April 2005

maryland Board of Pharmacy

# PRESCRIPTIONS SENT THROUGH THE INTERNET

*Submitted By: Melvin Rubin, Board President*

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.

The Board of Pharmacy has received questions from pharmacists regarding the practice of filling prescriptions sent to them via the internet which may be written by physicians from states other than the state where the pharmacy and patient are located. This could be in conjunction with an internet service that allows patients to request certain medications, then forwards the request with the medical information provided by the patient on-line to a prescriber. The physician may then authorize the prescription by just electronically signing the request.

This is a quote from the Maryland Board of Physicians Newsletter of March 1999 (then known as the Maryland Board of Physician Quality Assurance): "Any doctor providing the consultation or prescribing for a patient in Maryland who is not licensed in Maryland can be subject to up to a $50,000 fine for practicing medicine without a license."

The specific area of Maryland Pharmacy law that affects pharmacists who are filling prescriptions for controlled substances in scenarios such as or similar to the above is found in COMAR 10.19.03.07:

C. Purpose of Issue of Prescription (21 CFR § 1306.04).

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist** who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment, or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501--5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances. The wording above appears in Maryland law and in 21 CFR § 1306.04 of the Code of Federal Regulations.

The above regulation is also applicable to any prescription containing a controlled substance that a pharmacist fills when he or she should have reason to believe it is not written in the usual course of practice for a legitimate medical purpose, even when the prescriber is contacted and indicates that the medication is appropriate. COMAR 10.34.08: Refusing to Dispense a Controlled Substance describes the steps a pharmacist must take, if after consulting with the prescriber, he or she decides not to fill the prescription.

Please do not confuse the above responsibilities with the need to fill appropriate prescriptions for patients who have legitimate need for pain relief. Pharmacists have to be willing to participate in the treatment, when palliative care is necessary.

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# PRESIDENT'S MESSAGE

*Melvin Rubin, President*

The consumer sounded incensed because we did not take away the pharmacist's license after receiving their complaint! The person representing the pharmacist could not understand why we disciplined his friend at all! My Newsletter article is late! Did I forget about the Council of Boards meeting? Will I go to Washington next week for a seminar on Emergency Preparedness? Six interviews for open staff positions next week, and at least 7 pharmacists needed for each of 2 hearings? Discipline Committee and Licensing Committee meetings today? There are 2 regulations to review and 18 bills from the legislature on which to help formulate a position! Can I be on another task force? Do I have to go to Annapolis to testify this week? I really must stop answering the phone or reading my e-mails in the Board Office.

While not all of the above messages should even have gotten to me, it gives a small snap-shot of what a Board member is exposed to – a very small sampling. Anyone who becomes a Board of Pharmacy Commissioner thinking that all they have to do is come to one meeting a month, make a few decisions and feel important is in for a rude awakening.

With my third and probably last term on the Board of Pharmacy about to end, I can sum up the experience in 4 words – "It was worth it!"

Now that I will have time to take my wife to lunch once in a while, like good retired husbands are supposed to, I look back over the highlights of my Board experiences and see that perhaps the one I most cherish came right at the beginning. It started in 1992, when my peers in the Maryland Pharmacist Association thought enough of me to place my name on the list of nominees to be presented to the Governor to become a Commissioner —even though I did not ask to be considered. That memory is enough to make my chest swell, if not my head.

Pharmacy has been good to me as well as most of my colleagues. We feel the responsibility to give back to the profession, and those with whom I served on the Board — each of them –have offered more of themselves than should be reasonably expected, in order to help maintain the high standards expected of us by the consumer.

The same can be said for the Board Staff. Most of those I have had the honor and pleasure to work with are living proof that, yes, you really can use the words 'government' and 'worker' in the same sentence.

Perhaps the hardest part of being a Board Commissioner is being exposed to what I call the 'soft underbelly' of the profession. Of over 7300 pharmacists that we license, probably less than 2% have come before the Board during my terms for issues that made us seriously consider formal disciplinary action. A relative handful were for problems that were way off the charts, but most of the time bad decisions, often followed by cover-ups, brought the pharmacist in front of us. Since the mission of the Board is to protect the public, the Commissioners have to feel certain that pharmacists who come before us understand what they did wrong and Board members need to feel that the pharmacist is not going to be a danger to themselves or patients in the future. Taking action that denies a person even a temporary period when they are not allowed to practice in their chosen profession, is neither a responsibility taken lightly nor decisions easily come by.

I will offer just one piece of advice to the vast majority of pharmacists who try to practice to the highest standards. Many, perhaps a majority, of the consumer complaints that come to the Board speak more to the way the pharmacist handled a situation than to a problem itself. Don't try to cover-up an issue, try to solve it to the satisfaction of the patient, whenever possible, and to the extent that you can legally do so. If the Board becomes involved, don't try to escape appropriate blame –be honest. Fortunately for everyone, one of the best ways we know to protect the consumer is to provide tools for pharmacists with which to work, and then to help them understand what they mean. Use pharmacy regulations as your guide to best practices.

I purposely did not offer thanks for the help given to me by specific people with whom I worked and admire. In thirteen years, there have been many and each one shares a place in my memories. My allotted space would allow me room to name those I did not like working with — but I couldn't think of any. ■

# LEGISLATION UPDATES

*Submitted By:*
*Christina M. Harvin, Legislative/Regulations Manager*

*The Maryland Board of Pharmacy continues to track bills and regulatory initiatives that could impact the provision of quality health care by the pharmacy profession. 2005 legislation that affect the practice of pharmacy include:*

SB 24 Making it a felony to practice specified health occupations without a license.

HB 65 Requiring the Department to develop a plan to implement a Canadian Mail Order Plan.

HB 113 Providing immunity from civil liability for specified individuals (Health Care Providers).

HB 114 Providing that an apology or expression of regret made by a health care provider in writing or orally may not be used in specified civil actions.

HB 115 Prohibiting a lawyer from dividing a fee in a health care malpractice claim against a health care provider with another lawyer in the same firm.

HB 203 Allowing a credit against the State income tax for specified health care professionals

HB 231 Requiring DHMH to seek approval of a waiver from FDA to operate a program to purchase and import prescription drugs from Canada.

SB 742 Companion bill to HB 231

HB 233 Requiring the Secretary of DHMH and a workgroup studying the legibility of prescriptions to submit an interim report.

SB 251 Establishing a Task Force to Study Electronic Health Records.

HB 317 Requiring the Board of Pharmacy to establish a Prescription Drug Repository Program.

SB 441 Requiring Medbank of Maryland, in collaboration with the Maryland Board of Pharmacy, to establish and administer a Prescription Drug Repository Program.

SB 372 Prohibiting with specified exceptions the sale, distribution, or dispensing of specified drugs containing pseudoephedrine.

HB 618 Authorizing the State Board of Pharmacy to regulate pharmacy technicians.

HB 835 Prohibiting a wholesale distributor from knowingly taking specified actions with regard to prescription drugs or devices.

HB 1058 Prohibiting a pharmacy benefit manager (PBM) from establishing the amount of reimbursement based on the type of prescriber.

For more information regarding the above legislation, please visit the Maryland General Assembly's website at www.mlis.state.md.us. Once you are on the main page, click "Bill Information and Status."

# WORKING TOGETHER TO PROTECT THE HEALTH AND SAFETY OF THE PUBLIC

*Submitted By: LaVerne G. Naesea, Executive Director*

It's important to share the Board of Pharmacy's organizational structure with licensees to keep them informed of whom to contact when they have questions or comments regarding the Board and its involvements. Doing so in this issue is particularly timely since several new employees have been recruited. Board members are appointed volunteers who ensure that the purpose and mission of the Board are carried out. Maryland law allows the Board to hire sufficient staff in order to implement decisions made during meetings. Under the direction of Executive Director LaVerne G. Naesea, Board staff members work in five (5) co-dependent units. The Licensing Services and Compliance units perform primary board functions, but rely on (and are complemented by) the Administration and Public Support, Legislative/Regulations, and Management Information Systems units. The Board employs its own Administrative Secretary, Aiyana Waldron, who also provides support to Ms. Naesea and the Legislative and Compliance Units. Temp employee, Keisha Wise, currently serves as the Staff Receptionist. She is often the first person callers speak to when telephoning the Board.

The Licensing Services Unit is responsible for all activities related to the issuance of new and renewal pharmacist licenses and establishment permits. The Unit is required to operate at a very fast pace, usually responding to the highest volume of calls and processing the greatest number of correspondences daily. Ms. Shirley Costley manages the Licensing Services Unit and must ensure that all required standards of practice, education and continuing education have been met before licenses and permits are issued. Many licensees have communicated with Doris James, who processes new and renewal applications. A third staff position, Licensing Secretary (currently vacant) also provides support to the Licensing Services Unit. Temp Dwarne Hawkins currently acts in that position. If the pharmacy technician bill goes forward during the current legislative session, the Licensing Services unit will be working with the Board Licensing Committee to develop regulations and procedures for technician registration.

The Board Compliance Unit has all relatively new staff. Some of you may have met the unit manager, Pharmacist Compliance Officer Chandra Mouli. Mr. Mouli joined the staff in November 2004 and jumped right in to recruit support specialists. He retired as Chief of Pharmacy Service from the Department of Health and Human Services, Program Support Center, where he worked in the capacity of supervising pharmacist. The Board recently recruited two other staff members to support unit's activity — Colin Eversley (Compliance Investigator) and Linda Prince-Garrison (Compliance Specialist). Compliance also works with PEAC (Pharmacist Education Assistance Committee), the Board's pharmacist rehabilitation contractor, to track Board referred cases. Feel free to contact any of the staff with questions or concerns regarding general practice issues. Remember, that much of the disciplinary functions of this unit are confidential until a public order has been issued.

The Administration and Public Support (APS) Unit provides internal support not only to all units and staff members, but also to the Board, licensees and the public. Unit manager, Patricia Gaither, joined the Board staff in the late in the summer of 2004, having most recently worked in the Procurement Department at Morgan State University. The APS unit is responsible for administration of daily fiscal, personnel and public information activities. It manages such activities as timekeeping and member/staff expense accounts, tracking expenditures and program budgets, processing members' expense reports, license and permit fees, procuring contracts, and recruiting staff. The Unit's Public Information Officer (currently vacant) fields inquiries from professionals, consumers and the media about a myriad of issues and is responsible for the quarterly newsletter. Ms. Sandra Hines provides administrative support for this very busy Unit.

New staff has also joined the Legislative/Regulations Unit. Most of you will remember James Slade, who aptly ushered through several pieces of legislation, as well as drafted several new and amended regulations. He also staffed several key committees and task forces, including the Pharmacy Practice, Drug Therapy Management, Pharmacist Technician Workgroup and Long Term Care Task Force. Jim left the Board in the fall of 2004 to become the Deputy Legislative Officer for the Department of Health and Mental Hygiene (the Board's parent agency), and subsequently left there to join the federal CMS team in developing the Medicare Part D program. Board members often wondered how Jim achieved so much in a one-man unit and feared that Jim's four-plus years of achievement at the Board would leave a large gap.

The Board was fortunate during the FY 2005 Legislative session to have quickly filled the gap left by Mr. Slade with two very competent staff replacements. Christina Harvin joined the staff late in the summer of 2004.

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# WORKING TOGETHER TO PROTECT THE HEALTH AND SAFETY OF THE PUBLIC

*Submitted By: LaVerne G. Naesea, Executive Director—continued from page 4*

Possessing a MBA from Johns Hopkins, Ms. Harvin manages the Legislative/Regulations Unit with finesse and political savvy as she has quickly become familiar with pharmacy issues. Beginning in January 2005, Anna Jeffers, joined the Legislative/Regulations Unit. Ms. Jeffers, who has a law degree from the University of Baltimore, was the former Regulations Officer for fourteen different health occupations boards for more than five years. The Board scored a coup in acquiring these two individuals, whose compatible work styles will help achieve much to insure pharmacy patient safety.

Last, but definitely not least, the Management Information Systems (MIS) Unit (the heartbeat of the Board organization), is quite effectively led by Tamarra Banks, with support from Database Specialist, Vladimir Konstantinov. The MIS Unit developed and maintains all databases, electronic licensing systems, web site postings, e-mail accounts, and disaster recovery systems for the Board. In addition to fixing crashed computers, tracking and attacking computer viruses, maintaining and ordering hardware and software equipment and procuring service and equipment contracts related to all Board machinery and computers (e.g., printers, copiers, scanners, fax machines, etc.) the MIS Unit is responsible for insuring that all of the Board systems are run on secure networks. Ms. Banks and Mr. Konstantinov make quite a team.

That's the Board staff organization in a nutshell. Board of Pharmacy employees are a fine team of committed personnel who work together in meeting the Board's mission of insuring the safety of Maryland consumers. If you're in the area, stop by or e-mail/phone-in your comments to the staff. The Unit contact information is listed on the last page of this issue. ■

# COUNTERFEIT DRUGS

*Submitted By: Jeanne Furman, Secretary to the Board*

You have probably heard the quote, "If a deal seems too good to be true, it probably is." Well, if someone tells you that they can procure prescription drugs at prices far below wholesale prices, you should be very suspicious. There is a real possibility that the drugs being offered are counterfeit, especially if the seller is not a well-known, reputable wholesaler.

Recent studies have shown that worldwide about 10% of prescription drugs are counterfeit; in third-world countries the rate often exceeds 50%. But don't be fooled—this is not just a problem for the rest of the world. There have been some high-profile cases of counterfeiting in the United States. Counterfeit drugs may have little or no active ingredient or may be super-potent. Access to technology often makes these counterfeit drugs very hard to visually distinguish from real products.

We are pleased to report, however, that initiatives to assure the integrity of our drug supply are proceeding quickly. State Boards of Pharmacy, the National Association of Boards of Pharmacy (NABP), the Food and Drug administration (FDA), major drug manufacturers and wholesalers have been cooperating in a number of ways. To date efforts include:

- Development of a listing of the prescription drugs most susceptible to counterfeiting;
- Development of model legislation regarding licensure of drug wholesalers. The model language calls for background checks for owners and designated supervisors. Wholesalers will also have to post a surety bond;
- Development of "drug pedigrees", a tracking system for medications from manufacture to end-user. Hopefully, these pedigrees will be maintained electronically using new technologies, such as radio frequency identification devices (RFID).
- Proposed stronger penalties for trafficking in counterfeit drugs.
- Development of an accreditation process for wholesalers. In fact, NABP launched the Verified-Accredited Wholesale Distributors (VAWD) program on February 28, 2005.

For more information on VAWD and related matters you may visit the NABP website at www.NABP.net

# FREQUENTLY ASKED QUESTIONS
# QUESTIONS FOR THE PRACTICE COMMITTEE

*Submitted By: Raymond Love, Chairperson Practice Committee*

*Q Can an original paper or faxed prescription be destroyed, if the pharmacy maintains a scanned image of the prescription?*

A. The statute relating to prescription records is listed below:

§ 12-403. Required standards.

(b) In general.- Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(13) Shall:

(i) Make and keep on file for at least 5 years a record of each prescription prepared or dispensed in the pharmacy;

The Board interprets this language to mean that an original paper prescription or faxed prescription copy can be destroyed once it is scanned into imaging software, so long as the image is maintained securely, is readily accessible and is of sufficient quality for interpretation by a pharmacist. Pharmacist generated prescriptions subsequent to a phone call or verbal order can also be maintained in electronic format once the paper on which the pharmacist records the information is scanned into imaging software. Because of federal regulations, paper copies of prescriptions for controlled substances may not be destroyed and should be retained. The Board also wishes to note that this answer relates only to the question of compliance with state law. Specific prescription plans may have differing requirements for recordkeeping that are detailed in their contracts.

*Q. If the expiration date on a manufacturer's original container (such as the crimp of an ointment tube) is longer than the one year dating on a label, can a new label be generated with the manufacturer's expiration dating? Can a health care facility keep using the product until the manufacturer's expiration date?*

A. The statute relating to expiration date labeling is listed below:

§ 12-505. Labeling requirements for prescription medicines.

(b) Required information.- In addition to any other information required by law, the pharmacist shall include on the label:

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices, which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drugs or devices expire;
3. The appropriate expiration date for repackaged drugs or devices; or
4. A shorter period as determined by the pharmacist;

Once a manufacturer's original container has been opened and exposed to the environment, the manufacturer's expiration date is no longer valid. Manufacturer expiration dating is determined by studies of closed containers under controlled temperature, humidity and light. It is for these reasons that the above statute exists. In those cases where a conflict between the label and manufacturer's expiration date conflict, the statute is clear. The pharmacist and/or facility must abide by the shorter date.

# DISCIPLINARY ACTIONS

*Submitted by Chandra Mouli, Pharmacist Compliance Officer*

Cardinal Health, Pharmacy Permit # PW 0080/D01333
(2003 Greenspring Road, Timonium, Maryland 21093)
Permit to operate pharmacy and distribution center in Maryland was summarily suspended on January 11, 2005.

Priscilla Bisong, License # 12654
License to practice pharmacy in Maryland was suspended and immediately stayed and the license was placed on probation on February 16, 2005.

Jim Su Pak, License # 12280
License to practice pharmacy in Maryland was summarily suspended.

# LEGIBILITY OF PRESCRIPTIONS WORKGROUP

*Submitted By: Jeanne Furman, Secretary to the Board*

During the 2004 Maryland Legislative Session, the General Assembly passed House Bill 433, requiring the Secretary of Health and Mental Hygiene, in conjunction with the Maryland Health Care Commission and the Boards of Pharmacy and Physicians, to convene a workgroup to study the issue of prescription legibility and to make recommendations for any statutory or regulatory changes that would improve prescription legibility to enhance patient safety. The workgroup has representation and input from various stakeholders including pharmacists, physicians, dentists, nurses, hospitals, long term care and local health departments.

The workgroup has met several times and has submitted a requested interim report to the legislature of the group's progress to date, along with the issues that will need more consideration and study. The workgroup will continue to meet throughout the legislative session and submit a final report by August 15th, 2005.

The workgroup has discussed possible recommended changes to the required content and format of handwritten and verbal prescriptions, and means to inform and educate prescribers and pharmacists of any changes along with mechanisms that would aid in compliance with any statutory or regulatory changes. The group will continue to discuss these issues, but will spend the majority of the remaining meetings exploring the use and cost of electronic prescribing/computerized physician order entry, and the feasibility of eliminating handwritten prescriptions after a specified date.

For more information on the Legibility of Prescriptions Workgroup, please contact Christina Harvin at 410-764-4756 or cmharvin@dhmh.state.md.us. ■.

# HOSPITAL INSPECTION WORKGROUP

*Submitted By: Jeanne Furman, Secretary to the Board*

In 2002, the Board voted to update the current Inspection Forms used by the Division of Drug Control (DDC) in performing the requisite annual inspections. The outpatient/community Pharmacy Inspection format has been updated and should be implemented very soon.

A peer-review committee of experts, along with Board member Jeanne Furman, will be reviewing and making recommendations for revising the format and updating the Hospital Pharmacy Inspection form. The group will also develop criteria for compliance on some of the newer regulations dealing with automation, patient safety and quality assurance, and support personnel.

Once the group makes its recommendations to the Board, representatives from the Board and DDC will meet to revise the format for inspections, update the inspection form, and set a timetable for implementation. ■

# FLOWER MART 2005 -

*"Spring in Baltimore is Pinking Up All Over"*

Mark your calendars for May 18, 2005 to join the Board of Pharmacy and the Maryland Pharmacy Coalition at the Annual Flower Mart at the Historic Mt. Vernon Square in Baltimore.

The Board of Pharmacy and the Maryland Pharmacy Coalition [which consists of Maryland Pharmacists Association (MPhA), Maryland Society of Health System Pharmacists (MSHP), Maryland Chapter of the American Society of Consultant Pharmacists (MD-ASCP) and Maryland Pharmaceutical Society (MPhS)], will jointly participate in the Baltimore's 88th Annual Spring Flower Mart on Wednesday, May 18, 2005 (rain day May 19) at the Washington Monument in Mount Vernon Square.

We are soliciting pharmacists and pharmacy students to volunteer for one to two hours between 11:00 a.m. and 5:00 p.m. to educate, answer consumer questions concerning medications and to distribute health related educational materials. The Board's very own John Balch/Pharma-Care, will donate a beautiful wreath to be raffled to those who receive blood pressure/diabetes screenings. Our award-winning booth continues to be one of the most popular in the Health-Village section of the Flower Mart.

If you would like to volunteer to assist in one of our booths located in the Health Village please contact one of the pharmacy associations listed above or sign up with the Maryland Board of Pharmacy, Patricia Gaither, 410-764-5924, pgaither@dhmh.state.md.us.

# Maryland Board of Pharmacy

Board Members
*Front row left to right:*
Ramona McCarthy Hawkins
Melvin Rubin, *President*
Jeanne Furman, *Secretary*
Dr. Raymond Love, *Treasurer*
Margie Bonnett; Mark Levi

*Back row left to right:*
Mayer Handelman, Donald Yee, Joseph DeMino
John Balch, Christiaan Blake, Donald Taylor

Board Counsel (*not in photograph*)
Linda Bethman

## LET US KNOW HOW WE ARE DOING…

Please email your questions, concerns or comments to the Board at the following emails. We value your feedback.
General: LaVerne Naesea at: lnaesea@dhmh.state.md.us
Licensing: Shirley Costley at: scostley@dhmh.state.md.us
Compliance: Chandra Mouli at: cmouli@dhmh.state.md.us
Personnel: Patricia Gaither at: pgaither@dhmh.state.md.us
Legislation/Regulations: Christina Harvin at: cmharvin@dhmh.state.md.us
Website: Tamarra Banks at: tbanks@dhmh.state.md.us

## 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.

## SPECIAL NOTICE

The Maryland Board of Pharmacy Newsletter is considered an official method of notification to pharmacists and pharmacies.

## CORRECTION

We apologize for the error made in Cynthia Anderson's credentials in our January 2005 edition under the article "Board Assigns USP Chapter 797 Task Force". Ms. Anderson's credentials as a participant on the 797 Task force were listed as "MD, RPh," but in fact, she is a pharmacist with a Master's of Science (MS) degree in Health Care Administration (Not an MD).

## Meetings

The public session of 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 PUBLIC MEETING DATES:

*(All meetings begin at 9:00 a.m.)*

Wednesday, January 19, 2005

Wednesday, February 16, 2005

Wednesday, March 16, 2005

Wednesday, April 20, 2005

Thursday, May 19, 2005*

Wednesday, June 15, 2005

Wednesday, July 20, 2005

* This meeting date was originally changed to May 17, 2005. It has been rescheduled to Thursday, May 19, 2005. Be sure to update your calendar. The MBOP will participate in the Annual Flower Mart Wednesday, May 18, 2005.

Maryland Board of Pharmacy

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