

WINTER 2007-2008

# Maryland Board of Pharmacy news

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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 pharmacy 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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## From the Executive Director's Desk

*LaVerne G. Naesea*

**H**appy New Year! January 1, 2008 marked the beginning of quite an active period in the life of the Board because of the many plans that are anticipated to come to fruition. Beginning with the January 2007 Open House, the Board and staff members never stopped to catch their collective breaths. A review of the year will better explain projected activities in 2008.

The Board and Division of Drug Control representatives began meeting in January 2007 to develop plans to transition annual pharmacy inspection responsibilities from the Division of Drug Control to the Board. That endeavor was very successful and the Board has begun to train inspectors who will assume responsibilities some time before the end of FY 2008 (June 30<sup>th</sup>). Various Board committees engaged in reviewing and updating the community and hospital pharmacy inspection forms, while others developed new inspection forms for use when inspecting long-term care and sterile compounding pharmacies. Those inspection forms will be implemented in the very near future and posted on the Board web site so practitioners may utilize them to assist in preparation for an inspection. The system for electronically recording inspection reports for all of the new and revised forms will also be completed and implemented for use in 2008.

The Board began direct monitoring of pharmacists under public orders in 2007. Previously, the Pharmacist Education and Assistance Committee (PEAC) performed monitoring and rehabilitation referral services on behalf of the Board. Now that the Board procedures and staff are firmly in place, the Board anticipates better assurance of patient safety as well as long-term, successful rehabilitation outcomes for involved pharmacists. The Board continues to fund PEAC to monitor, mentor and make treatment referrals for self-referred pharmacists and technicians.

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# From the Executive Director's Desk

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After failure over the past three years to attract *and retain* appropriate pharmacist staff to lead the Compliance Unit, the Board recruited a very competent Manager, Dr. Dorcas Ann Taylor (Ann), at the end of 2007. Dr. Taylor, a pharmacist and law school graduate, has enthusiastically begun to reorganize the Compliance Unit in anticipation of the new oversight responsibilities due to start in 2008. Compliance oversight will expand to include enforcement of the new, strengthened wholesale distributor requirements and the final adopted pharmacy technician regulations.

Early during the 2007 Legislative Session the Board sponsored educational presentations before House and Senate subcommittees featuring Katherine Eban, author of *Dangerous Doses*. She discussed the problem of counterfeit drugs entering the legal drug distribution chain and described what other states have done to address it. Those presentations led to the passage of significantly strengthened statutory language for drug distribution by wholesale distributors in Maryland. Final regulations for that statute have been submitted adoption and the Board will begin enforcement in 2008.

## Pharmacy Technician Regulations

The Pharmacy Technician regulations were adopted effective January 28, 2008. Permit holders may now submit their training and examinations for Board approval. Eligible pharmacy technicians and pharmacy students may obtain applications from the Board's website ([www.mdbop.org](http://www.mdbop.org)). Technician candidates and students will have at least six months to meet state registration requirements. The deadline is July 28, 2008. See details related to application and fees posted on the Board's web site ([www.mdbop.org](http://www.mdbop.org)). Students and nationally certified and grandfathered candidates are encouraged to register with the Board as soon as possible. Applications and Criminal Background Check forms will be mailed to all permit holders and also sent upon direct request to interested parties.

Several other initiatives in 2007 are anticipated to be *taking off* in 2008, including, inspection of pharmacies under the new sterile pharmaceutical compounding regulations, Drug Therapy Management, Administration of Influenza Vaccines and Prescription Drug Repositories.

FY 2007 was a challenging but fruitful year. Board members are to be congratulated for the many hours spent in Board, committee and other special meetings to develop and carry out the 2007 initiatives. Board managers and their staffs are acknowledged and thanked for their diligent and painstaking efforts to usher in new practice requirements and for creating systems to operationalize the many Board decisions. Their efforts promise to yield successful implementation of initiatives in 2008. Last but not least, thanks to all of those who made the Board's progress possible in 2007. The input, expertise and encouragement received from the community, including consumers, pharmacists, permit holders, legislators and federal and state agents help the Board to meet its mission to promote quality pharmaceutical health care while insuring patient safety for Maryland citizens. ■

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# Emergency Preparedness

## *Emergency Volunteer Training a Success*

The Board of Pharmacy conducted an updated training entitled “Maryland Pharmacist Emergency Response – An Update” for both new and existing pharmacist volunteers at the Radisson Hotel in the Village of Cross Keys in Baltimore, Maryland on Sunday, October 28, 2008. Over 160 pharmacists attended this training.

The program was coordinated by the Board’s Emergency Preparedness Coordinator, Summar J. Goodman. The program featured presentations by

the Board President Donald Taylor; Dr. Bruce Anderson from the University of Maryland; Bruce Baker and Terry Sapp from the Department of Health and Mental Hygiene DHMH; Dr. Jennifer Thomas from St. Agnes Hospital; and former Board President and Pharmacist Volunteer Corps founder, Mel Rubin. The Maryland Professional Volunteer Corps Coordinator Mark Bailey and Christine Vias-Plumer were on hand to assist with volunteer badges. ■

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# Compliance Corner

## *DEA Publishes Rule on Issuing Multiple Prescriptions for Controlled Substances*

On November 19, 2007, the Drug Enforcement Agency (DEA) published a Final Rule titled “Issuance of Multiple Prescriptions for Schedule II Controlled Substances.” The rule became effective on December 19, 2007. This Final Rule amends DEA’s regulations to allow practitioners to provide individual patients with multiple prescriptions for a specific schedule II controlled substance, written on a specific day, to be filled sequentially. The combined effect of such sequential multiple prescriptions is that it allows a patient to receive over time up to a 90-day supply of that controlled substance. The Final Rule maintains that the refilling of a prescription for a controlled substances listed in Schedule II is prohibited. The Controlled Substances Act (CSA) requires that a new prescription be issued for each quantity of the schedule II substance.

The intent of the Final Rule is address patients’ needs for schedule II controlled substances while preventing the diversion of these substances. DEA believes that the Final Rule provides an option for practitioners to treat their patients, which is legally permissible and consistent with the text, structure, and purposes of the CSA.

The Final Rule is available for review on the DEA’s Office of Diversion Control website, [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) under “Federal Register Notices>Rules2007.

Adapted from communication received from Mark W. Caverly Chief Liaison and Policy Section, Drug Enforcement Administration, Office of Diversion Control; 72 FR 64921; 21 CFR Part 1306. ■



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# Practice Committee Corner

## **1. What would be the appropriate manner for long-term care (LTC) communities to handle leave of absence (LOA) medications when a resident requests to leave the community for a short period of time, such as an afternoon, without prior notice; thereby, not allowing sufficient time for a pharmacist to package and label necessary medications?**

Maryland law does not provide for the practice of LTC communities or nurses dispensing medications to residents on LOA. If a LTC community is compelled to accommodate a resident, then the LTC community must have appropriate policies and procedures in place to ensure proper labeling and clear directions. The safety of the resident should be the primary concern. Whenever possible, LOA medications should be dispensed by a pharmacy if sufficient time is available for a pharmacist to package and label necessary medications.

## **2. Is a pharmacist required to do anything different for an animal than for a human when filling a prescription and is the pharmacist required to keep a patient profile for an animal?**

The Maryland Board of Pharmacy regulates the dispensing of all prescription drugs and devices for both humans, and their companion animals, through Health Occupations Article, Title 12, Annotated Code of Maryland, the Maryland Pharmacy Act. The Maryland Pharmacy Act does not distinguish between a prescription for a human and one for a companion animal. There is also no distinction in the Maryland Pharmacy Act between maintaining patient profiles for humans and maintaining patient profiles for companion animals. It would behoove pharmacists to maintain patient profiles for companion animals because they also could suffer drug interactions.

## **3. Has the DEA finalized the regulatory revision to allow the issuance of multiple prescriptions for Schedule II CDS?**

Yes, effective December 19, 2007, the DEA amended the regulation to allow practitioners to provide individual patients with multiple prescriptions for a specific Schedule II controlled substance, written on the same date, to be filled sequentially. The combined effect of such sequential multiple prescriptions is that it allows a patient to receive over time up to a 90-day supply of that controlled substance. The Controlled Substances Act does not permit the refilling a Schedule II controlled substances, requiring that a new prescription be issued for each quantity of the substance. Following publication, the rule will appear on the DEA's Office of Diversion Control website, [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) under "Federal Register Notices>Rules 2007."

## **4. What are the licensing requirements for a pharmacist working for an after hours service from an out of state pharmacy, office, or home setting? Would a Maryland Board of Pharmacy permit be required for all three settings?**

In recent years many pharmacists have been employed at remote locations, inside and outside of Maryland, to verify and process Maryland prescriptions. Telepharmacy or "central prescription processing" is not specifically addressed in Maryland law and regulations, yet is allowed in Maryland under certain conditions. Please be advised that any pharmacy participating in central prescription processing or telepharmacy is required to be a licensed pharmacy or licensed nonresident pharmacy in Maryland. See Health Occupations Article, 12403(e), Annotated Code of Maryland. Any pharmacist participating in central prescription processing or telepharmacy, at a location that is not a pharmacy, is required to be licensed in Maryland. ■

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## Baby Aspirin in the Baby Aisle Equals Confusion

Placing low dose aspirin, frequently referred to as “Baby Aspirin,” in the baby products aisle is commonplace in some retail stores. It is important to know that aspirin products should not be located near baby or children’s products in retail stores.

The U.S. Food and Drug Administration (FDA) has adopted regulations that require the following posting of contraindications on the labels of over-the-counter (OTC) aspirin products:

Allergy: Aspirin is contraindicated in patients with known allergy to nonsteroidal anti-inflammatory drug products and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin may cause severe urticaria, angioedema, or bronchospasm (asthma).

**Reye’s Syndrome: Aspirin should not be used in children or teenagers for viral infections, with or without fever, because of the risk of Reye’s syndrome with concomitant use of aspirin in certain viral illnesses.**

See 21 CFR 343.80

In light of this labeling requirement, placing aspirin products in or near the baby products aisle may lead to consumer confusion regarding the risks associated with the use of aspirin products for children. The Maryland Board of Pharmacy strongly recommends that permit holders maintain all aspirin products in areas of the store that are intended for treatment of adult patients. ■

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## Guidelines for Unauthorized Refills

A common scenario for pharmacists is a customer coming into the pharmacy on weekends or holidays and requesting a refill for a prescription that is more than a year old or has no more refills remaining. The Maryland Pharmacy Act provides guidelines for just such a scenario in Health Occupations Article, §12-506, Annotated Code of Maryland. A pharmacist may refill a prescription for a drug or device for which the refill has not been authorized if the pharmacist attempts to obtain an authorization from the authorized prescriber and is not able readily to obtain the authorization. This allowance is often applied on weekends, evenings and holidays.

The pharmacist may then refill a prescription for a drug or device for which the refill has not been authorized if the drug or device is essential to the maintenance of life. It may also be refilled if the drug or device is essential to the continuation of therapy in chronic conditions and in the

pharmacist’s professional judgment, the interruption of the therapy reasonably might produce an undesirable health consequence, be detrimental to the patient’s welfare, or cause physical or mental discomfort.

The pharmacist may not, however, refill a prescription for controlled dangerous substances (Schedule II).

The pharmacist must also enter on the back of the prescription or on another appropriate uniformly maintained, readily retrievable record, such as a medication record, the date and the quantity of the drug or device dispensed and must sign or initial the record. He must notify the authorized prescriber of the refill of the prescription within 72 hours of dispensing the drug or device. Keep in mind that the pharmacist may provide only 1 refill of the prescription and the refill quantity dispensed shall be in conformity with the prescriber’s directions for use and may not exceed a 14-day supply or unit of use. ■

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## COMAR REMINDER \*\*

### *Reporting Changes in the Pharmacist’s Place of Employment*

Many Maryland licensed pharmacists are not aware that they are required by law to inform the Board of Pharmacy in writing within 30 days of a change in the pharmacist’s primary employment location. If the pharmacist’s primary employment location changes and the new location

is owned by the same corporation, partnership, or individual owner, the pharmacist is not required to report the change until a license renewal application is submitted. See COMAR 10.34.06.04. Forms are available on the Board’s website at [www.mdhop.org](http://www.mdhop.org) ■





# Maryland Board of Pharmacy

## How are we doing?

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

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## Meetings

The Pharmacy Board meetings are held the third Wednesday of each month and are open to the public from 9:00 a.m. - 12 noon at 4201 Patterson Ave., Baltimore Maryland 21215. The Board encourages all interested parties to attend. Dates are:

**February 21, 2008**

**March 19, 2008**

**April 16, 2008**

**May 21, 2008**

## Address or Employment Change

Submit the Pharmacist Change of Information form found on the Board's website, [www.mdbop.org](http://www.mdbop.org) under Forms and 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 notifications. Please read them carefully and keep them in the back of the Maryland Pharmacy Law Book for future reference.

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**Newsletter Design:** Summar J. Goodman

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# Maryland Board of Pharmacy

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