

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

Online License Renewal for Pharmacist

In November 2003, the Board successfully tested and launched an online license renewal system for pharmacists. The Board of Pharmacy licenses 7,200 pharmacists. The system, created by David Mitchell, Programmer/Analyst for the Maryland Health Care Commission (MHCC) will allow pharmacists to renew their license online prior to the license expiration date. MHCC Deputy Director of Data Systems and Analysis, Ben Steffen, began developing the process two years ago in an effort to reduce data entry costs for MHCC processing Board of Physicians data. At no additional cost to the Board of Pharmacy or its licensees, the system is now available to all renewing Maryland pharmacists.

Pharmacists renew their licenses every two years, by the end of their month of birth. Initially, notification was only mailed to 100 pharmacists renewing in November 2003, giving the Board Licensing and Information Services Staff an opportunity to ensure that it was operating properly. Vladimir Konstantinov, Board of Pharmacy Database Specialist, working with Sandra Jones, Information Resources Management Administration (IRMA) for the Department of Health and



L. Naesea presents Ben Steffen and David Mitchell with Certificate of Appreciation from the Board of Pharmacy

Mental Hygiene (DHMH) created additional internal processes to help ensure that renewal information is updated in 1-2 days after the pharmacist completes the renewal online.

The Online Renewal system currently accepts Visa and Master Card payments online. Board Fiscal Officer, Shirley Costley worked with Karen Johnson, Senior Business Analyst at Bank of America's Electronic Payment Services division to implement the credit card payments. Pharmacists also have the option of mailing in their payment by check; however, the license will not be issued until payment is received by the Board. The Board hopes to accept electronic checks soon.

The system may not be used to obtain a new Maryland pharmacist license. Newly licensed pharmacists will be able to use the system when it is time for them to renew. The system will only allow pharmacists to renew 60 days prior to their renewal expiration date. A paper renewal application, along with online instructions, will be mailed to all pharmacists eligible for renewal. For more information, visit the Board's web site at www.mdbop.org, and click on Renew Online, or contact Tamarra Banks, Information Services Manager, at (410)764-4701.

President's Address

Dear Colleagues,



Stanton G. Ades, President

"I am proud that I had an opportunity to work and lead a most energetic and thought-provoking Board, that performed outstandingly despite a year fraught with budget cuts and staff deficits."

Happy New Year to each of you! On the occasion of the New Year, I wanted to summarize a few of the many accomplishments by Board committees and staff units in 2003. The Board bid farewell to consumer member Barbara Faltz-Jackson and at-large pharmacist member/Board Secretary, Irving Lottier, and welcomed three new Board members, appointed by Governor Ehrlich: Joseph DeMino, representing chain pharmacy, Christiaan Blake, representing consumers and Mark Levi, appointed as the at-large member.

The Public Information Unit continued emergency preparedness efforts, with over 500 volunteers receiving Phase I training and pharmacist liaisons and local health department representatives participating in an initial training session.

The Long Term Care Task Force has remained committed to reviewing and refining related regulations. The Information and Technology Unit successfully implemented the online renewal system for establishments (pharmacies and distributors), and the online renewal system for pharmacists was also enabled in November 2003. The Maryland Health Care Commission worked with the Board's staff at no charge to design the system. Estimates for similar systems ranged from \$70,000 to well over

\$100,000, which should make the \$34.00 fee paid to MHCC a bit more palatable, in addition to the bi-annual pharmacist license fee.

The Practice and Licensing committees worked on several regulations during 2003, including:

10.34.02 Examination for Licensure and Professional Experience Programs, which repealed the requirement for pharmacy school graduates and reinstating pharmacists to pass the Maryland laboratory exam;

10.34.09 Fees, which decreased the pharmacists reciprocity fee from \$250.00 to \$120.00 to offset the cost of the Maryland Law Exam given by NABP;

10.34.13 Reinstatement of Expired Licenses for Pharmacists, which delineated Board response to various circumstances under which a pharmacist may be reinstated, and eliminated the requirement for reinstating pharmacists to pass the lab exam;

10.34.01 Formal Hearings procedures revised; and

10.34.29 Drug Therapy Management, which established regulations pursuant to the statutory language passed in 2003.

Working closely with the Compliance Unit, the Disciplinary committee streamlined the complaint process in order to ensure standardized reviews

and facilitate a systems approach to medication errors. In addition, the committee is developing guidelines for responding to persons engaged in unlicensed practice. In meeting its strategic plan objective to keep pace with the ever-changing trends in the field of pharmacy, the Licensing committee reviewed several requirements during 2003 and eliminated those that were no longer useful to meeting its mission. The requirement for new licensure candidates to mail MPJE and NAPLEX scantron applications to the Board for preliminary review is one example of an eliminated requirement.

As my tenure with the Board comes to an end in FY 2004, I am proud that I had an opportunity to work and lead a most energetic and thought-provoking Board, that performed outstandingly despite a year fraught with budget cuts and staff deficits. I conclude by thanking each Board member, Board staff, as well as all Maryland pharmacists, for making my job as president over the past eight years thoroughly satisfying. The Board I leave behind is infinitely strong, well balanced and in capable hands.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stanton G. Ades".

Stanton G. Ades, President

Pediatric Dosing Errors

The Board of Pharmacy's Disciplinary Committee continues to receive medication error complaints from consumers dealing with pediatric medications. Using the wrong concentration of oral liquids when medications are available in different formulations is a recurring problem. Some recent examples are:

A prescriber ordered Ferrous Sulfate Syrup for a small child, to be given as 5ml t.i.d. along with a notation that the dose was 54 mg of elemental Fe/day. The pharmacist dispensed Fer-In-Sol drops with instructions to give 5ml three times a day. Because the drops are much more concentrated, this would be equivalent to 250mg of elemental Fe/day—Five times the correct dose! Fortunately,

the mother questioned the dose and the prescription was corrected before it was given to the child.

A child was prescribed Decadron Liquid, 1mg/ml, with directions to give 1ml q 6h. Despite the inclusion of the concentration by the prescriber on the order, the pharmacist dispensed the oral liquid with the concentration of 0.5mg/5ml, which resulted in a dramatic under dosage. The error led to an exacerbation of the illness and a prolonged treatment time.

These are just two examples that highlight the problems in choosing the wrong concentration of an oral liquid. To help avoid errors with oral solutions, we offer the following recommendations:

- Encourage prescribers to write prescriptions in terms of total mg per dose rather than volume to be given
- Request the age and weight on pediatric prescriptions
- Recalculate dosages to catch any errors prior to dispensing
- Be aware that oral liquids often come in more than one concentration. What you currently carry in your pharmacy may not be what the prescriber intended
- Change computer descriptions so that "Pediatric" appears as part of the drug name during medication selection when entering an order and on the label
- Set weight-based dose limits on oral liquids to alert staff

when the order exceeds a safe dose.

- Once filled, place all oral liquids in a separate place or otherwise mark them, to alert the staff to call for a pharmacist when the prescription is picked up to have the directions and the instructions for accurate measuring explained to the parent or caregiver

The Board is aware that pharmacists are diligent about dispensing the correct medication to their patients. However, with increased volumes and various distractions, errors can occur. Examine your current practice to determine what you can do to prevent errors like these from happening in your pharmacy.

Three Board of Pharmacy Commissioners to be Appointed in 2004

Maryland Pharmacy Law requires that all Maryland pharmacists be notified when the terms of Board of Pharmacy members will expire to permit eligible pharmacists to seek appointments as Commissioners. The Board consists of ten pharmacists and two consumer members. In 2004, three Board members will have completed their second consecutive terms on the Board and none will be eligible for re-appointment. Seats will be open for:

Chain Pharmacist. A pharmacist who is, at the time of appointment, practicing primarily in chain store pharmacies.

Long Term Care Pharmacist. The person who is appointed to this position must, at the time of appointment, be prac-

ticing primarily in a pharmacy that provides services to a long-term care facility.

Consumer Member. This position is one of the two reserved for persons who are not pharmacists, do not have any household members in pharmacy, do not participate in the pharmacy field nor have any financial interests in pharmacy.

In order to qualify, for a pharmacist seat, a pharmacist must be a Maryland resident, a licensed Maryland pharmacist, in good standing with the Board, skilled and competent in practicing pharmacy and have at least 5 years of active pharmacy practice. Potential candidates may obtain information on the duties of a Board Commissioner and

applications for the 2004 openings by writing or calling the following associations:

Chain Seat:

NACDS
Attn: Gary Wirth
Ahold USA Pharmacy
Department
Giant Food of Maryland, Inc.
6300 Sheriff Road, Dept 518
Landover, MD 20785
(301) 341-4823

Long Term Care Seat:

MD Chapter ASCP
Attn: Anna Leonhardt
10222 Maple Glen Court
Ellicott City, MD 21042
(410) 465-7011

The Maryland Association of Chain Drug Stores and the Maryland Chapter of the American Society of Consultant Pharmacists will choose 3 pharmacists for the respective

seats and forward those names to the Secretary of Health and Mental Hygiene. He will advise the Governor, who will make the appointments.

The Consumer member is appointed by the Governor, with the advice of the Secretary and the advice and consent of the Senate.

All appointments are for a four-year term, and the appointee is eligible to be considered for a second consecutive term. Deadline for applications to be received by NACDS and MDASCP is February 15, 2004. Appointments take place after the terms of the incumbents expire on April 30, 2004. Commissioners' whose terms have expired, serve until a replacement is sworn in.

Regulations Updates

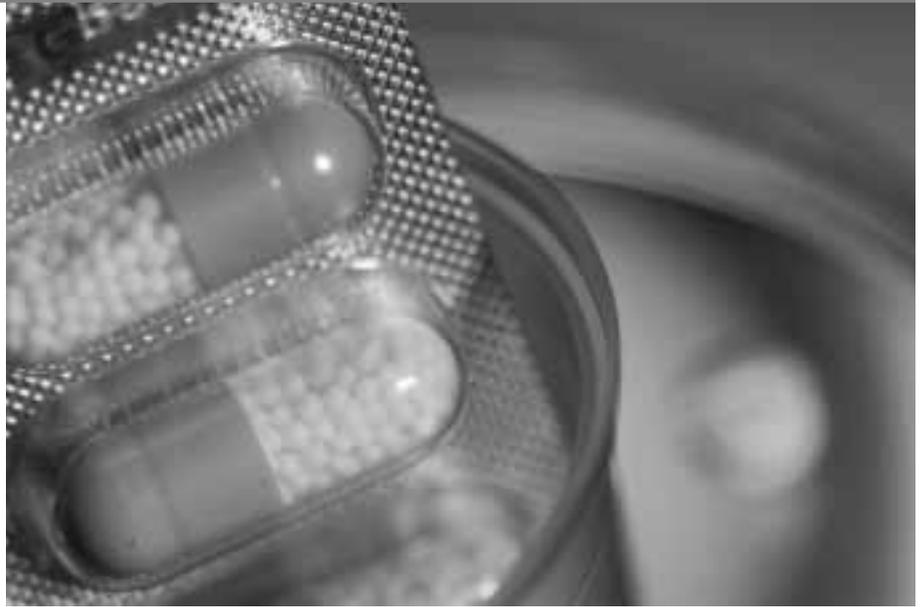
COMAR 10.34.26

Patient Safety Improvement

Patient Safety Improvement regulations went into effect on October 27, 2003, which will require pharmacy permit holders to:

1. Provide certain information to patients,
2. Provide certain annual education of pharmacy staff, and
3. Institute an ongoing quality assurance program.

The regulations are aimed at reducing medication errors. The specific requirements of the regulations can be reviewed on COMAR 10.34.26 on the Division of State Documents' website at www.dsd.state.md.us. The records of the ongoing quality assurance program are protected from discoverability in civil proceedings. Please review Health Occupations Article §1-401, Annotated Code of Maryland. This section may be reviewed on the Maryland General Assembly's website at www.mlis.state.md.us.



COMAR 10.34.30

Name Change-Pharmacy or Distribution Permit Holder

Effective November 10, 2003, a pharmacy or distributor permit holder that wants to change only the name of the pharmacy or distributor on its permit may do so for

free within 30 days of the actual name change. If there are changes beyond that of the name, the permit holder will have to file an application for a new permit. If the permit holder does not submit the request for a name change within 30 days, before or after the actual name change, a fee of \$100 will be charged.

Legislative Updates

Consumer Information

Information on Generic Drug Option

Notice of Availability of Generically Equivalent Drug and Approximate Cost Difference.

Effective October 1, 2003, if a prescription is written for a brand name drug, the pharmacist or the pharmacist's designee must inform *retail* consumers to the best of the pharmacist or pharmacist designee's knowledge:

1. Whether there is a generically equivalent drug available, and
2. If there is a generically equivalent drug available, what the approximate cost difference is between the cost of the brand name drug and the generic drug.

Exceptions

The information is only required to be given to retail consumers. The pharmacist or the person working with the pharmacist is not required to relay the availability and cost-difference information to the consumer under the following circumstances:

1. When a prescription is specifically written for a generic drug;
2. When the authorized prescriber writes that the prescription should be dispensed as written;
3. When the pharmacist works in a pharmacy that primarily serves institutional or hospitalized patients; or
4. When the prescription is reimbursed by third party payers.

Emergency Preparedness

Pharmacist LHD Liaison Training

The Board of Pharmacy conducted training for Pharmacists selected to serve as liaisons between the Board of Pharmacy and Local Health Departments (LHD) in Columbia, Maryland on November 1, 2003. The liaisons are key to the Board's ability to ensure that volunteer pharmacist and technician activities carried out during a state emergency are coordinated between the state and local health departments. Of the twenty-eight (28) "Pharmacists LHD Liaisons" recruited to date, twenty-one (21) participated in the training. Also, in attendance were representatives from the Department of Health and Mental Hygiene (DHMH), Maryland Emergency Management Agency (MEMA), Board of Pharmacy, and Local Health Departments (LHD) representatives from Baltimore City, Frederick, Montgomery, Charles, Garrett, Prince Georges, St. Mary's, Harford, Queen Anne's, Howard, Anne Arundel, Baltimore and Allegany Counties.

Stanton G. Ades, Board President and Chair of the Emergency Preparedness Committee, gave the welcome address and the training objectives. A detailed presentation on the Incident Command System (ICS) was presented by Donald M. Lumpkins, Director,

Domestic Preparedness Division, MEMA, followed by Melvin Rubin, Board Member and LaVerne Naesea, Executive Director, outlining the liaisons' roles, responsibilities and administration duties.

Following the break was a 60-minute interactive panel discussion/Q & A, facilitated by Stanton Ades. The panel consisted of Donald Lumpkins, MEMA; Gail Wowk, Emergency Management Coordinator, Office of the Deputy Secretary for Public Health Services; Percina Curtis, Director, Office of Emergency Preparedness & Response, Anne Arundel County Health Department; Bill Kelly, Strategic National Stockpile (SNS) Coordinator, Montgomery County Health Department; Barbara Rosvold, Program Supervisor, Homeland Defense, Frederick County Health Department, and Dr. Raymond Love, Board of Pharmacy Member, and Professor & Vice-Chair, Department of Pharmacy Practice & Science, University of Maryland School of Pharmacy.

The participants at the training provided very positive feedback about the half-day session. Pharmacists LHD liaisons will subsequently become involved with the planning and other activities conducted by local health departments.

Pharmacist LHD Liaisons on Alert for "Possible" Anthrax Outbreak

The Board of Pharmacy and LHD liaisons from Prince Georges and Montgomery counties were on full alert in response to the "possible" anthrax outbreak reported on November 7, 2003. The Board worked with DHMH, MEMA and the local health departments of Prince Georges and Montgomery counties to provide pharmacist volunteers at the treatment centers for dispensing of medications and counseling. Later that afternoon, all tested samples were proven to be negative for harmful products and the alert was canceled.

The Board of Pharmacy thanks the pharmacist LHD liaisons and volunteers for promptly responding in this "possible" emergency in Prince Georges and Montgomery counties. The following pharmacist LHD liaisons were on alert: Dwight Roberson, Aki Hirayama, Joe DeMino, Michael Hoopes, and Stan Smith, including volunteers Phil Cogan, Mel Lessing, Melvin Rubin, Dr. Raymond Love, Donald Yee, and Herb Kwash.

Pharmacists can play an important role in responding to state catastrophic events, especially those involving biological agents. To join the "Maryland Pharmacist Volunteer Corp" (MPVC) as a pharmacist or pharmacy technician, please visit the Board's web site at www.mdbop.org and register. For more information, contact Joan Lawrence at 410-764-4755 or email: jlawrence@dhmh.state.md.us.

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

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.



Internet Prescribing

Does it Meet the Standard of Care?

The 1999 Maryland Board of Physicians newsletter declared that an out-of-state doctor using telemedicine to diagnose and treat a patient residing in Maryland would need a Maryland license or be acting as a consultant to a Maryland licensed physician who has a bona-fide doctor/patient relationship with the patient.

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. Anyone with information about online consultation leading to prescription medications should contact Charles Cichon, Chief Compliance Analyst, Maryland Board of Physicians at 800-492-6836.

Frequently Asked Questions

In day-to-day pharmacy practice, unusual situations sometimes occur generating questions. So to help out 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.

Compliance

Q. A long-time customer came into my pharmacy around closing time with a prescription that authorized refills of the beta-blocker anti-hypertensive medication that he had been taking as a maintenance drug for years. He was in a hurry and it was one of our REALLY busy times of the day. He told me that he only needed a few days supply for now and he could come back at a later time for the rest of the prescription. He has been responsible with his medication regime in the past and appears to be knowledgeable about his drug therapy. Because of the back up at the computer station, I put a few tablets in a vial, placed the prescription in the "to be filled" box and made a mental note that I had given him a 5 day supply. He thanked me for being so helpful when I handed him his medication. But, after thinking more about it, I am worried that I should not have given him medication in an unlabeled container. Has the Board ever addressed this issue or does the Board ever find out about this practice?

A. Interesting that you should ask, and the answer is, YES, the Board does find out about this practice. Unfortunately, the Board finds out when complaints are made regarding wrong medications being dispensed in unlabeled vials. Every pharmacist knows that unlabeled medications, whether they are on a pharmacy shelf or in the customer's possession, are considered misbranded according to Maryland Law (Health General 21-217). Labeling requirements for prescription drugs are listed in Health General 21-221 and in Health Occupations 12-505. Anytime that the usual and customary procedure for filling a prescription is not followed, a system error

is much more likely to occur. The labeling of a prescription is not only required by law, but is an integral part of the compounding and dispensing process that contributes to the total system that assures patient safety. What appears at the time to be facilitating and helpful to the customer may only be compounding the problem.

Q. Sometimes a prescription is written on a blank that has two lines for the prescriber's signature with the initials DAW (Dispense as Written) under one of the lines for the prescriber's signature. Do I take that to mean that when the prescriber signs her/his name on that line, then the prescription is to be filled as written with no substitution of the generic equivalent?

A. The Law as stated in Health Occupations 12-504 allows the pharmacist to substitute a generally equivalent drug for a brand name if "the authorized prescriber does not state expressly that the prescription is to be dispensed only as directed." Signing a name on the line above a printed "DAW" direction may be interpreted to mean that the prescriber is stating that the prescription is to be "dispensed as written." Depending upon the reimbursement source(i.e. MEDICAID) the prescription may require the prescriber to write in his/her handwriting that the "brand is medically necessary" and may also require the medical condition to be stated.

In case of doubt, it is always recommended that the pharmacist contact the prescriber to clarify the DAW directive. Communication and familiarity among the patient, prescriber, and pharmacist are important to assure that the indicated medication is dispensed.

Questions for the Practice Committee

Will the Board of Pharmacy endorse my product or process, or make a statement that it meets the Board's standards? Can I come and show my new product or system to the Practice Committee?

A. The Board of Pharmacy Practice

Committee receives frequent requests to endorse products, systems or services. Neither the Committee nor the Board have the time to accommodate all of these requests or receive presentations. The Practice Committee and Board of Pharmacy have developed the following statement regarding this type of request:

“THE BOARD AND ITS COMMITTEES WILL NOT ENDORSE ACTIVITIES, PRODUCTS, SYSTEMS OR SERVICES. Entities are welcome to share information with the Board regarding its activities, products, systems and/or services. However, receipt of the information by the Board does not represent the Board's approval or endorsement of the product, system

or service. If a stakeholder has a specific question relating to a pharmacy or licensing issue, please forward the specific question, along with contact information, to the Executive Director.”

We are a pharmacy associated with an office-based dispensing prescriber. Can a pharmacist review the prescription orders of the dispensing, prescriber for appropriateness, interactions, allergies, duplications, et cetera as a service to the dispensing prescriber?

A. The Practice Committee does not endorse specific systems relating to prescriber dispensing as the Board does not have jurisdiction over prescriber dispensing. However, the Committee felt that pharmacist review of a medication regimen was well within the scope of pharmacy practice.

A specialty pharmacy dispenses a high-cost, limited availability agent in an

FDA approved, program, that requires manufacturer approval of the prescription and patient. Can we have the physician send the prescription to the manufacturer and have the manufacturer send us the prescription?

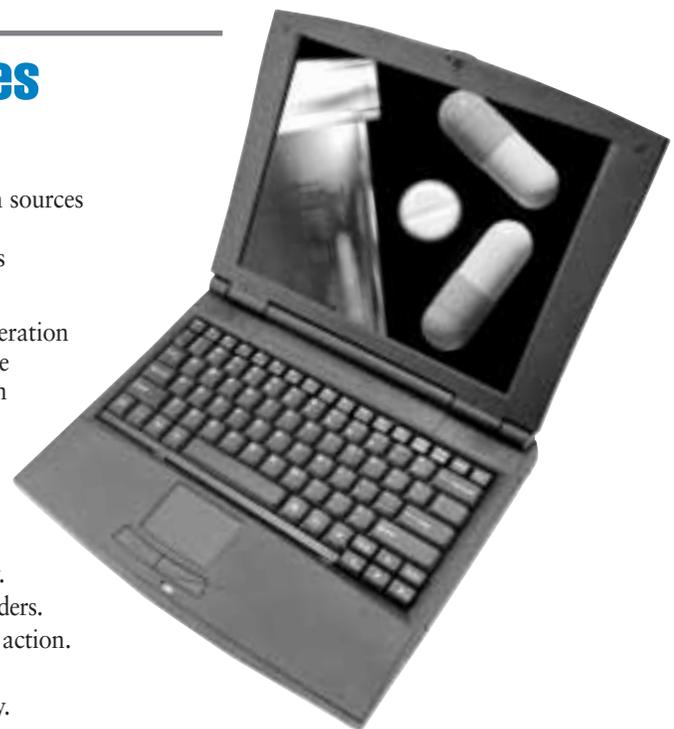
A. The Committee is concerned that the integrity of the prescription becomes suspect when it does not arrive directly from the prescriber or patient. For instance, the manufacturer might alter the prescription to meet its guidelines without informing the prescriber. Since the manufacturer is not an agent of the prescriber or the patient, this would not be proper. Instead, the physician should forward prescriptions to both the pharmacy and manufacturer. Once the approval is received from the manufacturer, the specialty pharmacy could fill from the prescription received directly from the physician.

International and Internet Drug Sales

THE BOARD IS COMMITTED TO PROTECTING the health, safety, and welfare of Marylanders. Although the cost of some medications and devices from sources not regulated by the United States government or the Board may be less, neither a federal regulatory body nor the Board can ensure that these medications or devices are safe for use by the citizens of Maryland.

Strategies to ensure the safety of the public health include the promotion of cooperation between state and federal regulatory authorities, and educating of consumers. The Board is currently deliberating on these recommendations from the Task Force on International and Internet Drug Sales:

- Educate consumers, policymakers and health care professionals on issues relating to Internet pharmacies and purchasing prescription drugs and devices from foreign sources.
- Provide information to consumers, policy makers and health care professionals on ways to obtain legitimate medications and devices safely and cost-effectively.
- Work closely with other state and federal agencies to ensure the safety of Marylanders.
- Monitor legislative and industry activity on related issues and take appropriate action.
- Investigate and respond to alleged violations of Maryland and Federal law.
- Refer cases not under Board of Pharmacy jurisdiction to the appropriate agency.



Maryland Board of Pharmacy

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Doris James-*Licensing Specialist*
Vladimir Konstantinov-*Database Specialist*

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 21215-2299 or fax/e-mail: 410-358-6207; jlawrence@dhhm.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 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 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, January 21, 2004
Wednesday, February 18, 2004
Wednesday, March 17, 2004
Wednesday, April 21, 2004
Wednesday, May 19, 2004
Wednesday, June 16, 2004
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:

Linda Bethman, *Board Counsel*
Jeanne Furman, *Board Member*
Ramona McCarthy Hawkins,
Board Member
LaVerne Naesea, *Executive Director*

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