One of the major functions of the Board of Pharmacy in protecting the health and safety of the public is responding to consumer complaints, which most often deal with medication errors. Most prescription errors are resolved between the pharmacist and the consumer. Also, in order to comply with the new Patient Safety Regulations (COMAR 10.34.26), the error should be reported internally as part of the pharmacy’s ongoing Quality Assurance Program, that addresses medication errors and ways to prevent similar occurrences.

All errors should be periodically reviewed so that flaws in the medication delivery system can be corrected and the occurrence of similar errors prevented. Most consumer complaints to the Board are accompanied by reports of less than adequate remediation by the pharmacy and/or pharmacist in response to the complaint or concern.

When dealing with your patients, in response to a possible medication error, the Disciplinary Committee of the Board of Pharmacy recommends:

1. Having the pharmacist on duty handle the problem instead of technical or support personnel.

2. Taking the error/complaint seriously and not trivializing it to the patient with statements such as “Mistakes happen”, “Well, at least you didn’t take any” or “Just bring it back to the pharmacy, we’ll give you a refund.”

3. Show real concern for the health and well-being of the patient especially if he or she has taken some erroneous medication. Contact the prescriber and follow up with the patient by phone or return visit to see how the patient is feeling.

4. Sincerely apologize and let the patient know that the error/complaint will be communicated to the management/owner and steps will be put in place to help prevent a similar incident.

Although you may feel that some complaints are without merit, it is advisable to truly listen to the consumers and resolve any complaints before they reach the Board. It will save much time and anxiety in the future if the Board is required to investigate.
Speaking of volunteering...have you signed up as a Maryland Board of Pharmacy Emergency Preparedness Volunteer? The Board and its volunteer recruits will play a significant role during state, local or national emergencies. The Department of Health and Mental Hygiene recently conducted a statewide drill to test all of the training and planning that its units have been involved with over the past two years. We are still awaiting the outcome review of the drills. Log on to the Board web site to register www.mdbop.org or contact Joan Lawrence at (410) 764-4755, email: rxemergency@dhmh.state.md.us and we will contact you in the near future to provide a training schedule. To those who recently participated, the Board and State of Maryland cannot thank you enough for your commitment to caring for Marylanders in need.

Stay cool this summer and as you vacation, take a minute to reflect on why we celebrate Independence Day. HAPPY SUMMER EVERYONE!

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From the Executive Director’s Desk

Summer brings change for the Board.

 Hopefully, you have had an opportunity to take a break from the hustle and bustle of your busy lives to enjoy these summer days (despite the cicadas!). Things have been busy as usual at the Board. Renovations for expanded offices were completed in May, the Board initiated the Drug Therapy Management review committee with the Board of Physicians in June, and discussions between the Board and the Office of Health Care Quality regarding Long Term Care/Assisted Living facility pharmacies are underway.

Staff has been extra busy due to recent vacancies at the Board. Board Pharmacist Compliance Officer, Catherine Putz retired, effective June 8, 2004 in order to spend more time with her family and explore a new life of leisure. Cathy worked very hard at the Board on very important cases, in order to insure public health safety. The Board appreciates all of the contributions she made. Also, Board Secretary, Latonya Dickerson resigned from the Board to pursue personal career goals outside of state service. She too supported the Board in achieving its goals and vision and we wish her the very best in her new endeavors. Some of you may know Sandra Hines or have heard her pleasant voice when you telephone the Board. I am sorry to inform you that she recently suffered a serious illness. Fortunately she is on the road to recovery and would appreciate any cards of endearment and well wishes (don’t worry...we’ll get them to her).

As if these events haven’t kept us busy enough two new pharmacist members were appointed to the Board. Mayer Handelman was appointed to replace former President Stanton G. Ades as the Board’s Long Term Care representative, and Donald Taylor was appointed to replace former member Wayne Dyke as the Chain representative. Board members and staff have been busy orienting these two new members while reveling in the knowledge that they have “fresh,” energized “blood” to help address all of the Board’s initiatives through committee work. Attend one of the upcoming Board meetings to meet all of the new members and greet the “old.” Be careful... we may just swoop you up as a volunteer.

Speaking of volunteering...have you signed up as a Maryland Board of Pharmacy Emergency Preparedness Volunteer? The Board and its volunteer recruits will play a significant role during state, local or national emergencies. The Department of Health and Mental Hygiene recently conducted a statewide drill to test all of the training and planning that its units have been involved with over the past two years. We are still awaiting the outcome review of the drills. Log on to the Board web site to register www.mdbop.org or contact Joan Lawrence at (410) 764-4755, e-mail: rxemergency@dhmh.state.md.us and we will contact you in the near future to provide a training schedule. To those who recently participated, the Board and State of Maryland cannot thank you enough for your commitment to caring for and protecting Marylanders in need.

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LEGISLATION UPDATES

The 2004 Maryland legislative session ended April 12, 2004. There were many bills of interest, including the following:

1. Maryland Pharmacy Act- Practice of Pharmacy-Administration of the Influenza Vaccination (HB 384/SB 389)

Once regulations are jointly developed and adopted by the Boards of Pharmacy, Physicians and Nursing, a pharmacist will be able to administer influenza vaccinations to patients. The regulations will also establish reasonable fees to be charged for the administration of the vaccination, but not for the actual product.

2. Prescription Drug Safety Act (HB 433)

Although this bill has not been signed as of the writing of this article, the Prescription Drug Safety Act passed the General Assembly. The bill requires prescriptions to be legible and further requires the Department of Health and Mental Hygiene to convene a workgroup, including the Board of Pharmacy, to study certain issues relating to the legibility of prescriptions. The workgroup will discuss issues such as appropriate format and content of prescriptions, as well as the “use and cost of computerized physician order entry, and the feasibility of eliminating handwritten prescriptions.”

Other bills that are referring to, or are related to go to, summer study include Health Occupations Boards- Misdemeanor Offenses- Delegation of Authority, Fines, and Penalties (SB 330/HB 1321), Health Insurance- Pharmacies- Electronic Reimbursement (HB 512), Pharmaceuticals- Marketing- Disclosure and Registration (HB 519), and State Board of Pharmacy- Registration of Pharmacy Technicians (HB 998).

To access these bills, log on to the Maryland General Assembly’s website at www.mlis.state.md.us. Once on the website, click “Bill Information and Status”. Type the bill number into the query slot.

REGULATION UPDATES

The Board’s regulations entitled “Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit” became effective March 1, 2004. To review the new regulations, log on to www.dsd.state.md.us. The new regulations are COMAR 10.34.31.

QUESTIONS FOR THE PRACTICE COMMITTEE

Q. Is it legal to dispense a prescription that was written for the prescriber or a member of the prescriber’s family?

When prescribers write prescriptions for themselves or family members, pharmacists are placed in difficult ethical and legal positions. In most cases, it is legal for prescribers to write prescriptions for themselves or a family member. However, this practice is ethically questionable. It may be difficult for a prescriber to maintain an objective perspective when prescribing for himself or herself or a family member. Furthermore, family members may not wish to disclose all of their health information to a prescriber who is a family member, because it may affect the relationship with the prescriber. For example, a teenage daughter may not wish to disclose treatment for a sexually transmitted disease or use of birth control to a parent who is a prescriber. The determining factors in this circumstance are:

a) Is the prescription being written for a legitimate purpose?

If the pharmacist has cause to believe that the prescription is not being written for a legitimate purpose, the pharmacist has an obligation to not fill the prescription. This is especially an issue when the drug is a controlled substance. If the pharmacist fills a controlled substance in this case he or she is in violation of COMAR 10.34.10.08. Furthermore, the pharmacist is obligated under this regulation to report the prescriber to the prescriber’s licensing board.

b) Is the prescription being written by the prescriber in the course of his or her usual professional practice?

A dentist who writes a drug for erectile dysfunction is obviously prescribing outside of the normal course of professional practice. In this case, the prescription is no longer legitimate and thus may not be filled. Furthermore, the Board strongly advises the pharmacist to report the prescriber to the prescriber’s licensing board. In fact, if the pharmacist has consulted with the prescriber and the pharmacist has reason to believe that the prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber’s practice, the pharmacist is required to report the prescriber to the prescriber’s licensing board under the Pharmacist Code of Conduct.

The illegitimate use of controlled substances and the advent of lifestyle drugs makes self-prescribing and family prescribing a practice that must be carefully monitored. The pharmacist is responsible for determining the legitimacy of any prescription before filling it. This includes assuring that the prescription is written for a legitimate purpose in the course of the prescriber’s usual professional practice.
ON-LINE RENEWALS
Renewal process more efficient with new system.

The April issue of the Newsletter described the procedure for renewal of pharmacist licenses including on-line renewal. It is preferable for pharmacists to use this system well before the expiration of their license to allow time for processing and corrections if necessary. State law specifies that a person whose completed application for renewal is received 14 or more days prior to expiration may still practice, if they do not receive their license by the expiration date. Although the Board makes every effort to send renewed licenses out as fast as possible, anyone applying either by mail or on-line the last few days before expiration may have a gap of one or more days in which they cannot practice until they physically receive their license.

One advantage of on-line renewal is that when you use it and pay with a credit card you have proof that the Board received your application. Assuming that you have filed a completed application you can be certain that your license will be mailed. One mistake often made is leaving out the required approval number of an ACPE or Maryland Board of Pharmacy approved continuing education course, which makes the application incomplete. Remember that if you elect to use on-line renewal but mail a check, the application is not complete until the payment is received at the Board.

When mailing your application or check, you may want to call the Board if you do not receive the new license within several days before the expiration of the old one. If you find that you must renew in the last two weeks, consider bringing the completed application to the Board in person. To use the self-guiding and easy to use online system, go to www.mdbop.org and click on “online renewal.”

NEW BOARD MEMBERS

New Board Members
Governor Ehrlich has appointed two new Commissioners to the Maryland Board of Pharmacy, filling seats vacated by pharmacist members who have completed their terms.

- Mayer Handelman, of Baltimore County, has been appointed to the seat reserved for a representative of Long-term Care pharmacy. Mr. Handelman is a former owner of Woodhaven Pharmacy and Woodhaven Institutional Services and currently works with Neighbor-Care Pharmacy.
- Donald W. Taylor is one of the members on the Board representing Chain Pharmacy. Mr. Taylor, of Salisbury, is a pharmacist manager and training manager for Rite Aid Pharmacy on the Eastern Shore, and has been very active as a Board of Pharmacy liaison to several counties in his area.

Officers and Committee Chairs

Elected officers of the Board:
- Melvin Rubin–President
- Jeanne Gilligan Furman–Secretary
- Raymond Love–Treasurer

The following Board members were appointed chairs of standing committees and Task Forces:
- Raymond Love–Pharmacy Practice Committee
- Joseph DeMino–Licensing Committee
- Ramona McCarthy-Hawkins–Technology Committee
- John Balch–Long Term Care Task Force

Jeanne Gilligan Furman–Disciplinary Committee
Jeanne Gilligan Furman–Budget Committee
Christiaan Blake and Mark Levi–Legislative Committee
Melvin Rubin–Emergency Preparedness, Bioterrorism Committee
Jeanne Gilligan Furman–Public Relations
PHARMACY INSPECTION

The Division of Drug Control and the Board of Pharmacy are always working to improve the inspection process. The inspections conducted by inspectors from the Division of Drug Control consist of two parts. One part relates to compliance with pharmacy regulations, that are the responsibility of the Board of Pharmacy. The second is a review of compliance with controlled dangerous substance and other regulations, that are the responsibility of the Division of Drug Control.

Suggestions or concerns regarding the process in general can be sent to either Drug Control or the Board. Questions regarding pharmacy law or its interpretation should be sent to the Board. Similarly, inquiries about controlled dangerous substances should be sent to Drug Control.

All questions and concerns are best addressed if submitted in writing. Questions and concerns in writing give Drug Control and the Board an opportunity to investigate and research in order to respond accurately. Feedback from licensees is essential to improving the inspection process and the Board and Drug Control are glad to receive correspondence from you, with regard to inspections or other issues.

Correspondence to both agencies can be addressed to 4201 Patterson Avenue, Baltimore, MD 21215.

2004 Flower Mart

The Maryland Board of Pharmacy and the Maryland Pharmacy Coalition [consisting of the Maryland Pharmacists Association (MPhA), Maryland Society of Health System Pharmacists (M SHP), Maryland Chapter of Consultant Pharmacists (M D-ASCP), Maryland Pharmaceutical Society (M PhS), and the Maryland School of Pharmacy Student Government Alliance (SGA)], participated in the City of Baltimore’s 87th Flower Mart, on Mt. Vernon Street, Washington Monument, Mount Vernon Square, Wednesday, May 12, 2004. It was a successful endeavor thanks to the joint efforts of the Board of Pharmacy and the Maryland Pharmacy Coalition.

Health concerns were addressed with products and literature received from various pharmaceutical companies. Consumers appreciated the outreach project, and agreed that education is a very important part of the health care process.

Thanks to the volunteers who worked tirelessly from 7:00 a.m. to 6:00 p.m. and provided over 1,000 consumers visiting the booth with general safety tips and health care services. In addition to providing information, blood pressure monitoring, diabetes screening, and consultation on medications, information was given to the public on nutrition, diabetes, cholesterol, high blood pressure, smoking cessation, osteoporosis, and over-the-counter prescriptions.

Again, John Balch, Board Member/PharmaCare, donated a magnificent wreath to raffle for those who received blood pressure screenings. The winner was Mary Chvostal of Baltimore, who was thrilled to win such a beautiful prize.

If you would like to volunteer for upcoming consumer events, please contact Joan Lawrence, at 410-764-4755 or email jlawrence@dhmh.state.md.us

To view pictures of the booths visit the Board’s website at www.mdbop.org and click on Consumer Information, click on Upcoming Events, and then scroll down and click on Flower Mart 2004.
Compliance

Q: I work for an independent community pharmacy and one of my regular customers picked up a prescription refill for his mother. When he got to his mother’s home, he found out that the doctor had changed his mother’s drug regimen and had discontinued this medication. The next day he brought the prescription back to the pharmacy in the original stapled closed store bag and asked to return the medication and receive a refund for the money he had paid. Our pharmacy has no set policy regarding returns and sometimes in these cases we will give a refund to keep the customer “happy.” Is there a Law that prohibits returns of prescription drugs? Can returned prescription drugs be returned to stock?

A. Pharmacy Law states that a pharmacist may accept the return of a drug or device that is:
   1) Properly labeled and in a properly sealed manufacturer’s package, or
   2) An individual unit dose of drug or a device that:
      - the pharmacist determines to have been handled and stored appropriately to preserve the strength, quality, purity, and identity of the drug during the time it has been out of the store. (COMAR 10.34.10.07 (A))
      - The pharmacist may not return to stock or sell a previously sold prescribed drug or device that has left the pharmacy’s possession unless the pharmacist can determine that the above requirements have been met. (COMAR 10.34.10.07 (B)(1)) A pharmacy may develop its own store monetary refund policies.

Q. Does Maryland still have a list of non-substitutable drug products?

A. The Department adopted the FDA book of “Approved Drug Products with Therapeutic Equivalence Evaluations” (APDP) as a reference for determining generic equivalent drug products. The pharmacist may reference the “Orange Book,” as it is commonly called, online at http://www.fda.gov/cder/ob. Maryland lists six drug products that continue to be non-substitutable which the Department has determined to be therapeutically non-equivalent. (Health Occupations 12-504 (e)). Included on this list are Carbamazepine Oral Tablets 200 mg; Phenytoin Sodium Extended Oral Capsules 100 mg; Primidone Oral Tablets 250 mg; Valproic Acid Oral Capsules 250 mg; Theophylline Extended Release Oral Tablets 100 mg, 200 mg, and 300 mg, and Warfarin Sodium Oral Tablets 2 mg, 2.5 mg, 5 mg.

Q. If our manager who usually signs the DEA Order Form #222 goes on vacation can one of the other store pharmacists sign for him?

A. Official DEA Order Forms are signed and dated by a person who is authorized to sign a DEA registration application for a pharmacy. The pharmacy is considered the registrant since the DEA does not register pharmacists. One or more individuals may be authorized by the registrant (pharmacy) to sign DEA order forms by being granted power of attorney. A suggested format for a power of attorney for DEA order forms is available from the DEA. (Code of Federal Regulations Title 21; Part 1305.07) The power of attorney form must be signed by both the person who signed the most recent application for registration or renewal and by the individual being authorized to sign official DEA #222 Order Forms. The completed power of attorney form should be kept with the copies of the completed DEA #222 forms. They do not need to be submitted to the DEA but should be kept up to date and readily retrievable for possible inspection. A power of attorney may be revoked at any time. Only if a different person signs the pharmacy DEA renewal registration is it necessary to grant a new power of attorney.
FAST-BYTES

Potential For Error
Computer label programs limit the number of characters in each field, which sometimes allow for an error in interpretation. For example, if your label truncates the name of the drug from hydrocodone 5-500 to hydrocodone 5-50 since only 16 spaces are allowed for the product name, it is possible for a prescriber viewing the bottle to feel that the patient is only getting 50 mg of acetaminophen, and may then allow the patient to take a toxic amount of the generic Tylenol. A prescription for generic Fiorinal may also have the name shortened so as not to identify one of the three ingredients. Be sure that your program prints full names or add it to the typed label. If necessary, attach an auxiliary label with the full name of the product onto the vial or bottle.

Duty To Report
Pharmacists are reminded that COMAR 10.34.10.05 indicates the Duty to Report certain conduct by pharmacists and non-pharmacists, such as the unauthorized practice of pharmacy, to the Board. The same section also requires that a pharmacist shall report conduct by a pharmacist that involves drug or alcohol abuse or dependency to Pharmacists’ Education and Assistance Committee (PEAC). This allows the dependent pharmacist to receive assistance and treatment without Board intervention as long as the involved pharmacist signs a contract with PEAC and follows the conditions. This is considered a self-referral and information is shielded from the Board as long as the pharmacist works with the rehabilitation committee. For a private, confidential referral, call 410-706-7513 or 800-833-7587. These are NOT Board of Pharmacy numbers, and again, a pharmacist seeking treatment and working with PEAC is not reported to the Board of Pharmacy.

Canadian Internet Pharmacies
The Board of Pharmacy is well aware of the problem of illegal prescription medication being sent to Maryland consumers by pharmacies or those purporting to be pharmacies from outside of the U.S. Maryland law requires the Board to license out-of-state pharmacies as non-resident pharmacies and provides methods to oversee their operations. Since the law requires inspection reports from the state in which the pharmacy is located, the Board cannot license a pharmacy in Canada or any other foreign country.

The Board of Pharmacy can take action against any pharmacy and pharmacist licensed in Maryland for aiding the dispensing of prescriptions from foreign pharmacies to Maryland residents, and can take action against “store fronts” if it can be shown that they are acting as pharmacies. However, the only action that the Board can take directly against foreign pharmacies is to inform them of our laws and issue a “Cease and Desist” letter.

This has been done a number of times as sites are brought to the Board’s attention, and foreign pharmacies have already responded indicating compliance.

DISCIPLINARY ACTIONS

Yussuf Gbadamosi (License# 09802)
Effective May 19, 2004 license to practice pharmacy is suspended.

UPCOMING EVENTS

The 11th Annual M D-ASCP Mid-Atlantic Conference is being held Thursday, August 5th through Sunday, August 8th at the Rocky Gap Lodge & Golf Resort in Western Maryland.

The Conference begins with a dinner and program on Thursday evening. Highlights include: 20 hours of CE, an address by Secretary Jean Roesser, Maryland Secretary of Aging, and a forum on Assisted Living, featuring representatives from the Federation of Assisted Living, Lifespan, Maryland Office of Health Care Quality, and other legislative representatives.

There is also the Education Fund Golf Tournament on Friday morning and an Industry Trade Show featuring over 40 booths.

For a Conference brochure, contact M D-ASCP Headquarters at 410/465-7011 or check the website: http://www.ascp.com/public/meetings/2004/MiAtl/Pharmacists Safeguarding the Health of Patients - M SH P 39th Annual Seminar
The Maryland Society of Health System Pharmacists will hold its annual seminar Oct 15-17, 2004 at the Hyatt Regency in Reston, VA. 12.5 hours of C.E. credit will be available on a variety of topics dealing with patient safety and error prevention including presentations on automation, bar-coding, human error, system design and ways to handle an impaired pharmacist. There will also be a New Drug update and a legislative/regulatory update.

Many of the programs will qualify for CE in patient safety /medication error prevention that some states now require. For more information or to register, go online at www.mshp.org or call 410-465-9975.
Maryland Board of Pharmacy

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Vladimir Konstantinov, Database Specialist

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.

2004 BOARD MEETING DATES
Wednesday, July 21, 2004
Wednesday, August 18, 2004
Wednesday, September 15, 2004
Wednesday, October 20, 2004
Wednesday, November 17, 2004
Wednesday, December 15, 2004

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

Editorial Committee:
Jeanne Furman, Board Member
Ramona M. McCarthy Hawkins, Board Member
LaVerne Næsea, Executive Director
Linda Bethman, Board Counsel

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.

Send information to:
Joan Lawrence, Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215 or fax/email: 410-358-6207; jlawrence@dhmh.state.md.us

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 with 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; Jeanne Furman, Board Editor; Ramona McCarthy Hawkins, Assistant Board Editor