Spring 2014

Maryland Board of Pharmacy news

In This Issue

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.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215
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From the Executive Director's Desk

LaVerne Naesea, Executive Director

The new Health Occupations Article, Title 12, Subtitle 4A, Annotated Code of Maryland, Sterile Compounding Permits (HO §12-4A), passed during the 2013 Legislative Session as House Bill 986, provides statutory authority for the Maryland Board of Pharmacy (Board) to regulate and monitor entities that prepare sterile compounded drug for patients. The Board has made progress in its preparations for the April 1, 2014 effective date of HO §12-4A. In addition to preparing and proposing revisions to related regulations, COMAR 10.34.19, the Board's recruitment process and training of personnel to support the Board's new program responsibilities are in progress. The Board is working with its computer system vendor to determine the appropriate workflow, configure necessary fields and functionalities to accommodate the new sterile compounding permit category, and test those functionalities to assure efficient and simple licensing as well as adequate program reporting.

Over the past year, the Board has also received feedback from certain non-pharmacy practitioners about their inability to immediately comply with requirements, such as USP 797, that would allow them to obtain a Sterile Compounding Permit. The Board understands that many affected practitioners may need time to make changes to the physical environment of their practices and/or workflow in order to fully comply with HO §12-4A and the USP 797 requirements.

Given the time and many preparations still required to implement and assure compliance with HO §12-4A and revised regulations, the Board voted to institute the following steps, policies and safeguards:

1. Provide an effective date of January 1, 2015 for the revised implementing regulations entitled, COMAR 10.34.19 - Sterile Compounding Preparations and Sterile Drug Products and issuing Sterile Compounding Permits;
2. Advise sterile compounding entities that plan to operate (or to continue operating) in Maryland after January 1, 2015, to prepare to meet new requirements of HO §12-4A and revised regulations, C.O.M.A.R. 10.34.19 as adopted in the *Maryland Register*;
3. Require all Maryland licensed pharmacies that engage in sterile compounding to continue to meet USP 797 standards as incorporated in the State's sterile compounding regulations currently in effect;
4. Continue annual Board inspections of all pharmacies, including those that are engaged in sterile compounding, to evaluate compliance with state and federal laws; and

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From the Executive Director's Desk
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5. Issue Board wholesale distributor permits to pharmacies and outsourcing facilities that are registered with the FDA to allow them TO DISTRIBUTE NON-PATIENT SPECIFIC STERILE DRUG PRODUCTS in Maryland.

The Board will also continue to work with all stakeholders to clarify and answer any questions to facilitate a safe and smooth provision of sterile compounding preparations and sterile drug products for patients in Maryland as well as those who are served by entities located in Maryland. Nonetheless, all non-pharmacy sterile compounding entities, to the extent that they are not already compliant, are strongly encouraged to meet USP 797 safety standards as soon as practically possible.

DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	STATUS	DATE
Matthew Vaccari	16372	Suspended	01/30/14
Stephen Cappelli	17402	Surrendered	02/19/14
David Russo	09176	Revoked	03/19/14
Aderonke Adebanjo	11971	Probation	04/14/14
Michael Gallotte	Applicant	Probation	04/19/14

PHARMACY TECHNICIANS	REG. #	STATUS	DATE
Michelle Wiles	T11109	Revoked	01/22/13
Keisha Davis	T09272	Revoked	11/20/13
Keiffer Subero	Applicant	Denied	11/20/13
Alberta Gerald	T05674	Revoked	11/20/13
Ashley Reid	T08681	Revoked	11/20/13
Amanda Kosinski	T10129	Revoked	11/20/13
Gabrielle Sagi	T08218	Revoked	11/20/13
Dante Fowlkes	T01701	Suspended	12/20/13
Jessica Richard	T02083	Revoked	01/15/14
A.K.A. Jessica Stonesifer			
Dominique Holmes	T12247	Suspended	01/28/14
Sunil Rami	T07970	Probation	02/19/14
Tekia Marcus	T02794	Revoked	02/19/14
Ashley Dinan	T02532	Revoked	02/19/14
Amber Coleman	T04395	Revoked	02/19/14
Kijana Glispery	T02555	Revoked	02/19/14
Angela Morfe	T02574	Summary Suspension	03/18/14
Ariel Johnson	T03507	Summary Suspension	03/18/14
Thomas Martino	T12340	Summary Suspension	04/07/14
Diana Lubic	T11601	Summary Suspension	04/24/14
Tabitha Palm	T05697	Surrendered	04/24/14
Michelle Hahn	T02323	Summary Suspension	05/01/14

ESTABLISHMENTS	PERMIT #	STATUS	DATE
Advantage Pharmacy	P05770	Probation	01/15/14
Rx3 Compounding Pharmacy	P05099	Fine	02/19/14
CVS Corporate Office	CORP01	Fine	03/21/14
Dundalk Pharmacy	P00439	Fine	04/01/14
Hope for All Pharmacy & Stores	P04150	Fine	04/14/14
Cubist Pharmaceuticals	Unlicensed	Fine	04/24/14
Brookville Pharmacy	P00923	Reprimand & Fine	05/13/14

COMPLIANCE CORNER – Sterile Compounding Questions and Answers

YuZon Wu, Compliance Manager

1. **As a pharmacy that currently performs sterile compounding, when does the establishment need to be in full compliance with USP 797?**

   Answer:

   In order to perform sterile compounding, the pharmacy must be in compliance with the Board's regulations governing sterile compounding, COMAR 10.34.19, which incorporate USP 797. The Board will continue to perform annual inspections to monitor for compliance with USP 797.

2. **Would my existing sterile compounding pharmacy be subject to an opening inspection before the Board issues me a Sterile Compounding Permit?**

   Answer:

   A pharmacy which already has a pharmacy permit and has been performing sterile compounding, will not be subjected to an opening inspection before it receives its new Sterile Compounding Permit. If, however, a pharmacy or establishment has never performed sterile compounding and is now applying for a sterile compounding permit, then it would be subject to an opening inspection prior to commencing sterile compounding.

Implementing the Expanded Authority of Pharmacists to Administer Vaccinations in Maryland

During the 2013 Legislative Session, the pharmacists' administration of vaccinations statute was expanded in Maryland. A pharmacist may now administer a vaccination to an individual who is at least 11 years old but under the age of 18 years with a prescription from an authorized prescriber,if it is listed in the Centers for Disease Control and Prevention's (CDC) recommended immunization schedule. With administration to minors, the Board reminds pharmacists that under existing law administration records for minors must be maintained until the minor patient attains the age of majority plus 3 years, or for 5 years after the record is made, whichever is later.

Pharmacists will also be allowed to administer vaccinations to an adult that are listed in the CDC's Recommended Immunization Schedule or recommended in the CDC's Health Information for International Travel. The adult vaccines must be administered under a written protocol that is vaccine specific and meets criteria set forth in the newly amended COMAR 10.34.32. The new regulations are anticipated to be effective on April 28, 2014. Please check the April 18th Maryland Register or the Board's website for confirmation.

Additionally, all vaccinations administered by a pharmacist are required to be reported to the ImmuNet Program. The pharmacist is also required to document at least one effort to notify the authorized prescriber of the administration of the vaccine. If the authorized prescriber is not the individual's primary care provider, or if the vaccination has not been administered in accordance with a prescription, then the pharmacist shall document at least one effort to notify the individual's primary care provider of the administration of the vaccine.

Be mindful that the laws regarding the administration of influenza vaccinations have not changed and a pharmacist may continue administering influenza vaccines to an individual who is at least 9 years old.

The Maryland Board of Pharmacy (MDBOP) has an Emergency Preparedness Task Force (EPTF) that works closely with the State of Maryland to prepare for any emergencies that may occur. This task force has enabled pharmacy to be recognized as being a vital part of the emergency teams. The MDBOP has been instrumental in writing the State Emergency Preparedness Plan to include pharmacy's role.

In order to maintain the EPTF more efficiently, the Board would like to secure representatives from various locations throughout Maryland. This would allow for the most effective response; to have trained personnel available, regardless of where an emergency may take place.

If you would be willing to serve on the EPTF, as a representative from your specific area of Maryland, please contact Janet Seeds at janet.seeds@maryland.gov or 410-764-5988. All interested persons will be contacted.

Also, to register as an Emergency Volunteer, please go to www.mdresponds.org. Click onto 'register now'.

AN ANNOUCEMENT TO IMMUNIZING PHARMACISTS: REGISTER AND REPORT IMMUNIZATIONS TO THE MARYLAND IMMUNIZATION REGISTRY, IMMUNET

Maryland's Immunization Information System (ImmuNet IIS)

The Maryland Legislature passed and the Governor signed into law in 2013 expanded pharmacist immunizations authority with the mandate to **REPORT ALL VACCINATIONS ADMINISTERED BY THE PHARMACIST to IMMUNET PROGRAM ESTABLISHED UNDER § 18–109 OF THE HEALTH – GENERAL ARTICLE.**

It is preferable that pharmacies report data electronically to the ImmuNet IIS via Flat File or HL7 data exchange. DHMH has a SFTP site available to receive electronic immunization data submissions. Web services will be another option available for electronic data submissions in the near future. In the event that a pharmacy does not have the means to submit electronic data, direct manual entry into the ImmuNet IIS is also available. http://phpa.dhmh.maryland.gov/OIDEOR/IMMUN/immunet/SitePages/Pharmacists.aspx

Requirements for Pharmacies/Pharmacists:

1. **Complete the Maryland Immunization Registry, "ImmuNet" Site Enrollment Form**

   https://www.mdimmunet.org/ir_docs/Provider_Site_Enrollment.pdf

   Under EHR Vendor: - enter the pharmacy information system vendor/platform and version

   NOTE: For pharmacists in chain pharmacies the company may determine the site enrollment for each store, check with your company/corporate system for requirements for you to gain an access to ImmuNet. Each chain store number will have a registration report number.

2. **Complete a Password Request Form**

   https://www.mdimmunet.org/ir_docs/Password_Request_Form.pdf

   Fax both forms in step 1 and step 2: "Attention ImmuNet Help Desk"

   The ImmuNet staff will contact you to complete the process for either manual or electronic data transmission. If you do not hear within 2-4 weeks, re-fax and phone AND email the ImmuNet staff; telephone 410-767-6606 OR BY EMAIL dhmh.mdimmunet@maryland.gov. If there is no response, contact the pharmacist member of the Maryland Statewide Advisory Commission for Immunizations (MSACI) with pertinent dates of communications and information. Current pharmacist member through June 2014, Jennifer Thomas, PharmD, email: thomasjen@dfmc.org

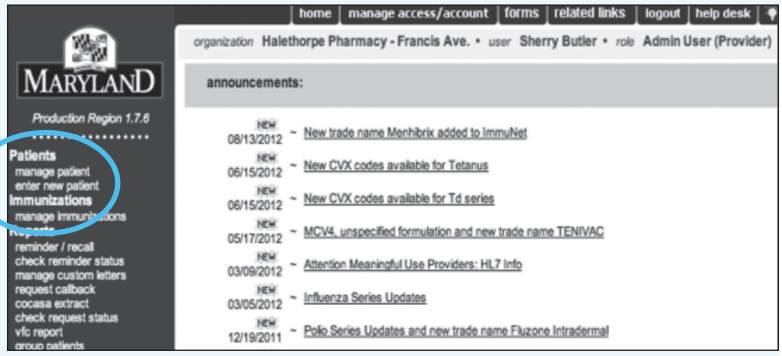
3. **Ensure that all immunizing pharmacists are trained to use ImmuNet.** Multiple training videos are available at https://www.mdimmunet.org/prd-IR/portalHeader.do

4. **Report immunizations to ImmuNet**

   Reporting will be either electronic or manual. For chain pharmacies and/or independent pharmacies that have batch electronic transmission to the ImmuNet, the report function will occur in the background through the pharmacy information system, likely invisible to the pharmacist. However the pharmacist should be aware of the ImmuNet and obtain a login through the pharmacy to assess and review the patient/customer immunization history.(for the pharmacy site there will be an administrator to assign a site or individual login). Use of the ImmuNet is important not only for reporting purposes, but also to determine other potential opportunities for providing necessary vaccines. Pharmacists may find the Quick Reference below useful in review of a patient's immunization history and/or to manually enter immunization information.

Quick Reference: Recording Vaccinations on Maryland ImmuNet

1. **Click *manage* patient on main menu and search for existing patient record.**



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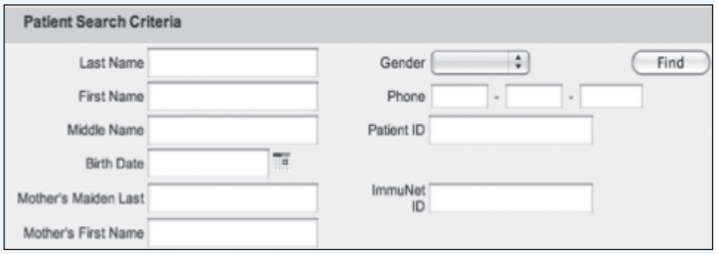
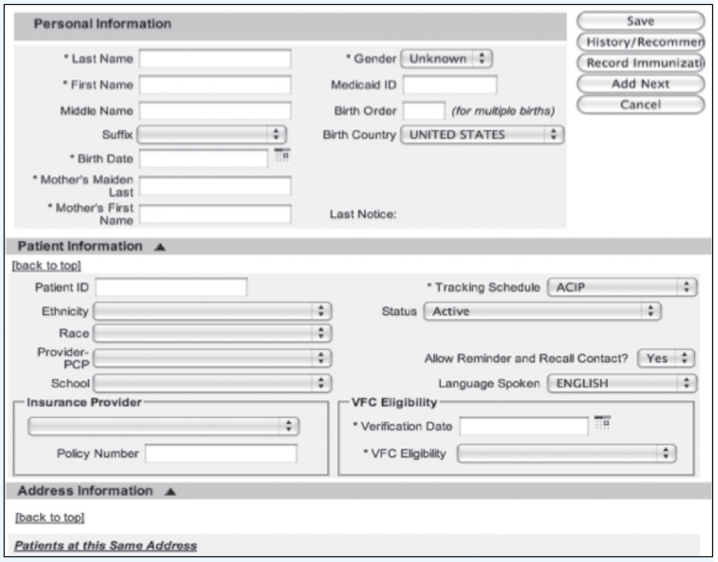
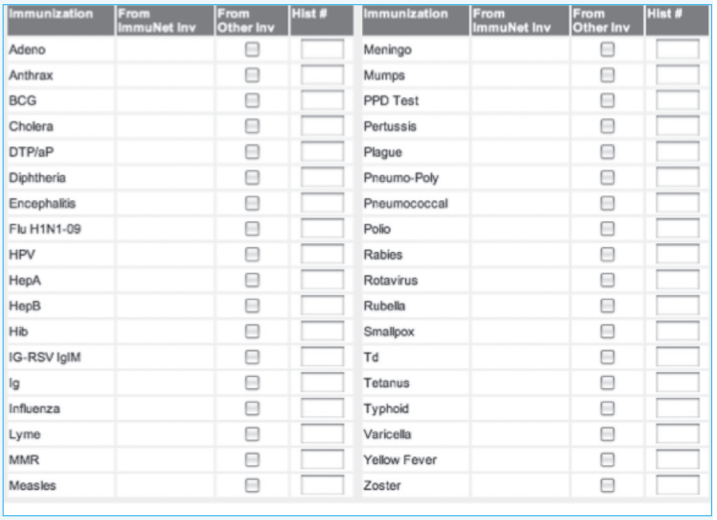
2. **Search for at least 3 letters of last name and 2 letters of the first name.**



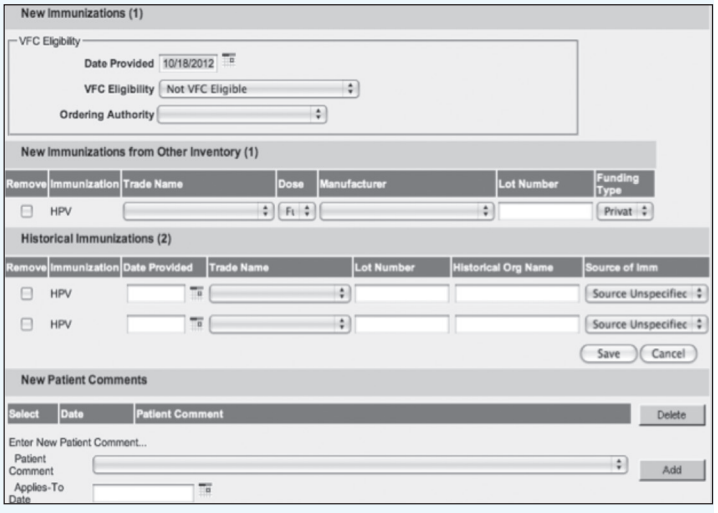
3. a. **Select appropriate patient record if information matches and go to step 5.**
   b. **If no patient match found, click enter new patient on main menu.**
4. **Add patient and click save.**
   a. **Personal information: Last name, first name, gender, birth date, mother's maiden name, mother's first name**
   b. **Patient information: VFC verification date, VFC eligibility**
   c. **Address**



5. **Click Record Immunization.**
6. **Check all new vaccinations and historical vaccinations to be recorded and click OK.**
   a. **If it is a historical vaccination, enter number of doses to be recorded in Hist # box.**



7. **Record vaccine information and click save.**
   a. **New vaccination: trade name, dose, manufacturer, lot number, funding type.**
   b. **Historical vaccination: date provided, trade name, lot number, organization that administered vaccine, and source if available.**



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Quick Reference Provided by Halethorpe Pharmacy

Issues:

Patient Matching – if there is a change in patient address and/or an entry error, a patient that is or may be in the system will not match and the user (or electronic transaction) will create a new patient entry. The pharmacist should be aware that if they do not find a patient in ImmuNet after reasonable search efforts, enter the patient as a new patient. The ImmuNet staff and application algorithms will match the patient entries.

Mother's maiden name issue – mandatory field. Patients do not understand why this is necessary, some do not know, or they do not want to provide the information. Provide the patient the reason for the request; the maiden name is used as a patient identifier for matching records in the registry.

Vaccine For Children (VFC) mandatory field - Pharmacists do not currently have authorization as providers in the Vaccine For Children (VFC) program, but pharmacists can apply for this program. If you are not a VFC provider you select Not VFC eligible.

Private/public/cash – specific definitions and/or qualifications; these desginations for payment require clear definitions, but in general: private - a non-government payer; public - a government payer; cash - self pay.

IMPORTANT PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) INFORMATION

Please take note of regulation §10.47.07.03 regarding reporting patient identification in the new PDMP system.

A. For each monitored prescription drug dispensed, the dispenser shall report the following prescription monitoring data to the Department . . .
   (2) Identifying information for the patient, including:
      (a) Last name;
      (b) First name;
      (c) Date of birth;
      (d) Gender;
      (e) Address, including residential house or building number, apartment number, street name, state, and zip code; and
      (f) *A patient identification number which MAY include:*
         (i) A state-issued driver's license or identification card number;
         (ii) A residential telephone number;
         (iii) An insurance or third-party payer identification number;
         (iv) A passport identification number;
         (vii) A United States Permanent Resident Card identification number;

PRESCRIPTION DRUG MONITORING PROGRAM REMINDER

The Prescription Drug Monitoring Program (PDMP) has been up and running since last fall. Keep in mind that pharmacists may access prescription data on their patients at no cost. This may be helpful as pharmacists try to meet the medication needs of their patients who require pain medications. For more information access the following link to the Maryland Alcohol and Drug Abuse Administration's site, where the program is housed.

http://adaa.dhmh.maryland.gov/PDMP/SitePages/Home.aspx

MARYLAND OVERDOSE RESPONSE PROGRAM

DHMH has launched the Maryland Overdose Response Program under which it will authorize private and public entities to train individuals to administer naloxone to reverse an opioid overdose. Trained individuals will receive a certificate that entitles them to obtain a prescription for naloxone from a physician or nurse practitioner. Since this will increase the demand for the medication, DHMH seeks to determine which pharmacies plan to stock naloxone or put into place other mechanisms to ensure that naloxone can be efficiently dispensed. Please respond with this information by email to dhmh.naloxone@maryland.gov or by fax (attn: Naloxone) to 410-402-8601.Thank you for your assistance in providing this helpful information.

NABP COLLABORATES WITH HEALTH CARE STAKEHOLDERS ON ENSURING DELIVERY OF RESPONSIBLE AND EFFECTIVE PATIENT CARE CONSENSUS DOCUMENT ON PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES ISSUED

Deborah Zak, Communications Manager

The National Association of Boards of Pharmacy® (NABP®), along with a coalition of health care industry stakeholders, has issued a consensus statement regarding the collaborative steps that will be taken to help ensure the delivery of responsible and effective patient care as it relates to the prescribing and dispensing of controlled substances (CS). The agreement indicates the need to work collaboratively to address the prescription drug abuse epidemic and to help practitioners comply with their legal responsibilities for prescribing, dispensing, and distributing CS. With the intention of restoring and improving coordination among stakeholders, the 13 participating organizations, which represent physicians, pharmacists, pharmacies, regulatory boards, wholesalers, manufacturers, and government agencies, will develop two subsequent consensus documents. The first document will identify the "red flags" that warrant the need to review the legitimacy of CS prescriptions. The second document will outline the actions stakeholder organizations will take to improve dialogue so that such "red flags" are addressed, in compliance with federal and state law, and so that practitioners are supported in delivering the most appropriate patient care.

While some policies recently implemented by stakeholders were intended to protect patients and prevent prescription drug abuse, participants agreed that coordination and collaboration must be improved to ensure that this public health problem is addressed and that patients receive responsible and effective patient care. Additionally, participants recognized that such policies were implemented to help practitioners comply with regulations and were not intended to "intrude into the scopes of practice or authority of other stakeholders." The forthcoming consensus documents are intended to restore and improve collaboration among all health care practitioners, and to eliminate confusion caused by "the diversity of current proprietary policies."

"The dialogue and consensus among organizations representing the spectrum of the health care team will be instrumental in ensuring that patients with legitimate medical needs receive the most appropriate and safest medication therapy," states NABP President Karen M. Ryle, MS, RPh. "By coordinating on actions that help reduce rates of prescription drug abuse, the forthcoming stakeholder discussions and ongoing collaboration will benefit patient care and the public health."

The consensus document was the result of stakeholder meetings convened by NABP in October 2013 and December 2013. The document was finalized at the December meeting and was developed by NABP and the following organizations:

- American Academy of Family Physicians
- American Medical Association
- American Osteopathic Association
- Cardinal Health
- CVS Caremark
- Federation of State Medical Boards (observer)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Pharmaceutical Care Management Association
- Pharmaceutical Research and Manufacturers of America
- Rite Aid
- Walgreen Co.

All participating organizations acknowledge support for the consensus document, which is available in the Members section of the NABP website, under Position Papers, at www.nabp.net/members/position-papers. NABP is the independent, international, and impartial association that assists its member boards of pharmacy for the purpose of protecting the public health.

MIS CORNER — FREQUENTLY ASKED QUESTIONS

John M. Johnson, MIS Unit Manager

1. **The online renewal system will not let me register or accept login information I've used in the past.**
   If you registered with the online renewal system prior to Fall 2012 you must register again with the new system. Information required to register includes at least 2 of the following: 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 email in their changes, the 'change of information' form is located under On-line Services on the Board of Pharmacy's website http://dhmh.maryland.gov/pharmacy.
3. **The online system will not accept my credit card payment and I know my card is working properly.**
   We currently only accept Visa or MasterCard. One other common problem experienced is when users enter an incorrect email address. You must also enter a valid USA billing address.

Maryland Board of Pharmacy
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Maryland Board of Pharmacy

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BOARD COMMISSIONERS

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Treasurer: **Mitra Gavgani**
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Trinita Robinson
Charmaine Rochester
Sajal Roy
Jermaine Smith
Zeno W. St. Cyr, II
Bruce Zagnit

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.

2014 PUBLIC BOARD MEETINGS DATES

Third Wednesday of each month

July 16, 2014
August 30, 2014
September 19, 2014 (off-site)

Location: 4201 Patterson Avenue, Baltimore, MD 21215

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