WINTER 2017

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

The Maryland Board of Pharmacy—Looking Back at 2016

The Maryland Board of Pharmacy has devoted a significant amount of time and energy this year to systems improvement and personnel training and productivity. In order to fulfill our mission to serve the public we realized the importance of also improving services to our stakeholder community, so that they would be empowered to better serve the citizens of Maryland. To this end, I'd like to highlight some of the Board of Pharmacy's significant achievements in 2016. These achievements have resulted in improved response times, a better informed stakeholder population, improved relationships with stakeholders, and more effective customer service.

Systems Improvements

- ✓ **New computer software system for phone calls, emails, and faxes** that records every incoming query and response. This new system has helped us to improve our response time and create a permanent record that can be used to verify queries and update responses
- ✓ **Additional phone lines** have been added to our call center to respond to calls more quickly during peak license renewal periods
- ✓ **Call Center and Data Entry staff have been cross-trained** creating a more knowledgeable staff to be able to respond to the areas needing increased resources
- ✓ A contract was established with a national vendor to process license renewals **using a lock box system.** The use of the system has significantly reduced the number of processing errors and has improved our rate of speed in creating and mailing licenses
- ✓ **Weekly staff customer service trainings** using a nationally recognized on line library of training modules has produces a well trained staff focused on providing quality customer service. Call center in person and phone surveys administered to callers have indicated customer satisfaction rates with Board of Pharmacy customer service at excellent or good levels 99% of the time.
- ✓ Procurement of **software engineering services that will create a hand held data entry tool** that will create an environment for the real time entry of inspection data directly into the boards licensing database by board inspectors. This will improve the board's ability to share data with the national pharmacy board as well as other state boards; and it will improve follow up to pharmacies requiring technical support

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- ✓ **Additional staff hired to improve services**: 1 laboratory scientist to conduct sterile compounding inspections and follow up technical assistance; 2 additional pharmacists on our compliance team (one already hired, one currently in interview process); 1 new social media specialist; 1 new call center lead employee to train and assign tasks; 2 new licensing staff to process applications and 1 new licensing manager(interviews in process)
- ✓ **Addition of board lobby information kiosk and two renewal kiosks**, allowing technician renewals.
- ✓ **Development of distributor renewals on line** to be available for use in March of 2017
- ✓ **Restored exchange of information with the National Boards of Pharmacy (NABP)** resulting in improved speed in processing reciprocity and license verification requests

Public Relations/Communications

- ✓ **Improved quarterly newsletter** that includes NABP articles, new Frequently Asked Questions column, and increased pharmacy articles of interest
- ✓ **New Facebook and Twitter Access**
- ✓ **First Continuing Education event offered in person and by web access**
- ✓ **Increased use of surveys**
- ✓ **Increased involvement in pharmacy conferences and events**

Licensing and Compliance

- ✓ **Increased training** in inspection and investigation techniques
- ✓ **Staff certification** in sterile compounding
- ✓ Inspection staff now verifying licensing data at inspections and sharing with data entry staff to ensure the accuracy of licensee data

None of these achievements would have been possible without the hard work and dedication of a staff of professionals that work hard for the Board of Pharmacy every day, and a smart and dedicated group of Board Commissioners that provide guidance and support.

I am confident that 2017 will be yet another year of landmark improvements as the board focuses on reestablishing internships with pharmacy school students, partnering with stakeholders on legislative initiatives, growing our pharmacy community by enabling them to practice innovative programs that have been successful in other states, increasing our ability to monitor prescription drug repository programs, and implement an expanded rehabilitation committee across the entire state of Maryland.

Happy New Year Everyone!

INTRODUCING THE NEWEST BOARD STAFF MEMBERS….

Tom Evans has joined the Compliance Unit as an Inspector. Obtaining his B.S. in pharmacy from the University of Maryland at Baltimore and his MBA in business from Johns Hopkins University, he obtained employment at the University of Maryland Medical Center, Midtown Campus, and then at Sinai Hospital of Baltimore where he supervised the pharmacy as the Operations Manager. The Board is privileged to have his expertise.

The new Deputy Director of Operations is **Edward Fields**. In this capacity Ed will manage Board of Pharmacy procurements, contracts, vendors, and budget, as well as supervise the information systems staff. Ed has an MBA from the University of Baltimore and a B.S. from Towson State University in Accounting. He most recently served as a deputy director in the Maryland Medicaid program, and before that as budget director and fiscal officer for the Harford County and Baltimore County school systems respectively. He has also served as Financial Director at University of Maryland at Baltimore. The Board is greatly looking forward to having him as an integral part of its staff.

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Maryland
Board of Pharmacy

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- Stay informed about new laws, regulations and forms as they come out
- We'll provide you with articles and news updates in the respective field of pharmacy; including exclusive articles published through our newsletter
- Find out more about our FAQs and possibly find answers to questions and concerns you already have
- Interact with us, participate in our surveys and provide us feedback

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A FEW FAQs about Pharmacy Technicians

•Who can apply to become a pharmacy technician?

To be eligible as a pharmacy technician, you must be currently certified by a national pharmacy technician certification program or have successfully passed an examination and completed a pharmacy technician training program approved by the board, which includes 160 hours of work experience and is no longer than 6 months in duration. All applicants must currently be enrolled in high school (at least 17 years old), be a high school graduate, or have a GED.

•How can I become a nationally certified pharmacy technician?

The following board approved programs have examinations you can take in order to become nationally certified: Exam for the Certification of Pharmacy Technicians (ExCPT), Institute for the Certification of Pharmacy Technicians (ICPT), National Health Career Association (NHA), and Pharmacy Technician Certification Board (PTCB). Please visit their sites in order to learn more about becoming a nationally certified pharmacy technician.

•What forms and documents are required to apply as a new Maryland pharmacy technician?

The following is required in order to obtain a Maryland pharmacy technician license (instructions listed on the pharmacy technician application at dhmh.maryland.gov/pharmacy):

- •Proof of Birthdate – Birth Certificate, Driver's License, Passport, and other government issued ID;
- •Proof of National Certification – For nationally certified technicians only;
- •Proof of passing a Board Approved Examination – For non-nationally certified technicians only;
- •Proof of state registration and good standing – For reciprocity applicants only;
- •Pharmacy Work Experience Affidavit (Attachment 1) – For reciprocity applicants;
- •CJIS Criminal Background Check (Third party background checks not accepted);

•How current should my CJIS Criminal Background Check be?

Your Criminal Background Check should be completed within 6 months of its submission to the Board of Pharmacy.

•Can I get my Criminal Background Check through another party other than CJIS (Criminal Justice Information System)?

No, the Maryland Board of Pharmacy only accepts CJIS background checks. To contact CJIS please call 1.888.795.0011 or 410.764.4501. Our CJIS authorization number is 060006201, you will need this authorization code when you get your finger prints done.

*Please keep in mind that having a conviction will not necessarily disqualify you from obtaining a license.

FINGERPRINTING FEE CHANGES

The fee as of October 1, 2016 is 30.00 for a full background check, 18.00 for State only, and FBI only is 12.00 plus the fingerprinting fee which varies at each location in Maryland.

If an applicant sends in an over payment we will have to return the application and fee back to them. This will slow up the process of receiving the criminal history. T**he CJIS locations no longer accepts money orders for payment. It must be a personal or cashier check, Visa, or MasterCard.**

To those out-of-state applicants the only option is personal or cashier check for payment when they mail it in. The check must be written out for the exact amount.

REMINDER to Check and Update your Contact Information

Please check your contact information (e-mail address, residential address, name, employer) by completing and submitting the Name/Address/Employer change form at: dhmh.maryland.gov/pharmacy (see left column, under Online Services**)**

DISTRIBUTOR RENEWALS

Who?	Maryland licensed Wholesale Distributors and Manufacturers that engage in distribution
What?	Format has changed 1. Previously had to provide lease or deed; now only certificate of occupancy is required 2. Fingerprints / Criminal Background Check process has been clarified
When?	Begins March 15, 2017 – May 31, 2017
Where?	Go to dhmh.maryland.gov/pharmacy. Click onto 'online renewal' and, under MENU, register as an establishment. Follow prompts to complete the renewal process.

MSHP CONFERENCE

The Maryland Board of Pharmacy (Board) was honored to participate in the October 21, 2016 MSHP conference held in Baltimore. The Board had a table set up directly in front of the entrance to the exhibit room.

It was great to see many licensees that may not have been at other events in which the Board was present. Thanks to Commissioner David Jones for answering many questions on a wide variety of pharmacy topics. In addition, the Board provided literature pertaining to operations, licensing, medicine safety, vaccination requirements, and emergency situations. Information about becoming an emergency volunteer, recent newsletters, and updates on various pharmaceutical legislation were also available.

Many flyers and volunteer applications were distributed at this extremely successful exhibit. The Board is looking forward to its continuing partnership with MSHP…partnering with YOU.

RECOGNITION DINNER at McCormick & Schmick's on January 18, 2017

Past Board Commissioners were recognized for their service and were awarded with Governor's Citations and gifts.

Lenna Israbian-Jamgochian, PharmD served as Chain Drug Store Representative from 4/2007 through 4/2015. She was Board President for four of those years. ***Lynette Bradley-Baker, RPh, PhD*** served as At-Large Representative, Board Secretary, and was represented on numerous Board committees, from 4/2007 through 4/2015. ***Jermaine Smith, R. Ph,*** served as Chain Drug Store Representative and Board Treasurer from 4/2012 through 4/2016. ***David H. Jones, RPH, FASCP*** served as Long Term Care Representative, Board Secretary, and was represented on numerous Board committees from 4/2012 through 4/2016.

In addition, ***Anna D. Jeffers, Esq.*** was the Board Legislative Regulations Staff Unit Manager from 1/2005 until 2/2016.

DHMH CAREER DAY

The Maryland Board of Pharmacy (Board) participated in the Department of Health and Mental Hygiene (DHMH) Career Day held on October 19, 2016 at 201 W. Preston Street, Baltimore, MD. This was a great opportunity for people to find out about job openings and to hand out their resumes.

Prospective applicants were encouraged to periodically check the DHMH website for future employment opportunities. Some individuals left their resumes, but will continue the application process when openings become available. All in all, it was a great day. The exposure was quite beneficial and this is certainly an event that will be repeated.

AMERICAN PHARMACISTS' MONTH

One of the reasons that the Maryland Board of Pharmacy has its annual Continuing Education Breakfast during the month of October is because of American Pharmacists' month. October was a great month for pharmacists to make more of an effort to talk with their clients.

With the changes in society…so many professions going the way of electronics and decreasing the need for human interaction, it is great to still have pharmacists who are ready and willing to interact with their patients. With the ever expanding role of pharmacists, communication is more important than ever in the lives of those they serve.

CONTINUING EDUCATION BREAKFAST

One hundred fifty four people entered the doors to participate in the Continuing Education Breakfast on Sunday, October 23, 2016. *Opioids: Prescribing, Distributing, Preventing Abuse, and Monitoring* was the title of this event. People seemed to be excited to be there and hear about the relevant subjects discussed. Board President, Mitra Gavgani and Public Relations Chairman, Bruce Zagnit, welcomed all attendees and introduced the speakers.

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The first speaker, Dr. Greg Hobelmann from Ashley Treatment Center, identified the prevalence and characteristics of chronic pain complaints, the risks and benefits of opioids for chronic vs. acute pain treatment, described some of the available opioid prescriber guidelines, and their potential to help or hinder pain management. Dr. Hobelmann ended by stating that "consensus is needed that balances access to adequate pain management with devastating harms of addiction."

The second speaker was Erin Haas, Local Programs Manager for the Overdose Prevention Program at the Behavioral Health Administration in Catonsville, MD. Ms. Haas identified the opioids that are causing the most deaths in Maryland and explained overdose prevention and how naloxone is distributed. After sharing many statistics she described a harm reduction approach to substance use, and the state plan to dispense naloxone to patients.

This year Board President, Mitra Gavgani, and Executive Director, Deena Speights-Napata, were fortunate to honor six pharmacists who had been licensed for 60 years or more. Those in attendance were Ralph L. Gittleson, Jerome L. Fine, and Alfred Lawson (69 years). Those unable to attend were Lee Crewell, Richard A. Miller, and Michele Splinter (64 years). It was extremely interesting to hear from pharmacists who have been licensed for that long. In fact, Mr. Lawson still works 24 hours a week and even had to take off of his job in Fredericksburg, VA to come to this CE breakfast. Talk about dedication! Each honoree received a Governor's Citation thanking them for their years of service to Maryland's citizens.

After the recognition ceremony, Jason Clements, the Laboratory Scientist Surveyor at the Maryland Board of Pharmacy gave an update for sterile compounding. Having just heard Mr. Lawson relate his experiences with compounding almost 70 years ago, it was great to hear how procedures have advanced.

The final presenter for the day was Kate Jackson from the Prescription Drug Monitoring Program (PDMP) at Behavioral Health Administration within DHMH. Ms. Jackson spoke about PDMP and Opioids and explained how this process protects Maryland citizens. This program collects all Schedule II-V prescriptions dispensed in Maryland and provides the data for clinical access and other uses to combat the opioid epidemic.

EMERGENCY PREPAREDNESS TASK FORCE

Over the years the number of emergency volunteers has decreased tremendously. The Board is encouraging you to sign up with MD Responds in order to be deployed during emergencies. Please register at www.mdresponds.dhmh.maryland.gov. Not only will this enable you to be called during emergencies, but to also be contacted for various exercises sponsored by the Emergency Preparedness Task Force and/or MD Responds. In addition, this registration provides protection by the State of Maryland. Contact janet.seeds@maryland.gov or call 410-764-5988 for more information.

CDC: FLU VACCINATION

Excerpts from www.cdc.gov/flu/protect/whoshouldvax.htm#flu-shot

Influenza is a serious disease that can lead to hospitalization and sometimes even death. Every flu season is different, and influenza infection can affect people differently. Even healthy people can get very sick from the flu and spread it to others. During recent flu seasons, between 80% and 90% of flu related deaths have occurred in people 65 years and older. "Flu season" in the United States can begin as early as October and last as late as May. During this time, flu viruses are circulating at higher levels in the U.S. population. An annual seasonal flu vaccine is the best way to reduce the chances that you will get seasonal flu and spread it to others. When more people get vaccinated against the flu, less flu can spread through that community.

Flu vaccines cause antibodies to develop in the body about two weeks after vaccination. These antibodies provide protection against infection with the viruses that are in the vaccine.

The seasonal flu vaccine protects against the influenza viruses that research indicates will be most common during the upcoming season. Traditional flu vaccines (called "trivalent" vaccines) are made to protect against three flu viruses; an influenza A (H1N1) virus, an influenza A (H3N2) virus, and an influenza B virus. There are also flu vaccines made to protect against four flu viruses (called "quadrivalent" vaccines). These vaccines protect against the same viruses as the trivalent vaccine and an additional B virus.

Both trivalent (three-component) and quadrivalent (four-component) flu vaccines will be available.

Trivalent flu vaccines include:

- Standard-dose trivalent shots (IIV3) that are manufactured using virus grown in eggs. Different flu shots are approved for different age groups. Most flu shots are given in the arm (muscle) with a needle. One trivalent vaccine formulation can be given with a jet injector, for persons aged 18 through 64 years.
- A high-dose trivalent shot, approved for people 65 and older.
- A recombinant trivalent shot that is egg-free, approved for people 18 years and older.
- A trivalent flu shot made with adjuvant (an ingredient of a vaccine that helps create a stronger immune response in the patient's body), approved for people 65 years of age and older (new this season).

Quadrivalent flu vaccines include:

- Quadrivalent flu shots approved for use in different age groups.
- An intradermal quadrivalent flu shot, which is injected into the skin instead of the muscle and uses a much smaller needle than the regular flu shot. It is approved for people 18 through 64 years of age.
- A quadrivalent flu shot containing virus grown in cell culture, which is approved for people 4 years of age and older (new this season).

For the 2016-2017 flu season, the Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccination for everyone 6 months and older with either the inactivated influenza vaccine (IIV) or the recombinant influenza vaccine (RIV). The nasal spray flu vaccine (live attenuated influenza vaccine or LAIV)

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should not be used during 2016-2017.There is no preference for one vaccine over another among the recommended, approved injectable influenza vaccines. There are many vaccine options to choose from, but the most important thing is for all people 6 months and older to get a flu vaccine every year.

CDC recommends use of the flu shot (inactivated influenza vaccine or IIV) and the recombinant influenza vaccine (RIV). The nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) should not be used during 2016-2017. Different flu vaccines are approved for use in different groups of people. Factors that can determine a person's suitability for vaccination, or vaccination with a particular vaccine, include a person's age, health (current and past) and any allergies to flu vaccine or its components.

People who can get the flu shot:	**People who can't get the flu shot:**	**People who should talk to their doctor before getting the flu shot:**
Different flu shots are approved for people of different ages (see Note), but there are flu shots that are approved for use in people as young as 6 months of age and up. Flu shots are approved for people with chronic health conditions.	Children younger than 6 months are too young to get a flu shot. People with severe, life-threatening allergies to flu vaccine or any ingredient in the vaccine. This might include gelatin, antibiotics, or other ingredients.	If patient has an allergy to eggs or any of the ingredients in the vaccine. Talk to your doctor (or patient) about allergies. If patient has ever had Guillain-Barré Syndrome (a severe paralyzing illness, also call GBS). Some people with a history of GBS should not get this vaccine. Talk to your doctor (or patient) about GBS history. If patient is not feeling well, talk to your doctor (or patient) about your symptoms.

Note: There are certain flu shots that have different age indications. For example, people younger than 65 years of age should not get the high-dose flu shot or the flu shot with adjuvant, and people who are younger than 18 years old or older than 64 years old should not get the intradermal flu shot.
***The above CDC information is intended for a general audience of healthcare providers. Please note that pharmacists in Maryland may only administer influenza vaccinations to individuals 9 years or older and in accordance with all other Board regulatory requirements in COMAR 10.34.32.*

Reminder about the MARYLAND PRESCRIPTION DRUG MONITORING PROGRAM

On April 26, 2016, Governor Hogan signed into law HB 437 which includes the following legal changes:

1. **Mandatory PDMP Registration for CDS Prescribers & Pharmacists**
   Beginning July 1, 2017, prescribers and dispensers licensed to prescribe and/or dispense CDS in Maryland must be registered with the PDMP through CRISP at https://crisphealth.org. For registration help, call 1-877-952-7477.
2. **Mandatory PDMP Use by CDS Prescribers & Pharmacists**
   Beginning July 1, 2018:
   - Prescribers must, with some exceptions, query and review their patient's PDMP data prior to initially prescribing an opioid or benzodiazepine AND at least every 30 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine. Prescribers must also document PDMP data query and review in the patient's medical record.
   - Pharmacists must query and review patient PDMP data prior to dispensing ANY CDS drug if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition.
   - Information regarding Mandatory Use is available on the DHMH PDMP website, http://bha.dhmh.maryland.gov/PDMP. DHMH will provide additional information and reminders closer to, but before, the implementation date.
3. **CDS Prescribers & Pharmacists May Delegate PDMP Data Access**
   Prescribers and pharmacists may delegate healthcare staff to obtain CRISP user accounts and query PDMP data on their behalf. Delegates may include both licensed practitioners without prescriptive authority and non-licensed clinical staff that are employed by, or under contract with, the same professional practice or facility where the prescriber or pharmacist practices.

To learn more, visit the DHMH PDMP website for updated information, important compliance dates and frequently asked questions: http://bha.dhmh.maryland.gov/PDMP. For more information about the opioid addiction and overdose epidemic in Maryland and what healthcare providers can do to help, visit http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/.

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been mis-programmed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews

found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf.*

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.*

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov /NewsEvents/ Newsroom/ PressAnnouncements/ ucm518697.htm.*

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars.*

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm.*

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

PHARMACIES: NEW, MOVING, REMODELING (ex., for USP800) AND/OR EXPANDING

The pharmacy, for which a permit has been issued, shall notify the Board in writing of any remodeling changes in the pharmacy. Blue prints or schematics of the new layout of the pharmacy must also be provided to the Board. Depending upon the extent and type of remodeling being done, the Board will conduct an opening inspection of the new facility.

DEA Releases 2016 National Drug Threat Assessment, Highlights Nationwide Opioid Epidemic

Approximately 129 people died every day as a result of drug poisoning in 2014, and 61% of those deaths were related to prescription opioids or heroin, indicates Drug Enforcement Administration (DEA). The opioid epidemic has been exacerbated by the reemergence of fentanyl, a synthetic opioid that is more potent than heroin. The DEA press release notes the increase in overdose deaths also coincides with the arrival of Carfentanil, a fentanyl-related compound approximately 10,000 times more potent than morphine, in illicit drug markets in the United States. Carfentanil is often mixed into heroin or into counterfeit prescription drugs. Deaths from synthetic opioids increased 79% from 3,097 in 2013 to 5,544 in 2014. Public health officials maintain that fentanyl is contributing to most of this increase, notes the DEA press release. Nationally, heroin overdose deaths more than tripled between 2010 and 2014, with the highest number of heroin overdose deaths in the Northeast and Midwest regions of the US. The most recent data show a nationwide total of 10,574 heroin overdose deaths in 2014.

For the report, DEA used 2014 data from the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). DEA notes prescription drug poisoning deaths include deaths from prescription opiates and benzodiazepines. The report also indicates that the information provided is current as of August 2016.

The DEA's *2016 National Drug Threat Assessment Summary* (PDF) was produced in partnership with local, state, tribal, and federal partners to provide a comprehensive annual assessment of the threat posed to the US by illicit and prescription drug abuse and trafficking.

DISCIPLINARY ACTIONS

PHARMACIST	LIC. #	SANCTION	DATE
Anthony Grzib	21110	Probation	09/29/16
Mitchell McKinney	22085	Fine	10/25/16
Bradley Burton	17977	Probation/Fine	01/18/17

PHARMACY TECHNICIAN	REG. #	SANCTION	DATE
Ingrid Critchlow	T11539	Probation	01/18/17
Jessica McCorkel	T09748	Suspended	10/14/16
Robin Lamontagne	T03741	Revoked	10/19/16
Malikah Scriber	T15361	Suspended	10/27/16
Contessa Allen Starks	T05556	Suspended	11/21/16
Jennifer Smith	T04339	Suspended	11/22/16
Patrice Shelton	T17157	Suspended	11/22/16
Tawanda Shephard	T08948	Suspended	12/28/16
Kristal Wallace	T08868	Suspended	01/18/17

ESTABLISHMENT	PERMIT #	SANCTION	DATE
ABH Pharmacy & Medical Supplies	P02613	Fine	12/22/16
Neb Doctors of Maryland, LLC	D06006	Fine	01/17/17

ASSOCIATION CORNER–

This section is designated to allow various pharmacy associations to provide information regarding their mission and relevant initiatives. This edition highlights…

Maryland Pharmacists Association – Representing the Profession of Pharmacy in Maryland

Aliyah N. Horton, CAE, Executive Director, Maryland Pharmacists Association

Maryland Pharmacists Association (MPhA) was founded in 1882 and continually evolves to meet the needs of today's professionals. However, our mission remains the same "to strengthen the profession of pharmacy, advocate for all Maryland pharmacists and promote excellence in pharmacy practice." Our membership is as diverse as the profession, representing a wide–array of practice settings and locations throughout the state.

MPhA works to tell the pharmacists' "story" to members of the public, healthcare stakeholders, elected and appointed officials. Each time the pharmacists' story is told, there is a new understanding of the education and expertise pharmacists have; the role played in the healthcare system and the community; and the opportunities for Maryland residents to receive quality medication information and patient care. We share the pharmacists' story to support the expansion of pharmacist scope of practice, enhance collaborative practice opportunities and other areas where pharmacists can positively impact patient outcomes, while getting paid for those services.

Many of our members have joined MPhA through the encouragement of a colleague or friend or attended one of our public board meetings or CE Events. Participants feel welcomed and see that we are living our mission and values to advance and protect the profession. Volunteer experiences on MPhA committees or in leadership positions have forged a professional and collegial community that has fostered life-long friendships. We work closely with the three schools of pharmacy to foster relationships with students and faculty and to ensure that the practice environment meets the education level of the next generation of pharmacists.

MPhA's member value lies in key components that impact pharmacists' day-to-day work.

ADVOCACY – We cooperate with state and national pharmacy organizations as well as the Board of Pharmacy to ensure the best outcomes to protect and enhance pharmacy practice in Maryland. MPhA provides members a voice in the future of pharmacy and the profession by initiating legislation and offering testimony to the General Assembly. As a part of the Maryland Pharmacy Coalition we also participate in an annual Pharmacy Legislative Day in Annapolis.

ADVANCING PRACTICE – We work collaboratively with pharmacy stakeholders to remove barriers and enable pharmacists to practice at the height of their education. In recent years MPhA has been actively involved in promoting provider status, PBM transparency, access to naloxone, emergency preparedness and "any willing" provider legislation.

PROFESSIONAL DEVELOPMENT - MPhA hosts diverse live continuing education programs. Our MPhA Mid-Year Meeting, Annual Convention, Annual Medication Error CE and other programs are held around the state with content focused on current clinical issues, pharmacy policy and advanced practice topics. Members help identify the relevant content they need.

PROFESSIONAL RECOGNITION – MPhA also hosts annual awards that recognize individual achievements and professional innovation. We also provide two scholarships for pharmacy students. MPhA is the organization recognized by the Governor's office to provide recommendations for

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several pharmacy seats on state commissions and task forces.

COMMUNICATIONS – MPhA works to provide information to members that keep them up-to-date on pharmacy issues at the state and national level. The *Maryland Pharmacist* is a peer-reviewed quarterly journal that includes articles on current issues, an opportunity to earn CE credits, updates on MPhA activities and professional recognition of our members. The latest news, activities and awards are also included in a biweekly e-newsletter, the M*onday Message*. We also engage with the healthcare community via Twitter and Facebook.

NETWORKING - MPhA facilitates opportunities for members to meet and develop professional relationships with practitioners in all types of healthcare settings. We also provide a forum for affinity groups through our "networks." Practitioners collaborate on projects, community service activities and social outings that support professional collegiality.

- New Practitioners Network- for pharmacists who have graduated within the last five years
- Pharmacy Technician Network – for Pharmacy Technicians interested in expanding their network and finding peer support outside of the work place
- Federal Pharmacist Network – for pharmacists who have served as pharmacists in the federal government, or any public agency.

MPHA CAREER CENTER - Located on the MPhA Website the career center allows employers to post positions. Members can create "job seeker" accounts, set up automated job alerts, post resumes and seek general career advice.

MARYLAND PHARMACY LAW BOOK - The MPhA law book provides all the pharmacy laws and regulations in the State as well as explanations in layman's terms. The publication is used as both a reference for practicing professionals and a study guide for new practitioners.

Of course there are added member benefits including discounted rates on CE programs as well as discounts on insurance policies, pharmacy quality assurance programs, DSCSA Track and Trace Software and entertainment and travel.

MPhA headquarters hosts a variety of displays of pharmacy tools, artwork and memorabilia dating as far back as the late 1800s. Stop by and visit and attend an event. You are welcome.

For more information about MPhA's latest activities check us out at www.marylandpharmacist.org and follow us on Facebook/MarylandPharmacists Association or Twitter @MDPharmacists.

2017 MPhA Mid-Year Meeting – Sunday, Feb. 12, 2017 – Double Tree Hilton-Columbia

Credits: 6 CE Available

Registration Type	Member Rate	Non-Member Rate
Pharmacists	$179	$229
Pharmacy Technicians/Students	$ 99	$139

All Meals included and discounted hotel accommodations available; Go to www.marylandpharmacist.org for more information.

COMPLIANCE: Inspection Deficiencies

Emory Lin, Inspection Supervisor

The Maryland Board of Pharmacy is required to perform annual inspections of all pharmacies in Maryland. There are sample inspection forms on the Board's website (dhmh.maryland.gov/pharmacy) detailing what pharmacies will be inspected for. Below are examples of frequent deficiencies noted by Board inspectors. Please ensure that your pharmacy is operating in accordance with the Board's regulatory requirements and is taking necessary corrective actions to address any deficiencies.

Frequent deficiencies are: expired medications in pharmacy inventory; shortage/overage in CII audits; missing staff training documentation for medication error prevention; missing technician training; lack of written policies and procedures; expired CPR registrations for certified vaccinators; expired vaccination registrations; missing biennial inventories for CDS medications; and food in the refrigerator or freezer designated for medication.

COMPLIANCE: Security Responsibility

(COMAR 10.34.05)

YuZojn Wu, Deputy Director of Programs and Compliance Unit Manager

The Maryland Board of Pharmacy (the "Board") has specific regulations concerning pharmacy security. It is the pharmacy permit holder's responsibility to ensure that a pharmacy is secure not only in reference to its physical space, but also the operations of a pharmacy:

- Physical space/aspect (includes but not limited to): temperature, ventilation, unauthorized entry, pharmacist on the premises during the stated hours of operation, and sign indicating hours of operation if prescription area hours of operation are different than the rest of the establishment.
- Operations of a pharmacy (includes but not limited to): to protect the integrity and security of patient records, confidentiality of data and documents, and to protect against theft, diversion, or counterfeiting of drugs and prescription medical devices.

The law, further states that when a pharmacy discovers that there have been a loss of prescription drugs, the pharmacy permit holder is responsible for assuring that this theft is reported, with the appropriate forms and documentation, to the following agencies:

- Board
- Local Police
- Division of Drug Control (DDC) (now known as the Office of Control Substance Administration OCSA)
- U.S Drug Enforcement Administration (DEA)

The Board has been made aware of some inconsistencies to this reporting. Please ensure that in addition to reporting the loss/theft of prescription drugs to the DEA and OCSA, that this is also reported to the Board.

BOARD COMMISSIONERS

President: **Mitra Gavgani**	Home Infusion Representative
Secretary: **Zeno W. St. Cyr, III**	Consumer Representative
Treasurer: **Charmaine Rochester**	At-Large Representative
Daniel Ashby	Acute Care Hospital Representative
Efstratios (Steve) Bouyoukas	Chain Drug Store Representative
Jennifer Hardesty	Long Term Care Representative
Kevin Morgan	Chain Drug Store Representative
Roderick Peters	Independent Pharmacist Representative
Trinita Robinson	Consumer Representative
Sajal Roy	Acute Care Hospital Representative
Zeno W. St. Cyr, II	Consumer Representative
Ellen H. Yankellow	At-Large Representative
Bruce Zagnit	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 CEs to all licensees.

2016 PUBLIC BOARD MEETINGS

Third Wednesday of each month
February 15. 2017
March 15, 2017
April 19, 2017
May 17, 2017
Location: 4201 Patterson Avenue
Baltimore, MD 21215

CONTACT DIRECTORY	
Customer Service Center 410-764-4755 ▪ dhmh.mdbop@maryland.gov ▪ dhmh.maryland.gov/pharmacy ▪ 1-800-542-4964	
Executive Director *Deena Speights-Napata*	
Administration and Public Relations Unit	Legislation and Regulations Unit
Deputy Director of Programs *YuZon Wu*	**Deputy Director of Operations** *Edward Fields*
Licensing Unit	Data Integrity Unit
Compliance Unit	Management Information Services Unit

Maryland Board of Pharmacy

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215-2299