#### Fall 2015

# Maryland Board of Pharmacy The Control of Pha

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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; registering pharmacy technicians; issuing permits to pharmacies and distributors; setting pharmacy practice standards through regulations and legislation; receiving and resolving complaints; and educating the public.

Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, MD 21215 Tel: 410-764-4755 Fax: 410-358-6207





## FROM THE EXECUTIVE DIRECTOR'S DESK LaVerne G. Naesea

#### There's a Change a Comin'!

Shortly after my February 2000 appointment as the Executive Director, the then Board and staff members engaged in a retreat to develop a strategic plan. Six goals statements were established and have guided the Board's actions since that time. Despite the Board's subsequent expansion in responsibility and size, the original retreat goals still direct Board actions. I will retire this December, and wish to summarize a few ways that Board Commissioners have realized those goals over the past fifteen years.

# Communication: The Maryland Board of Pharmacy will utilize various means of communication to maximize the efficiency and effectiveness of Board activities.

The expanded popularity of web posting, e-mails and other new modes of communication made it easier to maximize Board communications. Eventually, new applications and renewal reminders will be processed and sent on-line. The Board initiated quarterly newsletters and began publishing and updating biennially, a comprehensive, non-editorialized law book provided at no charge to all new pharmacists and Maryland pharmacies. Board members initiated live continuing education sessions and encourages licensees' to learn about Board activities and actions by offering up to four (4) live CE credits for attending two Public Board meetings biennially. The Board is also considering live streaming of Board sessions in the future.

# Compliance: An efficient, fair and consistent compliant process that enhances the quality of care provided through licensed health care professionals and the regulated industry.

The Board developed and published sanctioning guidelines to assure the rendering of fair and consistent disciplinary decisions. Additionally, an increase in investigator staff and the Board assumption of responsibility to perform annual inspections of Maryland pharmacies and biennial inspections of wholesale distributors, has contributed to more efficient complaint reviews and resolutions. Soon all establishments may renew applications on-line. Direct on-going monitoring by the Board staff has also served to enhance public protection. Technology currently under Board review may further enhance the inspection process by allowing inspectors to remotely access information from its databases.

# Public Awareness: The Public is informed about the availability of pharmaceutical services and how appropriate medication use can enhance the quality of care and safety.

As a result of the creation of Public Relations and Emergency Preparedness committees, the Board engages in several public safety campaigns, as well as routine drills to test systems developed to protect Maryland citizens during emergencies. The work of the Emergency Preparedness Committee has greatly contributed to its umbrella agency, the Department of Health and Mental Hygiene consistently receiving the highest rating for emergency preparedness in the country. Also, outreach to consumers and licensees at exhibitions at state and local events and pharmacy associations' meetings are now on-going.

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

#### FROM THE EXECUTIVE DIRECTOR DESK - Continued From Page 1

govern the practice of pharmacy, as well as the policies of the Board, reflect current standards of practice. Pharmacists and permit holders have access to timely and relevant information and guidance that helps improve their practice, safely utilize new technology and remain current with the regulatory policies of the Board.

Close to thirty legislative proposals and several more implementing regulations have been passed and promulgated over the past 15 years to keep pace with practice and patient trends. Key patient protection successes have included the expansion of laws governing the oversight of wholesale distributors, non-resident pharmacists and pharmacies, pharmacy technicians, pharmacy student interns, foreign graduates and dispensing practitioners; ensuring safe pharmacy practices by entities that perform sterile compounding; protecting Maryland's most vulnerable pharmacy patients in long term care facilities; assuming direct Board inspections of pharmacies and wholesale distributor establishments; enacting and enforcing patient safety and quality assurance requirements at pharmacies; and expanding pharmacists' scope of practice to include engagement in administration of vaccines, collaborative drug therapy and a variety of other new practice venues.

Political Relationship: Strong partnerships with stakeholders (to include governmental officials, consumer groups and the regulated pharmacy industry) who are educated and informed about pharmacy related issues that affect health care quality, and the safety and welfare of the citizens of Maryland.

The Board's relationships with political stakeholders are very strong thanks to its efforts to communicate initiatives both informally and formally. An important driver of the Board's success in meeting this goal has been Anna Jeffers, the Board's Regulations/Legislation Manager. Board Commissioners, staff members and I have had the good fortune of working with Anna to communicate, support, and implement key statutory and regulatory initiatives for nearly 11 years. Anna's law degree, legislative and regulatory expertise, superior organization skills and amicable, yet professional demeanor contributed greatly in strengthening Maryland's pharmacy and patient safety laws. She has guided the passage of successful legislation and regulations, staffed numerous Board and legislature appointed workgroups, and responded to consumers, practitioners, politicians, and the media with ease and commitment. Anna also plans to retire in the first quarter of 2016. She has; however, set a model standard and foundation for building strong political relationships that will help carry the Board's success in the future.

#### Staffing: The Maryland Board of Pharmacy currently has well qualified human resources that can accomplish the Board's mission.

Over the past fifteen years, staff membership at the Board increased from seven to 28 and monitored licensees grew from less than 10,000 to close to 30,000. During the same period, new staff categories such as investigators; inspectors; public information officer; health care

Addressing Change: Statutes and regulations that coordinator; database, customer service and data integrity specialists; and most recently a lab scientist and deputy director have been recruited; and approved appropriations grew from less than \$1,000,000 to over \$4,000,000. Board offices have moved from the third floor to the first floor to its current location on the fifth floor to accommodate growth.

> In spite of the many Board accomplishments during my tenure, increased regulatory mandates and related tasks have profoundly and visibly strained the Board's efforts to meet its mission of protecting Maryland patients. Board data has been transferred from a simple Access software database to a SOL-based system. Nonetheless. successes in this and other areas mentioned have not been sufficient to fully support the Board's operational

> infrastructure. The Board still struggles in securing the "right" MIS system to meet operational requirements and has not yet acquired staff sufficient to carry out necessary

> Managing Board operations made it impossible for me to consider retiring in good conscience -- until now. But I tell you there's a change a comin'! The Board's operations reengineering project began June 2015. This project helped open the door to my retirement. It involves the use of Lean Six Sigma methods to map the Board's business flow by analyzing the current people, policies and technologies used to support the Board's operations, and incrementally implement actions to eliminate resource waste (personnel, time, money, etc.), revise and update Board policies and procedures, and restructure the way business is done at the Board of Pharmacy. The ultimate goals are to develop bid specifications for a new MIS system that reflects the many current and future processes required for the Board to receive and route information, incorporate modern digital and social media technologies to interface with other MIS systems (e.g., CPE Monitor, NABP testing, other state systems and perhaps even state and federal criminal background check systems), identify and acquire the necessary staff and other resources required to successfully support the Board's current and future operational needs.

> The Board also appointed its first Deputy Director of Operations, Stephanie Ennels, in October. Working under the direction of the Board and my impending successor, Deputy Ennels will manage the Board's personnel, MIS, and fiscal units and strengthen its operational infrastructure. Possessing over 25 years experience as the Director of Budget and Reporting at the University of Maryland, Baltimore; the Budget Director and Fiscal Officer with the Baltimore County Public School System; and the Budget Analyst with the MD Department of Budget and Management, Stephanie is more than able to support new Board initiatives.

> Change is good and the Board is prime for the above described changes that promise to support essential operational requirements. The recent retirement of former Administration Unit Manager, Patricia Gaither, and pending retirements of Anna Jeffers and me, will occur before the reengineering project is complete. Nonetheless, I am confident that the Board's operational structure will become more robust, more efficient and possibly a

#### FROM THE EXECUTIVE DIRECTOR DESK - Continued From Page 2

model for Maryland's other health occupation boards and pharmacy boards throughout the country.

Working for the Board has been a highlight of my 33 years of State service. It has also been an opportunity of a lifetime to contribute in a small part to the Board's 113 year legacy. There are so many with whom I worked that I must thank for their unwavering commitment, leadership and hard work in continuously pursuing successes in meeting Board goals. They include: current and former Board Commissioners; former Board presidents Stanton Ades, John Balch, Mark Levi, Donald Taylor, Michael Souranis, Lenna Israbian-Jamgochian and last, but not least, current President Mitra Gavgani; current and

former Assistant Attorneys, General Linda Bethman, Paul Ballard and Brett Felter; loyal Board staff members and Unit managers; Maryland's licensed pharmacy practitioners; State officials and agencies; and my state and national peers who lead and have led other health occupation boards. Maryland's patients have benefited from our collective efforts and continue to receive safe, quality prescription drugs and pharmaceutical services. They remain in good hands under the Board of Pharmacy's watch and may look forward optimistically to greater protection as a result of the changes that are "a comin'" very, very soon!!

REMEMBER: Please update your email address and residential address by completing and submitting the Address/Employer Change form at:

dhmh.maryland.gov/pharmacy
(see right column, under Online Services)

Now is the time to voice your opinion!
Go to <a href="https://www.dhmh.maryland.gov/pharmacy">www.dhmh.maryland.gov/pharmacy</a>
and complete the Working Conditions Survey

#### PHARMACY INTERN REGISTRATION

#### YuZon Wu, Licensing Manager

The Student Technician Exemption Registration expired on October 31, 2015 and will cease to be effective. In its place, the Maryland Board of Pharmacy (the "Board") promulgated the Pharmacy Intern regulations, COMAR 10.34.38, which came into effect on July 1, 2015.

Effective July 1, 2015, a pharmacy intern must register with the Maryland Board of Pharmacy in order to practice pharmacy under the direct supervision of a pharmacist. Eligible pharmacy intern applicants must be:

 Currently enrolled and have completed 1 year of professional pharmacy education in a doctor of pharmacy program (program must be accredited by the Accreditation Council for Pharmacy Education or have pre-candidate or candidate status by the Accreditation Council for Pharmacy Education);

ΛR

 Have graduated from a doctor of pharmacy program accredited by the Accreditation Council for Pharmacy Education;

OR

 Have graduated from a foreign school of pharmacy and established educational equivalency as approved by the Board (FPGE Certificate).

#### **INITIAL REGISTRATION PROCESS:**

Eligible first-time pharmacy interns may apply for registration with the Board of Pharmacy using the below procedure:

- (1) Submit a signed completed application on a form provided by the Board;
- (2) Pay the \$45.00 fee as set forth in COMAR 10.34.09;
- (3) Submit a request for a State Criminal History Records check; and
- (4) Be of good moral character.

The Board will not approve an application until the State Criminal History Records Check is completed. Upon registration, the Board of Pharmacy will provide pharmacy interns with a registration card and pocket identification card.

If you are a foreign graduate pharmacist working towards your intern hours, you must apply, obtain, and work under this pharmacy intern registration post October 1, 2015 in order for the Board to consider your hours worked to be intern hours. Any hours worked prior to October 1, 2015 will still count towards fulfilling the 1560 intern hour requirement needed for the pharmacist license.

There is an FAQ section on the Board's website (click the INTERNS tab on the Board homepage: www.dhmh.maryland.gov/pharmacy) or contact the Board's Customer Service Unit at 410-764-4755.

#### **MEDICATION ERRORS: AN OVERVIEW FOR 2015**

#### David Jones, Board Commissioner

This article is written in partial response to risks for medication errors that have been identified in two Board of Pharmacy (the "Board") Working Condition Surveys (the "Survey").

Medication errors present a risk for harm to the patient. Adverse events account for up to 700,000 Emergency Department visits, annually, and 100,000 acute care admissions. Such errors may injure 1,500,000 people, annually, and add billions of dollars to direct health care costs. <sup>1,2</sup> In 2012, the Institute of Medicine (IOM) reported that up to 400,000 deaths, annually, were linked to medication errors. This compares with figures for 1999 that noted 98,000 deaths.

The Institute for Safe Medication Practices (ISMP) notes that there is no accepted national benchmark for medication error incidence. Data must be practice-setting specific. If airline accidents happened at the same frequency as seen in some practice settings, IOM states that three to five jumbo jets would fall out of the sky daily.

So just what is a medication error? From definitions provided by ISMP,

- A. A medication error is "any error occurring in the medication use process." Note that this definition includes any and all errors at any time.
- B. Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."4

Maryland law reflects the second definition above (COMAR 10.34.26 B (2)(a) and (b).

Medication errors may be broken down into two separate categories: mechanical errors that relate to the prescription, per se, and judgmental errors that involve professional interaction and intervention.

- A. Mechanical errors include anything that varies from the traditional rights of medication safety. These include the right drug, dose, dosage form, quantity, directions, indication, route, duration, and, of course, the right patient.
- B. Judgmental errors include failure to check for drug interactions or full allergy information, inadequate drug use review, and inadequate or missing counseling, education or support. An additional way to look at medication errors may include the following statement. "An unintended act, either of omission or commission, or any act that does not achieve its intended effect." Thus, errors may be labelled as those of omission or commission. These may overlap mechanical and judgmental classifications.

The FDA reviews medication errors through the Division of Medication Error Prevention and Analysis within the Center for Drug Evaluation and Research. This applies to all marketed human drugs, whether legend or OTC.

Dr. Gregory House (TV show "House") advises us that, "It is in the nature of medicine to screw up." However, it is essential that all pharmacists and pharmacy technicians exercise every effort to avoid medication errors. A culture of patient safety must address all issues, systemic and human, involving medication errors. An ongoing quality assurance program is legally required in Maryland for all pharmacies. See COMAR 10.34.26.04. The quality assurance program must address ways to minimize medication errors, mechanisms to detect and investigate all occurrences, analysis of causes, and communication to all involved, and documentation. Periodic review of such programs is also required at least every 3 months.

Medication errors can occur at any stage of filling and dispensing prescriptions. Assessment of errors must address level of risk for harm. Assessment of harm should consider frequency and severity. Although all errors must be investigated, more frequent and more harmful errors must receive immediate and aggressive attention.

Risk for harm may be considered according to levels based on ISMP-IOM guidelines:

- A. Circumstances exist to allow an error to occur.
- B. An error happened, but did not reach the patient.
- C. An error reached the patient but no harm occurred.
- D. An error reached the patient requiring monitoring but no other action.
- E. An error reached the patient causing temporary harm with some level of intervention.
- F. An error reached the patient, causing temporary harm and requiring some acute care intervention.
- G. An error causes permanent patient harm.
- H. An error required life-saving intervention at any level.
- I. An error causes death.

An error that is caught internally prior to dispensing may not present a risk to the intended patient, but it is nonetheless an error. Evaluation of its cause can provide means to avoid that same type of error in the future and provide for better patient safety in the event that the next error is not caught internally. An error not documented presents a risk for recurrence. All errors that reach the patient, regardless of any harm, must be fully assessed and documented.

The patient or caregiver is always an essential part of medication error prevention. A process to provide awareness of risk, need for communication, and appropriate participation in evaluation and correction is important. A number of factors can contribute to the risk for medication errors. These identified pharmacist working condition risks include those identified on the Survey as well as AHRQ data. They include, but are not limited to the following.<sup>7</sup>

- 1. Distractions and interruptions;
- 2. Staffing shortages;
- 3. Workflow and volume;

#### MEDICATION ERRORS – Continued From Page 4

- procedure statements;
- 5. Communication problems;
- 6. Failures in communication;
- 7. Human error;
- 8. Technical failures;
- 9. Patient-related issues;
- 10. Computer-driven risk, including data and dropdown menu risks; and
- 11. Look-alike, sound-alike drug names or similar issues

There are a number of tools and guidelines that can assist pharmacists and pharmacy technicians in reduction of risk for medication error occurrence. These include, but are not limited to, the following.8

- 1. High-alert Medication Modeling and Error Reduction Scorecards (HAMMERS)
- 2. Root Cause Analysis (RCA) Workbook Community/Ambulatory Pharmacy
- 3. High-alert Medications Consumer Leaflets
- 4. ISMP's Medication Safety Self-Assessment for Community/Ambulatory Pharmacy
- "Use Medicines 5. America's Medication Cabinet Safely" Campaign
- 6. ISMP's Medication Error Reporting Program
- 7. The Agency for Health Care Quality & Research (AHQR): Patient-centered "20 Tips to Help Prevent Medical Errors"
- 8. The American Society of Health-system Pharmacy (ASHP) "Guidelines on Preventing Medication Errors in Hospitals"
- 9. The American Society of Consultant Pharmacists (ASCP): "ASCP's Guidelines on Preventing Medication Errors in Pharmacies and Long-Term Care Facilities Through Reporting and Evaluation"
- 10. Maintaining existing tools such as Tall Man Lettering, Look-alike, Sound-alike Drugs, Do Not Use Abbreviation List and High-Alert Medication List
- 11. Root Cause Analysis (RCA) and Failure Mode and Effects Analysis (FMEA) approaches to analyzing medication errors and methods to prevent them.

Any plan of correction as part of a quality assurance process should address the issue from a proactive, nonpunitive, approach to be fully effective. A survey released in February of 2012 by the Agency for Healthcare Research and Quality (AHRQ) showed that a majority of health care practitioners in acute care settings fear punishment rather than welcome open communication when reporting medication errors...9 Of those responding to the survey, 54% felt that the person rather than the problem was being addressed. The recently completed Board Survey found that 61% of respondents worried

4. Inadequate or missing quality assurance policy and about a punitive culture in dealing with medication errors. In the AHRQ report, nearly 70% worried that such mistakes would be reported in their personnel file.

> AHRQ encourages a Culture of Safety rather than the "Find them and fire them" approach as the optimal way to awareness and avoidance of medication errors. This includes, but is not limited to, the following steps.

- 1. Awareness and acknowledgement of high-risk medications and processes;
- 2. Establishing and maintaining a blame-free environment so that errors of all types can be reported without fear of punishment;
- 3. Encouraging full collaboration among all staff; and
- 4. Maintaining a comprehensive quality assurance and improvement protocol that addresses all safety concerns.

Additional data about establishing and maintaining a "Culture of Safety" is available on the AHRQ website.<sup>10</sup> Note: COMAR 10.34.26 addresses additional definitions, requirements for patient and staff education, and the mandated ongoing Quality Assurance Program regarding medication errors and patent safety.11

Additional information about comprehensive awareness and prevention of medication errors, documentation, and avoiding an exclusionary, punitive approach will be included in future Board newsletters and other communications.

#### References/ resources:

- 1. ISMP website, accessed July 2015
- 2. National Academy of Sciences, Institute of Medicine website, accessed April 2015
- 3. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. 1995. Relationship between medication errors and adverse drug events. Journal of General *Internal Medicine* 10(4): 100–205.
- 4. The National Coordinating Council for Medication Error and Prevention
- 5. J. Lazarou, *JAMA*, 1998.
- 6. Quotation from TV series House, MD Season 7:
- 7. AHQR data, 2012
- 8. Websites for AHQR, ASCP, ASHP and ISMP for tools and guidelines.
- 9. AHRQ website, accessed August 2015
- 10. Adapted from Denham, CR. "TRUST: The Five Rights of the Second Victim", Journal of Patient Safety, 2007; 3:107-119
- 11. Maryland Pharmacy Laws, 2014 edition.

NOTE: The Working Conditions Survey will remain on the Board's website for approximately 4 weeks from publication of this Fall newsletter.

#### **CONTINUING EDUCATION CONFERENCE**

#### Janet Seeds, Public Information and Education Officer

There was nearly 100% attendance at the Board of Pharmacy's (Board) Annual Continuing Education Conference, held on October 18, 2015 at the Maritime Institute. Entitled, "The Future is Here" featured presenters who commanded the audience's attention as they discussed issues related to the future of pharmacy practice in Maryland.



Board President, Mitra Gavgani opened the breakfast and introduced the first speaker, Michael Baier, Director of the Office of Overdose Prevention at the Behavioral Health Administration (BHA). Mr. Baier discussed the causes and scope of the opioid addiction and overdose epidemic in the U.S. and in Maryland and summarized the new State naloxone distribution initiative to the over 170 attendees at the breakfast. Mr. Baier oversees the operations of the BHA Office of Overdose Prevention, and has become a State authority on drug and alcohol overdose prevention and response programs. As a result of his work with the Overdose Response Program (naloxone distribution), Prescription Drug Monitoring Program, Controlled Dangerous Substance Integration Unit, Overdose Fatality Review, Overdose Survivor Outreach Project and other State initiatives, his presentation was both interesting and informative.

The second speaker was Angela Evatt, who is Division Chief for Health Information Exchange at the Maryland Health Care Commission's (MHCC) Center for Health Information Technology and Innovative Care Delivery. Ms. Evatt identified telehealth technologies and adoption levels among health care providers in Maryland and discussed how to advance telehealth in Maryland. She manages the 45 member health information exchange (HIE) Policy Board and has played an integral part in drafting the State's HIE Privacy and Security regulations. In her position, Ms. Evatt coordinates various health information technology (health IT) regulatory and research initiatives of the MHCC to advance secure health information exchange and widespread adoption and use of electronic health records and telemedicine.





Again this year, five (5) pharmacists were honored for being actively licensed for 60 years. Governor's Citations for Lawrence Abrams, James Ortt, John Murphy, Melvin Rubin and Morton Silverman were read. Melvin Rubin and Morton Silverman received their citations in person. The other three honorees' citations were mailed. LaVerne G. Naesea, Executive Director of the Maryland Board of Pharmacy, shared information about honorees based on information they shared with board staff before the event.



The final speaker, David Jones, presented information on Medication Errors, based on his personal experiences as a practicing pharmacist and information collected from more than three thousand pharmacists who participated in the Board of Pharmacy's recent Working Conditions survey. Providing stories about errors made in the past, Mr. Jones was able to highlight the serious negative consequences that could result from common practice mistakes. Commissioner Jones is Board Secretary and the Board's Long Term Care representative. He quoted "House, MD" character Dr. Gregory House, who said, "It is the nature of medicine that you are going to screw up" to emphasize his point that pharmacists are responsible for thousands of patients each year so it is extremely important to "check, re-check, and check again."

Attendees had opportunities to ask questions and share their thoughts, experiences and challenges as pharmacists working in Maryland, following the last presentation. They also voiced appreciation of the Board's effort to bring relevant information about the current and future state of pharmacy practice in Maryland. ACPE Continuing Education units were available for participants who completed the on-line program survey.

The Board of Pharmacy is constantly learning from these events and looks forward to seeing you at next year's CE conference!

DISCIPLINARY ACTIONS				
PHARMACIST	LIC. #	SANCTION	DATE	
Jackie McCall, Jr.	21799	Probation	6/26/15	
Jessica McLaughlin	22852	Probation	8/13/15	
Francisa Onobobi	18666	Summary Suspension	10/5/15	
PHARMACY TECHNICIAN	REG. #	SANCTION	DATE	
Lakira Whitaker	T08517	Summary Suspension	7/30/15	
Kisa Bridges	T11311	Summary Suspension	8/06/15	
Angela Morfe	T02574	Revoked	8/19/15	
Nicole Cox	Applicant	Denied	8/19/15	
Giovanni Vittoriano	T08462	Suspended	9/28/15	
Vandever Rash	T14348	Revoked	10/21/15	
Beverly Winn	T10372	Revoked	10/21/15	
Vipinkumar Patel	T04387	Revoked	10/21/15	
Thomas Martino	T12340	Revoked	10/21/15	
Diana Lubic	T11601	Revoked	10/21/15	
Treneda Allen	T05558	Revoked	10/21/15	
Brian Boddie	Applicant	Denied	10/21/15	
Timur Yusufov	T03304	Reprimand/Probation	11/7/15	
Mary Kreysa	T12108	Summary Suspension	11/9/15	
Jasmine Smith	T13015	Summary Suspension	11/9/15	
Jigar Patel	T08246	Revoked	11/18/15	
ESTABLISHMENT	PERMIT #	SANCTION	DATE	
OK Compounding	P06041	Fine	10/21/15	
Midwest Veterinary Supply, Inc.	unlicensed	Fine	10/28/15	
Health Rite Pharmacy & Medical	P06677	Probation/Fine	11/9/15	
Supply (formerly Health Way Pharmacy)				
Time Organization	PW0349	Letter of Surrender	11/18/15	

<sup>\*\*</sup> For more complete information on the actions listed above, or for copies of other Board disciplinary actions, please visit the Board's website at www.dhmh.maryland.gov/pharmacy

#### PRESCRIPTION DRUG REPOSITORY PROGRAM

#### YuZon Wu, Compliance Unit Manager

The Prescription Drug Repository Program (the "Program") was established to allow the Board to provide a mechanism for pharmacies, after being approved as repositories and/or drop-off sites, to:

- Accept donated prescription drugs and medical supplies for the purpose of dispensing the donated drugs and medical supplies to needy individuals; and/or
- (2) Accept prescription drugs and medical supplies returned to a pharmacy of the purpose of proper disposal.

Applications for pharmacies to become a Prescription Drug Repository site are available on the Board's website (http://dhmh.maryland.gov/pharmacy/SitePages/establishmentforms.aspx). It is only through the submission of this application and Board's approval that a pharmacy may engage in this voluntary Program (HO § 15-601 - 15-609 and COMAR 10.34.33).

On October 9, 2014, the U.S. Department of Justice, Drug Enforcement Administration (the "DEA") published its final rule authorizing ultimate users to transfer unwanted and unused controlled substance medications

to an authorized collector, to include pharmacies, for safe disposal. These authorized collectors may collect controlled substance medications by the following methods: collection receptacles, or mail back programs. For more information, please go to <a href="http://www.deadiversion.usdoj.gov/21cfr/cfr/1317/subpart b.htm">http://www.deadiversion.usdoj.gov/21cfr/cfr/1317/subpart b.htm</a>.

If a pharmacy wishes to take-back controlled substances for safe disposal, it must obtain a modified DEA registration as a retail pharmacy collector, IN ADDITION TO being Board approved as a repository. If a pharmacy only wishes to take-back non-controlled substances, it must only obtain approval from the Board as a repository; no modified DEA registration is necessary. A pharmacy may not take-back prescription drugs, controlled or non-controlled, or medical supplies, unless it is approved by the Board as a repository.

The Board has proposed revised regulations governing the return of prescription drugs and medical supplies for disposal, which will be published in the Dec. 28, 2015 Maryland Register for comment as well as posted on the DHMH website (<a href="https://www.dhmh.maryland.gov">www.dhmh.maryland.gov</a>).



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### **Maryland Board of Pharmacy**

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Consumer Representative
At-Large Representative
Independent Representative

#### **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.

#### 2015 PUBLIC BOARD MEETINGS DATES

#### Third Wednesday of each month

December 16, 2015 January 20, 2016 February 17, 2016

Location: 4201 Patterson Avenue, Baltimore, MD 21215