committee serves as a model for recruiting, training, and deploying healthcare professionals. Board member David Chason, former Board members Melvin Rubin and Raymond Love, and pharmacist Bart Regan assist Chairman Taylor.

Change and patience have been hard at work at the Board of Pharmacy during the last year. Moreover, together they have produced results. Executive Director, LaVerne Naesea, is a master of patience, wading through every bureaucratic obstacle to make change possible at the Board, and teaching patience to the Board of Pharmacy Commissioners. Change and patience, a wonderful combination! ■

MANAGEMENT & INFORMATION SERVICES (MIS)

Tamarra J. Banks, Manager, Information Services

An organization's ability to effectively utilize automation technology can make the difference between success or failure, and sometimes growth or stagnation. Automation first came to the Board in 1993 in the form of three (3) brand new IBM PS/2 personal computers. Before then, the Board's automated systems were comprised of typewriters on every desk, and a mainframe computer that was managed off site — accessible only through Request of Information Forms, Data Entry Forms, and a few follow-up telephone calls.

Today, through automation, pharmacists, consumers, governments, and the pharmaceutical industry can access the Board's web site to obtain a variety of information 24 hours per day, 7 days per week.

Sample List of Information Available on the Web:

Pharmacist Renewal Application
Examination Application
Reciprocity Application
Pharmacy Applications(new & renewal)
Distributor Applications
Influenza Applications
Access Maryland Law Online
Discount Medication Programs
Verification of Pharmacist Licensure
Verify Permits
Board Meeting Minutes & Agendas
Download Pharmacy Addresses
Verify Other Maryland Practitioner Licenses
Online and Live Continuing Education

Ask any pharmacist who's renewed online – it's fast, secure and the most effective way to ensure they'll be no delays with your application.

MIS supports all the Board Units by providing rapid, real-time access to information by developing databases to which licensing, disciplinary, fiscal and other pertinent records can be inputted. The MIS Unit maintains the information for critical business functions including data for secure online renewals, revenues, incoming mail, new licensures and disciplinary actions.

The unit consists of an Information Services Manager, a Database Specialist and a Data Support Assistant Intern who together provide troubleshooting and repair, revenue and data auditing, assist with implementation of new legislative programs and provide innovative ways to perform important daily tasks. For example, the Board's system for receiving inspection reports from the Division of Drug Control was enhanced through the Board's newly created automated inspection system. This system allows DDC Inspectors to enter inspection information directly into laptops replacing the DDC carbon copy paper form. The information is then electronically loaded into the Board's local network daily for review by the Board's Compliance Unit. The new system eliminates errors associated with reading hand written reports and reduces the time required to receive the paper forms. Storing this information electronically also makes it easier to search, collate and report data.

In Fiscal Year 2005, the Board had 125,623 visitors to its web site. Visit the Board web site at www.mdbop.org or www.dhmh.state.md.us/pharmacyboard. Email requests are also accepted by the Board at mdbop@dhmh.state.md.us, Most requests by email are opened within 24 to 72 hours (weekends). ■

NOTICE

All Emergency Preparedness Volunteer Identification Badges will expire on October 31, 2006. The Board will be issuing procedures for renewing Identification Badges in the near future. Meanwhile, please do not discard of your current volunteer badge until you receive a replacement badge. If required for Board or state-sponsored training (or if deployed by the state for an actual emergency), please present your badge along with your pharmacist license and driver's license.

REMEMBER: If your badge is not renewed before November 1, 2006, keep your volunteer badge on hand. ■

Maryland Board of Pharmacy

How are we doing?

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

Telephone: 410-764-4755

Licensing:	Shirley Costley	scostley@dhmh.state.md.us
Compliance:	Colin Eversley	creversley@dhmh.state.md.us
Personnel:	Patricia Gaither	pgaither@dhmh.state.md.us
Regulations:	Anna Jeffers	adjeffers@dhmh.state.md.us
Website:	Tamarra Banks	tbanks@dhmh.state.md.us
Public Relations:	Summar Goodman	sjgoodman@dhmh.state.md.us
General:	LaVerne Naesea	lnaesea@dhmh.state.md.us

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 Goodman, Patricia Gaither, LaVerne Naesea, Jeanne Furman and Donald Taylor

Newsletter Layout and Design: Summar Goodman

***Have an Upcoming Event or Story Ideas?** E-mail 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:

August 16, 2006

September 20, 2006

October 18, 2006

November 15, 2006

December 20, 2006

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Secretary: Jeanne Furman

Treasurer: Mark Levi

Joseph DeMino

Donald W. Taylor

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Mayer Handelman

Donald Yee

Rodney H. Taylor

David Chason

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Alland Leandre

Executive Director: LaVerne Nasea

Maryland Board of Pharmacy

NABP DISTRICT I AND II MEETING
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AT THE
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Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215-2299

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