

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, distributors and manufacturers; 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.
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410-764-4755
www.mdbop.org

Interim Report on the Study of Patient Safety in Maryland

The “Patients’ Safety Act of 2001,” which was passed during the 2001 legislative session, charged the Maryland Health Care Commission (MHCC) with studying the feasibility of developing a system for reducing the incidences of preventable adverse medical events in Maryland, including, but not limited to, a system for reporting such incidences.

MHCC worked along with the Delmarva Foundation and the Maryland Patient Safety Coalition, which consists of representatives from health professional associations, various health agencies, and licensing Boards (including the Maryland Board of Pharmacy). The interim report that was presented to the Maryland General Assembly in January 2002 contained various recommendations including:

1. Maryland’s Patient Safety initiative should build on policies and programs currently in place. System initiatives to be considered should be prioritized based on cost and effectiveness, including:
 - Automation
 - Computerized Physician Order Entry (CPOE)
 - Electronic Medical Records (EMR)
 - Bar-coding
 - Labeling
 - Abbreviations
 - Pharmaceutical support
 - Specialized ER and intensive care unit staffing
 - Standardization of orders
2. Resources for funding of major costly initiatives, such as CPOE, EMR, and Bar-coding, need to be explored either through the State’s rate setting system or other opportunities in the State’s regulatory structure.

3. Quality Improvement initiatives and “best practices” need to be shared across facilities and organizations.
4. Leadership in healthcare organizations should promote a culture of safety.
5. Systemic change should be promoted beyond hospitals to nursing homes, pharmacies, and outpatient care settings.

The report also describes some regulatory and legislative issues that should be explored in an effort to improve and strengthen patient safety programs, including:

1. The State’s Department of Health and Mental Hygiene (DHMH) should explore standardization of definitions, protocols, and reporting requirements.
2. Maryland statutes should be amended, clarifying those protections for civil immunity that exist for all health care practitioners reporting to health occupation boards and medical review committees.
3. Protection against job loss for those reporting system failures or errors affecting patient safety. (Whistleblower protection)

Over the next year, MHCC will explore several issues in order to develop final recommendations, due in January 2003, including:

1. Should a non-punitive system be set up to encourage voluntary reporting?
2. How does staffing impact patient safety?
3. Should Quality Assurance programs required in hospitals be mandated in other facilities as a condition of licensure?

The full Interim Report can be found on www.mhcc.state.md.us.

From the Executive Director's Desk

Happy Spring to all of you who continue to provide quality pharmaceutical services to Maryland consumers! Spring is a time for new beginnings; especially at the Maryland Board of Pharmacy, as we celebrate the Board's 100th year anniversary (April 8, 2002) of protecting Maryland consumers. Baltimore City government began regulating Maryland pharmacy practice in 1870. The State assumed regulatory responsibility through the Board in 1902. This significant milestone will be celebrated throughout the year by a variety of activities intended to educate practitioners, consumers and other stakeholders about the Board's important mission to promote and ensure the delivery of quality health care in the field of pharmacy. Congratulations also to the Maryland Pharmacists Association, which is celebrating the beginning of its 120th year of supporting Maryland pharmacists.

As a consequence of the events of 9/11/01, as well as a general downturn in the economy, state cost containment efforts have impacted the Board's operations. A significant decision to maintain a balanced budget necessitated the Governor imposing a statewide hiring freeze. This has delayed the Board in filling its vacant Licensing Secretarial position. Consequently, licensees may have experienced slight delays in the processing of their applications. If you do not receive a response to your submitted renewal application at least two weeks prior to the expiration of your current license, please call or e-mail the Board. Remember, it is the RESPONSIBILITY OF THE PHARMACIST to ensure that your license is current!

The hiring freeze may also prevent the Board from replacing staff that may potentially leave the Board. Exceptions to this mandate may be allowed on a case-by-case basis. This is indeed fortunate, because it is with deep regret that I must announce that the Board's Pharmacist Compliance Officer, Michelle Andoll, has resigned her position, effective mid-May 2002. Ms. Andoll began working with the Board in June 1999. With slightly less than three years at the Board, she holds the record for serving the longest in the capacity of Pharmacist Compliance Officer. She was instrumental in directing the Board's day-to-day complaint reviews; coordinating disciplinary activities; standardizing Board compliance and disciplinary procedures; developing and maintaining the Unit's database; and providing significant support to Board members and staff, as well as pharmacists and pharmacy establishment representatives in Maryland and across the country. Ms. Andoll has been an asset to the Board and State, and on behalf of both, I wish her much success in all of her future endeavors.

The Board is not discouraged by these temporary setbacks, but motivated to develop new methods and more efficient uses of resources to protect consumers and support licensees and permit holders as it ends its 1st century. It will act swiftly to attempt to fill its vacancies. To keep abreast of the status of vacancies and other activities planned throughout the Board's anniversary year, I encourage you to log on to the Board's website (www.mdbop.org).

Request for Pharmacist Mentors



The Board is currently seeking pharmacist volunteers interested in serving on the pharmacy review committee. Section 12-318 of the Pharmacy Act defines a "pharmacy review committee" as an advisory committee appointed by the Board from a pool of Board approved pharmacists to aid the Board in licensing and disciplinary matters. The specific functions of the committee are listed in this section of the Act.

As part of its duty to protect the public health and safety, and ensure the quality of pharmacy services being provided in this state, the Board of Pharmacy may take disciplinary action against a pharmacist or pharmacy permit holder. One measure the Board may take is to assign a mentor who will offer guidance or supervision during a period of probation. Members of the pharmacy review committee would, among their other duties, serve as mentors for these licensees.

The specific duties of a mentor are determined by the terms of probation imposed upon the individual pharmacist. In the past, mentors have been asked to observe the pharmacist's practice, make recommendations to improve the pharmacist's practice, and provide progress reports to the Board. Mentors may assist in the establishment and implementation of policies and procedures, quality improvement programs, or medication error prevention systems. Mentors may also be asked to periodically review pharmacy records for proper documentation, conduct audits on controlled dangerous substances, or assist the pharmacist in selecting appropriate training and continuing education programs. The licensee compensates mentors for their time and expenses while on probation.

Pharmacists interested in serving as a mentor should submit a resume or letter to the Board detailing their professional experience, their place of employment and geographical area of residence. This information is needed so that mentors and probationees may be appropriately matched. Potential mentors will be kept on file with the Board and contacted if their services are needed. Once a potential mentor is selected from the list, they will be contacted by Board staff to discuss the particular case. The decision to serve as a mentor on a particular case is at the discretion of the mentor, the probationee, and the Board.

Please send your information to the attention of:
LaVerne G. Naesea, Executive Director
Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215

Medication Error

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

A common dispensing error involves the switching of Zyrtec and Zyprexa. If your pharmacy shelves are arranged alphabetically by brand, this arrangement can lead to

accidentally choosing the wrong medication from the shelf. These products should be stored separately from each other and shelf stickers or other alarms should be used to distinguish the two products. Also, the first few letters of these products are the same, which can lead to an accidental switch, especially if the writing on the prescription is not clear. Computer short codes or abbreviations can also contribute to errors with these two drugs. If your computer system utilizes codes or abbreviations for data entry, measures should be taken to make them distinct for these two drugs.

A second common error involves labels being switched

when two prescriptions for the same patient are being filled at the same time. Commonly, both prescriptions have been entered with the correct drug, strength, quantity, and directions. However, the labels get switched at the end of the dispensing process and end up on the wrong containers. Only one prescription should be worked on at a time. This type of error can be detected by opening each vial to check the contents before bagging the prescription and again during patient counseling when the prescription is picked up.

A practice that raises consumer concern is the re-labeling of products that were previously

prepared for a patient, but never left the pharmacy. There have been many complaints about old labels not being removed and the concern it causes for patients that may not understand why someone else's name is on their prescription. This practice may also result in the disclosure of confidential patient information. Steps should be taken to remove these old labels before re-labeling and dispensing drug products. However, if the old label cannot be removed without damaging the product packaging, steps should be taken to delete or obscure any patient information on the old label, before applying the new label to the product.

Regulations Updates

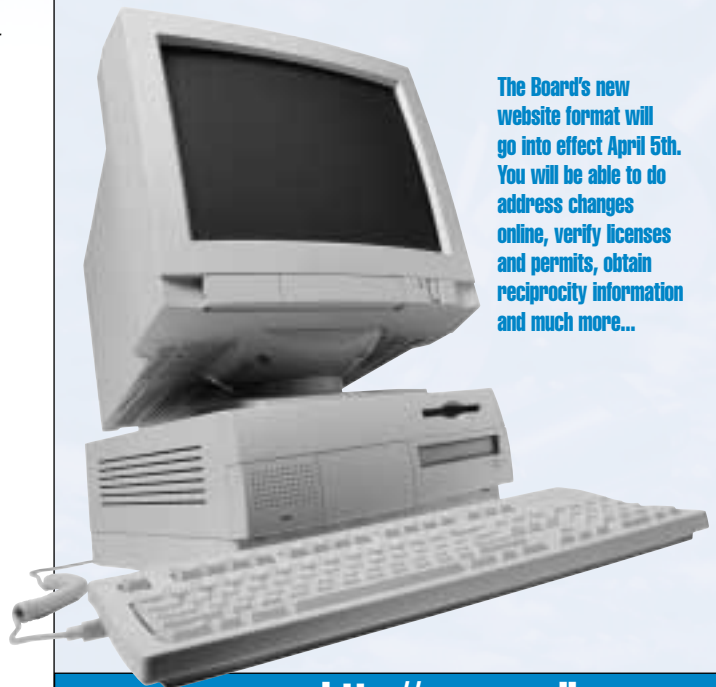
COMAR 10.34.27, Compelling Purpose Disclosure, became effective January 7, 2002. The regulations will allow the Board to share certification, licensing or investigative information with certain entities, if the Board finds that there is a compelling public purpose to do so. A request for the information need not be made by the entity receiving the information.

Pursuant to this new chapter, information relating to possible criminal activity can be "disclosed to a federal, state or local law enforcement or prosecutorial official or authority." Additionally, information concerning a possible violation of the law may be disclosed to a federal, state or local authority with jurisdiction over the individual at issue. The disclosed information in this instance

must be "limited to information relevant to the possible violation" by the individual. Finally, information relating to "[c]onduct by an individual which the Board reasonably believes may pose a risk to the public health, safety, or welfare," may be "disclosed to a law enforcement authority, administrative official, or agency that regulates the individual[.]" This information may also be disclosed "to a hospital or other health care facility where the individual has privileges."

The new chapter does not affect the ability of the Board to disclose general licensing information under the Public Information Act, including the name and business telephone number of a licensee, or information that may be otherwise disclosed by the Board.

New Website Format Unveiled



The Board's new website format will go into effect April 5th. You will be able to do address changes online, verify licenses and permits, obtain reciprocity information and much more...

<http://www.mdbop.org>



Delivery of Prescription Regulations

The Board of Pharmacy published regulations in December 2001, which govern the way that prescriptions are delivered in Maryland. These rules are timely in that they cause steps to be taken to assure the privacy and confidentiality of prescriptions at a time when Federal regulations are being put into effect. This will cause pharmacists and other medical practitioners to examine many of their practice habits as they relate to confidentiality.

The regulations reinforce the fact that prescriptions cannot be delivered to a location that the pharmacist knows to be a depot. However, the patient may authorize delivery to a

location other than the patient's residence, provided that the pharmacist documents the authorization with the identity of the agent, the location where the medicine will be sent, and the date, time and prescription number or description of the medication sent.

The regulation on packaging will prohibit sending a bag with information about the medication on the outside. Thus, the container should be sealed and packaged in a manner that will reveal to the patient any tampering that might have occurred during delivery or storage; must be packaged so as not to indicate that the contents are medications; and must have any

special storage conditions noted on the outside. A local or toll free phone number must be contained in the package, along with written information regarding the contents considered significant by the pharmacist.

Although these rules do not necessarily apply to prescriptions picked up in the pharmacy, the new federal regulations, which will be enforced as of April 2003, will make it necessary to

assure that no one has access to patient information unless necessary. Prescription bags with information on it exposed to the view of other persons may well be in violation of the federal regulations, which are currently undergoing some modifications.

Following are taken from Medscapes' pharmacist Medpulse, an e-mail service, during the week of Feb 11-15.



Generic Substitution

On November 7, 2001, the Pharmacy Practice Committee considered whether a blanket form letter from an authorized prescriber, instructing a pharmacy or pharmacist not to dispense generics for his or her patients, was sufficient to prevent generic substitution under the Maryland Pharmacy Act. The Pharmacy Practice Committee considered several factors, such as the generally accepted standards of practice, the current systems in place for maintaining dispensing records and patient profiles, and the impact of third party contractual agreements mandating the use of generics.

The Committee concluded that a non-patient specific letter from a prescriber, instructing a pharmacy or pharmacist that generic substitutions are prohibited for that prescriber's patients, is not sufficient to prevent a pharmacist from making a lawful generic substitution. The prescriber's instruction relative to the permissibility of generic substitution should be communicated with each prescription order, whether verbal or written.



Misbranded Medications Returned to Stock



It is not uncommon for a pharmacy to have reason to return to stock medications that have been labeled and prepared for a specific patient but never dispensed. Medications that are returned to the pharmacy stock shelves in vials labeled for a patient, however, may be considered misbranded because they may not be labeled with a manufacturer's lot number or expiration date. It is a violation of state and

federal law to offer misbranded drugs for sale.

The Pharmacy Practice Committee considered this issue at its meeting on November 7, 2001 and reached the conclusion that drugs that have been labeled for a specific patient but never left the pharmacy may be returned to stock and used to fill subsequent prescriptions if done under certain conditions. The two main issues the

Committee discussed were expiration date and lot number. When medication is returned to stock and the actual lot number is not known, it cannot be assumed that the medication being returned to stock is from a lot that is currently in stock. Under no circumstances is it permissible to return these medications to the stock bottle. Medications for which the actual expiration date and lot number are not known, however, may be returned to stock if the following conditions are met:

(A) The drug's expiration date shall be the expiration date given to the prescription when it was first labeled for dispensing. For example, if a prescription filled on October 1, 2001 is given an expiration date of October 1, 2002, was returned to stock and reused for a subsequent order filled on November 1, 2001, the proper expiration date for the new prescription must remain October 1, 2002.

(B) In the event of a recall or product defect affecting a particular lot, it must be assumed that any products on the shelf for which the original manufacturer's lot number is not known came from the affected lot.

The FDA was consulted on this matter. The comments received indicate that this activity would be considered the practice of pharmacy and therefore, the FDA would defer to pharmacy regulations and state authorities to determine the acceptability of this practice.

In conclusion, it is the Committee's opinion that prohibiting the reuse of medications that were used to fill a prescription and labeled for a patient, but never leaves the pharmacy creates unnecessary waste. Medications that are returned to stock in patient specific vials may be safely used if done under the above conditions.

Who's Minding the Store?

The Maryland Board of Pharmacy received a report that in December 2001, on two separate occasions, a man presenting himself as an exterminator requested access to the pharmacy for the purpose of setting traps. Access was given each time. After the second visit, pharmacy personnel discovered that four bottles of controlled dangerous substances were missing. Among the missing bottles were, Oxycontin CR 10 mg and 20mg, Tylox and Vicodin ES. Immediately upon discovery of the loss, the pharmacy management implemented a policy. This policy specified that a store manager as well as a pharmacist must accompany any and all service personnel into the pharmacy.

It was later determined that this individual was not an exterminator. Please take precautions to ensure that any non-pharmacy personnel seeking access to the pharmacy area are properly identified and are accompanied by authorized personnel at all times.

"...take precautions to ensure that any non-pharmacy personnel seeking access to the pharmacy area are properly identified..."

FAQs

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

Licensing

ERRATA - Reinstatement of pharmacist licenses

In the January 2002 issue of the Maryland Board of Pharmacy Newsletter, the answer regarding procedures for reactivating a lapsed Maryland pharmacist license was incomplete. The Board apologizes for any inconvenience that its omission of information may have caused. The following provides a more comprehensive explanation of what a pharmacist must do to reinstate a Maryland pharmacist license that he or she has allowed to expire before applying for a renewal:

1. Contact the Board of Pharmacy for a Reinstatement application. Pharmacy Regulations do not recognize a 'late renewal'; therefore, anyone who has not applied for a renewal by the date that their bi-annual license expires must apply for reinstatement.

2. A reinstatement fee must be paid in addition to the renewal fee. The amount of the fee is higher for persons whose license has expired for more than 2 years. (reference COMAR 10.34.09.02).

3. There are several different circumstances which affect the requirements for reinstatement of a pharmacist's license, depending on the length of expiration and whether the

pharmacist has been in active practice in other states:

- a. Not actively engaged in the practice of pharmacy, license expired less than 2 years:
 - i. Must meet continuing education requirements.
 - ii. Must provide evidence of good standing in other states in which they are licensed.
 - iii. Must pay the appropriate fee.

- b. Not actively engaged in the practice of pharmacy, license expired more than 2 years, less than 5 years:
 - i. Must meet the requirements in 'a' above.
 - ii. Must pass the Practice of Pharmacy Reinstatement Examination, a pharmacy law test, and a laboratory test. At this time, the laboratory examination is given 3 times a year, the reinstatement examination is usually given at the same time, and the pharmacy law test is taken electronically at a Sylvan Learning Center.

- c. Not actively engaged in the practice of pharmacy, license expired more than 5 years:
 - i. Must meet the requirements in 'a' and 'b' above.
 - ii. Must submit evidence of having performed

1000 hours of pharmacist supervised service in a community or hospital pharmacy.

- d. Actively practicing in another state, license expired less than 2 years.
 - i. Must meet the same requirements as in 'a' above.
- e. Actively practicing in another state, license expired 2 years or more:
 - i. Must meet the requirements as in 'a' above
 - ii. Must pass a pharmacy law test. This is available electronically at Sylvan Learning Centers nationwide.
 - iii. Must provide evidence of pharmacy experience during the 2 years immediately preceding the date of the applicant's reinstatement application.
4. The Board has the right to waive any of the requirements for sufficient reason. Generally, the continuing education requirements are waived for persons who have to take the reinstatement examination ('b' and 'c' above).
5. There is no requirement for applicants for reinstatement to take an oral English examination.
6. The Board is presently reviewing this Regulation

and may modify it later in 2002. The changes should not dramatically affect the above categories and will not be in effect until at least the second half of the year.

Visit the Board's website www.mdbop.org, click on "newsletter" and "reinstatement" to view the Regulations in its entirety.

Compliance

Q1. Does the Board of Pharmacy have required pharmacist/ technician ratios or workload limits?

No. However, the Pharmacy Act does require the permit holder to provide adequate personnel, automation, and technology as are necessary to allow the licensed pharmacist employee sufficient time to utilize the pharmacist's knowledge and training to perform the functions of a licensed pharmacist as required by law. A permit holder may not offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill. Annotated Code of Maryland, Health Occupations Article, Title 12-403(b) (7) and (15). Violation of these provisions may be grounds for disciplinary action against the permit holder.

Fast Bytes

DEA Forms Available on Website

The US Drug Enforcement Administration (DEA) will be offering the following registration requests interactively on the Diversion Control website:

- Name Changes
- Address Changes
- Schedule Changes
- Drug Code Changes
- Duplicate Certificates
- Order Forms (DEA Form 222)

There will be a new button on the front page of the site that will take you to the on-line forms. This will enable the DEA to process your requests more rapidly than by telephone or mail. Visit the DEA website at www.deadiversion.usdoj.gov.

FDA CFR21 - New Labeling Requirements

Two new laws regarding prescription medication labels, which affect manufacturers and distributors, will officially go into effect April 2, 2002.

The previously required statement "Caution: Federal Law prohibits dispensing without a prescription," now need only say "Rx only."

The statement "Warning –may be habit forming" will not have to be on the label, but must be discussed in the package insert. Manufacturers have until February 2003 to revise their labeling.

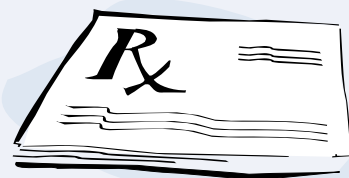
Visit the Board's website at: www.mdbop.org, click on Legislation & Regulation to view in its entirety.

Nationwide Poison Hotline

Maryland Poison Center launches new national toll-free hotline.

1-800-222-1222

410-706-1858 (TDD)



Q2. Can blister packages prepared and dispensed by the pharmacy be returned to stock if returned to the pharmacy?

COMAR 10.34.10.07 permits a pharmacist to accept the return of a properly labeled and properly sealed manufacturer's package or individual unit dose of a drug or a device that the pharmacist determines to have been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy.

In 2000, the Board of Pharmacy considered whether medications prepared and dispensed by a pharmacy in blister packaging

could be returned to the pharmacy stock and used for subsequent dispensing. Such packages are neither sealed manufacturer's packages or individual unit doses.

The Board has concluded that a pharmacist may not return to stock for subsequent dispensing blister packages prepared by the pharmacy that intermingles different drugs in a single compartment. However, a pharmacist may return to stock, for subsequent dispensing, blister packages prepared by the pharmacy if the packages contain a single drug entity in each compartment of the package and repackaging is not required for subsequent dispensing.

Disciplinary Actions

John Hoelscher, (#11115)

Effective November 9, 2001, license to practice pharmacy was placed on probation.

Surinder Singal, (#08093)

Effective January 11, 2002, license to practice pharmacy was suspended for 30 days, placed on indefinite probation, and a monetary penalty assessed.

Friendly Pharmacy (P01903)

Effective January 11, 2002, pharmacy permit was placed on probation and a monetary penalty assessed.

Lawrence Ekaney, (#12095)

Effective January 18, 2002, license to practice pharmacy was suspended for one month, all of which was stayed, and placed on indefinite probation.

Grace Pharmacy, Inc. (P01877)

Effective January 18, 2002, pharmacy permit is revoked.

Michael Rombro, (#09849)

Effective January 30, 2002, license to practice pharmacy was suspended indefinitely, all of which was stayed, placed on probation and a monetary penalty assessed.

Maryland Board of Pharmacy



Board Members

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Laura Schneider, Stanton G. Ades,
Jeanne Furman, Ramona McCarthy
Hawkins, Irving Lottier, Jr.,
Back row from left to right:
Dr. Raymond Love, Donald Yee,
Wayne Dyke, John Balch,
Rev. William Johnson, Melvin Rubin
Board Counsel (not in photograph):
Paul Ballard, Linda Bethman



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Front row left to right:
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Deitra M. Gale-Compliance Specialist,
Doris James-Licensing Supervisor,
Angela Hamlin-Executive Secretary,
Joan Lawrence-Public Education Officer,
Michelle Andoll-Pharmacist Compliance Officer
Back row left to right:
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Shirley Costley-Fiscal/Personnel Officer,
Vladimir Konstantinov-Database Specialist,
LaVerne G. Naesea-Executive Director,
James Slade-Regulations/Legislative Officer,
Brenda Seaman-Data Entry Clerk,
Tamarra Banks-Network & Information Specialist

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

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

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

Joan M. Lawrence, Staff Editor

Meetings

Pharmacy Board meetings are open to the public at 4201 Patterson Avenue, Baltimore, MD 21215. The Board encourages all interested parties to attend.

Board Meeting Dates

Wednesday, April 10
Wednesday, May 8
Wednesday, June 19
Wednesday, July 17

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

CONTRIBUTE YOUR IDEAS

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

Send information to:

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4201 Patterson Avenue
Baltimore, MD 21215

or fax/e-mail: 410-358-6207;
jlawrence@dhmh.state.md.us.

Maryland Board of Pharmacy

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