

Maryland Board of Pharmacy news

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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.

Maryland Board of Pharmacy
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From The Executive Director's Desk *LaVerne Naesea, Executive Director*

Notice of Acceptance of Nominations for Board Commissioners Independent, Acute Care Hospital and At-Large

The second terms of three commissioners appointed to the Board of Pharmacy will end on April 30, 2013. The Maryland Board of Pharmacy is comprised of ten (10) pharmacist Commissioners and two non-pharmacist (2) consumer Commissioners. A Commissioner may be appointed to a total of two consecutive four-year terms. Commissioners' terms are staggered and Maryland statute requires the Board of Pharmacy to notify all licensed pharmacists and other interested parties when four-year terms are scheduled to end. In addition, the Board must provide contact information for groups to which letters of interest may be submitted by eligible individual interested in being considered for nomination to the Board. The full text of the statute may be found in Health Occupations §12-202 of the Annotated Code of Maryland.

Maryland law delineates specific categories of representation for the 12 Board seats. Consumer representatives are appointed by the Governor to the Board with the advice of the Secretary and the consent of the Senate. Pharmacist representatives are appointed by the Governor with the advice of the Secretary of the Department of Health and Mental Hygiene, from lists submitted by the appropriate association. The requirements for appointment to the Board are as follows:

PHARMACIST APPOINTEES (10)

- Maryland Resident
- Licensed Maryland pharmacist
- In good standing with the Board
- Skilled and competent
- Possesses at least five years of professional experience within two years prior to the appointment

CONSUMER APPOINTEES (2)

- Maryland Resident
- May not have been a pharmacist
- May not have a pharmacist in the household
- May not have participated in pharmacy field
- May not have had a substantial financial interest in a person regulated by the Board

The *Independent, Acute Care Hospital and At-Large Commissioner* categories will be open for nominations to terms beginning May 1, 2013 through April 30, 2017. Eligible licensed pharmacists who wish to be considered for nomination to any of the three commissioner seats should provide a letter of interest along with a biographical form to the appropriate association as noted below. The biographical form is available from the associations listed

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

From The Executive Director's Desk
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below or the Board's web site at: <http://dhmh.maryland.gov/pharmacy/SitePages/about-the-board.aspx>.

Independent: The Governor shall appoint the independent pharmacist member with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor from the Maryland Pharmacists Association (MPhA) and the Maryland Pharmaceutical Society (MPhS). Candidates for consideration must practice primarily in an independent pharmacy at the time of appointment.

MPhA: 1800 Washington Blvd., Suite 333
 Baltimore, Maryland 21230
 Phone: 410-727-0746 Fax: 410-727-2253
 Email: hrschiff@mdpha.com

MPhS: P.O. Box 1182, Owings Mills, MD 21117-1123
 Email: admin@mdpharmsociety.org

Acute Care Hospital: The Governor shall appoint the acute care hospital pharmacist member with the advice of the Secretary, from a list of names submitted to the Secretary and the Governor from the Maryland Society of Health-System Pharmacists (MSHP). Candidates for consideration must practice primarily in an acute care hospital pharmacy at the time of appointment.

MSHP: Attention Sara Neiswanger, 800 SW Jackson Street, Ste. 1500, Topeka, KS 66612
 Phone: 785-271-0208 Fax: 785.271.0166
 Email: sara@centrichq.com

At-Large: The Governor shall appoint the at-large pharmacist member with the advice of the Secretary, from a list of names submitted to the Maryland Pharmacists Association and then forwarded to the Secretary and the Governor.

MPhA: 1800 Washington Blvd., Suite 333 • Baltimore, Maryland 21230
 Phone: 410-727-0746 Fax: 410-727-2253
 Email: hrschiff@mdpha.com

Interest Letters and Biographical form must be submitted on or before February 1, 2013

*The Independent, Acute Care Hospital
 and At-Large Commissioner
 categories will be open for nominations
 to terms beginning
 May 1, 2013 through April 30, 2017*

DISCIPLINARY ACTIONS			
PHARMACISTS	LIC. #	SANCTION	DATE
Uchenna Ekwunazu	18065	Probation	8/09/12
Robb Foote	12098	Suspended	10/16/12
McKinley Guess, Jr.	10936	Probation	8/30/12
Stephen Klebrowski	07202	Probation	9/11/12
James Morrow	08394	Suspended	10/22/12
Nguegni Fobi-Takusi	16750	Probation/Fine	10/26/12
PHARMACY TECHNICIANS	REG. #	STATUS	DATE
Toya Johnson	T06895	Probation	8/17/12
Hillari Boches	T05587	Revoked	10/17/12
ESTABLISHMENTS	PERMIT #	STATUS	DATE
New England Compounding Center NEB 24 d/b/a Maryland Respiratory Group	P03113	Suspended	10/05/12
Quality Care Pharmacy	PW0305	Suspension stayed	11/14/12
Zonetak Pharmacy	P05148	Fine	8/9/12
	P05380	Probation/Fine	10/26/12

COMPLIANCE UPDATE

Pharmacy Student Interns

YuZon Wu, Compliance Unit Manager

There seems to be some confusion as to whether a pharmacy student needs to be registered with the Board in order to work at a pharmacy establishment.

Maryland regulations for pharmacy students allow them to work in a pharmacy performing technician duties if they are currently a pharmacy student enrolled in an accredited pharmacy school, have applied with the Board for a pharmacy student exemption to pharmacy technician registration, and the registration is confirmed yearly while they are in pharmacy school. This exemption to registration must be re-confirmed on October 31 of each year to insure that the technician is still actively enrolled in a school of pharmacy. Once the pharmacy student graduates from pharmacy school, they no longer have a student status and may not work under their pharmacy student exemption. The exemption is only effective while the pharmacy student is actively enrolled in an accredited school of pharmacy. The pharmacy graduate may continue to work and perform technician duties after graduating from school only if they obtain a pharmacy technician registration or work as a technician trainee in a Board-approved technician training program for no more than 6 months.

Pharmacy students are completely exempted from the Board's licensure and registration requirements only if they are practicing pharmacy as part of school of pharmacy sanctioned professional practice experience (i.e.: experiential practice rotation or experiential learning rotation). As long as the pharmacy where the students are placed can document and provide proof that the students are part of a school of pharmacy sanctioned experiential learning rotation, no registration or license is required of the students. The schools/colleges of pharmacy must provide the preceptor and student with a letter/document (via email from the school or on school letter head) stating that the student is assigned to the site and when student is to commence this experiential rotation. This letter or documentation needs to be presented to the inspector at the time of inspection.

Registration requirements for pharmacy students are provided in COMAR 10.34.34.05. The requirements are as follows:

10.34.34.05 Pharmacy Students.

- A. Pharmacy students who are practicing in a pharmacy as part of a school of pharmacy sanctioned experiential learning rotation are not subject to the registration requirements of Regulation .04 of the chapter.
- B. Pharmacy students performing pharmacy technician functions and who are not in a school of pharmacy sanctioned experiential learning program shall:
 - (1) Submit to the Board a signed completed application for exemption from the registration requirements of Regulation .04 of this chapter; and
 - (2) Comply with the following conditions:
 - (a) Provide verification of enrollment and good standing at an accredited school of pharmacy;
 - (b) Pay an exemption fee as set forth in COMAR 10.34.09; and
 - (c) Submit a request for a State Criminal History Records check.
- C. A pharmacy student may begin work under this exemption upon compliance with §B(1) and (2) of this regulation.
- D. Pharmacy students granted an exemption from registration requirements of Regulation .04 of this chapter:
 - (1) Are not subject to renewal requirements as set forth in Regulation .08 of this chapter; and
 - (2) Shall provide to the Board proof of enrollment in good standing at an accredited school of pharmacy once a year and upon request of the Board.

STERILE COMPOUNDING

Ensure Your Patients' Safety

In light of the recent outbreak of meningitis from drugs compounded in a pharmacy, all pharmacists and pharmacies are reminded of the importance of using aseptic techniques when compounding sterile prescription products and abiding by USP 797 and COMAR 10.34.19.

Take this time to review COMAR 10.34.19 and USP 797 for facility requirements, equipment requirements, attire, policy and procedure requirements, record keeping requirements, packaging, labeling and beyond use dating, and staff training requirements.

The Board's goal in conducting annual inspections

at all Maryland pharmacies is to ensure that pharmacies operate in compliance with state and federal rules and regulations. They are provided to assure public safety; thus, preventing a similar outbreak to that which recently occurred in Maryland and elsewhere across the country. Remember also that compounding medications without a patient-specific prescription is a violation COMAR 10.34.19.08, as well as other provisions in the Maryland Pharmacy Act.

All inspection forms are found on the Board's website at the following link: <http://dhmh.maryland.gov/pharmacy/SitePages/Establishments.aspx>

Did You Know???

Stolen/missing prescriptions pads may be reported by prescribers to the Board of Pharmacy.

Please visit the Board website at <http://dhmh.maryland.gov/pharmacy/SitePages/missing.aspx> to view the list of reported stolen/missing prescription pads.

This list is routinely updated but only reflects reported thefts.

PRACTICE CORNER

Electronic Prescription Applications

Anna Jeffers, Legislation/Regulations Unit Manager

The transition from traditional hard copy Schedule II prescriptions to the implementation of electronic prescribing of Schedule II prescriptions has been complex processes. Federal regulations require that electronic prescription applications and electronic prescriptions must be audited by a third party, or a certifying organization approved by the Drug Enforcement Administration (DEA), for compliance with 21 CFR 1311.

The DEA has addressed this and many other questions on its website at: http://www.deadiversion.usdoj.gov/e-comm/e_rx/faq/pharmacies.htm

Below are FAQs from the DEA website that address the auditing by a third party and a list of organizations whose certification process has been approved by DEA.

Audits and Certification of Applications

Q. Who can conduct an audit or certify an application?

A. Application providers must obtain a third-party

audit or certification to certify that each electronic prescription and pharmacy application to be used to sign, transmit, or process controlled substances prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.

- The application may undergo a WebTrust, SysTrust, or SAS 70 audit conducted by a person qualified to conduct such an audit.
- The application may undergo an audit conducted by a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.
- The application may have a certification organization whose certification has been approved by DEA verify and certify that the application meets DEA's requirements.

Q. When must a third-party audit or certification be conducted?

A. The third-party audit or certification must

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ADMINISTRATION AND PUBLIC SUPPORT

Board and State Receive High Marks for Emergency Preparedness

Janet Y. Seeds, Public Information Officer

In the midst of the threats that often surround us, including natural and man-made disasters, it is great to get good news. The Maryland Board of Pharmacy's (MDBOP) Emergency Preparedness Taskforce (EPT) participated in the Center for Disease Control and Prevention (CDC) evaluation of Maryland's emergency preparedness plan, referred to as the Technical Assistance Review (TAR). The State received a score of 100%. This achievement was due in part to the planning efforts and diligence of the EPT, led by former Board Member and Chair of the EPT, Donald Taylor.

In preparation for the TAR, the EPT submitted documents such as agendas, minutes, and attendance sheets to demonstrate that planning meetings had been conducted. Not only did the EPT members meet routinely (monthly), they engaged in pharmacy drills, and also updated various state documents. The Department of Health and Mental Hygiene's (DHMH) Emergency Protocols were revised and

incorporated into Maryland's emergency plan. The Strategic National Stockpile (SNS) plan was also revised, delegating specific roles to pharmacists at the Receipt, Staging, and Storage (RSS) site. The Pharmacy Incident Action Plan (IAP) is presently being revised by the EPT and will be presented to the State upon completion.

Many State and Federal relationships have been developed by the EPT and maintained throughout the years. These have allowed the EPT to become increasingly recognized within the state of Maryland. Other states have reviewed the EPT plans to better understand roles that pharmacists can play during emergency situations. Donald Taylor recently participated in a CDC-sponsored training in Atlanta, GA on RSS set-up and procedures. CDC has asked the MDBOP's EPT to share their plan with California. Never could the Board predict that the efforts of the EPT would be so far-reaching, but it is truly a great accomplishment!

IMPORTANT CORRECTION

The Maryland Board of Pharmacy (MDBOP)

website remains: dhhm.maryland.gov/pharmacy

The new website address for renewals is:

<https://egovpharmacy.dhhm.maryland.gov/Mylicense%20Enterprise/>

which can also be accessed from the MDBOP homepage.

ADMINISTRATION AND PUBLIC SUPPORT

Public Relation Committee Hosts Successful Continuing Education Breakfast

Janet Y. Seeds, Public Information Officer

The Board of Pharmacy held its annual Continuing Education (CE) Breakfast at the Radisson Hotel at Cross Keys in Baltimore, Maryland on Sunday, October 21, 2012. Approximately one hundred pharmacists, pharmacy technicians and pharmacy students attended this event entitled, "Drug Shortages: What Pharmacy Professionals Should Know."

The breakfast, moderated by Board President, Michael Souranis, opened with Nancy Grimm, the Director from the Office of Health Care Policy who provided greetings on behalf of Francis Phillips, Deputy Secretary for Public Health at the Maryland Department of Health and Mental Hygiene.

of wisdom offered by him to the younger pharmacists present were, **"When you find yourself looking at the clock to see if it is time to go, then it is time to go."** A Governor's Citation was



presented to Mr. Street by Board President, Michael Souranis and Executive Director, LaVerne Naesea. The other honorees were unable to attend the event and were sent their Governor's Citation.

Ms. Bona Benjamin, Director of Medication-Use Quality Improvement at the American Society of Health-System Pharmacists (ASHP) in Bethesda, MD opened the second half of the breakfast program. Ms. Benjamin described how health care organizations and health care providers can prepare for and address drug shortages. She also discussed potential avenues that pharmacy professionals can utilize to assist patients and caregivers affected by drug shortages. Following the presentation, Dr. Bina joined Ms. Benjamin in responding to questions from the audience.

The pharmacist and technicians attending this event received two live CE credits. The attendees greatly enjoyed the training experience, offering many positive comments.



Captain Christine Bina, RPh, MPP, Senior Program Management Officer for the Drug Shortage Program, Center for Drug Evaluation and Research (CDER), housed at the Food and Drug Administration, was the first speaker. Dr. Bina described the role of the federal government and other national health care organizations in identifying, mitigating, and preventing drug shortages. She also described how to recognize deceptive schemes that target health care providers and patients affected by drug shortages. At the end of her presentation, Captain Bina addressed questions from the audience.

Following Dr. Bina's presentation the Board honored four pharmacists, Lawrence Sheer, Zelick Waganheim, Anthony J. Petralia, and Mecham (Eugene) Street, for having been continuously licensed in Maryland for 60 or more years. Honoree Eugene Street spoke about his life as a pharmacist. Words



ADMINISTRATION AND PUBLIC SUPPORT

Public Relations Committee Represents Board at Baby Boomers Expo

Janet Y. Seeds, Public Information Officer

For the first time, the Maryland Board of Pharmacy joined hundreds of people at the Baby Boomers Expo held at the Timonium State Fairgrounds on October 10 and 11, 2012. Approximately 10,000 seniors obtained information from the dozens of booths including the Board of Pharmacy's.

Board staff, Board Commissioners and pharmacy students were present to assist at the Board's booth. Many individuals, initially attracted to the Board's booth because of the giveaways, spent significant time at the booth because of the valuable information available. The pharmacists on hand answered numerous questions throughout the day. Many of the attendees were not familiar with the Board; some stating they had never even considered that pharmacists are monitored by the state. The consensus seemed to add a sense of security to attendees in knowing that the Board was looking out for the well-being of pharmacy patients. This event was a rewarding experience for the Board. Readers are urged to attend future Senior Expos to experience and comprehend the magnitude of this event!



PRACTICE CORNER

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be conducted before the electronic prescription application is used to sign or transmit electronic prescriptions for controlled substances, or before the pharmacy application is used to process electronic prescriptions for controlled substances, respectively. Thereafter, a third-party audit or certification must be conducted whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

9. To whom does the third-party audit/certification requirement apply?

A. The requirement for a third-party audit applies to the application provider, not to the individual practitioner, institutional practitioner, or pharmacy that uses the application. Unless an individual practitioner, institutional practitioner, or pharmacy has developed its own application, the practitioner or pharmacy is not subject to the requirement.

Approved Certification Processes

DEA recently amended its regulations to specify the conditions under which controlled substance prescriptions may be issued electronically. As set forth in the regulations, before any electronic prescription or pharmacy application may be used to transmit prescriptions, a third party must audit the application for compliance with the requirements of 21 CFR part 1311, or a certifying organization whose certification process has been approved by DEA must verify and certify that the application meets the require-

ments of 21 CFR part 1311. The following list provides the names and contact information of certifying organizations whose certification processes have been approved by DEA.

InfoGard Laboratories, Inc.

709 Fiero Lane
San Luis Obispo, CA 93401
Phone: 805-783-0810
Email: epcs@infogard.com
Web: www.infogard.com

See - Electronic Prescriptions for Controlled Substances Clarification (October 19, 2011)

Drummond Group Inc.

13359 North Hwy 183, Suite B-406-238
Austin, TX 78750
Phone: 817-294-7339
Email: info2@drummondgroup.com
Website: www.drummondgroup.com

iBeta LLC

2675 South Abilene Street Suite 300
Aurora, CO. 80014
Phone: 303-627-1110
Email: epcs@iBeta.com
Web: www.iBeta.com

See: http://www.dea diversion.usdoj.gov/fed_regs/notices/2012/fr0801_4.htm



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Maryland Board of Pharmacy

CONTACT DIRECTORY	
EXECUTIVE • 410-764-4794 - Attn: Stephen.Holmes@maryland.gov	
LaVerne Naesea, Executive Director; Stephen Holmes, Executive Assistant	Responds to inquiries regarding General Board Operations, Board Issues and Information
ADMINISTRATION • 410-764-5929 - Attn: Anasha.Page@maryland.gov	
Patricia Gaither, Administration & Public Support Manager; Janet Seeds, Public Information Officer; Anasha Page, Office Secretary; Rhonda Goodman, Receptionist	Responds to inquiries regarding Fiscal, Budget, Procurement, Travel, Personnel and Public Information
LEGISLATION AND REGULATIONS • 410-764-4794 - Attn: Stephen.Holmes@maryland.gov	
Anna Jeffers, Legislation and Regulations Manager	Responds to inquiries regarding Legislation and Regulations and Pharmacy Practice Issues
COMPLIANCE • 410-764-5928 - Attn: Courtney.Jackson@maryland.gov	
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
LICENSING • 410-764-4756 - Attn: Tiffany.Duncan@maryland.gov	
Doris James, Acting Licensing Manager; Keisha Wise, Licensing Specialist; LaToya Waddell, Licensing Specialist; Tiffany Duncan, Licensing Secretary	Responds to inquiries regarding Licensing, Permits, Registrations, Reciprocity, Certifications, Scores and Verifications
MANAGEMENT INFORMATION SERVICES • 410-764-4685 - Attn: Michelle.Hsu@maryland.gov	
Michelle Hsu, Database Officer	Responds to inquiries regarding Computer, Database and Website and On-line Renewals

BOARD COMMISSIONERS

President: Michael Souranis
 Secretary: Rodney Taylor
 Treasurer: Lynette Bradley-Baker
 David Chason
 Harry Finke, Jr.
 Mitra Gavvani
 Stephanie Hammonds
 Mayer Handleman

Lenna Israbian-Jamgochian
 Richard W. Matens
 Zeno W. St. Cyr, II
 Donald Taylor

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.

2012-2013 PUBLIC BOARD MEETINGS DATES

Third Wednesday of each month 9:30 am – 12:30 pm	December 19, 2012 February 20, 2013	January 16, 2013
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Location: 4201 Patterson Avenue, Baltimore, MD 21215