

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 health care in the field of pharmacy through licensing pharmacists and registering pharmacy technicians and student interns, 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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FROM THE EXECUTIVE DIRECTOR'S DESK

Deena Speights-Napata, Executive Director

Coming together is beginning, Keeping together is progress, Working together leads to success

I am honored to have been selected as the new Executive Director of the Maryland Board of Pharmacy. In assuming this position I bring over twenty years of senior management and supervisory experience with agencies that include Maryland Medicaid, the Maryland Center for Immunization, and both the Maryland and National offices of AARP.

By the time this newsletter reaches your in box, I will be celebrating close to 8 weeks in this position. My focus has been on staff roles and responsibilities, and staff ability to resolve complaints and provide consumer protection. To this end I have met individually with all staff, initially focusing on procurement, call center, and inspector roles, having accompanied inspectors on close to twenty pharmacy audits. I was able to learn a lot about the work of our office in procuring and processing vendor contracts, resolving complaints, and providing quality assurance.

My initial findings have led me towards implementation of the following strategies:

- Require staff training on the procurement process to improve processing and payment of vendor contracts
- Increase call center staff efficiency by providing upgrades in equipment that will improve response time to pharmacist, technician, and public inquiries
- Encourage effective staff communication by rearranging seating to allow increased meeting space for our information system staff and more secluded space for call center and investigative staff
- Develop and improve data bases and systems for sharing information between divisions to decrease the length of time of individual calls and increase accuracy of responses
- Improve accommodations in the public area where applications and fees are submitted and create board office space
- Increased opportunities to meet and talk with pharmacy community partners to better understand how we can support pharmacists, technicians, and wholesale distributors in the important service they provide to the public
- Implementation of an on-line pharmacist application renewal system to improve the renewal process
- Filling of staff vacancies in the audit and data processing areas, necessary to process license renewals and interpret lab data.

Yes, coming together is important, but it's only the beginning. I looking am forward to serving each of you in the coming months as we, as a team, make progress in our quest for success.

SPOTLIGHT ON....
NEW EXECUTIVE DIRECTOR



Deena grew up in Catonsville, MD as the youngest of five girls. As a child she played the flute for over 10 years and always loved animals. Her love for animals led her to become a vegetarian at the age of 18, and she still is today.

Deena attended college at Hampton University where she earned a bachelor's degree in journalism and television production, and a minor in political science. Upon graduation from college she married and had two children, a boy and a girl. She now also has two granddaughters, 11 and 8 years of age. Deena pursued and earned a graduate degree in Legal Studies from the University of Baltimore, where she minored in Public Administration.

Her professional career includes brief pursuits as a model, journalist, and legal assistant, but the bulk of her career has been in the field of health program administration: 4 years as a health program administrator in Head Start, 4 years as a health program manager at the Baltimore City Health Department, 4 years as Deputy Director of Maryland Medicaid Policy/Data Analysis Division, 6 years as Deputy Program Manager of the Maryland Center for Immunization, and nearly 4 years as the Maryland AARP Deputy Director.

Please join us in welcoming Deena as the Maryland Board of Pharmacy Executive Director.

NEW MAIL SYSTEM

Stephanie Ennels, Deputy Officer of Operations

Beginning March 28, 2016, the Maryland Board of Pharmacy will be implementing a lockbox service to accept all applications, payments, and correspondence sent to the Board. A lockbox is a [post-office box](#) that is accessible by a bank. All correspondence, applications, and payments are sent to the post office box and Citibank, the Board's financial vendor, will collect and sort the mail, process payments directly and deposit them to the Board's account.

The Board has established four individual post office boxes to accept mail specific to Pharmacists and Interns, Pharmacy Technicians, Pharmacies and Distributors, and a miscellaneous post box to handle non-cash correspondence not associated with the other post boxes.

The following post office addresses have been established for the Board of Pharmacy:

For Pharmacist & Intern Applications (new and renewal), Vaccination Forms, Law Books and E-books, and Duplicate Licenses for Pharmacies and Pharmacists, and all related correspondence, send to:

Maryland Board of Pharmacy
P.O. Box 1991
Baltimore, Maryland 21203-1991

For Pharmacy Technicians Applications (new and renewal), Duplicate Licenses for Technicians, Written Verification Forms, Technical Training Programs and Exams, and all related correspondence send to:

Maryland Board of Pharmacy
P.O. Box 2013
Baltimore, Maryland 21203-2013

For Pharmacies, Wholesale Distributors, and Manufacturers (new and renewal), Non-Resident Pharmacies, Pharmacy Waivers, and all related correspondence send to:

Maryland Board of Pharmacy
P.O. Box 2024
Baltimore, Maryland 21203-2024

For Return Check Processing, Failure to Maintain Address, Request for Printed Rosters, Fines, Drug Therapy Management, Prescription Drug Repository, and Name and Address changes, send these types of forms and all correspondence to miscellaneous post box at:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051

REMEMBER

Please update your email address and residential address by completing and submitting the Address/Employer Change form at: dhmh.maryland.gov/pharmacy (see left column, under Online Services)

LICENSING CORNER

David H. Jones, RPh, FASCP. Board Commissioner

Anyone working as a pharmacy technician and/or performing any duty related to the prescription dispensing process must have an active pharmacy technician registration with the Maryland Board of Pharmacy (“Board”) or be currently enrolled in a Board-approved pharmacy technician training program (“Training Program”).

Anyone enrolled in such a Training Program has a six-month window of exemption from the Board’s registration requirement. However, if the trainee has not successfully completed the Training Program within a six-month time frame, he or she cannot work any longer as a pharmacy technician under the exempt trainee status.

The Pharmacy permit holder has the ultimate responsibility to verify the license and registration status of all of its employees. This includes verifying active technician registration with the Board, or

participation in an approved Training Program.

Generally, if the person does not have current registration as a Pharmacy Technician or is not enrolled in an approved Training Program, he or she cannot work as a pharmacy technician. Please note that an individual may not begin working as a pharmacy technician solely because he or she has submitted an application for registration to the Board. The application must be reviewed and approved by the Board before the individual may begin working as a technician. Lastly, remember that the registration exemption for technician trainees is only for six months from starting the approved Training Program.

Unlicensed individuals may perform non-prescription dispensing duties that may include such functions as inventory control, housekeeping activities, and ringing the cash register.

DISCIPLINARY ACTIONS

| <u>PHARMACIST</u> | <u>LIC. #</u> | <u>SANCTION</u> | <u>DATE</u> |
|-----------------------------------|------------------------|------------------------|--------------------|
| Anne Gingher | 10636 | Suspended | 01/12/16 |
| Joel Smith | 16811 | Suspended | 01/15/16 |
| <u>PHARMACY TECHNICIAN</u> | <u>REG. #</u> | <u>SANCTION</u> | <u>DATE</u> |
| Jigar Patel | T08246 | Revoked | 11/18/14 |
| Germaine March | T03288 | Suspended | 11/30/15 |
| Murphy Paschall | T15533 | Suspended | 11/30/15 |
| Murphy Paschall | T15533 | Suspended | 02/02/16 |
| Vincent Knight | T16928 | Suspended | 02/02/16 |
| Mary Jones | T06581 | Suspended | 03/18/16 |
| Melinda Fink | T16671 | Suspended | 03/21/16 |
| Emmanuel Smith | T14194 | Suspended | 03/22/16 |
| Eric Robinson | T15618 | Suspended | 03/22/16 |
| <u>ESTABLISHMENT</u> | <u>PERMIT #</u> | <u>SANCTION</u> | <u>DATE</u> |
| Time Organization | PW0349 | Voluntary Surrender | 11/18/15 |
| Precision Pharmacy | P05110 | Probation | 12/09/15 |
| American Specialty | P06661 | Fine | 12/28/15 |
| Hopkinton Drug | None | Fine | 02/04/16 |
| Advanced Pharmacy | PW0476 | Fine | 02/19/16 |
| College Pharmacy | P04714 | Reprimand | 01/20/16 |
| Main Street Pharmacy | P05425 | Fine – Stayed | 02/17/16 |

PRESCRIPTION DRUG REPOSITORY PROGRAM

David H. Jones, RPh, FASCP. Board Commissioner

The Board of Pharmacy (the “Board”) has received a number of questions about the Prescription Drug Repository Program (“PDRP”). At the outset, please note that the PDRP laws allow for both prescription drugs to be returned for the purpose of re-dispensing to needy individuals, AND return of prescription drugs for the purpose of proper disposal. This review will address only those requirements applicable to pharmacies that wish to accept returned drugs for purposes of disposal. The requirements for returned drugs to be re-dispensed to needy individuals can be found at COMAR 10.34.01-06-1..

The Board has revised the COMAR 10.34.33 regulations to distinguish the requirements between those pharmacies that wish to dispose of non-CDS drugs only, and those that wish to dispose of CDS or a mixture of CDS and non-CDS drugs.

Some initial comments to remember:

- Participation in PDRP is and always has been completely voluntary, with no associated Board fees.

The Board requires that a pharmacy submit an application to be able to take part in PDRP if the pharmacy will be accepting ANY returned drugs for disposal.

There are two scenarios in determining which requirements apply to allow a pharmacy to dispose of returned drugs. These are: (1) the pharmacy will accept the return of CDS, or a mixture of CDS and non-CDS; or (2) the pharmacy will accept the return of, non-CDS only.

For those pharmacies that will only accept the return of non-CDS drugs, Maryland law applies and requires that a secure container be kept behind the prescription counter. Only a pharmacist may accept non-CDS drugs to be placed in this secure container. This duty cannot be delegated to a pharmacy technician. No Controlled Dangerous Substances may be accepted. The pharmacy is responsible for defining a reverse distributor or disposal company for final disposal of these drugs.

The federal law, Federal Secure and Responsible Drug Disposal Act of 2010 and its corresponding regulations, addresses disposal of CDS. This means both CDS alone and any comingling of CDS with non-CDS. Pharmacies must modify their DEA registration to be an “authorized collector” for these purposes.

The federal law specifically defines what constitutes a “collection receptacle” for these agents and states that it must be located in the immediate vicinity of the prescription area, but NOT behind the prescription counter. Only the individual returning the drugs, referred to as the “ultimate user” in Federal Code, may deposit them in the secure container for disposal. In other words, the pharmacist is not permitted to accept the returned drug directly from the ultimate user. The ultimate user is the patient for whom the drugs were prescribed or an assigned designee. The federal regulations specify the manner in which the drugs are to be accounted for and disposed of. Please see the DEA’s website at www.DEAdiversion.usdoj.gov for the publication of the federal regulations and other related information.

Just a Reminder.....

- **Transfer of Intern hour requests MUST be in writing and are free of charge.**
- **Verification of licensure requests MUST be in writing and cost \$25 per letter/verification.**

WORKING CONDITIONS SURVEY SUMMARY

David H. Jones, RPh, FASCP. Board Commissioner

The Board of Pharmacy has conducted three separate versions of a Pharmacist Working Conditions Survey. All were intended to address patient safety issues that may be related to working conditions in pharmacy practice throughout the state. Medication errors that might be consequences of medication errors were one focus of the Surveys

This summary will address medication errors later in this article.

Based on the surveys, a profile of the average Maryland Pharmacist could be generated. Thus, we see that he or she:

- Works for a chain drug store, with hospital and community settings following;
- Has been in practice for more than 20 years;
- Works 40 to 45 hours per week;
- Supervises 2 to 4 pharmacy technicians;
- Fills 100 to 300 prescriptions or orders daily;
- Performs a variety of tasks including;
 - Ring the register,
 - Briefly consult with patients, upon request,
 - Consult with other health care professionals,
 - Supervise personnel,
 - Verify prescriptions,
 - Answer phone calls,
 - Complete administrative records and/or tasks, and
 - Order medications and other pharmacy supplies
- Agrees that the pharmacy is well organized and supports good workflow;
- Does not feel that new staff receive adequate orientation;
- Agrees that staff are trained on the need to prevent medication errors;
- Is able to talk to patients about medications most of the time but does so only sometimes;
- Communicates well across shifts about issues;
- Always feels rushed when filling prescriptions or orders;
- Rarely has enough staff to handle the real workload
- Has breaks scheduled but is seldom able to take them effectively;
- Does not routinely have back up for breaks and meals;
- Staff is treated fairly when a medication error occurs, but 61% worry about a punitive culture;
- Staff learns from medication errors that occur;
- There is a system focus on patient safety;
- Are unsure about effective and positive changes in addressing medication errors;
- No stratification of the severity of the errors was available:
- Makes 2 to 3 medication errors in any given month;
- No stratification patient risk from the severity of the errors was available:

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**DEA
to hold next
National Prescription Drug
Take-Back Day in April**

Drug Enforcement Administration (DEA) has announced another opportunity for consumers to dispose of unneeded and expired prescription drugs during the 11th DEA National Prescription Drug Take-Back Day, which will be held April 30, 2016. On this day, from 10 AM to 2 PM, thousands of collection sites will be available across the country to accept unneeded prescription drugs, including controlled substances, for safe and legal disposal. To date, DEA's Take-Back Day initiative has collected a combined total of more than 5.5 million pounds (over 2,750 tons) of unneeded medications, helping to prevent diversion, misuse, and abuse of the drugs. More information about safely disposing of medications at home and finding a permanent local drug disposal program is available in the Dispose Safely section of the AWA_RX_E[®] website.

According to the DEA website at www.dea.org, actual locations for this Take-Back Day will be listed as of April 1, 2016.

INCREASED ACCESS TO NALOXONE

Now available without a prescription at Maryland Pharmacies

Erin E. Hass, MPH, Local Programs Manager, Overdose Prevention, Behavioral Health Administration

The Department of Health and Mental Hygiene (DHMH) continues to expand the Overdose Response Program (ORP), a public health initiative providing overdose education and naloxone distribution to community members across the state. The ORP includes free educational resources for training patients and other laypersons on responding to an opioid overdose with naloxone, a prescription medication that safely and quickly reverses an overdose and restores breathing. While naloxone can be prescribed to patients at risk for overdose or likely to witness and respond to an overdose emergency, the ORP provides a way to increase awareness, training, and access to the drug at the community-level.

In December 2015, Dr. Howard Haft, Deputy Secretary for Public Health Services at DHMH issued a statewide standing order for naloxone to all

Maryland pharmacists. ORP certificate holders can now obtain naloxone without a prescription at any participating pharmacy through the standing order. The certificate proves the individual received adequate training to carry and use naloxone through the ORP. The standing order was faxed to all pharmacies in order to meet the standard for tamper-proof prescription and allow for coverage by Maryland Medical Assistance (generic versions are available with \$1 copay).

To date, the ORP has trained and certified over 18,000 individuals in Maryland. Facilitating expanded access to naloxone through pharmacies supports DHMH efforts to curb rising numbers of opioid overdose death. For more information, visit bha.dhmh.maryland.gov/naloxone.

- Most frequent types of errors are: wrong dose, directions, or strength;
- Almost all errors (91%) are caught prior to dispensing;
- But these are seldom to never documented;
- Does not consider this as a real medication error;
- Medication errors that cause any level of harm are always documented, though 3% reported never documented;
- Reporting to the prescriber about harmful medication errors occurs routinely, but 4% reported no documentation or contact;
- A majority reported that quotas are a source of stress;
- Reporting of prescription spending in a queue are a special stressor for 60% of respondents;
- Interruptions, stressors, and distractions were reported as a potential cause of medication errors;
- These included:
 - High prescription volume,
 - Shortage of support personnel,
 - Inability to take breaks, regardless of the shift length, and
 - Fatigue
- 62% perceive a punitive culture related to reporting medication errors; and
- However, a majority do report in a corporate structure.

While there may be no absolutes in the data gathered, there are indications of issues to address.

One of these is an understanding of medication errors. These go directly to patient safety and patient trust in professional skill and competence.

Other issues include the ability to take breaks, availability of adequate support staff, and general stress levels. Consider the following information about Medication Errors.

Remember that Maryland Law defines medication errors as:

“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.”¹

Additionally, medication errors have been defined as:

A medication error is “any error occurring in the medication use process.”² Note that this definition includes any and all errors at any time.

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.

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Risk for harm may be stratified according to levels based on guidelines from the Institute for Safe Medication Practices (ISMP) and the Institute of Medicine (IOM):^{3,4}

- 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.

More frequent and more harmful errors must receive immediate and aggressive attention.

Repetitive errors by any one pharmacist, pharmacy technician, or the pharmacy dispensing system, must receive priority attention to correction and avoidance. Communication to and education for all practitioners is critical part of any correction. The pharmacy's QA/QI system must reflect all such critical correction, education, and resources.

A potential error (as in A) above or an error that is caught internally prior to dispensing (B) may not present an obvious risk to the patient, but the latter is nonetheless an error.

Errors for Risk Category A include those that may be computer-driven. These are system-risk errors.

One example can be found in drop-down menus that list a non-preferred item as an upfront listing. Some examples of such errors include the following, all based on drop-down priority.

- Selection of the wrong concentration of insulin:
- Selection of once daily dosing instead of once weekly as ordered; and
- Inappropriate identification of pediatric compounding data.

For Type-B errors, evaluation of 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, documented, and reported.

A number of factors can contribute to the risk for medication errors. These identified pharmacist working condition risks include those identified in the Surveys as well other data. They include, but are not limited to the following.

FAQs ABOUT VACCINATIONS

- What vaccinations may be administered?
Any listed on the CDC website recommended immunization schedule (www.cdc.gov). In addition to the above, for adults only, any recommended in the CDC's Health Information for International Travel.
- Do they require a prescription?
No prescription is required for adults; however, vaccination specific protocols must be in place. See COMAR 10.34.32. Patients between 11-17 years old must have a prescription.
- Can pharmacists administer vaccinations to pediatric patients?
Yes. A pharmacist may administer the flu vaccine to patients ages 9 and above WITH NO prescription, but in accordance with an influenza administration protocol.

SURVEY continued from page 9

1. Distractions and interruptions;
2. Staffing shortages;
3. Breaks not routinely available or the inability to take them;
4. Workflow and volume;
5. Inadequate or missing quality assurance policy and procedure statements;
6. Communication problems;
7. Failures in communication;
8. Human error;
9. Technical failures;
10. Patient-related issues;
11. Computer-driven risk, including data and drop-down menu risks; and
12. Look-alike, sound-alike drug names or similar issues

The Board of Pharmacy has addressed concerns about Medication Errors as an educational opportunity. A previous Newsletter discussed these in some detail. Additionally, a presentation was part of the Board's 2015 Annual Continuing Education Breakfast. Educational opportunities will continue.

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Concerns about the other issues, including staffing, breaks, and general stress will be addressed as part of the Pharmacy Practice Committee agenda for 2016.

Additional information will be forthcoming.

References:

1. COMAR 10.34.26 B (2) a, b.
2. 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.
3. www.ISMP.org
4. <http://iom.nationalacademies.org>

PHARMACISTS WITH VACCINE CERTIFICATION

(HO §12-508 and COMAR 10.34.32)

Pharmacists who are registered with the Board as an immunizer may administer influenza vaccination and vaccination that is listed in the Center for Disease Control and Prevention’s Recommended Immunization Schedule. This vaccine certification will expire at the same time as the pharmacist license. Therefore, upon renewal of the pharmacist license, one must also renew the vaccine certification, along with 4 hours of CE on vaccination and attest that he/she has a current CPR card. During annual inspection, Board inspectors will be asking pharmacists who hold a Vaccine Certification to show their active and current CPR card.

Pharmacy students working in a pharmacy through a Pharmacy Experiential Program and have successfully completed a Board approved certification course, may also administer vaccine under the supervision of a licensed and vaccine certified pharmacist.

Pharmacy interns working in a pharmacy, but not in a Pharmacy Experiential Program, may administer vaccination only at the discretion of the supervising pharmacist.

Emergency Preparedness Task Force

The Maryland Board of Pharmacy (Board) sponsors an Emergency Preparedness Task Force (EPTF) that works closely with the State Office of Preparedness and Response to prepare trained pharmacy personnel who are available during declared States of Emergency. The EPTF pharmacist volunteers are recognized as vital members of the State’s emergency teams. The Board was instrumental in writing the State Emergency Preparedness Plan, which includes roles for pharmacists, pharmacy technicians and pharmacy establishments.

Currently the Board is recruiting new task force members from locations throughout Maryland. If interested in serving on the EPTF as a representative of your specific area in Maryland, please submit your resume and a brief explanation of your interest to Janet Seeds at janet.seeds@maryland.gov or call 410-764-5988 for more information.

BOARD COMMISSIONERS

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 Chain Drug Store Representative
 Independent Pharmacist Representative
 Consumer Representative
 At-Large Representative
 Acute Care Hospital Representative
 Consumer Representative
 At-Large Representative
 Independent Pharmacist Representative

BOARD MEETINGS

Public Pharmacy Board meetings begin at 9:30am 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 and awards 2 LIVE CE's to all licensees.

2016 PUBLIC BOARD MEETINGS

Third Wednesday of each month

April 20, 2016

May 18, 2016

June 15, 2016

Location: 4201 Patterson Avenue,
 Baltimore, MD 21215

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|---|---|
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| Administration and Public Relations Unit | Legislation and Regulations Unit |
| Deputy Director of Programs <i>YuZon Wu</i> | Deputy Director of Operations <i>Stephanie Ennels</i> |
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