April 2003

maryland Board of Pharmacy

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; receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland.

Maryland Board of Pharmacy
4201 Patterson Ave.
Baltimore, MD 21215-2299
410-764-4755
www.mdbop.org

Board of Pharmacy Bio-terrorism and Emergency Preparedness

The Maryland Board of Pharmacy is leading the state's effort to develop and implement an Emergency Preparedness Response Plan for volunteer health care practitioners to assist during a terrorist or other catastrophic event. To date, the Board has recruited nearly 900 volunteer pharmacists and pharmacy technicians, of which approximately 500 have been trained. In the event of a state emergency, the Maryland Department of Health and Mental Hygiene would direct the Board to deploy volunteers to assist local health departments with the receipt and breakdown of the National Pharmaceutical Stockpile. Volunteers would also provide counseling and dispense medications to affected persons based on levels of illness and special considerations (i.e., pregnancy, drug interaction, allergies, etc.), and assist with other activities as authorized. Volunteer recruitment, coordination and trainings are ongoing.

To join the "Maryland Pharmacist Volunteer Corp" as a pharmacist or technician, please visit the Board's web site at www.mdbop.org and register. For more information, contact Joan Lawrence, Public Information Officer at (410) 764-4755 or email: jlawrence@dhmh.state.md.us.

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From the Executive Director's Desk

In addition to ushering in brisk winds and beautiful blossoms, spring is a time for cleaning out closets and attics — tossing out the old in order to make room for the new. The Board has been spring-cleaning to make room for implementing more modern, safe and/or practical processes.

So, what has been tossed this spring? Effective February 17, 2003, the Board tossed the requirement for pharmacy school graduates and reinstating pharmacists to pass a laboratory examination before becoming licensed in Maryland. The Board also threw out the requirement for new licensure candidates to mail MPJE and NAPLEX scantron applications to the Board for preliminary review. Candidates now submit the two applications directly to the National Association of Boards of Pharmacy (NABP) concurrent with submitting required information to the Board. This change reduces application-processing time.

The Board, in collaboration with the Division of Drug Control (DDC), scrubbed the old handwritten pharmacy inspection reporting process. Inspection forms are now installed in portable laptops, so that legible reports can be immediately printed by inspectors and left with the pharmacist when an inspection is completed. Additionally, inspection reports can now be electronically transmitted to the Board within ten days of an inspection. The Board is also reorganizing the content currently collected on the forms to review compliance with laws and regulations that were changed after the forms were last updated and to address patient safety concerns.

The Board's Long Term Care Committee, aptly led by member John Balch, has been scouring two sets of assisted living regulations to address outdated provisions — one developed by the Board and the other by the Office of Health Care Quality (OHCQ - formerly the Division of Licensing and Certification). This longer-term cleaning task may lead to changes in pharmacy procedures for assisted living and other long-term care facilities. Anticipated results may include greater protection and safety for incapacitated residents of long-term care facilities and better, continuous communication between the Board and OHCQ on long-term care issues.

The Board's spring-cleaning has been enhanced by the addition of two new staff persons. Ms. Catherine Putz (pronounced "puts"), was hired in February as the Compliance Officer and Ms. Latonya Dickerson was employed as the new Board Secretary. Both Ms. Putz and Ms. Dickerson are veteran state employees. Many of you may have met Ms. Putz during a pharmacy inspection since she previously worked as an

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Pharmacy Corner

Every month the Board's disciplinary committee identifies consumer complaints related to medication errors and dispensing. These complaints appear to be more common than other types of complaints reported to the Board. By bringing these incidents to your attention, the Committee recommends that pharmacy permit holders and their staffs take the necessary steps to prevent similar errors from occurring at their pharmacies.

Dispensing errors that the committee encounters frequently are the dispensing of the wrong strength of the correct medication. Contributing factors noted in the pharmacist's responses are the failure to compare the computer generated label with the original prescription and to perform the final visual inspection of the contents of the vial. Special markings on the stock bottle, in a way that brings attention to the difference in strengths, could be done in the pharmacy to alert the pharmacist.

Other error reports that the committee reviews involve the dispensing of the correct medication, but not the correct form of the medication. Please be careful to distinguish between ophthalmic and otic agents. When handling sound-alike and look-alike medications it is recommended that these products be stored separately from each other and shelf stickers used to distinguish the products.

The committee has received complaints that the patient's prescription vial contained two different strengths of the same medication. This error can at times be traced to the practice of returning medications to stock and inadvertently placing them into the incorrect bottle.

Medications should not be returned into a stock bottle on the shelf, as the lot number and expiration date of the products may differ. All pharmacies should have in place clear "return to stock" policies that prevent the likelihood that one stock bottle contains two different medications.

Disciplinary Actions

Alex Opoku Acheampong, (#14860)
Effective January 15, 2003, license to practice pharmacy is revoked.

Thomas Shern, (#12286)
Effective March 19, 2003, license to practice pharmacy is voluntarily surrendered.

Emmanuel T. Ereme (#11100)
Effective March 11, 2003, license to practice pharmacy is summarily suspended.

Hremt Pharmacy, (Permit# P02010)
Effective March 24, 2003, permit to operate a pharmacy is summarily suspended, suspension is stayed with restrictions on dispensing.

Medication Error

Misidentification of alphanumeric characters

PROBLEM: It's not uncommon to read a letter or number differently than the writer intended. Recently, while reviewing a handwritten, faxed order, a pharmacist read the word "IODINE" in the space for allergy alerts. Yet, a second pharmacist read the allergy as "LODINE." The prescriber was contacted for clarification, and she identified LODINE (etodolac) as the drug to which the patient was allergic. In another case, a patient listed Lodine 400 mg BID as a medication she was taking prior to admission. However, the admitting resident misread the notation and wrote an order for saturated solution of potassium iodide 400 mg BID. The patient received two doses before the error was discovered.

Computerized physician order entry (CPOE) can overcome most problems with poor handwriting. However, even typed or computerized physician orders may not help prevent all of them. Anyone familiar with e-mail knows how easy it is to misidentify a computer-generated lower case letter L (l) in an e-mail address as the numeral one (1), or the letter O as a zero (0)! Even when using character recognition software, drug names may be translated incorrectly. For example, when we tested Lodine, typed with a lower case L, the software recognized the drug name as Iodine. Likewise, it's easy to confuse the upper case letter Z with the number 2. In fact, research conducted by Bell Laboratories found that some symbols are more vulnerable than others to misidentification (Nierenberg GI. Do it right the first time. New York: John Wiley and Sons 1996). The previously mentioned characters (I/1; O/0 and Z/2) plus the number 1, which can look like a 7, accounted for over 50% of the errors caused by character misidentification in the study. Further, the context in which the order is being read may not always be helpful in properly identifying alphanumeric characters. While it would be unlikely to read ZETAR as "2TAR," it would be easy to read an order for "HCTZ50mg" as either hydrocortisone 250 mg or hydrochlorothiazide 50 mg.

SAFE PRACTICE RECOMMENDATION: Many drug name recognition errors can be reduced with block printing using upper case characters.

This was excerpted from a medication errors feature article from the Institute for Safe Medication Practices (ISMP). ISMP is an independent, nonprofit agency that works closely with US Pharmacopeia (USP) and the Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and then publishes its recommendations. To report a problem confidentially to these organizations, go to the ISMP web site (www.ismp.org) for links with USP, ISMP and FDA. Or call 1800-23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Road, Huntingdon Valley, PA 19006. Phone 215/947-7797, E-mail: ismpinfo@ismp.org.

The Maryland Board of Pharmacy continues to work on reducing medication-dispensing errors. The Board's Disciplinary Unit and Committee resolve the majority of substantiated dispensing error complaints under the leadership of Jeanne Furman, Board Commissioner.

New permits and licenses

On March 10, 2003, Nelson J. Sabatini began work as the newly appointed Secretary of the Department of Health and Mental Hygiene. The resignation of former Secretary Benjamin in mid-December prevented the Board from mailing the standard permit to pharmacies and distributors. The Board is in the process of printing new permits and licenses for establishments and pharmacists, and expects to begin mailing them out at the end of April. Those permit holders who were issued a Temporary Permit with Interim Secretary Stephenson's signature will receive a replacement permit. Additionally, newly licensed pharmacists and those requesting a duplicate license will not be issued until the new licenses are available at the end of April. The Board will issue letters of verification to those pharmacists who do not have a permanent license. Licensure status can also be checked on our web site. Go to: www.mdbop.org and click on Verifications.

Regulation Updates

COMAR 10.34.02 Examination for Licensure and Professional Experience Programs.

Effective February 17, 2003, the requirement that applicants for a pharmacist license complete a laboratory examination was repealed. If an applicant receives a passing score on the NAPLEX or Pharmacy Law Test, that score will remain valid for 1 year. If 1 year elapses before the applicant satisfies the requirements for licensure, the applicant will have to retake the part of the examination that was passed.

The number of hours that an applicant must complete in a professional experience program or in full-time training was not changed. Applicants must complete either 1,000 hours of a school-supervised professional experience program conducted by a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE), or 1,560 hours of a full-time training program under the direct supervision of licensed pharmacists pursuant to COMAR 10.34.02.05. The revised regulations clarify that the school conducting the school-supervised professional experience program must be accredited by ACPE. The revised regulations also clarify that the pharmacist supervising an applicant for full-time training must provide direct supervision.

COMAR 10.34.09 Fees.

Effective October 1, 2002, the Pharmacist Reciprocity Fee was decreased from $250 to $120. The fee was lowered to offset the cost of administering the Maryland Law Examination for reciprocity candidates. The examination, which was administered by the Board, is now administered through NABP at Thomson Prometric Centers. Applicants for reciprocity may now take the Multistate Pharmacy Jurisprudence Examination (MPJE which is the MD Law Examination) at any Thomson Prometrics Center, whether in Maryland or otherwise. The change in procedure for obtaining licensure by reciprocity was made so that pharmacists wishing to obtain licensure in Maryland would not have to pay the expense of traveling to Maryland to take the Pharmacy Law Examination.

COMAR 10.34.11 Monetary Penalties.

Effective January 20, 2003, the chapter of regulations relating to Monetary Penalties was revised. Among other revisions to this chapter, the regulations increase the maximum monetary penalty that may be assessed against pharmacies and pharmacists from $5,000 to $10,000, provided certain requirements are met. The Maryland Pharmacy Act was changed to reflect this increase several years earlier. The change in the regulation was made in order to conform to the requirements of the Act.

COMAR 10.34.13 Reinstatement of Expired Licenses for Pharmacists.

Effective February 17, 2003, individuals wishing to reinstate their license to practice pharmacy will no longer be required to pass the laboratory examination. Specifically, pharmacists that were not actively engaged in the practice of pharmacy, whose Maryland licenses were expired for more than 2 years but less than 5 years before applying for reinstatement were required to pass the laboratory examination. Pharmacists not actively engaged in the practice of pharmacy in another state, whose Maryland license expired more than 5 years before applying for reinstatement were also required to pass the laboratory examination. Now neither of the pharmacists in these categories are required to pass the laboratory examination.

Executive Director continued from page 2

inspector for the Division of Drug Control. Ms. Dickerson left a post with the state's Division of Parole and Probation to join the Board staff. An important first clean-up task for both new recruits is to wipe out the backlog of complaints accumulated during the Compliance Unit vacancy. Please assist the Board with its spring-cleaning by responding quickly to requests you may receive for information related to complaint reviews.

Fortunately, the Board will not stop its cleaning when spring ends. In fact, some folks may refer to the Board's activities as 'continuous quality improvements' or 'managing for results.' Whatever it is called, now is a perfect time for pharmacists and permit holders to clean up their own closets. The process is guaranteed to provide room for enhanced operations, customer services and patient safety.

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.

Reduced Processing Time for Licensure

Recently, the Board developed a new pharmacist application procedure to reduce processing time. Applicants must now mail the Board application and fee to the Board and the NABP application and fees directly to NABP. As soon as the Board receives the application and fee, a file is created, the application is reviewed, and a confirmation is mailed to the applicant. When NABP receives their applications and fees, they contact the Board for approval. Since starting this new procedure, if the applications are mailed on the same day, the Board and NABP can receive and approve the applications to take the NAPLEX or MPJE within 5 business days. Previously, it took 10 to 14 days because the Board had to mail the NAPLEX and MPJE applications to NABP for the applicant.

Fees Payable

Licensure Process	The Board	Fees Payable to NABP*
Pharmacist Examination	$100	NAPLEX $430, MPJE $170, FPGEE $700
Pharmacist Reciprocity	$120	Preliminary Application $300, MPJE $170

Reciprocity and Examination candidates must also pay $35 to take an oral competency examination at a Berlitz Language Center or other Board-approved language centers.

* The NABP examination fee includes the vendor fees for the computerized examination

Let Us Know How We Are Doing...

Please e-mail your questions, concerns or comments to us at the following e-mails. We value your feedback.

Licensing – E-mail Tamarra Banks at: tbanks@dhmh.state.md.us
General – E-mail Joan Lawrence at: jlawrence@dhmh.state.md.us

NABP to Administer a Paper-and-Pencil Foreign Pharmacy Graduate Equivalency Examination in June

The National Association of Boards of Pharmacy (NABP) is restarting the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) after a security breach in October 2002 prompted NABP to halt the examination. Applicants must register with NABP before April 30, 2003 and must indicate which location, in order of preference, that they wish to sit for the examination.

The examination date is **Saturday, June 21, 2003** and the locations are:

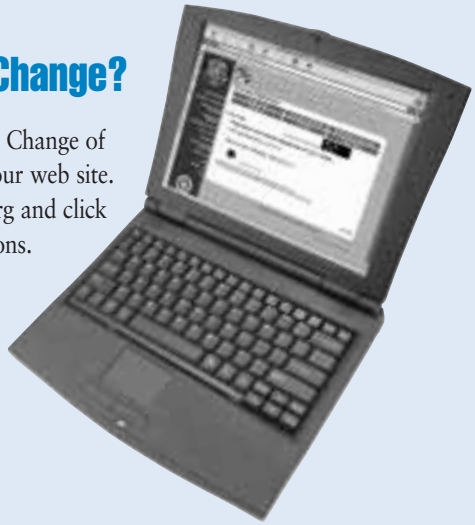
Dallas, TX
New York, NY
Northlake, IL
Oakland, CA

Board Eliminates Laboratory Examination

Effective February 17, 2003, applicants are no longer required to take and pass the laboratory examination. Maryland examination requirements for new graduates now consist of the NAPLEX, MPJE, Oral competency and FPGEE. For more details see page 4–Regulation Updates.

Address or Employment Change?

Submit the Pharmacist Change of Information form on our web site. Go to: www.mdbop.org and click on Forms & Publications.



Frequently Asked Questions

In day-to-day pharmacy practice, unusual situations sometime occur, generating questions. So to help our licensees, "Frequently Asked Questions" will be featured in each issue of the Board's newsletter. If you have a question you would like to see answered in this column, please fax your question to 410-358-6207 or e-mail Joan Lawrence at jlawrence@dhmh.state.md.us.

Licensing

Q: How do I become a Pharmacy Technician in Maryland?

A: Pharmacy technicians are not currently required to be licensed or certified to work in a Maryland pharmacy. However, all unlicensed personnel may only work in a pharmacy under direct supervision of licensed pharmacists.

The Board regulations that describe the responsibilities of licensed pharmacists and pharmacies that employ unlicensed personnel in the prescription area are entitled COMAR 10.34.21 Standards of Practice for Unlicensed Personnel. The Board may develop legal requirements specific to technician practice in the future. Some states currently regulate technicians and require them to be registered or licensed.

You may want to contact the Pharmacy Technician Certification Board (PTCB), a national pharmacy technician certification program, to learn of their certification program. The program may be reached by calling 202-429-7576 or visiting their web site at www.ptcb.org.

Compliance

Q. Can I fill a faxed prescription for a Schedule II drug for a patient in a hospice program who lives at home?

A. Yes, a prescription for a Schedule II drug for a patient in hospice care (as certified by Medicare under Title XVIII) may be transmitted to the pharmacy by the practitioner or the practitioner's agent by facsimile. The practitioner must note on the prescription that it is for a hospice patient. The patient can live at home and be in a certified hospice program. The facsimile prescription with the practitioner's signature and hospice notation is regarded as the original written prescription and must be treated the same as any Schedule II prescription.

Q. Can I fill a Schedule II prescription if a practitioner faxes a prescription for the Schedule II prescription to the pharmacy, so that the patient does not have to wait at the pharmacy while the prescription is being filled?

A. Yes, but you may not dispense it until you have the original prescription in your possession. The facsimile prescription serves as a "prompt" in order to expedite the dispensing process. The pharmacist must have the original prescription before dispensing the drug to the patient. The original prescription must be compared with the facsimile copy of the prescription and the prescriptions must match. The pharmacist must verify that the prescription is a valid one. The original prescription is then annotated and filed as any other Schedule II prescription. In this case, a Schedule II prescription should never be dispensed with only the faxed copy.

Fast Bytes

HIPAA Compliance

April 14 is the date that you must be compliant with the HIPAA privacy regulations. By now pharmacy permit holders should have completed all of the following with the exception of the administrative standards and code sets if you filed for an extension.

- HIPAA compliance Plan developed
- Business associate contracts signed
- System for privacy of signatures in place (electronic or manual)
- Assurance that software companies have made appropriate arrangements for secure transmissions
- Written policies and procedures in place
- Notice of Privacy Practices printed
- Have personnel training material ready and training completed
- Plan to initiate monitoring of effectiveness of HIPAA compliance plan
- Be sure that your vendor is on track for the HIPAA administrative standards and transaction code sets. They must be in place now unless you have applied for an extension to October 16, 2003.

Remember that HIPAA regulations apply to all pharmacies, no matter what size or what type of practice setting. Don't leave yourself exposed to disciplinary action and civil suits by ignoring the requirements or by not following through with them. Pharmacists are responsible for carrying out the policies developed by the permit holder.

OxyContin Replacement

Purdue Pharma announced that they will replace any OxyContin (oxycodone HCL, controlled-release) tablets which are stolen from a pharmacy if the pharmacy is not insured for the loss. Requests for replacement for all uninsured OxyContin lost due to robberies from July 1, 2001 until the program is rescinded should be made in writing to Purdue Pharma along with documentation of the theft, including a complete written police report, a photocopy of DEA form 106, and a written certification that any of the pharmacy's insurance does not cover the loss. A Purdue spokesman said "Purdue does not wish to profit from criminal activity..."

High Potency Steroids

A Dermatology Online Journal article tells of the overuse of high potency steroids such as Lotrisone in pediatrics for diaper rash or other problems. Their figures indicated that even experienced pediatricians do not realize that Lotrisone is a potent steroid and the problems it could cause with frequent use.

Antibiotics

A survey showed that one of three Americans mistakenly believes antibiotics are effective in treating viruses like cold and flu and take this class of drugs to fight the conditions. This adds greatly to the problem of antibiotic sensitivity, and is the focus of an initiative entitled Save Antibiotic Strength New York (SASNY).

Drug Name Confusion

Bristol-Myers Squibb reports that confusion is still continuing with the names of the drugs Serzone for depression and Seroquel, an AstraZeneca product for treatment of schizophrenia. The strengths, dosage form, and dosing intervals are all the same, providing more chance for error. Pharmacies usually stock the two products in close proximity alphabetically, adding another element to a potential error. Serzone has been linked to liver toxicity and has been taken off the market in Europe. FDA has required a black box warning in the U.S.

Depakote ER and Depakote Prescriptions

This is a reminder to be careful with Depakote ER and Depakote prescriptions. The extended release product now comes in a 250 mg and 500 mg tablet and is approved for preventing both migraines and seizures. It is a once daily product, compared to the original Depakote having a BID or TID dose. The Depakote ER gives a lower blood level, so they are not bioequivalent.

UPCOMING EVENTS

MPhA Annual Conference

The Maryland Pharmacists Association (MPhA) Annual Conference is to be held June 7th thru 10th, 2003 at the Clarion Resort Fontainebleau Hotel in Ocean City. For more information contact Howard Schiff at 410-727-0746 or email: mpha@erols.com.

MD-ASCP Mid-Atlantic Conference

The 10th Annual MD-ASCP Mid-Atlantic Conference will be held August 7th thru 10th, 2003 at the Hyatt Regency Chesapeake Bay in Cambridge, Maryland. Please contact: Anna M. Leonhardt, Tel: 410-465-7011, Fax: 410-465-7073.

Maryland Board of Pharmacy

Board Members
Front row left to right:
Irving Lottier, Jr.,
Linda Bethman (Board Counsel),
Stanton G. Ades, Ramona
McCarthy Hawkins, Jeanne Furman
Back row left to right:
Wayne Dyke, John Balch,
Rev. William Johnson, Melvin
Rubin, Donald Yee, Dr. Raymond
Love, Paul Ballard (Board Counsel)
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Joan Lawrence-*Public Information Officer*,
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Middle row left to right:
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Catherine S. Putz-*Pharmacists Compliance Officer (not in photograph)*
Latonya Dickerson-*Executive Secretary (not in photograph*
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James Slade-*Regulations/Legislative Officer*,
LaVerne G. Naesea-*Executive Director*,
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Vladimir Konstantinov-*Database Specialist*

Feel free to contact the Board staff for assistance with information, questions or concerns.

The services and facilities of the Maryland State Department of Health and Mental Hygiene (DHMH) are operated on a non-discriminatory basis. This policy prohibits discrimination on the basis of race, color, sex or national origin, and applies to the provisions of employment and granting of advantage, privileges, and accommodations.

The department, in compliance with the Americans and Disabilities Act, ensures that qualified individuals with disabilities are given an opportunity to participate in and benefit from DHMH services, programs, benefits, and employment opportunities.

Joan M. Lawrence, Staff Editor

Meetings

The Pharmacy Board meetings are open to the public 9:00 a.m. – 12:00 Noon at 4201 Patterson Avenue, Baltimore, MD 21215. The Board encourages all interested parties to attend.

Board Meeting Dates

Wednesday, April 16
Wednesday, May 21
Wednesday, June 18
Wednesday, July 16
Wednesday, August 20
Wednesday, September 17
Wednesday, October 15
Wednesday, November 19
Wednesday, December 17

Agendas and other information can be obtained by contacting the Board at 410-764-4755.

Contribute Your Ideas

This newsletter is created to keep you informed, and to cover topics that are of interest to you. If there is a particular topic that would be helpful to you, let us know.

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