FALL 2016

Maryland Board of Pharmacy news

In This Issue:

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality 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.

The Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215
Tel: 410-764-4755
Fax: 410-358-6207
Toll Free: 800-542-4964
TTYL BALTO-383-7555

FROM THE EXECUTIVE DIRECTOR'S DESK

Deena Speights-Napata, Executive Director

PARTNERSHIPS ARE IMPORTANT

During the past year the Maryland Board of Pharmacy processed licenses for nearly 30,000 Maryland pharmacies, pharmacists, technicians, interns, distributors, and vaccinators. We are the third largest board in the state, having a huge impact on thousands of Marylanders who utilize pharmacy services. We are in a perfect position to positively influence so many people as we continue to focus on our mission of protecting the public.

The Maryland Board of Pharmacy believes that in order to achieve our mission we must create and develop partnerships with educational, governmental, and private agencies that can inform our policy and programmatic decisions. Here are just a few of the partnerships we have established;

Maryland Schools of Pharmacy—Meetings with the deans of the schools of pharmacy, and attendance at pharmacy school graduations to discuss how we can improve school experience and graduation rates, while continuing to encourage pursuit of pharmacy as a career

Maryland Pharmacists Association-Support of annual meeting; survey of pharmacists and technicians; ongoing dialogue with executive director and board president on policy initiatives

Maryland Prescription Drug Monitoring Program- Advisory committee membership and internal dialogue with program administrators to reduce and prevent drug overdoses

Maryland Society of Health System Pharmacy—Ongoing discussions of relevant pharmacy issues

Maryland Medicaid—internal dialogue with Medicaid administrators on issues relevant to both programs, like reimbursement and the impact of drug costs

Public Health—Epipen questions concerning packaging of products used; providing information to Infectious Disease officials in an effort to prevent outbreaks; Office of Preparedness and Response; Expedited Partner Therapy program—impact on community pharmacists

Behavioral Health-Supporting pharmacists in their efforts at rehabilitation and re-entry into the practice of pharmacy

National Boards of Pharmacy—Provides relevant information on individuals and establishments licensed in more than one state; provides information on national issues impacting the practice of pharmacy

23 other Maryland boards and commissions- Collaboration with physicians, nursing, and other boards to increase the efficiency of services rendered

Through these partnerships the Board of Pharmacy will continue to positively impact health outcomes in Maryland, as we assume an important role in the facilitation of dialogue required to meet the public health physical and technological needs of future generations.

A FEW FAQs: Vaccination License Registration and Renewals

1. ***Who can apply for the vaccination registration?***

   Maryland licensed pharmacists or individuals applying to obtain a Maryland pharmacist license may apply for a vaccination registration.

2. ***What are the requirements to obtain a vaccination license?***

   You will need to submit a Pharmacist Administration of Vaccination Registration form along with a copy of your active CPR card from a LIVE course and a completed vaccination certification course received through ApHA.

3. ***When can I apply for the Vaccination registration?***

   You may register at any time. You can find the forms here. No fee is required. (http://dhmh.maryland.gov/pharmacy/Pages/pharmacistforms.aspx)

4. ***Is a fee required in order to obtain a vaccination registration?***

   There is no fee required in order to become registered to vaccinate.

5. ***Can I use credits earned from the vaccination certification for immunization towards the total 30 CEs required in order for me to renew my pharmacist license?***

   The 20 CEs earned in completing the vaccination certification course can be used towards the 30 total CEs required for pharmacist licensure.

6. ***What are the requirements to renew my vaccination registration?***

   A vaccination registration expires with the expiration of the pharmacist's license. A vaccination registration renewal form, along with proof of completing 4 continuing education hours regarding immunization and a copy of your current CPR card. CPR cards must be active. You can find the forms here. http://dhmh.maryland.gov/pharmacy/Pages/pharmacistforms.aspx

7. ***Can I renew my vaccination license online?***

   You can renew your vaccination license along with your pharmacist license renewal here. (https://egovpharmacy.dhmh.maryland.gov/Mylicense%20Enterprise/)

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 vaccinations that are 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 who have successfully completed a Board approved certification course, may also administer vaccine under the supervision of a licensed and vaccine certified pharmacists. Pharmacy interns working in a pharmacy, but not in a Pharmacy Experiential Program, may administer vaccination only at the discretion of the supervising pharmacist.

PRESCRIPTION DRUG REPOSITORY PROGRAM

Revised September 2016

David Jones, Board Commissioner

Maryland has established a Prescription Drug Repository Program ("PDRP") with oversight by the Board of Pharmacy (the "Board"). Legislation originated in 2006, with a revision in 2011 that expanded the Program.

PDRP has two purposes, allowing Board approved pharmacies:

1. To accept returned prescription drugs and medical supplies for the purpose of proper final disposal; and,
2. To accept donated prescription drugs and medical supplies for the purpose of re-dispensing to needy individuals.

This article will focus on the PDRP's primary purpose to allow pharmacies to accept returned drugs and medical supplies for proper disposal. For those pharmacies interested in participating in the PDRP for purposes of re-dispensing donated drugs and devices to needy individuals, please see the Board's regulations, COMAR 10.34.33, for information on specific requirements.

Disposal of Returned Drugs

Some initial points to remember:

- Participation in PDRP is and always has been completely *voluntary*.
- A pharmacy must submit an application to the Board for approval as a repository in order to accept returned drugs and devices for disposal. There is no application fee.

There are two categories to consider regarding the acceptance of returned drugs for proper disposal: (1) pharmacies that accept returned non-CDS only; or (2) pharmacies that accept returned CDS, or a mixture of CDS and non-CDS drugs.

Returned non-CDS only: Maryland law governs the acceptance of returned non-CDS only drugs for disposal. COMAR 10.34.33.07 requires that a secure container be kept behind the prescription counter. Again, this is for returned non-CDS exclusively. Only a pharmacist may accept returned non-CDS drugs to be placed in this secure container. This duty cannot be delegated to a pharmacy technician. No CDS may be accepted in this manner.

Ultimate disposal of the returned non-CDS should be done using the pharmacy's third party returns processor or reverse distributor. The pharmacy must have policies and procedures regarding the safe and secure handling and disposal of the returned drugs and devices.

Returned CDS or combination CDS/non-CDS: The Federal Secure and Responsible Drug Disposal Act (the "Act") of 2010 addresses disposal of CDS. This means both CDS alone and any comingling of CDS with non-CDS. The Drug Enforcement Administration's (the "DEA") Final Rule for the Disposal of Controlled Substances implemented this Act and was effective on September 8, 2014.

Pharmacies wishing to accept CDS or CDS/non-CDS drugs for disposal must establish a secure collection receptacle at the registered location. The secure container for these agents must be compliant with all DEA requirements and must be located in the immediate vicinity of the prescription area *but not behind the prescription counter*. The DEA regulations also set forth specific requirements for the type and manner of maintenance of the collection receptacle, to includes serialized receptacle liners and logs of disposed liner bags. Pharmacies must also obtain a modified DEA registration number to act as an authorized collector of CDS for disposal. Please see the DEA regulations, 21 CFR §1317, and the DEA website, www.deadiversion.usdoj.gov/drug_disposal, for more information.

Only the individual returning the drugs, referred to as the "ultimate user" in DEA regulations, may deposit the drugs in the collection receptacle for disposal. The ultimate user is the patient for whom the drugs were prescribed or an assigned designee. Long Term Care Facilities ("LTCF") are specifically defined as authorized designees for LTCF residents. The CDS medications being returned cannot be transferred to pharmacists for disposal. Final disposal must be done using a distributor or reverse distributor

To obtain an application to become a PDRP repository, please visit the Board's website at www.dhmh.maryland.gov/pharmacy.

Jason Clements has recently joined the Board as Laboratory Scientist Surveyor. He holds an A.S. in Life Science from Montgomery College, a B.S. in Biological Sciences from the University of Maryland, and is currently finishing out an M.S. in Biomedical Science at Hood College with a concentration in microbiology, virology, and immunology. His professional background is in microbiology quality control and validation services for the biologics sector of the pharmaceutical industry.

Jason is responsible for investigating compliance of sterile compounding pharmacies permitted with the Board. This is an area that requires a degree of expertise in scientific background in microbiology. He has been enhancing the adverse event reporting program and accompanying Board inspectors in the field.

INVOLVEMENT IN MD-ASCP CONFERENCE

Janet Seeds, Public Information/Communication/Training Coordinator

The Maryland Board of Pharmacy (Board) was honored to participate in the June 2016 MD-ASCP conference held in Alexandria, VA. The Board had two tables set up in the best location…at the end of the hall near the restrooms.

Eventually, most people found their way to that area and then visited our exhibit. Of course, they then told their friends and people came because of the great resources available.

This exhibit focused on the Board's Emergency Preparedness Task Force and had a wealth of information pertaining to possible emergency situations. Participants were able to obtain specific information based on their individual needs. Pharmacist Donald Taylor had a slide show running continuously. The profession of pharmacy certainly owes a debt of gratitude to Dr. Taylor for his commitment to emergency preparedness, which far exceeds all expectations. He has worked closely with the State of Maryland to ensure that pharmacists are now an integral part of the state emergency plan.

Not only are emergency volunteers now used for catastrophes such as earthquakes and floods, but they are now 'on call' for winter storms, hurricanes, tornados, fires, and other natural emergencies. (Please see the Emergency Preparedness article, on page 6 of this newsletter, for more information about how to register as an emergency volunteer.)

This exhibit was extremely successful as was indicated by the number of flyers and volunteer applications distributed. Much support seemed to be garnered for the Emergency Volunteer program and we are looking forward to assisting you in any way possible. Beneficial links are listed on the Board's website that can be used to help you as you face emergency situations AND as you prepare to become a volunteer!

ATTENTION LICENSEES

Provide the apartment number, if applicable, when providing the Board with mailing address. When moving, immediately notify the Board, to ensure that all documents go to the correct address.

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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*.

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). ISMP Medication Safety Alert! 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. *www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf*. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

1. Read and follow the label.
2. Know which medicines contain acetaminophen.
3. Take only one medicine at a time that contains acetaminophen.
4. Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of 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 FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm.*

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia*, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm.*

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy, or* contact CompAssess@nabp.pharmacy.

DISCIPLINARY ACTIONS

PHARMACIST	LIC. #	SANCTION	DATE
John Daskal	07117	Suspended	08/11/16
Joel Smith	16811	Probation	08/19/16

PHARMACY TECHNICIAN	REG. #	SANCTION	DATE
Edward Brady III	T05116	Suspended	07/28/16
Brandon Smith	T15589	Summary Suspension	08/25/16
Ryann Taylor	T17843	Summary Suspension	09/02/16
Siddharth Patel	T06208	Probation	09/06/16
Alea Citro	T09437	Summary Suspension	09/19/16
Corey White	T05762	Summary Suspension	09/20/16
Laurie Phillips	T00946	Summary Suspension	09/20/16
Ariel Johnson	T03057	Revoked	09/21/16
Tierra Windley	T10333	Suspended	09/26/16

ESTABLISHMENT	PERMIT #	SANCTION	DATE
Allergychoices, Inc.	P04854	Fine	08/05/16

EMERGENCY PREPAREDNESS TASK FORCE

Janet Seeds, Public Information/Communication/Training Coordinator

Years ago, when Hurricane Katrina hit New Orleans, the Maryland Board of Pharmacy had an abundance of emergency volunteers sign up for possible deployment. Emergencies have a way of bringing out the desire to assist others in need. However, that great number of emergency volunteers has decreased tremendously. This may be due to the fact that there have been no major disasters in our area so we tend to get comfortable in our present situations, not dwelling on what 'could' happen. This may also be due to the fact that it is now necessary to sign up with the Department of Health and Mental Hygiene at MD Responds rather than the Board. Actually, though, this is an easy process…nothing to shy away from.

Preparation is the key in these situations. One never knows when a natural disaster or man-made emergency will occur and we want to be ready. The 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, but individuals MUST be registered with mdresponds.dhmh.maryland.gov in order to be deployed.

As was mentioned in previous newsletters, many beneficial articles and links are being posted on the Board's website along with upcoming training information from MD Responds.

Feel free to contact janet.seeds@maryland.gov or call 410-764-5988 for more information.

FDA Provides Training Video on Keeping Medication Safe in Emergency Situations
Reprinted from NABP Innovatons, June/July 2016

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists. It's intent is to help patients make better. In the video, "Emergency Preparedness – Keeping Medications Safe," patient education regarding emergency medication, supplies, and pharmacist's resources are discussed. The program was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All videos may be viewed on the FDA website.

LIMIT PRESCRIBING OPIODS, BENZOS TOGETHER, FDA WARNS
Robert Lowes, Medscape Pharmacists, August 31, 2016

To reduce the risk for overdose deaths, clinicians should not prescribe opioid pain medicines together with benzodiazepines to patients unless there are no adequate alternative treatments available, the US Food and Drug Administration (FDA) announced today.

Both classes of drugs are central nervous system (CNS) depressants, which can trigger respiratory depression, coma, and death, especially when they are combined.

The FDA is spelling out this and other precautions in class-wide boxed warnings on the labels of opioid painkillers such as oxycodone, prescription cough medicines containing opioids, benzodiazepines, which include alprazolam (*Xanax*, Pharmacia and Upjohn), and other CNS depressants. All told, boxed warnings will be required for 389 products.

Warnings about the risks of prescribing opioids together with benzodiazepines are nothing new. They have long been featured on the labels of these drugs, but not in a so-called black box. Putting them inside one is the equivalent of the FDA raising its voice about the problem.

"When a boxed warning goes out, it alerts all kinds of people who might have missed the message," said FDA Commissioner Robert Califf, MD, in a news conference today.

The decision to essentially classify the combination of opioids and benzodiazepine as a last-resort therapy is the FDA's latest measure to battle the nation's epidemic of prescription opioid abuse. An agency review found that the rate of emergency department visits related to the nonmedical use of opioids and benzodiazepines in combination tripled from 2004 to 2011, going from 11 visits per 100,000 population to 34.2 visits. In this same time span, the rate of deaths related to overdoses on this mix of drugs tripled as well.
This rising death toll coincided with a 41% increase in the number of patients who were prescribed both an opioid painkiller and a benzodiazepine between 2002 and 2014, according to the FDA.

The agency advises clinicians that if they have no choice but to prescribe the opioid analgesics and benzodiazepines together, they should limit the dosage and duration of each drug to the minimum needed to effectively treat the patient. Clinicians should warn patients about the risks for slowed or labored breathing. They also should avoid prescribing opioid cough medicines for patients taking benzodiazepines and other CNS depressants, including alcohol.

A Victory for State and City Public Health Officials

Today's FDA decision represents a victory for public health officials from 17 states and territories and 13 cities who petitioned the agency in February to require a boxed warning on concomitant use of opioids and benzodiazepines. Dr Califf credited them during the news conference with "valuable input."

Baltimore City Health Commissioner Leana Wen, MD, one of the leaders of the petition drive, appeared with Dr Califf in the news conference. Dr Wen, an emergency medicine physician, said current clinical practice in prescribing the drugs in question is rooted more in tradition than scientific research.

"There is no scientific reason why in medical training I was taught to prescribe benzodiazepines and opioids together," said Dr Wen. "Like many other things, clinicians do what we do because it's routine care."

She recalled a common drug cocktail for car-accident victims. "To treat their back spasms, we give them a benzodiazepine, and to treat their pain, we give them an opioid," Dr Wen said. "And if a patient required (just) an opioid, we might ask if they are on another opioid, but we might not always ask if they are on a benzodiazepine, and vice versa."

In the US, 25 states and the District of Columbia now permit some medical use of botanical marijuana (Cannabis sativa).[1] It has been used for centuries to treat various ailments, but non-standardization of dosage makes available data difficult to interpret. Cannabis contains >60 pharmacologically active cannabinoids.[2]

Two oral prescription cannabinoids are available in the US. **Dronabinol** (*Marinol*, and generics) is a synthetic form of delta-9-tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis: it is classified by the DEA as a schedule III controlled substance (less potential for abuse or addiction than schedule I or II drugs; currently accepted medical use). A liquid formulation of dronabinol (*Synodros*) was recently approved by the FDA. **Nabilone** (*Cesamet*) is a synthetic analog of THC; it is a schedule II controlled substance (high abuse potential currently accepted medical use). Both dronabinol and nabilone are approved for treatment of nausea and vomiting associated with cancer chemotherapy. Dronabinol is also approved for anorexia associated with weight loss patients with AIDS.

Nabiximols, a standardized cannabis extract that contains a mixture of THC and cannabidiol (CDB), another major cannabinoid found in cannabis, is not available in the US, but is widely available in Europe and in Canada in an oral mucosal spray formulation (*Satives*) for treatment of cancer pain and multiple sclerosis (MS).

CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING – Dronabinol and nabilone have both been FDA-approved since 1985 for treatment of chemotherapy-induced nausea and vomiting that has not responded to other antiemetic treatments. They are effective for prevention and treatment of nausea and vomiting due to mildly or emetongenic drugs such as cisplatin, other drugs such as palonosetron (*Aloxi*) and aprepitant (*Emend*) appear to be more effective and better tolerated. No studies are available comparing cannabis to first-line drugs for treatment of chemotherapy-induced nausea and vomiting.[3,4]

INTRACTABLE CANCER PAIN – A randomized, double-blind, placebo-controlled, 5-week trial in 360 patients found that adjunctive use of low (1-4 sprays/day) and medium (6-10 sprays/day) doses of nabiximols oromucosal spray was significantly more effective than placebo in relieving intractable cancer pain and comparable to placebo in adverse effects. High doses were less effective and caused more adverse effects.[5] There are no acceptable studies on the effectiveness of cannabis for this indication.

MULTIPLE SCLEROSIS – Several studies have found that cannabinoids are effective in treating some symptoms associated with MS.[6] The American Academy of Neurology has recommended use of an oral cannabis extract containing a mixture of THS and CBD (not approved by the FDA) or dronabinol for treatment of spasticity and pain in patients with MS, and has recommended nabiximols for treatment of pain, spasticity, and urinary dysfunction associated with MS.[7]

EPILEPSY – Media reports of dramatic improvement after treatment with CBD in a few children with severe forms of epilepsy, particularly Dravet syndrome, have heightened interest in use of cannabinoids for these disorders. In an open-label, 12-week clinical trial in patients 1-30 years old with severe childhood-onset treatment-resistant epilepsy, addition of *Epidiolex*, an investigational purified cannabis extract containing 99% CBD, reduced the median monthly frequency of seizures by 36.5%.[8] Randomized clinical trials of *Epidiolex* are in progress in the US in patients with these disorders. Data are not adequate to recommend use of cannabinoids for treatment of patients with more common types of epilepsy.[9]

ADVERSE EFFECTS – Dry mouth, sedation, orthostatic hypotension, ataxia, and dizziness occur frequently with medical use of both cannabis and synthetic cannabinoids. Anxiety, tachycardia, agitation, and confusion are also common, especially in older patients, and driving may be impaired. Cannabinoids can cause sedation, motor dysfunction, altered perception, cognitive dysfunction, and dose-

related psychosis. Pure CBD, however, does not have psychoactive effects. Death from an acute overdose of cannabis used alone has not been reported.

PREGNANCY AND LACTATION – Well-controlled studies of cannabis or cannabinoid use during pregnancy are lacking, but animal studies and observational studies in children exposed to cannabis during pregnancy suggest that negative effects on neurodevelopment could occur. Teratogenic effect have not been reported. THC is secreted into breast milk; the effect on breastfed infants is unknown.[10]

DRUG INTERACTIONS – Cannainoids cause drowsiness and addictive effects can occur if alcohol or other CNS depressants are taken concomitantly. Low doses of alcohol can significantly increase blood concentrations of THC.[11] Dronabinol is metabolized primarily by CYP2C9 and 3A4; administration with inhibitors of these enzymes may increase the risk of adverse effects and use with enzyme inducers could reduce is efficacy.[12]

CONCLUSION – The cannabinoids dronabinol (*Marinol*, and generics) and nabilone (*Cesamet*) are effective for treatment of chemotherapy-induced nausea and vomiting, for which they have been approved in the US. Cannabinoid products may also be effective for second-line treatment of cancer pain and the neuropathic pain and spasticity of multiple sclerosis, but none are currently approved for these indications. Cannabidiol (CBD) alone, which is not psychoactive, may be effective for treatment of epilepsy, but more documentation is required. No adequate studies of cannabis (botanical marijuana) are available for any of these indications.

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2. PF Whiting et al. Cannabinoids for medical use: a systematic review and meta-analysis. JAMA 2015; 313:2456.
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12. Inhibitors and inducers of CYP enzymes and P-glycoprotein. Med Lett Drugs Ther 2016; 58-e-46.

Check out the Board's website at **dhmh.maryland.gov/pharmacy**

Some of the topics that may be of interest to you: In the left column of the face page, click onto…

- Board Publications for Past Newsletters, Annual Reports, Brochures, Regulations, and Public Minutes
- License Verification to check the validity of Maryland licensure
- Complaint Form to file a written complaint. Completed the form and fax to the Board.
- FAQs to find the answers to frequently asked questions.
- Formal Disciplinary Actions to check the disciplinary orders for licensees.
- Roster Request to request a specific list of information. This goes directly to the MIS unit.

In the right column, you will find information that is new and may be relevant to you.

- For any applications and/or information about certain licenses, click onto one of the words in the blue box above the picture.

To discover what pharmacies are registered to take back medications and/or donate them to needy individuals, click onto the site at the bottom left of the page.

To check on specific COMAR regulations, click onto the site at the bottom left of the page.

Additional news updates are listed at the bottom right of the face page.

We are compiling the information…putting it into 'an easier to find' format

YOU are needed to read the information we have compiled.

IMPORTANT INFORMATION
FOR INITIAL PHARMACIST LICENSURE

Modification of Licensure Requirements for Pharmacists:
Proof of Proficiency in English

Legislation enacted during the 2016 session will modify COMAR 10.34.02.03. Previously, all applicants for pharmacist licensure were required to prove competency in English in an examination. Effective October 1, 2016, applicants for licensure who have graduated from a recognized English-speaking School of Pharmacy accredited by the Accreditation Council for Pharmacy Education are exempt from the previous mandate.

Continuing Education Breakfast

Sunday, October 23, 2016
8:00 am - 12:30 pm

The Conference Center at the Maritime Institute
629 Maritime Boulevard, Linthicum Heights, MD 21090

ONLY $10

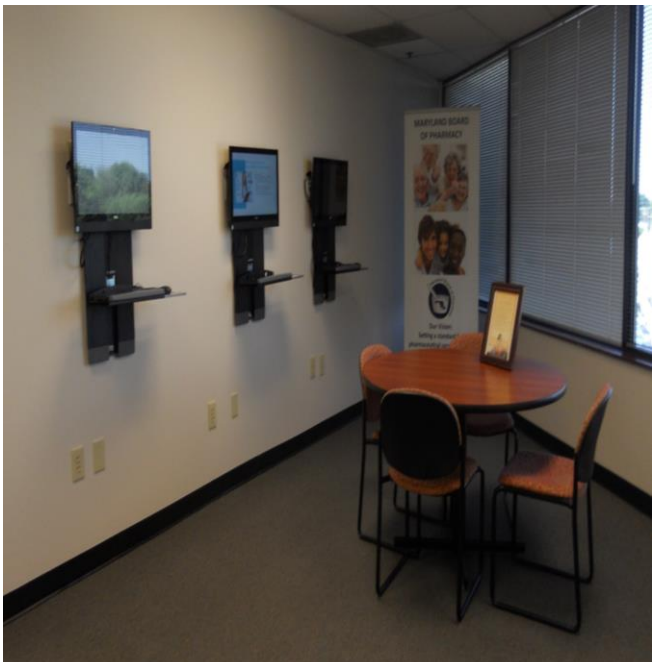
Registration is filled up for the LIVE Breakfast. Openings are still available for the Webinar until October 16th.
Locate the registration information on the Board's website at dhmh.maryland.gov/pharmacy.
After this event, check the website for online information.

"Opioids: Prescribing, Dispensing, Preventing Abuse, and Monitoring"

AGENDA

8:00 a.m.	Registration and Breakfast
8:30 a.m.	Welcome: Bruce Zagnit, Maryland Board Commissioner, Chair of Public Relations Committee Mitra Gavgani, President, Maryland Board of Pharmacy
8:45 a.m.	Speaker: Dr. Greg Hobelmann, M.D. – Physician Ashley Treatment (formerly Father Martin's Ashley) ***"Prescribing and Dispensing Opioids"*** *(including Q & A's)*
9:45 a.m.	Speaker: Erin Haas, MPH – Local Programs Manager, Overdose Prevention - Behavioral Health Administration ***"Opioids and Narcan"*** *(including Q & A's)*
10:15 a.m.	Break
10:30 a.m.	Recognition of Pharmacists in Practice for 60 years Mitra Gavgani. President, Maryland Board of Pharmacy Deena Speights-Napata, Executive Director, Maryland Board of Pharmacy
11:00 a.m.	Jason Clements, Laboratory Scientist Survey, Maryland Board of Pharmacy Update for Sterile Compounding
11:10 a.m.	Speaker: Kate Jackson, Prescription Drug Monitoring Program Behavioral Health Administration *"**PDMP and Opioids*** *(including Q & A's)*
12:10 p.m.:	Closing Remarks: Deena Speights-Napata, Executive Director, Maryland Board of Pharmacy

Enjoy our Updated Front Lobby - 3 Kiosks for registering and watching educational videos and a new literature rack filled with resources for 'reading while you wait'.



It's that time again ---- DEA Drug Back Take Day

The National Prescription Drug Take-Back Day aims to provide a safe, convenient, and responsible means of disposing of prescription drugs, while also educating the general public about the potential for abuse of medications.

October 22, 2016
10:00 AM - 2:00 PM

Visit www.dea.gov or call 800-882-9539 for a collect site near you.

The Biologics Price Competition and Innovation Act (BPCIA) of 2010 provided for the equivalent of generic products for biological drugs. BPCIA established an abbreviated licensure pathway for such alternative biologicals. As of September 27, 2016, there are four approved biosimilars with FDA approval. The Purple Book is the FDA reference compendium for such biologic agents. This book designates each agent as either "B" for biosimilar or "I" as interchangeable. Only products with the "I" designation can be automatically interchanged. The following chart summarizes the current status of FDA-approved biologicals.

Biosimilars Comparison Chart

Biosimilar Brand Name	Manufacturer	Biosimilar Generic Name	Originator Brand Name	Purple Book Designation	Interchangeable
Xarxio®	Sandoz	Filgrastim-sndz	Neupogen®	B	N
Inflectra®	Pfizer	Infliximab-dyyb	Remicade®	B	N
Erelzi®	Sandoz	Etanercept-szzs	Enbrel®	B	N
Amjevita®	Amgen	Adalimumab-atto	Humira®	B	N

INTRODUCING THE BOARD STAFF…WORKING HARD FOR YOU!

The Executive Team is made up of Deena Speights-Napata, Executive Director; YuZon Wu, Acting Deputy Director of Programs (Compliance Officer and Licensing Manager); John Johnson, Management Information Systems Manager; Brian Logan, Legislation & Regulations Manager; Anasha Page, Management Associate; Janet Seeds, Public Information/Communications/Training Coordinator and; Latoya Waddell, Budget Manager.

Management Information Systems, under John Johnson, consists of John Bozek, Computer Network Specialist, resident expert for most computer issues; Jacqueline Green, Database Specialist, who develops statistical reports, creates new programs, as well as supervises the Customer Service unit; and Janey Partin, Computer Graphics Specialist, responsible for revising documentation procedures and developing social media exposure.

Legislation and Regulations is now run by Brian Logan, the Board's Legislative Liaison. He develops and drafts regulatory proposals to protect the public health and to promote the pharmaceutical profession. He reviews and tracks legislation, prepares written position papers, determines fiscal impacts of bills and testifies before legislative committee. He also responds to legislative and regulations inquiries.

Anasha Page is serving as the Board Receptionist. She is responsible for all walk-in clients.

Licensing, the unit that is responsible for all the processing of applications. The licensing specialists are Keisha Wise (Lead), Courtney Jackson, and Doris James. Contractual employees are Christopher Ayers and Sara Isaacson.

Operations, the unit responsible for daily operations, is managed by Latoya Waddell, with the assistance of Lawrence Tates, Secretary, who daily records the mail coming into the Board.

Data Integrity, where applications first arrive from the lock-box and are scanned into individual files as well as being sent to specific places for the request to be completed, is staffed by Kimberley Goodman, Data Integrity Specialist. Two temporary employees will soon join her in this important phase of the licensing process.

Compliance is the unit that is responsible for investigating complaints received by the Board and deficiencies found at inspections as well as monitor cases under Board Order. The unit is comprised of investigators: Sandra Kracke, Vanessa Thomas-Gray, and Shiela West; Laboratory Scientist Surveyor, Jason Clements, who is responsible for evaluating USP 797 compliance of establishments permitted by the Board; and Coordinator, Heather McLaughlin.

Inspection is the unit responsible for performing random annual inspections of facilities permitted by the Board as well as opening and closing inspections. The inspectors are as follows: Emory Lin (Supervisor); Amanda Barefield; Cheryl Johnson; Nancy Richard; Kerri Weigley; and Shanelle Young.

Public Relations is implemented by Janet Seeds. All public information requests, quarterly newsletters, annual reports, marketing materials, letters of verification, intern hour transfers, and exhibits at professional/community functions originate from this unit.

Customer Service, our first line of communication, is composed of individuals that answer phone calls, respond to emails, and refer to other units, as necessary. This unit is manned by Rhonda Goodman, Leroy Jackson, Joy Lane, and Adrian McGowens.

BOARD COMMISSIONERS

President: **Mitra Gavgani**	Home Infusion Representative
Secretary: **David Jones**	Long Term Care Representative
Treasurer: **Vacant**	
Daniel Ashby	Acute Care Hospital Representative
Efstratios (Steve) Bouyoukas	Chain Drug Store Representative
Kevin Morgan	Chain Drug Store Representative
Roderick Peters	Independent Pharmacist Representative
Trinita Robinson	Consumer Representative
Charmaine Rochester	At-Large 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
October 19, 2016
November 16, 2016
December 21, 2016
January 18, 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** *Vacant*
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