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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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Quarterly Newsletter

The Maryland Board of Pharmacy: Fulfilling Its Mission- Protecting Maryland consumers and promoting quality healthcare in the field of pharmacy

Deena Speights-Napata, Executive Director

As fiscal year 2023 ends and a new fiscal year begins, it is only appropriate to reflect on some of the accomplishments of the Maryland Board of Pharmacy as we continue to focus on two critical parts of the board mission: protecting consumers and promoting quality healthcare. With a board of 12 commissioners and a staff of between 25-30 individuals, the Board has worked very hard to make sure the interests of Maryland pharmacists and the achievements in pharmaceutical policy initiatives and programs in Maryland is practiced locally and promoted and recognized nationally.

Protecting the Public

NABP DSCSA Tracing Pilot/119th NABP Annual Meeting Resolution

Maryland is one of a few pilot states that is participating in this important pilot program. Maryland has become an important part of national efforts to monitor and improve the efficiency of the national drug supply chain through its work with NABP and other national organizations, in preparation for the federal requirements of the Drug Supply Chain Security Act. Maryland also has aligned itself with an important resolution passed at the May 2023 annual NABP meeting.

DSCSA Education and Compliance Assessment

NABP will continue educating its member boards of pharmacy about upcoming requirements of the Drug Supply Chain Security Act (DSCSA) and develop tools to assist them. This includes developing an Inspection Blueprint for Wholesale Distributors and Third-Party Logistics Providers and further collaboration with the boards of pharmacy to increase utilization of the interoperability network (Pulse by NABP™) by state regulators and other stakeholders.

Another important policy initiative passed during the 2023 Maryland legislative session was expanding the role of the technician in the pharmacy to include authority to immunize under the direction of a pharmacist and the addition of a Pharmacy Technician Seat on the Maryland Board of Pharmacy.

The passing of this law will align Maryland with the National Board of Pharmacy and the resolution recently passed to expand the role of pharmacy technicians.

Board Weekly Interaction with licensees and the public:

Approximately 300 phone inquiries

Over 30 walk-ins for quick licensing payment and processing

Close to 100-150 applications

Over 1,100 distributor applications processed

320 cases

Approximately 30 inspections each week

Practice guidance: Responses to important pharmacy inquiries that recently have included USP 797 standards, implicit bias training, Maryland immunization protocol, injectable maintenance medication training, rules for shipping medication, and physician/pharmacist collaborative services.

****Monthly board meetings that are now available through live streaming**

Promoting Quality Healthcare

Committee on Law Enforcement/Legislation

The Maryland Board of Pharmacy has one board member and the executive director participating on the NABP committee that is designed to:

1. Develop model laws and regulations based on resolution adopted by the members of the association or reports of task forces or other committees of the association, or as assigned by the Executive Committee.
2. Review and comment on existing legislation and rules governing the practice of pharmacy and the distribution of prescription medications.
3. Recommend to the Executive Committee model pharmacy practice or prescription drug distribution regulations that are needed to improve the protection of the public health.

Through participating on this committee, the board representatives are able to share their knowledge and challenges of the practice of pharmacy to impact recommendations made in regards to the practice of pharmacy across the country.

The Maryland Board of Pharmacy has participated in NABP Annual Meeting poster sessions since 2018. Topics presented have included:

2023: Effective CDS data Collection and Use

2021: Impact of COVID-19 Emergency Orders on the Practice of Pharmacy in MD

2018: Expanding the Role of the Pharmacist from Dispenser to Prescriber of Contraceptives and Standing Order for Naloxone Dispensing in MD

The Maryland Board of Pharmacy also has been consistently a part of the MPJE question screening selection process assigning 2 board commissioners and most recently became a part of the NABP MPJE Task Force assigning one board commissioner.

Maryland Board of Pharmacy Executive Director Stakeholder Collaborations include:

Board Director collaborations with stakeholder organizations that include **MSHP, MD Pharmacy School Deans, MPhA, FDA, NABP, FARB, MDH PDMP, Maryland Medicaid DUR Committee, and the Maryland Center for Immunization, and MD State Legislative Workgroups** on workplace shortages, education pipeline, and pharmacist reimbursement in MD.

As you can see, the Maryland Board of Pharmacy continues to be on the move creating and sustaining influence in the local and national pharmacy community. Expect an even greater presence in FY 2024.

Ellen Yankellow Honors Dean Eddington Through Major Gift

By Andrew Tie, Reprinted from the University of Maryland School of Pharmacy News Center

The deanship of **Natalie D. Eddington, PhD, FAAPS, FCP**, proved to be a transformative period for the University of Maryland School of Pharmacy (UMSOP).

In honor of Eddington's 15-year tenure as dean, **Ellen H. Yankellow, PharmD '96, BSP '73**, president and CEO of Correct Rx Pharmacy Services, Inc., announced a \$500,000 gift to the School **during a celebration for Eddington on June 1, 2023**.

Yankellow is one of the School's Founding Pharmapreneurs, a member of the Board of Visitors and Center for Women in Pharmapreneurship task force, and namesake of the Ellen H. Yankellow Grand Atrium in Pharmacy Hall.

"When people ask me 'why do you give to the School of Pharmacy?' the answer is simple, people give to people they trust," Yankellow said. "Trust is earned, and Natalie earned my trust along with that of so many others that our gifts would be used wisely and impactfully."

"We are deeply appreciative of the incredible gift that Ellen Yankellow has provided to the School of Pharmacy," said **Ken Boyden, JD, EdD**, associate dean for development and alumni affairs. "This gift from a great pharmapreneur honors the pharmapreneurial vision of Natalie Eddington and will open many new opportunities for our students within these exciting programs."

The gift will be used for five initiatives at the School and university.

- \$100,000 over three years to the **Peter Lamy Center on Drug Therapy and Aging** to support a training fund for residents, fellows, and students.
- \$100,000 over three years to provide scholarship support for students from under-represented communities within the **MS in Regulatory Science**.
- \$100,000 over three years to support the **Center for Innovative Pharmacy Solutions** telehealth program in its leading collaboration with other University of Maryland, Baltimore (UMB) schools.
- \$100,000 over three years to provide student support in **the PhD in Pharmaceutical Sciences (PSC)** program and its NIH-awarded **Initiative for Maximizing Student Development** program, which strives to increase the number of students from under-represented groups in the PSC doctoral program.
- \$100,000 over three years to provide support for UMB's new EMBRACE initiative, a multi-faceted approach designed to increase the vibrancy of the greater UMB campus, boost UMB's community impact in West Baltimore, and strengthen UMB's profile with its internal and external constituencies. Eddington now has a leadership role with EMBRACE.

"Throughout my career and deanship, Ellen Yankellow has been a nationally recognized pharmacy leader, supporter, partner, and friend," Eddington said. "I'm truly humbled when I think about how a gift of this magnitude will propel our School and university forward through these five impactful and diverse initiatives."

Under Eddington's leadership, the School grew in many ways. Physically, the School's footprint expanded in 2010 with the opening of Pharmacy Hall addition, a 126,000 square foot, seven-story building that doubled the School's space. In its academic offerings, the School developed new graduate level

Continued on page 4

programs, such as the first-of-its-kind **MS in Medical Cannabis Science and Therapeutics** in 2019, and expanded its enrollment across 10 academic degrees.

Clinical and research portfolios grew with the addition of new practice sites, extramural funding, and new centers and programs. Eddington also led the School through the multi-year pandemic and launched the transformational **Pharmapreneurship** initiative in 2017, enhancing the School's national reputation.



HB 693 - State Board of Pharmacy - Board Membership, Delegated Pharmacy Acts, and Sunset Extension Signed into Law

On Monday, April 24, 2023, Maryland Governor Wes Moore signed HB 693 - State Board of Pharmacy - Board Membership, Delegated Pharmacy Acts, and Sunset Extension. Delegate Nicholas R. Kipke served as the lead sponsor in the Maryland House of Delegates and strategically guided the Maryland Board of Pharmacy as the bill traveled through the legislative process. Generally, the bill expands membership of the Maryland Board of Pharmacy to include one registered pharmacy technician, authorizes remote prescription-related data entry by registered pharmacy technicians and registered pharmacy interns, and authorizes administration of a COVID-19, influenza, or pneumonia vaccine by a registered pharmacy technician to an individual aged 18 and over, and a respiratory syncytial virus or shingles vaccine to an individual aged 50 and over. The Maryland Board of Pharmacy has worked to achieve these legislative initiatives for many years, and is pleased with the progress that was achieved during the 2023 legislative session.

Event Corner: Education Lecture & Panel Discussion – University of Maryland Baltimore, School of Pharmacy

On March 3, 2023 Emergency Preparedness Task Force (EPTF) members, Jennifer Thomas, Cynthia Anderson and Kimberly Pietropola joined the University of Maryland School of Pharmacy Public Health Course series with course Director, Assistant Professor Wendy Castillo, MD, PhD and Eposi Elonge to provide an update on Maryland Pharmacy efforts in emergency preparedness and response. There were approximately 70 students attending.

Jennifer Thomas, Co-Chair, EPTF provided a presentation on “Maryland Pharmacy Roles in Emergency Preparedness” to include a brief review of Incident Command, review of national and state agencies responsible for preparedness and response, a brief history of the EPTF and activities EPTF has been engaged prior to and up through COVID-19 deployments.

Kimberly Pietropola followed and highlighted opportunities for pharmacists to engage in emergency preparedness through both work and volunteer roles. Additionally, she shared how pharmacists contributed to the recent response to COVID-19 through informatics designing and building medications and clinical decision support tools in electronic health records.



L to R: Eposi Elonge, MS, Cynthia Anderson, RPh, MHA, Jen Thomas, PharmD, Kim Pietropola, PharmD, Wendy Camelo Castillo, MD MSc PhD

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L to R: EPTF Members Kim Pietropola, PharmD, Jen Thomas, PharmD, Cynthia Anderson, RPh, MHA

Cynthia Anderson presented her experience with health-system emergency planning, at the corporate pharmacy level and using examples from her recent “incident commander” leadership role within a regional home health agency. Emergency operations plans (EOPs) were developed, implemented, and modified using hazard vulnerability analysis (HVAs), entity-specific and system-wide event simulation, and drill and actual event after action review and planning.

The session concluded with a panel discussion with Dr. Castillo moderating questions and answers from the student audience. A question regarding the end of the public health emergency (PHE) left the group to consider the impact the end of the PHE that will have on pharmacy professionals in their work in the future.

Disaster and Emergency Preparedness and Response: An Opportunity for Interprofessional Collaboration and Education

Dr. Hoai-An Truong

In collaboration with the Somerset County Health Department and with support from the Maryland Board of Pharmacy Emergency Preparedness Task Force, the Eastern Shore Collaborative for Interprofessional Education (ESCIPE), an inter-institutional initiative of the University of Maryland Eastern Shore and Salisbury University reunited for the first in-person point-of-distribution (POD) drill/exercise on February 21, 2023.

The POD drill exercise was started in 2013 and continued through 2019 for almost seven years through collaborative partnerships of the above mentioned groups. However, this had to discontinue in 2020 and was held via virtual platform in 2021. Interprofessional collaboration among several faculty in medical laboratory science, nursing, pharmacy, physician assistant, and respiratory therapy brought together about response training.

This application- or skills-based training was on the preparation and implementation of a mass vaccination clinic for the influenza vaccination. Students swapped roles as patients versus providers in two rounds and rotated through five stations, including: greeting, registration, consultation, vaccination, and observation.



L to R: EPTF Members Lawrence Hogue, BSP Pharm, Cynthia Anderson, RPh, MHA, Jen Thomas, PharmD, Kim Pietropola, PharmD, Hoai-An Truong, PharmD, MPH, FAPhA, FNAP



Emergency Preparedness Taskforce, students and professors of UME who participated in the POD exercise

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The Board of Pharmacy is currently accepting submissions from readers for consideration for upcoming newsletter articles. Desired subjects covered may include public health or general educational topics. Submissions should be 500 words or less, in Microsoft Word document format.

Send any submissions to mdh.mdbop@maryland.gov



POD Exercise in action

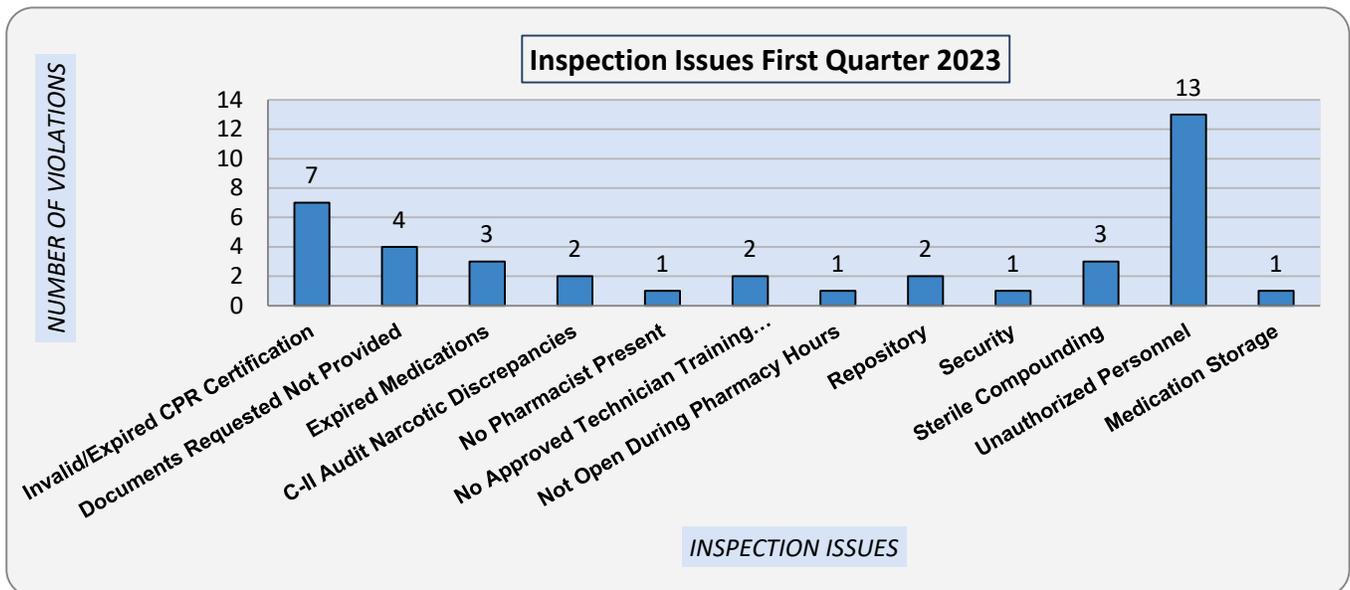
They also received just-in-time-training, which occurred immediately prior to the start of the drill exercise for students of all disciplines. During multiple rounds of the POD drill over three hour periods, interprofessional faculty and students worked side-by-side in different roles (greet patients, register them, then send them to consultation, vaccination, and observation) throughout the POD drill exercise. Faculty in different healthcare professions met after the POD drills for a debrief and after action report. Meanwhile, students are also given a survey after the POD drill to provide feedback on their interprofessional education experiences.

Inspection Trends- First Quarter 2023

The Maryland Board of Pharmacy investigates complaints that come to the Board from various sources. Complaints may come from consumers, healthcare professionals, pharmacy boards outside of Maryland, federal agencies, OCSA and from Board inspections of pharmacies, sterile compounding facilities, and distributors in Maryland. The Board requires that all pharmacies be inspected, at a minimum, on an annual basis and distributors be inspected on a biannual basis.

The following represents a breakdown of the issues that have come to the Board from the inspection of pharmacies across the state in the first quarter of 2023.

- | | |
|--------------------------------------------|-----------------------------------|
| 1. Invalid/Expired CPR Certification | 7. Not Open During Pharmacy Hours |
| 2. Documents Requested Not Provided | 8. Repository |
| 3. Expired Medications | 9. Security |
| 4. C-II Audit Narcotic Discrepancies | 10. Sterile Compounding |
| 5. No Pharmacist Present | 11. Unauthorized Personnel |
| 6. No Approved Technician Training Program | 12. Medication Storage |



DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
Michael Beatty	14861	Suspension	4/10/2023
Vincent Ippolito	09933	Revocation	4/13/2023
Lisa White	12969	Revocation	5/23/2023
Ugochukwu Ahubelem	27027	Reprimand/Probation/Fine	6/16/2023
Adekunle Onalaja	18593	Reprimand/Probation	6/21/2023

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Jessica Parsons	T26422	Summary Suspension	4/10/2023
Tesheah Wilson	T20588	Revocation	7/3/2023
Jasmine Moore	T20120	Revocation	7/13/2023

ESTABLISHMENTS	LIC#	SANCTION	DATE
TJ's Pharmacy	Applicant	Denial	3/10/2023
Northgate Pharmacy	P04037	Revocation	4/13/2023
Tri-Towns Pharmacy	P08133	Revocation	4/19/2023
Faith Pharmacy	P06678	Reprimand/Probation/Fine	6/21/2023
Archway Apothecary	P07935	Fine	6/23/2023

National Association of Boards of Pharmacy National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION

FDA Publishes Notice of COVID-19-Related Guidance Documents Expiring With PHE

Food and Drug Administration (FDA) published a [notice](#) that the guidance documents addressing the coronavirus disease 2019 (COVID-19) public health emergency (PHE) will no longer be effective after the PHE declaration ends on May 11, 2023. This notice will affect 72 COVID-19-related guidance documents. The agency is expected to monitor and assess the circumstances of the COVID-19 pandemic and alter the COVID-19-related documents, if necessary.

Confusion Among the Many Humira Products With More Biosimilars on the Horizon



This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at www.ismp.org.

A specialty pharmacy reported concerns with look-alike packaging with the many presentations of **Humira®** (adalimumab), which is used for nine different autoimmune indications in both pediatric and adult populations. The manufacturer produces 20 different prefilled syringe and pen carton configurations. There are 11 different starter packs based on the patient population (eg, pediatric, adult), indication, dose, and number of doses contained within each pack. The starter packs are designed to provide the larger initial dose required for some indications. Also, certain configurations are available in citrate-free formulations to reduce injection site pain.

Many Humira products share product and packaging similarities that can increase the risk of medication errors. For example, multiple products are available in the same concentration, some with the same strength (eg, 40 mg/0.8 mL, 40 mg/0.4 mL). Also, many of the product cartons look similar with either a blue or maroon color scheme. Humira products are stored in the refrigerator. As a result, the different formulations, concentrations, and package configurations often end up stored near one another (**Figure 1**).



Figure 1. Six similar looking Humira products are stored near one another in a specialty pharmacy refrigerator.

To prevent product mix-ups, scan each carton during production instead of scanning one carton multiple times. Ideally, pharmacy computer systems should require each product's barcode to be scanned. During product verification, the computer system should also alert the pharmacist if barcode scanning was bypassed during production.

If space permits, clearly label and utilize separate storage locations or bins for the different Humira presentations. Consider organizing and separating the different Humira products by age groups and indications. Explore ways to differentiate the products (eg, apply auxiliary labels or circle the dosage form and/or indication) when they are received from the supplier. Educate staff on the different Humira products and the potential to mix them up.

Also, please note that multiple adalimumab biosimilars are expected to become available in 2023. This means that, because of different payor formularies and requirements, pharmacies may need to store even more adalimumab products. These products have overlapping strengths and concentrations as well as nonproprietary names that only differ by adding the biosimilar suffix. As a result, the opportunity for mix-ups is likely to increase.

In anticipation of these biosimilar medications coming to market, the Institute for Safe Medication Practices (ISMP) is working to develop risk-reduction strategies to share with their readers and members. ISMP is interested in learning what steps pharmacies are planning to take to reduce the risk of errors with biosimilars. Share your thoughts and strategies by submitting a medication safety comment or question at www.ismp.org/contact.

Proposed Rules for Permanent Telemedicine Flexibilities Announced by DEA

Drug Enforcement Administration (DEA) has proposed permanent rules for prescribing controlled medications through telemedicine, which were established during the coronavirus disease 2019 pandemic. The proposed rules address telemedicine consultations by a medical practitioner who has never conducted an in-person evaluation of a patient and that would result in the

prescribing of a controlled medication. Under these circumstances, a medical practitioner would be allowed to prescribe a 30-day supply of Schedule III-V nonnarcotic controlled medications or a 30-day supply of buprenorphine for the treatment of an opioid use disorder without an in-person evaluation or referral from a medical practitioner who has conducted an in-person evaluation, as long as the prescription is otherwise consistent with any applicable federal and state laws.

Final Guidance Containing Definitions Relevant to DSCSA Released by FDA

Food and Drug Administration (FDA) released the final [guidance document](#), *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act*, as part of the preparation for implementation of the Drug Supply Chain Security Act (DSCSA). The terms “counterfeit,” “diverted,” “stolen,” “fraudulent transaction,” and “unfit for distribution” are clarified in the definitions of “suspect product” and “illegitimate product” to help trading partners in meeting verification obligations. This guidance replaces the previous draft guidance of the same name.

New Privacy Protections for Patients With Substance Use Challenges Proposed by HHS

The United States Department of Health and Human Services (HHS) declared proposed changes to the Confidentiality of Substance Use Disorder Patient Records under 42 Code of Federal Regulations (“Part 2”). Under this proposed change, coordination of care for patients would improve, and the protection of privacy for patients facing substance use challenges would be strengthened. This proposed change is intended to help prevent patients from declining lifesaving care due to fear of records disclosure. This notice of proposed rulemaking would implement provisions of the Coronavirus Aid, Relief, and Economic Security Act that, among other stipulations, require HHS to bring Part 2 into greater alignment with certain aspects of the Health Insurance Portability and Accountability Act of 1996.

Guidance for Compounding Ibuprofen Oral Suspension Products Issued by FDA

Food and Drug Administration (FDA) has issued [guidance](#) and revisions regarding compounding certain ibuprofen oral suspension products to address the ongoing demand for fever- and pain-reducing medications. The latest guidance revisions provide recommendations for ibuprofen oral suspension products compounded by outsourcing facilities and supplied to state-licensed pharmacies (including those within hospitals and health systems) and applicable federal facilities that dispense the medication to patients for home use following receipt of a valid, patient-specific prescription from a health care provider.

FDA Launches New Dietary Supplement Ingredient Directory

Food and Drug Administration (FDA) launched its new [Dietary Supplement Ingredient Directory](#), which is a database

that lists the ingredients used in products marketed as “dietary supplements” and FDA’s actions taken and statements made in response to those ingredients. The agency will update the directory periodically to show recent developments. FDA notes that additional feedback and information regarding these ingredients can be submitted to FDA’s Office of Dietary Supplement Programs.

Importation of Xylazine Restricted Due to Increasing Public Health Concern

Food and Drug Administration (FDA) announced that it is restricting the unlawful entry of xylazine active pharmaceutical ingredients and finished dosage form drug products into the United States to address growing concerns of the chemical appearing in drugs such as illicitly manufactured fentanyl, methamphetamine, and cocaine. The agency warns that individuals who inject products containing xylazine can experience life-threatening symptoms, such as depressed breathing, blood pressure, heart rate, and body temperature. Individuals may also develop severe skin wounds and patches of dead and rotting tissue that can easily

become infected and, if left untreated, may lead to amputation. Shipments of xylazine will undergo heightened FDA scrutiny to ensure that the imports of the drugs containing xylazine into the US are intended for legitimate veterinary supply. Veterinarians use xylazine to sedate large animals, such as horses and deer. More information is available on FDA’s website under [news releases](#).

Narcan Nasal Spray Becomes an OTC Drug

Food and Drug Administration (FDA) approved the Narcan[®] 4 mg naloxone hydrochloride nasal spray to be sold over-the-counter (OTC), making it the first naloxone product that will be available without a prescription. Naloxone is a life-saving medication that reverses the effects of opioid overdoses. The product will include instructions for consumers regarding how to use the drug safely and effectively without the supervision of a health care professional. While it may take months for the medication to transition from prescription status to OTC, the agency has plans to work with all stakeholders to ensure the continued availability of other naloxone nasal spray products during this time. Additional information is available on FDA’s website under **news releases**.

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

BOARD MEETINGS

Public Pharmacy Board meetings begin at 9:30am on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings and awards 2 LIVE CE's to all licensees.

2022/2023 PUBLIC BOARD MEETINGS

Third Wednesday of each month

August, 16, 2023
 September 20, 2023
 October 18, 2023

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