SUMMER 2016

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

Greetings to the Pharmacy community!

In Maryland it promises to be a long, hot summer with temperatures approaching, and in some instances, exceeding one hundred degrees. But here at the Maryland Board of Pharmacy we continue to work very hard, in spite of the heat, to achieve goals outlined in the Winter/Spring newsletter. With the help of an outstanding staff and Board, we proudly present the following accomplishments achieved during the past 6 months:

- **Procurement—Vendor payment and staff training**: Payment processing of all vendor contracts bringing all contracts to a current payment status; procurement staff have attended two procurement trainings and have drafted and submitted two procurements for review and approval by the Department of Health and Mental Hygiene Office of Information Technology;
- **Call Center Staff efficiency**: Call Center staff equipment has been repaired and installed in additional areas, increasing the number of call center staff by 15% and cross training other staff, adding an additional 3 staff members; completion of an initial phase of customer service training for our call center and reception staff and procurement of a digital library of customer service training modules to be used to provide ongoing training for current and new customer service staff;
- **Staff Communication and Expansion**: Additional desks added to increase space available for the investigative unit; one office area has been designated for temporary and contractual employees;
- **Public area improvements** include the installation of computers in the lobby area that are currently in operation and available for processing of application renewals and showing of educational videos. We maintain documentation of all visitors to our office, including the name, reason for visit, and e-mail. We review these numbers weekly to determine the types of applicants most likely to visit our office and how to better service them through use of the lobby computers or submission of applications through the lock box;

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MARYLAND OVERDOSE RESPONSE PROGRAM

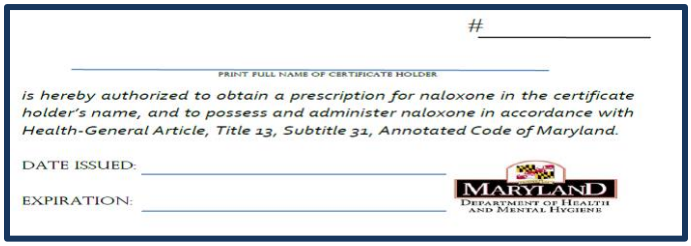
Statewide Naloxone Standing Order

Background

Naloxone is a prescription medication indicated for the reversal of respiratory depression or unresponsiveness due to opioid overdose. The Maryland Overdose Response Program (ORP) was established by the Department of Health and Mental Hygiene (DHMH) in 2013 to increase access to naloxone to reduce opioid overdose deaths throughout the state. The ORP allows non-medical community members to be trained in overdose recognition and response. DHMH authorizes organizations to provide trainings and certify individuals. Certificate holders may be prescribed and dispensed naloxone, either directly or through a standing order, and administer it to someone believed to be experiencing opioid overdose. Under state law, a physician who is employed by DHMH may issue a statewide naloxone standing order, which allows for pharmacists to dispense naloxone to ORP certificate holders in the absence of a person-specific paper or electronic prescription.[1]

Statewide Standing Order

This standing order is issued by **Howard Haft, M.D. (NPI #1639132152), Deputy Secretary for Public Health Services, DHMH**. The standing order authorizes any Maryland-licensed pharmacist to dispense naloxone to any ORP certificate holder in accordance with the conditions of this order, enumerated below.


#_____

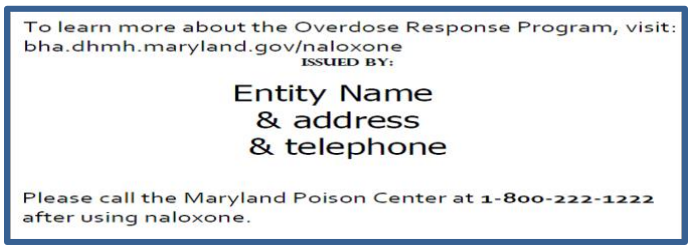
_____
PRINT FULL NAME OF CERTIFICATE HOLDER

is hereby authorized to obtain a prescription for naloxone in the certificate holder's name, and to possess and administer naloxone in accordance with Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland.

DATE ISSUED: _____

EXPIRATION: _____

MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE


To learn more about the Overdose Response Program, visit: bha.dhmh.maryland.gov/naloxone

ISSUED BY:

Entity Name
& address
& telephone

Please call the Maryland Poison Center at 1-800-222-1222 after using naloxone.

(*This is a sample of the current card. ORP cards previously issued are still valid.)*

Upon verification of an individual's ORP certificate, dispense two (2) doses of naloxone hydrochloride and necessary paraphernalia for administration. The specific naloxone formulation shall be selected from the list below in accordance with the certificate holder's preference or training to administer a particular formulation.

1. For intranasal administration
    a. 2mg/2mL single-dose Luer-Jet prefilled syringe. Include one luer-lock mucosal atomization device (MAD 300) per dose dispensed. Include face shield for rescue breathing, if available.
        i. Directions for use: Spray 1 mL in each nostril. Repeat after 3 minutes, if no or minimal response. Or
        ii. NARCAN® 4mg/0.1mL nasal spray of NARCAN® In one nostril. Repeat after 3 minutes, if no or minimal response.
2. For intramuscular injection
    a. 0.4/mL in 1mL single dose vials. Include one 3cc, 23g 1st syringe per dose dispensed. Include face shield for rescue breathing and alcohol swabs, if necessary.
        i. Directions for use: Inject 1 mL in shoulder or thigh. Repeat after 3 minutes, if no or minimal response.
3. For intramuscular or subcutaneous injection
    a. EVZIO® 0.4 mg/o.4mL auto-injector, #1 Two-pack
        i. Directions for use: Follow audio instructions from device. Place on thigh and inject 0.4mL. Repeat after 3 minutes, if no or minimal response.

I declare this standing order as a statewide prescription for the dispensing of naloxone.

Howard Haft, M.D., Deputy Secretary for Public Health Services, DHMH

Effective Date: Dec. 14, 2015 Expiration date: Dec. 14, 2017

[1]Health-General Article, Title 13, Subtitle 31, Code of Maryland

http://dhmh.maryland.gov/pharmacy/docs/LegsRegs/Statewide-Naloxone-Standing-Order.combined.pdf

EXECUTIVE DIRECTOR continued from page 1

- **Increased meetings with our partners in the pharmacy community** have included meetings and communication with the University of Maryland School of Pharmacy staff and the Maryland Society of Health System Pharmacists (MSHP), the Notre Dame of Maryland School of Pharmacy, and the Maryland Pharmacist Association;
- **Develop and Improve Data Systems and Databases**: Development and use of a call center and application processing database system that includes information on each call received in our call center to include the caller, information requested, information provided and an application database that documents all applications received from our vendor, the type of application, date of processing and processor. This information allows us the opportunity to know the number of call and applications received on a daily basis and we are able to predict peaks in work load and adjust staff resources accordingly, and in so doing better serve our pharmacy community;
- **Expansion of our newsletter** content and reach, to include link posting on the NABP website and an NABP sponsored centerfold in our newsletter that includes national information relevant to the pharmacy community;
- **Filling Staff Vacancies**: Additional staff that includes a legislative liaison, a licensing assistant, an investigator, and employment postings for two pharmacist inspectors and two additional investigators;

We continue to work on the development of an on line application process for pharmacists and technicians.

By working together as a team the Board Commissioners and staff have enjoyed a good sound beginning, and we anxiously await the next round of improvements and work needed to fulfill our mission of "protect(ing) Maryland consumers and promot(ing) quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public."

I look forward to the next edition of our newsletter in which I will provide a summary of new pharmacy, distributor, pharmacist, technician, and intern applications and some of the technology available to increase pharmacy efficiency.

PHARMACISTS SHOULD HAVE EXPANDED ROLE IN PROVIDING NALOXONE

American Pharmacists Association, June 21, 2016 – Rachel Balick, Assistant Editor

The American Medical Association (AMA) House of Delegates adopted a resolution encouraging a larger role for pharmacists in efforts to expand access to opioid overdose-reversing medication, specifically collaborative practice agreements and standing orders. The provision is part of a package of new policies aimed at increasing access to naloxone and other drugs that prevent opioid overdose deaths.

Pharmacists who provide non-patient-specific naloxone – not just to vulnerable patients but their families and friends – are qualified to educate patients on how to identify and respond to an opioid overdose, AMA noted in its recommendations.

Another policy supported liability protections for physicians and other authorized health professionals – including pharmacists – to prescribe, dispense, and administer naloxone. AMA encouraged similar leeway for community organizations, law enforcement agencies, correctional facilities, and schools where not otherwise prohibited by statute.

Connecticut, Idaho, North Dakota, and New Mexico currently allow pharmacists to prescribe naloxone, and several more allow pharmacists who have established collaborative practice agreements with physicians to do so.

Other policies promoted timely and appropriate access to non-opioid and non-pharmacologic treatments for pain and supported efforts to uncouple payments to health care facilities and patient satisfaction scores relating to pain evaluation and management. AMA also urged health plans to include naloxone in multiple formulations on its preferred drug lists and to minimize cost sharing. In addition, the association encouraged increasing third-party (e.g., family, friends) access to naloxone.

PRESCRIBING OPIOIDS FOR CHRONIC PAIN

CDC Guidelines, excerpts from Pharmacy Today, May 2016

Pharmacists should become familiar with the CDC guideline and understand the recommendations for appropriate opioid prescribing. They are on the front lines of dispensing opioid prescripts and providing associated patient care services and they have corresponding responsibility to make sure these prescripts are legitimate. "Many of the recommendations the physician colleagues are being encouraged to follow could also apply to the services pharmacists provide," said APhA Vice President of Professional Affairs, Anne Burns, PSPharm…..

"Pharmacists should stay up to date on the latest treatments for chronic pain that include non-pharmocologic therapies and non-opioid pharmacologic therapies as well as the opioids," Burns said. "Pharmacists can play a role in ascertaining whether patients, especially those on new prescriptions, understand their medications – including the risks and benefits, how to use them appropriately, and how to store and dispose of them: APhA advocates that patients should have access to pain medications for legitimate purposes, that pharmacists can make valuable contributions as part of an integrated approach to pain management, and that appropriate resources and incentives need to be in place for services provided….

[http://pharmacytoday.org/article/S1042-0991(16)30171-2/pdf] to read entire article; www.nabp.net;news/cdc-issues-guideline-for-prescribing-opioids -for-chronic-pain; original source: www.cdc.gov/drugoverdose/prescribing/guideline.html

HOW TO USE NALOXONE (NARCAN) TO REVERSE AN OPIOID OVERDOSE

Excerpts from the Department of Mental Health Addiction Services (DMHAS)

Opioid overdoses have become epidemic. Naloxone, also known as Narcan, can reverse an opioid overdose in a few minutes. Opioids include street drugs (like heroin) and prescription drugs (like Oxycontin). People do overdose and die from prescription drugs by using too much or mixing them with other pills, street drugs, or alcohol.

How to Recognize an Opioid Overdose

- The person does not respond when you call their name, shake them or cause pain by rubbing your knuckles hard on their breastbone
- Their breathing is too slow (less than 10 breaths/minute) or they aren't breathing at all
- Their skin is blue or gray, especially the lips and fingernails
- They may be making loud, uneven snoring or gurgling noises

What to do if you think the person has overdosed on opioids

1. **Call 911** – tell them the person isn't breathing or is having trouble breathing and explain your exact location
2. **Rescue Breathing** – you can help the person get oxygen
    - putting him on his back and opening his airway by tilting his head back and lifting their chin
    - pinching her nose and give 2 breaths first, then one breath every 5 seconds
    - **Don't stop** unless the person revives, EMS arrives, or to give Narcon
        i. ***To give injectable Narcan***:
            1. Pop off orange top of vial and insert syringe
            2. Remove 1 cc of Narcan by pulling down on the plunger
            3. Insert syringe into a large muscle and push the plunger in
        ii. To give intranasal Narcan:
            1. Remove the yellow cap atop the plastic tube and screw the atomizer on
            2. Remove the bottom yellow cap and the red cap from the vial; screw the vial into the bottom of the tube
            3. Spray half the vial up each nostril by pushing the vial up through the tube
3. **Recovery Position** – If you must leave the person alone at any time, roll him onto his side so he won't chock if he starts to vomit

A FEW FAQs: New Interns & Renewals

1. **Who can apply for a Pharmacy Intern registration?**

   (a) CURRENTLY ENROLLED and has completed 1 year of professional pharmacy education in a Doctor of Pharmacy program:
   - (i) Accredited by the Accreditation Council for Pharmacy Education; or
   - (ii) Having pre-candidate or candidate status by the Accreditation Council for Pharmacy Education;

   (b) GRADUATED from a doctor of pharmacy program accredited by the Accreditation Council for Pharmacy Education; or

   (c) GRADUATE OF A FOREIGN SCHOOL OF PHARMACY who:
   - (i) Has established educational equivalency as approved by the Board; and
   - (ii) Has passed an examination of oral English approved by the Board, (ie: FPGEC)

   See Health Occupations Article, 12-6D-03 and COMAR 10.34.38.06

2. **How should a background check be obtained?**

   (a) We recommend background checks be done no more than two weeks prior to the submission of an Intern application.

   (b) The Board only accepts state background check through Maryland Criminal Justice Information System (CJIS). To contact CJIS please call 1-888-795-0011.

3. **When does an Intern Student/Intern Graduate renew his/her license?**

   (a) An Intern currently enrolled can only renew once and will receive notification by mail.

   (b) An Intern Graduate and Foreign Graduate will not be able to renew after initial registration.

4. **I would like to mail my application overnight. Where should I send it?**

   All correspondence/Applications sent overnight or through priority mail should be addressed to the appropriate lockbox and sent to:

   First Data /Remitco
   Attn: Maryland Board of Pharmacy / LOCKBOX #XXXX (see below)
   400 White Clay Center Drive
   Newark, DE 19711

   Address applications to the lockbox number listed below:
   Pharmacists & Interns, Lockbox No. 7691
   Pharmacy Technicians, Lockbox No. 7692
   Pharmacies, Distributors, Manufacturers, Lockbox No. 7693
   Miscellaneous Correspondence, Lockbox No. 7694

MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

MARYLAND PDMP

IMPORTANT

Information Regarding

Maryland Prescription Drug Monitoring Program

New law requires providers to REGISTER with and USE PDMP

The **Maryland Prescription Drug Monitoring Program (PDMP)** was created to support providers and their patients in the safe and effective use of prescription drugs. The PDMP is part of Maryland's response to the ***epidemic of opioid addiction and overdose deaths.***

Maryland PDMP Facts

- Authorized by law in 2011
- Maryland Department of Health and Mental Hygiene (DHMH) program
- Contains data on Rx controlled dangerous substances (CDS) dispensed to patients in Maryland
- Providers get free, online access through Chesapeake Regional Information System for our Patients (CRISP)

What is CRISP?

- State-designated health information exchange (HIE) serving Maryland and the District of Columbia.
- Electronic system connecting all 46 acute care hospitals in Maryland
- Web-based portal gives providers secure access to patient PDMP, hospital and other clinical data

CRISP

Legal Changes Affecting Providers

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*

Prescribers: Beginning **October 1, 2016,** practitioners authorized to prescribe CDS in Maryland must be registered with the PDMP prior to obtaining a new or renewal state CDS Registration (issued by the Division of Drug Control) **OR** by **July 1, 2017,** whichever occurs sooner. *This applies to physicians, physician assistants, nurses, dentists, podiatrists and veterinarians.*

ALL Maryland licensed pharmacists are required to register by July 1, 2017.

REGISTER NOW with the PDMP through CRISP at https://crisphealth.org/. Click on PDMP 'Register' button on the left-hand side of the screen. 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 90 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. DMMH 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 Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

- Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med*. 2005;165(16):1842-1847.
- Mesteig M, Helbostad JL, Sletvold O, Røsstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res*. 2010;10:1.
- Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm*. 2008;65(15):1451-1457.
- Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc*. 2014;89(8):1042-1051.
- Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc*. 2013;61(11):1894-1899.
- American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch*. March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, 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*.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery*.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm*.

DISCIPLINARY ACTIONS

PHARMACIST	LIC. #	SANCTION	DATE
Venkata S. Mannava	19517	Probation	05/18/2016
Dipal Patel	18393	Probation	05/18/2016
Susan I. Nwoga	15990	Fine/Probation	06/15/2016
Parvin Ossareh	16232	Probation	06/15/2016

PHARMACY TECHNICIAN	REG. #	SANCTION	DATE
Taria Shird	T11164	Summary Suspension	05/12/2016
Kierstin Powers-Harvey	T16432	Summary Suspension	06/15/2016
Keiffer A. Subero	T18260	Probation	07/05/2016
Courtney Batts	T10631	Revoked	07/20/2016
Amanda Roles	T15126	Revoked	07/20/2016
Michelle Hahn	T02323	Revoked	07/20/2016
Kisa Bridges	T11311	Revoked	07/20/2016

ESTABLISHMENT	PERMIT #	SANCTION	DATE
Poplar Grove Pharmacy	P05639	Fine/Probation	06/16/2016
Wickliffe Pharmaceutical, Inc.	P05309	Probation	06/27/2016
Nelcha Pharmacy	PW0457	Revoked	07/20/2016
St. Mary's Medical Park	None	Fine	07/20/2016
Shavona Pharmacy	P05005	Probation	05/18/2016

STERILE PHARMACEUTICAL COMPOUNDING

(COMAR 10.24.19)
By Yuzon Wu, Compliance Manager

The Maryland Board of Pharmacy (the "Board") amended and promulgated regulations for Sterile Pharmaceutical Compounding found under COMAR 10.34.19 which became effective on February 1, 2016. Please refer to the Board's website for a complete and updated version of COMAR 10.34.19 under "Sterile Compounding News & Updates". Below is a highlight of some of the amendments and additions to the regulations:

- **Record Keeping Requirements** (COMAR 10.34.19.07): The pharmacy shall keep completed patient prescription records in a retrievable manner for at least 5 years, either:
  - (a) At the inspection site; or
  - (b) So as to be immediately retrievable by computer or other electronic means.

- **Minimum Facility Requirements** (COMAR 10.34.19.09): A pharmacy shall have a controlled environment that meets USP 797 standards.

- **Minimum Requirements for Inspection** (COMAR 10.34.19.17): Pharmacies will be inspected by the Board at least annually. During the inspection, the pharmacy shall provide quality assurance testing reports, documentation of reporting adverse events, microbial testing of a sampling of the sterile compounded products of the pharmacy, if applicable under USP 797, and any other information requested to ensure compliance with USP 797 standards.

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INVOLVEMENT IN MPhA CONFERENCE

The Maryland Board of Pharmacy (Board) was honored to participate in the June 2016 MPhA conference held in Ocean City, MD. Much information was displayed at our exhibit such as: immunization schedules; CDC recommendations for prescribing opioids; opioid overdose, naloxone, and ORP certification; the CRISP program; safety tips; and various brochures. Some of this information will be printed in the Board's newsletter and will also be available at other future professional events.

In addition to the exhibit, one of the Board's past presidents, Donald Taylor, had a session Saturday afternoon that highlighting the Board's Emergency Preparedness Task Force (EPTF). The EPTF works closely with Maryland Responds and has ensured that pharmacists are an integral part of the state emergency plan.

During this presentation, information was given that:

1. Used presented information to enable "fast track" completion of the Maryland Responds Medical Reserve Corps. ***Road to Readiness (R2R)*** steps are required for volunteer deployment beginning with completion of a volunteer profile and the orientation course;
2. Described the Maryland Responds Medical Reserve Corps (MRC) state program;
3. Described the intent of National Incident Management System (NIMS);
4. Described the key concepts and principles underlying NIMS, and;
5. Described the key concepts and principles of the Incident Command System (ICS).

The pharmacy community certainly owes a debt of gratitude to Dr. Taylor for his commitment which far exceeds all expectations.

Also, on Sunday, one of the Board Commissioner's, Ellen H. Yankellow, was honored with the Bowl of Hygeia Award. The Bowl of Hygeia is the most widely recognized international symbol for the pharmacy profession and is considered one of the profession's most prestigious awards. Established in 1958, the award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service. The Bowl of Hygeia award is sponsored by the American Pharmacists Association Foundation and the National Alliance of State Pharmacy Associations. Boehringer Ingelheim is the premier supporter.

Dr. Yankellow is committed to providing the highest quality services to her patients in residential care, senior care, and over 300 institutions. Dr. Yankellow's business acumen and success is equally matched by her passion for philanthropy and community activism. She is involved in multiple community, civic, and private organizations, and has created a culture of generosity within every aspect of her business and community.

She has provided scholarships, grants and mentor support for youth and women to achieve their educational goals. She has actively supported the advancement of pharmacy practice by serving as a preceptor, serving on the University of Maryland School of Pharmacy Board of Visitors as well as supporting endowed scholarships and fellowships to advance clinical pharmacy outcomes. She also serves in a myriad of capacities to advance the missions of local and international organizations that seek to improve human rights and alleviate human suffering.

Dr. Yankellow earned both her BS in Pharmacy (with honors) and her Doctorate of Pharmacy from the University of Maryland School of Pharmacy in years 1973 and 1996 respectively. She served on MPhA's Board of Trustees from 1991-94. Since 2003, Dr. Yankellow has held the positions of President, CEO, and Majority Owner of Correct Rx Pharmacy Services, Inc. Dr. Yankellow currently serves as a Commissioner on the Maryland Board of Pharmacy.

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- **"Adverse event"** (COMAR 10.34.19.03) is defined as:
  - Any adverse patient outcome related to the sterile compounding process; or
  - Evidence of environmental contamination, including microbial contamination above the threshold set forth in USP 797 Standards.

- **Adverse Event Reporting Requirement** (COMAR 10.34.19.18): A pharmacy shall document and perform routine testing as required by USP 797 Standards for the appropriate risk levels of sterile compounded preparations and report to the Board within 5 calendar days any adverse events that have been discovered including corrective actions taken or proposed.

- **Other Reporting Requirements (COMAR 10.34.19.18): A pharmacy shall also report to the Board within 5 calendar days** any deficiencies discovered related to the sterile compounding process, disciplinary actions imposed by other states or other state agencies, changes in accreditation status, disciplinary actions taken against a pharmacist who is an owner, operator, or employee of the pharmacy, and disciplinary action taken against any other permit or other authorization held by the pharmacy.

- **Sterile Compounding intended for Office Use** (COMAR 10.34.19.19): a person that prepares and distributes sterile compounded medications for office use into, out of, or within the State shall hold:
  - A manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile compounded medications for office use; and
  - If applicable, a wholesale distributor's permit, issued by the Board under Health Occupations Article, Title 12, Subtitle 6C, Annotated Code of Maryland.

Adverse events and other mandated reports should be reported to the Board with all supporting documents to the attention of Jason Clements, Lab Scientist Surveyor. Please refer to the Board's website for reporting processes and forms (http://dhmh.maryland.gov/pharmacy/Pages/SterileCompounding.aspx).

TWO PHARMACIES SHARING SPACE

The Board's inspectors have reported numerous issues relating to the sharing of space by a full-service pharmacy and a waiver (specialty) pharmacy. The Board's regulations, COMAR 10.34.17, allow for a full-service and waiver pharmacy to operate on the same premises provided certain conditions are met.

1. Each pharmacy must obtain a separate permit from the Board.
2. Each pharmacy must be supervised by a separate pharmacist at all times the pharmacies are in operation. In other words, if both pharmacies have the same hours of operation, each pharmacy must have a separate pharmacist. If the pharmacies have different, non-overlapping, hours of operation, the same pharmacist may supervise both pharmacies.
3. Each pharmacy must maintain separate inventory and recordkeeping.

Furthermore, because each pharmacy is a distinct permit holder. The Board's position is that each must independently meet and comply with all other establishment requirements relating to facility equipment (sink, refrigerator), personnel, quality assurance, and security.

NON-ADDICTIVE OPIOID IS UNDER DEVELOPMENT

University of Maryland researcher sees promise

Reprinted from The Baltimore Sun, by Carrie Wells (cwells@baltsun.com)

Researchers at the University of Maryland, Baltimore, have developed a new drug that promises a possible break-through by offering strong pain relieve while lowering the risk of addiction.

The drug, a synthetic opioid called UMB425 for now, is in the early states development – years away from human testing – and some experts cautioned that a number of complications could prevent it from ever coming to market. But there are high hopes for the drug as the nation looks for solutions to the opioid addiction epidemic.

"It's one of the biggest health care crises we have in the United States right now," said Andrew Coop, a professor at the University of Maryland School of Pharmacy who is developing the drug. "There are people who suffer daily from the side effects of the opioid."

While opioids are generally effective for pain relief, they can lead to addiction as users become more tolerant of them and require larger doses.

Opioids work the brain through their interaction with what are known as receptors, Coop said. There are three primary opioid receptors called mu, delta and kappa. Most opioids act on the mu receptor, causing pain relief as well as tolerance, dependence and feelings of euphoria.

UMB425 is unique in that it acts on both the mu receptor and the delta receptor. It's not clear why, but activating both at the same time reduces the side effects of tolerance and addiction, Coop said,

Past research established that taking a dug that acted on the delta receptor at the same time diminished those negative side effects, but Coop said his aim was to design a single drug to act on the two receptors.

Coop's team created UMB425 with the help of Alex MacKerell, director of the University of Maryland's Computer-Aided Drug Design Center. It has been under development for about 10 years. They published their research on its ability to act on the two receptors in the journal ACS Chemical Neuroscience in 2013.

The drug's effect on multiple receptors is a "unique feature," said David Thomas, a health science administrator at the National Institute on Drug Abuse. He called the 2013 study "solid" and said it showed that the drug results in less tolerance developing over time.

Still, more research is needed.

"It's a promising finding, but it's very preliminary," Thomas said.

While Coop said it's as effective as the opioid morphine, the drug has been tested so far only on rodents. Coop said his team hopes to start testing the drug soon on primates and begin clinical human trials in about five years.

UMB425 still creates a euphoric high for the user, which Coop wants to find a way to eliminate to reduce any potential for abuse.

The National Institute on Drug Abuse estimated in 2012 that 2.1 million people nationwide ere addicted to or abusing prescription opioid pain relievers. Another 467,000 people are addicted to heroin, a cheaper and readily available alternative.

About 28,000 people died from overdosing on prescription pain relievers and heroin in 2014, the highest number on record, according to the Centers for Disease Control and Prevention.

About 100 million American adults suffer from chronic pain, the Institute of Medicine estimated in a landmark study in 2011. Prince, the renowned musician who died in April from an accidental overdose of the powerful painkiller fentanyl, was the latest high-profile death in the opioid addiction epidemic.

"The [U.S. Food and Drug Administration] has a clear mandate that we need new ways to treat paid," said Dr. David Maine, director of the Center for Interventional Pain Medicine at Mercy Medical Center. "They're not going to entertain anything that's the same old…This is novel, it's exciting."

"It's clearly very promising," he added. "We know that there's pain-relieving potential there."

Drugs such as UMB425 generally face many obstacles to getting FDA approval, including the ability of patients to tolerate it, Main said.

"The opioid epidemic is here and now; I hope by the time something like this comes on the market, that issue will be headed in the other direction," he said.

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Besides the potential for addiction, opioids have a host of negative side effects that become more problematic as the patient develops tolerance and the dosage is increased. For example, too large a dose can depress breathing, which can lead to death.

If UMB425 doesn't cause tolerance in patient over time, doses won't need to be increased and the risk of other serious side effects, such as life-threatening constipation, will decrease, Coop said.

Patients also wouldn't experience painful withdrawal symptoms and wouldn't need to seek relief by taking even more opioids, he added.

"It would just be like taking any other drug," Coop said.

The National Institute on Drug Abuse's Thomas urged restraint in prematurely judging the new drug at this stage. "I wouldn't wave the flag and say, "This is it – we've found the alternative to opiates," he said.

"Whether this pans out or something else pans out is the question."

Thomas said he thinks the drug could be part of doctors' pain relief arsenal in the future, but he said many different new therapies could develop.

"We've been using opioids a lot for pain, and there's been a pretty profound impact to that many opioids being available to the American people," he said. "Opioids have their place in pain treatment, but they should be part of a more comprehensive pain treatment."

Coop said the drug had about $2 million in grant funding so far and that he needs another $2 million to get it to market.

"It's just not going to happen tomorrow," he said. "It needs significant investment."

Baltimore Health Commissioner Dr. Leanna Wen, who considers UMB425 more as potentially "one tool in the toolbox" to fighting opioid addiction, suggested an easier and more practical way to have an impact on the opioid addiction epidemic.

"There is a larger problem of overprescribing opioids…There is a culture of a pill for every pain, a quick-fix culture that doctors and patients have to change."

Pharmacy Technician Training Facility Open House

The Community College of Baltimore County is completing the construction of a Pharmacy Technician training facility in room 170 at the continuing education extension center located on 3637 Offutt Road, Randallstown, MD 21133. An open house preview for the local pharmacy community is being held on Tuesday August 30, 2016 at 6PM. For additional information contact: Richard D'Ambrisi, Program Coordinator at 443-840-1054 orrdambrisi@ccbcmd.edu

Upcoming Conferences that Staff are attending…so that they can share information with you!

September 15-17, 2016 – NABP-AACP, District 1 and 2 meeting – White Sulphur Springs, WV
September 17-18, 2016 – Citizen Advocacy Center – Washington, DC

To make it easier to process,
applications sent to the lock-box are requested to be sent 1-sided versus 2-sided.
Thank you!

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

SAVE THE DATE!!

Continuing Education Breakfast

Sunday, October 23, 2016
8:00 am - 12:30 pm
at
The Conference Center at the Maritime Institute
629 Maritime Boulevard
Linthicum Heights, MD 21090

ONLY $10

Registration will be open in September. Watch the website!

Check out the Board's website
dhmh.maryland.gov/pharmacy
We are diligently trying to make it as customer-friendly as possible…

Let us know if you have any issues with navigation and we will do our best to address the issue. Although we are constantly reviewing the website for accuracy, please let us know if any of the links do not work. We will repair them immediately.

Some of the topics that may be of interest to you:
Past Newsletters, Annual Reports, Brochures, Regulations, FAQs,
Applications for licensure, Upcoming Events, and LOTS MORE!

We are compiling the information…
YOU are needed to read the information we have compiled.

REMINDER

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

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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
August 17, 2016
September 21, 2016
October 19, 2016
Location: 4201 Patterson Avenue, Baltimore, MD 21215

CONTACT DIRECTORY Customer Service Center 410-765-4755 ▪ dhmh.mdbop@maryland.gov ▪ dhmh.maryland.gov/pharmacy ▪ 1-800-542-4964	
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