

Winter 2013

# Maryland Board of Pharmacy news

## In This Issue

From The Executive Director's Desk . . . . .	1
Disciplinary Actions . . . . .	2
Compliance Update . . . . .	3
Licensing Unit . . . . .	3
Practice Corner. . . . .	4
Emergency Volunteers . . . . .	4
MIS Corner . . . . .	5
Legislative Update . . . . .	5
From An Anonymous Pharmacist – (Reprint) . . . . .	6
Personnel/Contact Information . . . . .	8
Board Commissioners And Board Meeting Dates . . . . .	8

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**The Mission of the Maryland Board of Pharmacy** is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

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**Maryland Board of Pharmacy**  
4201 Patterson Avenue  
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## **From The Executive Director's Desk** *LaVerne Naesea, Executive Director*

By now many of you have read or heard about the recent meningitis outbreak in Maryland and across the country, allegedly caused by unsafe sterile compounding practices by a Massachusetts pharmacy licensed in Maryland and numerous other states. Several articles in this newsletter issue will discuss sterile compounding and how to avoid future problems related to unsafe sterile compounding practices.

Compounding, the mixing of pharmaceutical ingredients, may be performed in a manufacturing facility, a pharmacy, or a physician's, veterinarian's, dentist's or podiatrist's office. Compounding by a pharmacy is always patient specific and is typically performed by a pharmacy when a medication is not commercially available from a manufacturer. Hospital pharmacies and home infusion pharmacies licensed as waiver pharmacies are more likely to perform sterile compounding exclusively or as a primary function.

The practice of compounding and distributing any product (sterile or not) that is not patient-specific is consider manufacturing. Pharmacies that engage in this are violating pharmacy laws in Maryland, and would also be in violation in most states where they are licensed. Manufacturing drugs is regulated by the FDA.

The Maryland Board of Pharmacy developed regulations based on preliminary USP 797 sterile compounding standards, effective September 10, 2007. USP 797 standards categorize compounding under three risk levels- low, medium or high risk. Products prepared under the high risk categorization involve the use of some components that are non-sterile and must be sterilized as part of the compounding procedure. The Board's regulations establish requirements for the pharmacies' facilities, equipment, personnel policies, training and competencies, and other key provisions of the USP standards.

After Maryland's sterile compounding regulations became effective, the Board developed a Supplemental Sterile Processing Inspection form, for use with its general pharmacy inspection form when sterile compounding pharmacies were inspected for compliance with federal and state standards. The inspection form covers eleven categories which are taken directly from COMAR 10.34.19. They are: Permits and Licenses; Personnel; Facility and Equipment Standards for Compounding Sterile Preparations; Compounding Area; Policies and Procedures; Labeling Requirements; Record Keeping Requirements; Attire; Training of Staff, Patient, and Caregiver; Disposal of Waste Material; and Quality Assurance and Process Verification.

The Board enacted additional legislation, effective October 1, 2012, that in

*Continued on page 2*

Visit the Board online at <http://dhmh.maryland.gov/pharmacy>  
or email to [dhmh.mdbop@maryland.gov](mailto:dhmh.mdbop@maryland.gov)

**From The Executive Director's Desk**  
*continued from page 1*

general requires non-resident pharmacies licensed in Maryland to meet certain Maryland laws in addition to the laws in their home states. These pharmacies are required to employ at least one pharmacist also licensed in Maryland, to be responsible for assuring that drugs dispensed to Maryland residents are dispensed in accordance with Maryland's pharmacy laws. Sterile compounding standards and routine inspections are not uniform from state to state and are not necessarily compatible with Maryland requirements. Before enactment of the new requirements, Maryland law only required non-resident pharmacies to meet the laws of their home states, and the Maryland Board could only investigate a complaint if the home state did not take certain actions.

The Board is required to inspect all licensed, in-state pharmacies annually; including those that perform sterile compounding. Pharmacy records are inspected by Board inspectors to review compounding volume, types of compounded products, and prescriptive authority.

Annual inspections in FY 2012 resulted in the issuance of public disciplinary orders to five sterile compounding pharmacies for various violations of

USP 797 standards and/or Board of Pharmacy standards. The identification of non-compliant practices through inspections and subsequently requiring corrective action is a preventative approach aimed at averting possible dire health consequences to Maryland patients.

In light of the recent events, the Board is exploring requiring non-resident pharmacies that engage in sterile compounding to be inspected by a reputable entity prior to a Maryland permit being initially issued or renewed; and expanding regulations to specifically require non-resident sterile compounding pharmacies to meet MD's sterile compounding laws. The Board will also review with DHMH, possible reporting requirements for pharmacies that engage in sterile compounding.

If you or your pharmacy practice engages in sterile compounding, please ensure that it is performed in accordance with USP 797 Sterile Compounding Standards and Board of Pharmacy Regulations COMAR 10.34.19. The Maryland sterile compounding inspection form is available on the Board's web site at: [www.dhmh.maryland.gov/pharmacy](http://www.dhmh.maryland.gov/pharmacy).

<b>DISCIPLINARY ACTIONS</b>			
<b>PHARMACISTS</b>	<b>LIC. #</b>	<b>SANCTION</b>	<b>DATE</b>
Kenneth K. Kruk	19723	Probation	11/28/12
William R. Elliott	06640	Probation/Fine	11/28/12
Daniel McTaggart	14584	Suspension	12/12/12
<b>PHARMACY TECHNICIANS</b>	<b>REG. #</b>	<b>STATUS</b>	<b>DATE</b>
Naveed Afridi	T09087	Suspension	12/12/12
Amanda L. Braranowski	T07263	Revoked	1/28/12
Kaitlyn Ciaravella	T08163	Suspension	12/12/12
Patricia Flowers	T10562	Suspension	12/12/12
Michelle Wiles	T11109	Suspension	11/28/12
<b>ESTABLISHMENTS</b>	<b>PERMIT #</b>	<b>STATUS</b>	<b>DATE</b>
Eastern Shore Pharmacy	P02267	Probation/Fine	11/29/12
New England Compounding Center	PO3113	Surrender	12/19/12

## COMPLIANCE UPDATE

### What is Compounding?

*YuZon Wu, Compliance Unit Manager*

A pharmacy permit issued by the Board enables an establishment to practice pharmacy, which includes the compounding, dispensing, or distribution of prescription or non-prescription drugs as result of a practitioner's prescription drug order (HO § 12.101). It is only with this pharmacy permit issued by the Board that an establishment can legally engage in the practice pharmacy in Maryland.

What is Compounding? Compounding is defined in Maryland law under Health Occupations Article, 12-101, Annotated Code of Maryland (HO § 12-101(d)).

Pharmacies engaged in compounding, whether sterile or non-sterile, must perform this function using aseptic compounding techniques under acceptable compounding conditions. Furthermore, compounding must be performed in accordance with standards set forth in the U.S. Pharmacopeia (USP) Chapters 797, 795, 821, and USP 823, AND also comply with Board regulations (COMAR 10.34.19), if applicable. Compounding must be performed pursuant to a prescription and must be

patient specific.

Please be advised that under FDA guidelines, pharmacies should not compound drug products that are commercially available in the market place or that are essentially copies of commercially available FDA approved drugs products, including but not limited to Prascend® (pergolide myselate), Makena® (hydroxyprogesterone caproate injection), or Oxydone, is prohibited (20 CSR 2220-2.200(9)). FDA also states that there must be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound that would preclude the use of the FDA approved version prior to compounding.

The Maryland Pharmacy Act, Health Occ. §12-403(b)(1), requires that a pharmacy follow all laws pertaining to the operation of a pharmacy. To the extent that a pharmacy is operating in conflict with FDA regulations, it may also be violating the Maryland Pharmacy Act and therefore subject to disciplinary actions by the Board.

## LICENSING UNIT

### Regulating Sterile Compounding & Other Useful Information

*Latoya Waddell, Licensing Unit Manager*

The Maryland Board of Pharmacy continues to ensure the safety of Maryland patients by requiring adherence to the application process by sterile compounding pharmacies. The Board is currently considering revisions to all of its new and renewal application forms. Some changes will be made to assist Licensing Unit staff to assure compliance with USP 797 requirements. A part of the current application review process entails assuring that in-state pharmacies have been annually inspected by the Board's Pharmacy Compliance Inspectors. The application process for sterile compounding pharmacies is as follows:

1. Submit appropriate pharmacy application, referring to applications instructions and requirements to make certain that all requirements have been met. Sterile compounding must be indicated on applications if a pharmacy engages in this practice. If the pharmacy performs sterile compounding exclusively, a waiver application should probably be submitted. (Please see the Board's website for applications.)
2. Opening and annual inspections are performed by the Maryland Board of Pharmacy compliance unit for resident pharmacies. Sterile compounding

pharmacies are inspected to ensure that the facilities meet requirements to practice sterile compounding under COMAR 10.34.19.03 and USP 797. The Board requires the most recent inspections reports to be submitted, if available, for out of state pharmacies licensed (or seeking licensure) in Maryland. .

3. Once an opening inspection has been completed and the pharmacy application is approved, the pharmacy has sixty (60) days to open or the permit may be rescinded.

#### **Graduating Pharmacy School Students**

Graduation for student pharmacists is quickly approaching. Below are a few tips to help students prepare to become Maryland licensed pharmacists:

1. **What is the processing time of pharmacist applications?**  
Normal processing of new applications is 4-6 weeks. Applications that are incomplete may take longer to process.
2. **Where do I obtain study materials in prepara-**

*Continued on page 7*

## Practice Corner

### FAQ on Compounding

Anna Jeffers, Legislation/Regulations Unit Manager

**1) When compounding medications for patients at surgery centers or for patients for administration by a physician in his office, is there a requirement that these compounded medications be prepared pursuant to a patient-specific prescription?**

Health Occupations Article, 12-101, Annotated Code of Maryland defines “compounding: as:

“Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

- (i) As the result of a practitioner’s prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or
  - (ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.
- (2) “Compounding” includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

Please also see COMAR 10.34.19.01-16 for the requirements for compounding in Maryland.

[http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.34.19.\\*](http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.34.19.*)

**2) Can a pharmacy prepare sample compounded products for physician offices and send a sample compounded product to a physician’s office marked “For In Office Use Only?”**

A patient specific prescription is required in order to compound in Maryland. See Health Occupations Article, 12-101(d), Annotated Code of Maryland.

Compounding without a patient specific prescription is considered manufacturing and manufacturers are required to comply with U.S. Food and Drug Administration (FDA) requirements.

**3) When is “batch” compounding allowed in Maryland?**

See COMAR 10.34.19.08 set forth below:

- A. A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order.
- B. Batch preparation of specific compounded sterile preparations is acceptable if the:
  - (1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship; and
  - (2) Pharmacy maintains the prescription on file for such preparations dispensed.



### Become an Essential Part of “A Prepared Maryland”

Disaster can strike at any time. Would you be willing to help your community prepare for and respond to such emergencies? If so, you can become an essential part of “A Prepared Maryland” by registering as an MD Responds volunteer. Previously known as the MPVC, the MD Responds Program is the primary resource for public health and medical volunteers for the State of Maryland. Even though you may have registered as an Emergency Volunteer with

the Maryland Board of Pharmacy, in order to be activated you are required to register with MD Responds. **Join MD Responds today!** To register, visit <https://mdresponds.dhmh.maryland.gov/>. The initial registration process will take approximately 5 minutes to complete. For more information about the MD Responds Program, visit our website at [MDR.dhmh.maryland.gov](http://MDR.dhmh.maryland.gov) or call (410) 767-7772.



## MANAGEMENT INFORMATION SERVICES (MIS)

### Frequently Asked Questions

*John M. Johnson, MIS Unit Manager*

#### **1. The online renewal system will not let me login or accept my password.**

You must register again with the new system. Information required to register includes at least 2 of the following: Last Name, License Number, Date of Birth, and/or Social Security Number.

#### **2. How can I change my address or demographic information?**

Previously Demographic changes for Pharmacists and Pharmacy Technicians were allowed in our new system only during your renewal period. This can now be done any time for Pharmacists and Technicians only. For those wishing to mail in their changes, the 'change of information' form is located under On-line Services on the Board of Pharmacy's website <http://dhhm.maryland.gov/pharmacy>.

#### **3. I could not find my employer information when renewing.**

If unable to locate employer at time of renewal email the Board at: [dldbpharmmissupport\\_dhhm@maryland.gov](mailto:dldbpharmmissupport_dhhm@maryland.gov). Staff will add your employer to its licensing database within a couple of days. Once added, you will be able to return to the renewal process to select your employer information. You may also fax the information to us at (410 ) 358-6207.

#### **4. I am retired or unemployed, what employer information should I put in?**

If you are retired or unemployed but still wish to continue renewing your license you should use "unemployed" for the Employer box, "unknown" in the CITY box, and n/a for the STATE.

NOTE: In early 2013, Wholesale & Manufacturing Distributors will have the ability to renew online.

### Legislative Update

*Anna Jeffers, Legislation/Regulations Unit Manager*

For those interested in tracking legislation that may impact your practices, below is a list of key legislation that is being watched by the Board or Pharmacy. To follow any of these bills go to the Maryland General Assembly's website at: <http://mgaleg.maryland.gov/webmga/frm1st.aspx?tab=home>. The General Assembly is Maryland's legislative body and directly represents the electorate. Maryland has 47 districts represented by 47 Senators and 141 Delegates. The legislative session began on January 9, 2013 and ends on April 8, 2013.

**SB 139/HB 1237** - Health Care Practitioners - Prescription Drug or Device Dispensing - Medical Facilities or Clinics That Specialize in Treatment Reimbursable Through Workers' Compensation Insurance;

**SB 166/HB 1032** - Dentists, Physicians, and Podiatrists - Dispensing Prescription Drugs - Inspection by Division of Drug Control;

**HB 225/SB 273** - Veterans Full Employment Act of 2013;

**HB 179/SB 401** - Pharmacists - Administration of Vaccinations - Expanded Authority and Reporting Requirements;

**SB 591/SB 595** - State Board of Pharmacy - Wholesale Distribution - Pharmacies;

**SB 617/HB 716** - Drug Therapy Management -

Physician-Pharmacist Agreements;

**HB 736/SB 928** - Health Insurance - PBMs - Specialty Drugs;

**SB 515** - State Board of Pharmacy - Jurisdiction over Dentists Who Prepare and Dispense Dental Products and Antibiotics;

**HB 686** - Professional Boards Special Funds - Transfer of Funds - Three-Fifths Committee Vote;

**SB 761/HB 868** - Health Occupations - State Board of Pharmacy - Waivers - Pharmacies That Only Dispense Devices;

**SB 781** - Pharmacists - Biosimilar Biological Products - Substitutions;

**SB 815/HB 1014** - Nonpublic Schools - Epinephrine Availability and Use - Policy and Immunity;

**HB 986/HB 896** - State Board of Pharmacy - Sterile Compounding - Permits;

## TACTICS OF AN IMPAIRED PHARMACIST:

### **A Firsthand Account by an anonymous Maryland pharmacist from the December 2012 issue of PEAC Post**

Do you suspect someone at your workplace is using illicit drugs? Do you know how to spot the signs of drug abuse in your pharmacy? What would you do if you discovered your boss or another employee was addicted to drugs? Would you ignore it and try to cover for them? Would you confront them?

Far too often, no one addresses these questions or confronts the problems. Perhaps it's fear or the feeling of betrayal. Perhaps it's the idea of "getting involved." Whatever the reason, not addressing the issue is never the right option.

I will provide some clues to help confirm your suspicions, tell you precisely how to handle this very sensitive issue and explain the proper protocol for reporting drug abuse in the workplace. How do I know these things? I know because I am a pharmacist who was addicted to narcotics and got by with it for seven years.

The addicted pharmacist:

1. Will often seem erratic at work. My personality would alternate between appearing euphoric, almost giddy, and depressed, exhausted and sad. Routinely, I would be involved in customer confrontations which were uncharacteristic.
2. May volunteer for overtime shifts and come in on their days off. I volunteered to work extra hours and came in on my days off to acquire more drugs. Also, I would sometimes visit the pharmacy when it was closed because I had the key; no one ever questioned this.
3. Will often call in sick, be ill at work with nausea, or "nod off." Many times I was so nauseated from ingesting too much narcotic that I had to continually excuse myself to visit the ladies room where I would vomit. I missed many days of work due to exhaustion.
4. May insist on retrieving and counting the medications. I would go down the different bays of the pharmacy pretending to look for the drug I was dispensing, when, in reality, I was pouring tablets in my hand to ingest.
5. Will exhibit poor work performance and eventually not be able to keep up with workflow. On my really bad days, I would leave prescriptions undone and not finish routine daily tasks in the pharmacy. My partner would suffer the consequences and have to clean up the next day.
6. May change in appearance. During my addiction, it was an effort just to make it to work and I went

from an individual with a professional presentation, to someone who didn't care how I looked. Many days I came to work with wrinkled clothes looking like I just got out of bed.

If you are observing any of these behaviors in your colleagues, it is prudent to follow your hunch. You are probably working with someone addicted. During the many times I was confronted, no one ever asked me if I was on taking any type of mind altering drug. In the end, a technician called security because I was impaired at work.

Either the pharmacy didn't know about calling PEAC first, or they chose not to. My case was handed over directly to the Maryland Board of Pharmacy (BOP). I found myself hiring an attorney, losing my license, receiving probation for six years, and enduring numerous hearings with the Board. In my opinion, if PEAC had received my case, it could have been handled so much differently with ultimately the same result: a sober, drug free pharmacist.

Based on the Code of Maryland Regulations 10.34.10.05 (the "Duty to Report" law), it is our duty as pharmacists to report a suspected pharmacist with drug or alcohol abuse or dependency to PEAC. Reporting to PEAC satisfies the reporting requirement under the law and may make additional reporting to the BOP unnecessary. The lesson here is that if you ever find yourself wondering if a pharmacist or technician you are working with is addicted or impaired, do the right thing and protect yourself and the public by calling PEAC. If you report, you are protected from liability according to the law. Don't be afraid or feel like you're betraying the person because in the end, the impaired pharmacist will thank you.

## LICENSING UNIT

*continued from page 3*

### **tion of the Multistate Pharmacy Jurisprudence Examination (MPJE)?**

All applicants may submit a request form to the Maryland Board of Pharmacy for a Maryland Law eBook with their applications. The cost of Law eBook is \$20.00. Please see Pharmacy Law Book Request Form on the Board's website [www.dhmf.maryland.gov/pharmacy](http://www.dhmf.maryland.gov/pharmacy). Law Book form is located under Pharmacist Link.

### **3. Where do I obtain study materials in preparation of the North American Pharmacist Licensure Examination (NAPLEX)?**

Contact National Association Boards of Pharmacy (NABP) for more information about available study guides and pre-test at [www.nabp.net](http://www.nabp.net)

### **4. What is the first step for scheduling to take exams for new pharmacist?**

Be sure to have your pharmacy school confirm your graduation date. Exams cannot be taken until the Board of Pharmacy receives final confirmation of graduation (i.e. completion of college affidavit) enclosed with the completed Maryland Board of Pharmacy new pharmacist application. The Board will not provide authorization for you to be tested by NABP unless it receives this affidavit. To schedule an exam, applicants must contact NABP to learn how to apply to take the NAPLEX and MPJE examinations at [www.nabp.net](http://www.nabp.net). Please also visit the Board's website at [www.dhmf.maryland.gov/pharmacy](http://www.dhmf.maryland.gov/pharmacy) for more information.

### **Pharmacist Vaccine Certification**

Pharmacists who wish to be certified to administer vaccines must submit an initial vaccine application form, proof of completion of a vaccination certification course, current CPR card, and permit number of the MD Pharmacy where pharmacist plans to work (Please include permit number only if the pharmacist is not a Maryland resident). Pharmacists renewing vaccination applications on line must fax application if you plan to continue to immunize. Vaccination applications can not be renewed on line at this time.

### **Pharmacy Technician Update**

The Board of Pharmacy recently revised COMAR 10.34.06, Reporting Pharmacist's Mailing Address and Location of Employment, to include pharmacy technicians. This means that all registered pharmacy technicians in Maryland are now required to report to the Board any changes to their mailing address and place of employment within 30 days of changing their address or changing employers. Additionally, upon renewal pharmacy technicians are now required to report to the Board any changes to their mailing

address and place of employment. If the registered pharmacy technician's primary employment location changes and the pharmacy technicians' new primary employment location is owned by the same corporation, partnership, or individual owner, the pharmacy technician is not required to report the change except when completing a biennial registration renewal form.

### **1. What is the processing time for pharmacy technician applications?**

Normal processing of new applications is 4-6 weeks. Applications that are incomplete or indicate a criminal history may take longer to process.

### **2. What is the process for technician reinstatement applications?**

Certain applications for reinstatement may not be approved until the Board formally votes to approve the reinstatement. Reinstatement applications may therefore take up to 6 weeks to process. Applicants must submit a completed application (including reinstatement fee and CE's).

### **3. What is the process for pharmacy technician renewals?**

The Maryland Board of Pharmacy (Board) recently up-graded its on-line renewal system which now allows Pharmacy Technicians to renew on-line. The system may be accessed by going to the Board's website homepage at: [www.dhmf.maryland.gov/pharmacy](http://www.dhmf.maryland.gov/pharmacy) and clicking the following link: <http://egovpharmacy.dhmf.maryland.gov/Mylicense%20Enterprise>. Only VISA and MASTER credit cards can be used to pay fees on the on-line system. All technicians must retain their continuing education credits for four (4) years for auditing purposes. Alternatively, applicants may print a hard copy of the renewal application from the Board's website (or request an application to be mailed to you), and submit the completed application to the Board by mail at:

Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, MD 21215  
Attn: Licensing Unit

Please note:

- ✓ Hard copy renewal applications may take up to 2 weeks for processing. Please submit complete renewal applications at least 14 days prior to expiration date to avoid reinstatement and to ensure that you can continue to practice if your license has not been issued by the expiration date of your current license.
- ✓ The Board no longer provides free written verifications unless special circumstances permit. Verifications are available online at [www.dhmf.maryland.gov/pharmacy](http://www.dhmf.maryland.gov/pharmacy).



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# Maryland Board of Pharmacy

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Yu Zon Wu, Compliance Manager; Emory Lin, Pharmacist Inspector; Cheryl Johnson, Pharmacist Inspector; Nancy Richard, Lead Inspector; Jeannelle McKnight, Inspector; Shanelle Young, Inspector; Vacant, Inspector; Steven Kreindler, Compliance Coordinator; Vanessa Thomas Gray, Compliance Investigator; Courtney Jackson, Compliance Secretary	Responds to inquiries regarding Practice/Patient Complaints, Disciplinary Actions, Inspections, Compliant Investigations and Pharmacists Rehabilitation
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Latoya Waddell, Licensing Manager; Doris James, Licensing Specialist; Keisha Wise, Licensing Specialist; Vacant, Licensing Specialist; Tiffany Duncan, Licensing Secretary	Responds to inquiries regarding Licensing, Permits, Registrations, Reciprocity, Certifications, Scores and Verifications
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**BOARD COMMISSIONERS**

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**BOARD MEETINGS**

Public Pharmacy Board meetings begin at 9:30 a.m. on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings.

**2013 PUBLIC BOARD MEETINGS DATES**

Third Wednesday of each month | March 20, 2013 April 17, 2013  
 May 15, 2013

**Location:** 4201 Patterson Avenue, Baltimore, MD 21215