FALL 2007

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 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

By now, many establishment permit holders have or are in the process of renewing permits, which will expire on December 31, 2007. The on-line renewal system was opened for permit holders' use in mid-October and will close on December 31, 2007. Pharmacy permit holders please remember that applications submitted or postmarked after December 1, 2007, are considered late and an additional late fee of $150.00 must be paid. The Board still accepts paper applications; however, there are numerous advantages to renewing on-line, including time-saving and convenience. Once logged into the system, much of the required renewal information is pre-populated and applicants will be primarily required to submit additions and/or changes to previously provided information. The renewal application submissions are electronically linked to the Board's databases, therefore helping to avoid errors and expedite the entire application process.

State law requires that all Health Occupation Boards NOT issue renewal permits and licenses to persons and businesses that have State tax liabilities. To provide as much time as possible, the Board mails written notices of possible liabilities to practitioners earlier than it sends out the renewal applications. If a liability issue is not resolved before the license or permit expires, then the Board will inform the applicant that the renewal license has been denied.

Many pharmacy technicians are anxiously awaiting adoption of the Pharmacy Technician regulations, which were re-proposed in the Maryland Register on September 28, 2007. The Board is addressing the comments received during the 30-day comment period. If no substantive changes are required, the regulations should be submitted for final adoption before the end of the year. Once published, the Board will immediately make technician applications available for dissemination by mail and on the Board's web-site. Board staff will also mail a quantity of criminal background application forms to each pharmacy establishment for the convenience of applicants. Enforcement of the regulations will not begin until at least six months after the adoption of the final regulations.

Speaking of new initiatives, the Board is in the process of recruiting and training new establishment inspectors who will begin performing the pharmacy inspections previously performed by Division of Drug Control Inspectors. [See related article in Summer 2007 newsletter.] If your site is visited during the new inspectors' training period, two inspectors may visit, including training staff from the Division of Drug Control and the Board's new inspector trainees. Every effort will be made not to disrupt the usual workflow at businesses during these inspections. However, your patience and understanding are requested as this transition of inspection functions evolves.

The Board is pleased to announce the appointment of new members, Lenna Israbian-Jamgochian (Chain), Reid Zimmer (Acute Care), and Lynnette Baker-Bradley (At-Large). Each is appointed to four-year terms, which end April 30, 2011. Congratulations new members and best wishes as you begin in your new roles as State regulators. ■

MEDICATION SAFETY

Articles courtesy of NABP Compliance News

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments*.

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html*.

More information is available on the FDA Unapproved Drugs Web site at *www.fda.gov/cder/drug/unapproved_drugs/default.htm*.

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

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MEDICATION SAFETY

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- inadequate labeling for safe use;
- inappropriate packaging and, therefore, uncertain product integrity;
- possible previous withdrawal from the US market for safety or efficacy reasons;
- drug-specific risks requiring initial screening and/or periodic patient monitoring;
- potential harm or abuse, such as with the use of controlled substances; and
- potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

Tamper Resistant Pad Requirement Postponed

Congress unanimously passed and President Bush signed into law an extension for the mandate requiring pharmacies to only dispense Medicaid prescriptions written on tamper-resistant pads, or risk loss of reimbursement, from October 1 to March 31, 2008. The delay will be used by the National Community Pharmacist Association (NCPA) and others as time to work with state Medicaid Directors to educate prescribers and pharmacists alike about the federal requirements created to eliminate Medicaid fraud and allow time to transition into the new policy. ■

Practice Committee Corner

By Dave Chason and Anna Jeffers

1. May a patient, prescribed a CIII – CV CDS with 5 refills, receive only 5 refills (or partial fills) in 6 months regardless of the remaining amount prescribed or may a patient receive refills (or partial fills) until the total quantity prescribed has been dispensed within 6 months?

A patient who has been prescribed a CIII – CV CDS with 5 refills, may receive refills (or partial fills) until the total quantity prescribed has been dispensed within 6 months. See the Code of Maryland Regulations (COMAR) 10.19.03.09C. Partial filling of Prescriptions set forth below:

C. Partial Filling of Prescriptions (21 CFR §1306.23). The partial filling of a prescription for a controlled dangerous substance listed in Schedule III, IV, or V is permissible, provided that:
(1) Each partial filling is recorded in the same manner as a refilling;
(2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
(3) No dispensing occurs after 6 months after the date on which the prescription was issued.

2. Is an authorized prescriber permitted to write a prescription for a Schedule II controlled dangerous substance with 3 refills?

A prescription for a Schedule II controlled dangerous substance shall be dispensed within 120 days of the date of issue. See the Code of Maryland Regulations (COMAR) 10.19.03.08A(8). **Keep in mind that a refill of a prescription for a CII is prohibited.** See 21 CFR 1306.12 and COMAR 10.19.03.08B.

The U.S. Drug Enforcement Administration (DEA), however, is proposing regulations concerning whether a physician may write a CII prescription for dispensing at a later date. Those proposed regulations are located in the Federal Register: September 6, 2006 (Volume 71, Number 172), Proposed Rules, Pages 52724 52726. You may access the proposed regulations online at http://www.gpoaccess.gov/fr/index.html#content. Click on the "Browse" on the left menu. Then click on the year of the back issue (2006) under "Back issues" and click "GO." Scroll down and click on September 6, 2006. Once the table of contents appears, find "Drug Enforcement Administration" in the list of agencies. The proposal will appear under DEA. The DEA anticipates that the regulations may be final by the end of the year.

3. Is it acceptable to dispense generic medications where part of the prescription is from one manufacturer and the remaining portion is from a second manufacturer and the size &/or color may vary between the two manufacturers?

It is acceptable to put two types of generic tablets from different manufacturers in one bottle and counsel the patient upon dispensing. Since the directions are the same, one label with directions would be sufficient. The two types of medications should be separated by cotton. Professional judgment and discretion with the patient should dictate whether this is an appropriate manner of dispensing. Keep in mind to note or document both NDC numbers.

LICENSING CORNER

Pharmacist Online Renewal - Now Available Until the End of The Month

The online renewal system is now available to licensees beginning one month before the license expiration month through the last day of the license expiration month. For example: if the license expiration month is October, the license may be renewed online any time starting September 1st and ending October 31st.

Send Us Your E-mail

If you'd like to receive e-mail notification of Board actions, upcoming events and meetings or security related matters, such as Emergency Preparedness information and stolen prescription pads, make sure we have your e-mail address. Click the link below and update your employment, address or telephone numbers as well. If you've already received an e-mail from the Board confirming receipt of your e-mail address there is no need to send it again. http://www.mdbop.com/forms/addrchange.htm

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INFORMATION STATION

Centers for Medicare & Medicaid Services National Provider Identifier (NPI) News

Providers may find a recent Medicare Learning Network (MLN) Matters article helpful in determining how to use the National Provider Identifier (NPI) on Part A and Part B claims. You can view the article at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0725.pdf on the CMS website. Additional information and education on the NPI can be found through the Centers for Medicare & Medicaid Services webpage http://www.cms.hhs.gov/NationalProvIdentStand. ■

DISCIPLINARY CASES

Melissa Skarbelisi-License # 13546

License to practice pharmacy SUMMARILY SUSPENDED, effective August 24, 2007.

Robb V. Foote-License # 12098

License to practice pharmacy SUMMARILY SUSPENDED, effective July 25, 2007.

Katherine K. Emery, P.D. – License #11691

License to practice pharmacy SUMMARILY SUSPENDED, effective October 9, 2007. ■

Maryland Board of Pharmacy

How are we doing?

Please telephone or 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 Goodman, LaVerne Naesea, Linda Bethman 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:

****Note - Date and Location Changed for November Board Meeting**

November 14, 2007–Board of Nursing
4140 Patterson Avenue • Baltimore, MD 21205

December 19, 2007

January 16, 2008

February 21, 2008

March 19, 2008

Board Members

President: Donald Taylor

Secretary: David Chason

Treasurer: Michael Souranis

Cynthia Anderson

Margie Anne Bonnett

Lynette Bradley-Baker

Harry Finke, Jr.

Lenna Israbian-Jamgochian

Alland Leandre

Mayer Handleman

Rodney H. Taylor

Reid Zimmer

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