

maryland Board of Pharmacy

PHARMACISTS ONLINE RENEWAL

Pharmacists licensed in Maryland may renew their current, active pharmacist license online. Online license renewal is quick, and licenses generally get printed within 2 business days of completing the online renewal process using your credit card. Please read the online renewal instructions on our web site www.mdbop.org before you begin.

Remember, you may renew your active license online up to 60 days prior to its expiration. However, effective August 2004, if your pharmacist license is due to expire and you wish to use the Online Renewal System, you must do so more than 5 days prior to the end of the expira-

tion month. **The online system will not be accessible the last five (5) days of the expiration month.** If you wish to renew your license within 5 days of the expiration date you must send a paper renewal application to the Board, post marked before your license expires. Paper renewal applications may also be obtained from the Board's web site www.mdbop.org.

IMPORTANT: Unless the Board receives your renewal application at least 14 days before our current license expires, you will not be able to practice pharmacy in Maryland after your license expires until you physically receive your new license. ■

PHARMACY AND PHARMACEUTICAL DISTRIBUTOR ONLINE RENEWAL

What's new this year? Online renewal system is open to all pharmacies and distributors

The Online Renewal System for Pharmacies will be available October 15 thru December 26, 2004. Pharmacy Permit Holders should renew before December 1 to avoid the late fee.

The Online Renewal System for Distributor permit holders licensed by the Maryland Board of Pharmacy will be available October 15 thru December 26, 2004.

Those establishments who used the online system last year – remember, you will not need to re-type ownership information. You will, however, need to update your pharmacist information (i.e. license expiration dates, and new pharmacists).

The online system will not be accessible the last five (5) days of the expiration month. ■

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

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Board of Pharmacy Bio-terrorism and Emergency Preparedness

Visit the Board's web site at www.mdbop.org and on the home page under the heading of Bio-terrorism and Emergency Information click on Volunteer Newsletter. To become a volunteer of the "Maryland Pharmacists Volunteer Corps (MPVC)" visit the Board's web site and download the form and Fax 410-358-6207 or mail attention Joan Lawrence, Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215. Questions email: rxemergency@dhmh.state.md.us

Let Us Know How We Are Doing

Please e-mail your questions, concerns or comments to us at e-mail: jlawrence@dhmh.state.md.us. We value your feedback.

Address of Employment Change

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

PRESIDENT'S MESSAGE

An Oriole batter who gets on base or moves up runners 40 times out of every 100 has had a good year. A Raven quarterback who completes 60 out of every 100 passes may help the team wind up in the Super Bowl.

A pharmacist who fills 99 out of every 100 prescriptions accurately puts the health of one person, and the pharmacist's own license, in jeopardy.

Some of you reading this might be thinking that 'no one can be expected to be perfect.' Perhaps not, but let's put pharmacists in the same category as surgeons, airplane pilots or the crew responsible for getting a manned rocket off the ground. 'To err might be human' but the results might be tragic.

The Board has worked hard to try to develop ways to help pharmacists to become 'more perfect.' When a consumer reports a medication error and the Board sends a letter to the pharmacist to ask the pharmacist about it, the Board includes an Error Data Collection Form (EDCF). One purpose of the EDCF is to facilitate the pharmacist's review of how the error occurred so that corrective measures can be put in place to minimize the potential of the same type of error occurring again. Another reason for com-

pletion of the EDCF is to help the Board with its investigation into the consumer complaint.

The EDCF is used by the Board as an investigative tool. The Board's investigative records are confidential and cannot be used in any civil action. The same protection is offered to the quality assurance programs which the Board requires each pharmacy to have. The rationale is that when you record all errors and review them periodically, you are better able to identify your weaknesses and make appropriate system changes.

After reviewing complaints received from consumers at the Board it became obvious that the message in the cover article of July's Newsletter bears repeating. If, despite the pharmacist or other personnel's best efforts an error occurs the Board expects the consumer to be treated in an appropriate manner — with immediate, polite, and efficient attention. It may not be in the best interest of the patient's health nor is it professional practice to hide the error. Contact the physician if there is any possibility of harm, or just to assure the patient if the patient expresses concern.

COMAR 10.34.26, Patient Safety Improvement is another regulation that the Board established with the idea in mind of giving

pharmacists tools to work with to prevent errors and to allow them to practice their profession more accurately and efficiently. The on-going quality assurance program allows pharmacists to view in a context the possible errors and near-errors that happened over a period of time and for them to make adjustments in systems, resource allocations and work habits that will make better practitioners of the entire staff.

A word to the wise—many, perhaps the majority, of the complaints relate more to the way the patient was treated than to the error. Don't allow support personnel to tell patients that the pharmacist is too busy to talk to them later. Don't allow the patient who is reporting an error to be told they will have to wait until the prescriptions ahead of them are filled. Don't tell the patient they must have mixed up their pills, at least until you are sure that is what happened.

Pharmacy has always had one of the highest ratings of consumer satisfaction. Make sure the patients who come to you feel the same way. ■

LEGISLATION UPDATES

The Legislation and Regulations Unit has continued to effectively evaluate and review legislation that may significantly impact Maryland consumers and the Board. The division continues to partner with other Boards and Stakeholders to coordinate the passage of bills and regulatory initiatives that promote quality health care in the pharmacy profession. Bills that affect the practice of pharmacy include the following:

1. Senate Bill 389/House Bill 384 - Maryland Pharmacy Act –Practice of Pharmacy – Administration of Medication

Upon the final development and adoption of regulations by the Boards of Pharmacy, Physicians and Nursing, a pharmacist will have the ability to administer influenza vaccinations to patients. Regulations will establish reasonable fees for the administration of the vaccination but not for the actual product.

For more details, 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."

2. House Bill 433 – Prescription Drug Safety Act

The Prescription Drug Safety Act was passed during the 2004 Maryland Legislative Session. The original bill required changes in prescriptions written by health care practitioners in order to reduce the occurrence of medication errors. The Department of Health and Mental Hygiene has convened a workgroup to study the practicality of eliminating hand-written prescriptions.

The Board of Pharmacy has appointed Board member, Jeanne Furman, P.D., to co-chair the workgroup with a Board of Physicians' representative. The workgroup is addressing various issues and making recommendations that will improve public health, including:

1. Changes in content or format of prescriptions including adding the indications to prescriptions;
2. The best means to inform and educate prescribers of any changes that are enacted;
3. The appropriate time frame for implementation;
4. Mechanisms for enforcement;
5. The overall impact of any changes made;
6. The use, cost, and feasibility of eliminating handwritten prescriptions after a specified date.

The workgroup will include stakeholder input from prescribers, dispensers, those who administer medication and health care facilities that could be impacted. Both Boards are required to report their findings to the Senate Education, Health and Environmental Affairs Committee and the House Health and Governmental Affairs Committee.

3. House Bill 998 – Board of Pharmacy – Registration of Pharmacy Technicians

In order to protect the health of the public, House Bill 998 would have allowed the Board to register pharmacy technicians and individuals participating in technician training programs. The Chairman of the Health and Government Operations Committee referred the bill to the Board of Pharmacy for summer study. The Board subsequently formed a Pharmacy Technician Work Group to address the following issues: minimum age of registered pharmacy technicians, educational and examination requirements of technicians and pharmacy students, "grandfathering" of current technicians, acts that a pharmacy technician cannot perform and the role of the supervising pharmacist. The Board decided to remove other provisions from the bill that dealt with non-technician related issues. The Work Group is completing its work and a revised bill will be submitted during the 2005 legislative session allowing the Board the authority to register pharmacy technicians.

REGULATIONS

COMAR 10.34.29 Drug Therapy Management

The Boards of Pharmacy and Physicians are jointly implementing this chapter of regulations to allow pharmacists to manage patients' drug therapy, pursuant to a Drug Therapy Management contract and approval of the protocol(s) by a joint committee representing both Boards. The joint Board of Pharmacy-Board of Physicians Committee has established procedures and forms for submission of protocols, physician-pharmacist agreements and pharmacist credentials. Those interested in submitting Drug Therapy Management Agreements should contact the Board. For more information, please visit the Board of Pharmacy web site at www.mdbop.org and click the Legislation, Policy and Regulations link.

DISCIPLINARY ACTIONS

Howard Blumenfeld (License 08557)

License to practice pharmacy is reinstated, placed on probation effective April 15, 2004

Robert Bruce Sando (License 08615)

License to practice pharmacy is placed on probation effective September 2, 2004

John David Hoelscher (License 11115)

Probation is terminated; license to practice pharmacy is unencumbered effective September 2, 2004

Jeffery Lee Rodkey (License 10073)

Revocation of pharmacy license effective September 15, 2004

Carol Miller (License 10152)

A Consent Order of Reinstatement was issued September 21, 2004 to remove her license from suspended status and place her on indefinite probation after specified requirements are met.

FAST BYTES

New DEA Number

The Drug Enforcement Administration has new contact numbers. Tel. 1-877-330-6670 for registration, Fax. 410-962-0142 and www.deadiversion.usdoj.gov is the web site. Their address in Baltimore is Drug Enforcement Administration, Baltimore District Office, 200 St. Paul Place, Suite 2222, Baltimore, Maryland 21202, Attn: Diversion.

Can You Alter a CII Prescription?

According to a DEA policy statement issued December 7, 1999, the pharmacist is NOT allowed to make any changes on a prescription for a Schedule II substance to:

- The patient's name, the prescriber's signature, or the name of the controlled substance prescribed (except for generic substitution where allowed by the State).

To make any of the above changes, a new written prescription would be needed: Most other items on the prescription may be changed provided that the prescriber has authorized the alteration. This would include:

- The drug strength, drug quantity, directions for use and patient address.

Prescription vs. Prescription Order

There has been some confusion in the handling of prescription refills at pharmacies serving assisted living homes. Skilled care homes have orders signed monthly by a prescriber who has in effect authorized that medication for another month. The Board recognizes that these are prescription orders and can be filled until discontinued as long as the process is repeated. Most assisted living homes do not utilize this system, making it necessary for the pharmacist to contact the physician for refill authorizations beyond that given at the time of original prescribing. In these situations, you are filling a prescription, not a prescription order as in the example above. This holds for prescriptions that are sent to the homes on request and also when the pharmacy sends a months supply of each medication once a month. There have been instances when a pharmacy treats a prescription like a prescription

order and continually sends the medication without authorization only to find that the prescriber did not intend to have the patient to continue the medication indefinitely.

Pharmacists & Over-The-Counter (OTC) Sales

A recent complaint to the Board focused on the responsibility that a pharmacist has when a non-prescription product is recommended. With the help of the alerts on your computer and the auxiliary labels that newer systems print with the prescription label, pharmacists are usually reminded of the information that must be conveyed to the patient to be sure that the medication is appropriate and correctly utilized. However, when a pharmacist offers advice on an OTC, they have to keep in mind that the patient has asked a health care professional for advice and the pharmacist has the responsibility to offer that advice appropriately. Since non-prescription drugs can change ingredients and retain the same brand name, you are advised to read the ingredients when

offering advice on an OTC product, and then review precautions and limitations for using the product with the patient.

Electronic Signatures

Board of Pharmacy regulations allow for prescriber signatures to be sent electronically if they possess **ONE** of the four elements listed in COMAR 10.34.20 Format of Prescription Transmission:

- The signature of the prescriber
- An alternative method of communication acceptable for commerce which indicates that the prescriber personally originated or approved the prescription
- Audio or visual interaction with the prescriber or agent
- The prescription being processed by a commercial intermediary, which guarantees security of the transmission.

For the complete wording, read the regulation. Currently DEA will not allow Schedule II prescriptions to be filled without an original signature, with a few exceptions, such as for long-term care facility or hospice patients. ■

Board Member Transition

Rev. William E. Johnson Sr, a consumer member for 8 years, passed away June 23, 2004. Rev Johnson, whose term would have expired June 30 of this year, was Pastor of the Union Baptist Church of Turners Station, worked with Bayview Medical Center, served on the Boards of Constant Care Community Center, the YMCA, and

Dundalk Community College and traveled to the Middle East with the Mercy Corps to help facilitate discussions about the plight of the Palestinian people. Rev. William E. Johnson will be missed!

Ms. Margie Anne Bonnett, Vice President of Sandler Training Institute is the new Consumer Board member, appointed by Robert L. Ehrlich, Jr., Governor.

FROM THE PROCEEDINGS OF THE BOARD OF PHARMACY PRACTICE COMMITTEE

Peer Review Committees Formed

The Board periodically appoints peer review committees to assist it with reviewing technical issues. In turn, these committees report to standing committees of the Board. Most recently, the Board has appointed two committees to advise the Practice Committee. Input regarding the activities of these committees can be addressed to the Practice Committee.

The Institutional Pharmacy Inspection Form Committee has been charged by the Board with reviewing forms used by the Division of Drug Control in its inspections of institutional pharmacies. The Board expects this committee to recommend that irrelevant or duplicative parts of the inspections form be omitted, that other areas be modified and perhaps that additional items be added. In addition, the

Board is seeking input on whether some parts of the inspection should be conducted via a pre-inspection survey form (to get basic information on employees, registrations, policies and procedures, etc.) in order to streamline and/or focus the actual on-site inspection process.

The Chapter 797 Committee has been charged with reviewing the recently released US

Pharmacopeia chapter on Sterile Compounding. The Board expects this committee to assess the potential impact of this chapter and provide input as to what position the Board should take regarding USP Chapter 797. Options might include adopting all or part of the standards, adopting modified standards, adopting interpreted standards or adopting certain standards with time-lines. ■

SUBSTANCE ABUSE

Pharmacists — Do you know a colleague who is abusing alcohol or drugs, or who suffers from other issues that impair his/her ability to practice?

Employers/supervisors; Have you been faced with the dilemma of having to terminate an employee for substance abuse or drug diversion?

What can you do?

What SHOULD you do?

The Board of Pharmacy supports a Pharmacist Rehabilitation Committee as defined in H.O., §12-317. The Pharmacists Rehabilitation Committee was established to evaluate and provide assistance to any pharmacist in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependency, or other physical, emotional or mental condition. The Board currently contracts with the Pharmacists Education and Assistance Committee (PEAC) to perform these functions.

Pharmacists are required by the Board's Code of Conduct regulations (10.34.10.05) to report conduct of a pharmacist that involves drug or alcohol abuse/dependency to the Pharmacist Rehabilitation Committee. Pharmacists are not required to also notify the Board. Once the Committee receives and verifies a report, it will contact the impaired pharmacist to arrange a meeting and discuss allegations. The Committee does not disclose the identities of the person/persons making the reports and those reporting are protected from liability when acting in good faith under H.O., §12-317(d).

In addition, the records maintained by the Committee on these referrals and are not disclosed to the Board unless the pharmacist consents to their disclosure. (Note: If the pharmacist is Board-referred, treatment information may be disclosed to the Board without the pharmacist's consent.)

The Board and Pharmacist Rehabilitation Committee rely on all pharmacists in the profession to support their efforts to protect Maryland patients by properly referring a pharmacist with substance abuse problems. To make a referral, contact PEAC @ 410-706-7513 or visit www.peacmaryland.org. ■

Frequently Asked Questions

In day-to-day pharmacy practice, unusual situations sometimes 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 any questions you would like to see answered in this column, please fax your question to 410-358-6207 or email Joan Lawrence at jlawrence@dhmh.state.md.us.

Q. Can the pharmacy owner be in a pharmacy when it is closed if that person is not a pharmacist?

A. The Pharmacy Security regulations, COMAR 10.34.05, covers this issue. No one is permitted in the prescription area unless a pharmacist is immediately available on the premises. The prescription area is defined as the portion of an establishment for which a pharmacy permit has been issued, which contains: patient records, prescription devices, and prescription drugs. Because of security issues, the Board will allow persons to be present in other areas of the establishment in the absence of a pharmacist ONLY when the prescription area can be secured. This includes the non-pharmacist permit holder. Permit holders who allow non-pharmacists including themselves to enter an establishment with an unsecured prescription area when no pharmacist is present risk disciplinary action.

Q. Can a person who has passed the Pharmacy Technician Certification Board (PTCB) examination take oral prescription orders from a prescriber?

A. The Standards of Practice for Unlicensed Personnel regulations COMAR 10.34.21, governs this area. An unlicensed person who the pharmacist deems has had adequate training and can perform the task competently may receive authorizations for a refill of a prescription other than controlled substances provided the prescriber does not modify the order. No unlicensed person may accept a new order from a prescriber. At this time Maryland does not require certification from PTCB or other sources, relying on the permit holder and pharmacist on duty to assure that the unlicensed person is capable of handling the tasks, which are allowed under the regulation. ■

Questions for the Practice Committee

Q. Can prescription records be reduced to an electronic medium and maintained in that fashion?

A. The Maryland Pharmacy Act requires that permit holders shall make and keep on file for at least 5 years a record of each prescription prepared and dispensed in the pharmacy. At its August 2004 meeting the Board interpreted this to mean that prescriptions can be maintained in an electronic format in most circumstances. The major exception would be orders for DEA Schedule II substances. These must still be maintained in their original hard copy format. The Board is aware that some benefit managers and payers may require hard copies of prescriptions to be maintained. This is a business issue governed by the contractual relationship between the pharmacy permit holder and the payer and is not governed by the Board.

Q. Are there special requirements for “drive thru” pharmacy pick-up establishments?

A. The Board has no special requirements for “drive thru” windows. However, the Board cautions that pharmacists and permit holders must adhere to all of the statutes and regulations regarding security, storage, confidentiality, counseling, etc. when operating “drive-thru” windows.

Q. Are hospital emergency departments required to label medications being dispensed for patients as they are discharged from the emergency room?

A. The Health Occupations Article, section 12-505 indicates that prescribers must label medications with the patient’s name, the date, an expiration date, and storage and special handling instructions unless the drug is dispensed as a sample, for an inpatient or in an emergency situation. Discharge of a patient from an emergency setting does not constitute an emergency. Therefore, hospital emergency departments must label medications appropriately for patients being discharged. ■

PHARMACY INSPECTION

The Board of Pharmacy is updating the form that the Division of Drug Control will be using on routine annual inspections of community pharmacies to include reporting of compliance with a number of new regulations.

Pharmacies will be receiving a 'pre-inspection form' prior to the visit to guide them to have answers and material readily available on the day of the inspection. This process should provide for a more meaningful review of compliance with laws and require a shorter time period than previous inspection. The most time-consuming delays in the inspection process occur when the pharmacist on duty is not able to locate required documentation.

Completion or retention of a completed form is voluntary and it is **not** to be sent to the Board. The form is both an educational tool and an expedient in the inspection process. Items, which have been added to the new inspection form, include compliance with the documentation required for regulations related to:

COMAR 10.34.03 Long Term Care Facilities

- Policy and Procedure Manual
- Repackaging records if repackaging is done

COMAR 10.34.04 Transfer and Outsourcing

- Documentation by primary pharmacy
- Documentation by secondary pharmacy

COMAR 10.34.16 Portable drug kits for home health agencies

- Documentation kept when providing portable drug kits

COMAR 10.34.21 Unlicensed pharmacy personnel:

- Policy & Procedures manual
- Training Manual
- Documentation of Training

COMAR 10.34.25 Delivery of Prescriptions

- Delivery log

COMAR 10.34.26 Patient Safety Regulations

- Quality Assurance programs for staff education
- Quality Assurance programs for error prevention

COMAR 10.34.28 Automation

- System Failure reports
- Performance audits
- QA programs
- Level of Access Documentation
- Training records

HIPAA requirements such as naming Privacy and Security Officers (45CFR142.30, 164.530)

If one or more type of record is kept off-site the inspector will note that and the pharmacist will be asked to acknowledge by signing the inspection form. Chains and other pharmacies that do keep records off-site are asked to let pharmacists on duty know where the information is kept. The Board, however, reserves the right to physically review these records.

The above are only the highlights of some regulations that require pharmacy documentation and are provided as a guideline. It is not a complete list. Pharmacies that do not participate in practices such as outsourcing, long term care, delivery or automation will have n/a notations on the inspection.

If you have any questions, please contact the Board of Pharmacy or the Division of Drug Control. ■

THE NEW AMERICAN PHARMACISTS MONTH

The Maryland Pharmacy Coalition (MPC), composed of MD-ASCP, MPhA, MSHP, MPhS, and now the Student Government Association at the University of Maryland School of Pharmacy, will be promoting the new American Pharmacists Month throughout October. The coalition members are jointly sponsoring a banner reading "Know Your Medicine, Know Your Pharmacist" to be hung in Baltimore at Pratt Street and Greene Street in early October, and at Pratt Street and Light Street later in the month. Two examples of national organizations' web sites which provide excellent resources for promoting the profession and the roles of pharmacists in helping patients to make the best use of their medications include: <http://www.aphanet.org> and <http://www.ashp.org/pr/>. Each pharmacist is encouraged to feature a pharmacy service, a health event, and/or a media interview in October, and to report the activity to his/her affiliated organization. Ideas can be shared for future planning. Maryland pharmacists have been very visible this year in promoting access to medications, while assuring the safety of the drug supply and coordinated care, as the Montgomery County Council has considered prescription drug importation. The MPC expects that our joint efforts in October will yield positive results for Legislative Day, February 17, in Annapolis. Questions, contact Cynthia J. Boyle, Pharm.D. MPC Chairperson at 410-706-1495.

Maryland Board of Pharmacy



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Not in photograph
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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; Jeanne Furman, Board Editor; Ramona McCarthy Hawkins, Assistant Board Editor

Meetings

The Pharmacy Board meetings are held the 2nd Wednesday of each month, and 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.

MEETING DATES

2004

November 17
December 15

2005

January 19
February 16
March 16
April 20
May 18
June 15
July 20
August 17
September 21
October 19
November 16
December 21

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

Editorial Committee:

Joan M. Lawrence, *Editor*
Jeanne Furman, *Board Member*
Ramona McCarthy Hawkins,
Board Member
LaVerne Naesea, *Executive Director*
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