VOLUME XVIII, ISSUE 3

SPRING EDITION

Quarterly Newsletter

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.

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The Role of Pharmacies as a part of the National Drug Supply Chain

Deena Speights-Napata, Executive Director

The Maryland Board of Pharmacy is currently one of 10 state boards across the country working with the National Boards of pharmacy (NABP) PULSE program. The PULSE program was created to support the implementation of the FDA pending DSCSA (Drug Supply Chain Security Act) regulations These requirements, once implemented, will seek to join industry partners with federal and state regulators to stabilize the drug supply chain and decrease instances of fraud and abuse. Destabilizing supply chain activity occurs through 4 primary channels: illegitimate and suspect product investigations; fraudulent activity; product recalls; and routine compliance audits. To this end, pharmacies will play a critical role in several key areas:

1. Reviewing PULSE manufacturer contact information to support industry verification of products received
2. Verification of partner manufacturers and distributor information in PULSE
3. Participation with PULSE and other local and national systems in support of product tracing and product verification requirements

PULSE seeks to create a directory of trading partner staff, managers, and geographic resources as a reference for supply chain participants to verify the authenticity of manufacturers and distributors. To date the early onboarding phase has already begun. This phase included adding the largest supply chain dispensers first. This phase of the program will most likely end at the end of April 2024.

The onboarding of distributors and manufacturers is slated to begin after the dispenser on boarding phase is complete. NABP is currently working to develop an authentication process to roll out in mid to late summer of 2024.
Maryland Board of Pharmacy staff have participated in the early development phase of PULSE and we are excited about the potential the system has to reduce the proliferation of fraudulent drugs to an unknowing public. By protecting the public pharmacists too will be protected.

Stay tuned as this project continues to grow.

Meet Our New Board Members

Adetoro Oriaifo, At-Large Representative

Dr. Adetoro (Toro) Oriaifo obtained her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy in Baltimore, and a Master's in Business Administration from Colorado Technical University. She completed the Community Health Center Executive Fellowship program from the University of Kansas Medical Center and holds a 340B ACE certification. She has over 15 years of retail, long-term care, and FQHC 340B pharmacy experience. Her professional memberships include the Maryland Pharmacist Association and the American College of Healthcare Executives.

Karen Slagle, Independent Representative

Dr. Karen Slagle is our newest independent pharmacist representative. She received her Doctor of Pharmacy degree in 2009 from Massachusetts College of Pharmacy. After graduating, she moved back home to Maryland to practice as a community pharmacist. She is currently the pharmacist in charge at Northside Pharmacy Long Term Care and is a preceptor for the University of Maryland School of Pharmacy and Notre Dame School of Pharmacy. Her professional memberships include National Community Pharmacists Association and Maryland Pharmacist Association. In her free time, Dr. Slagle enjoys boating on the rivers of the upper Chesapeake Bay and traveling the world.

Billing Maryland Medicaid for Pharmacists Professional Services

In accordance with Senate Bill 678/House Bill 1151, the Maryland Department of Health (MDH), will allow Medicaid-enrolled pharmacist providers to bill Maryland Medicaid for Pharmacist Professional Services (PPS) rendered within their lawful scope of practice.

Medicaid-enrolled pharmacists can bill Maryland Medicaid using billing and coding information according to the CMS 1500 Billing Instructions at https://health.maryland.gov/mmcp/provider/Pages/ffsclaims.aspx
To bill Fee-for-Service (FFS) Medicaid for PPS, a pharmacist must be actively enrolled with Maryland Medicaid as a participating provider type "PH" through Maryland Medicaid's online Electronic Provider Revalidation and Enrollment Portal (ePREP).

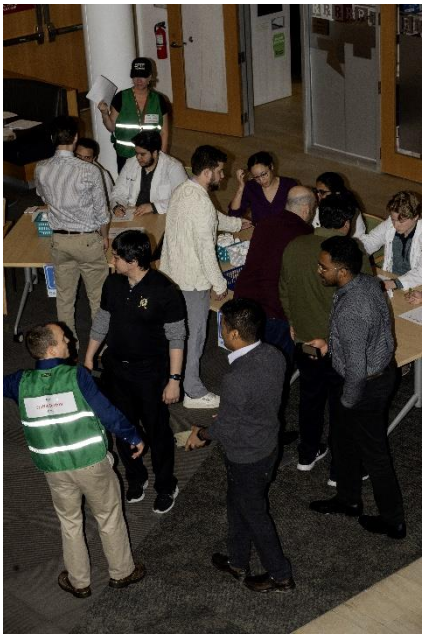
The link to the Pharmacist Providers ePREP instructions and training for the enrollment process is https://health.maryland.gov/mmcp/provider/Pages/eprepresources.aspx. These materials are available under the "By Provider Type" heading by selecting "Pharmacist".

- For questions related to PPS, please email mdh.pharmacistsprofservices@maryland.gov.
- Please visit https://health.maryland.gov/mmcp/pap/Pages/pharmacists-professional-services.aspx for future updates.

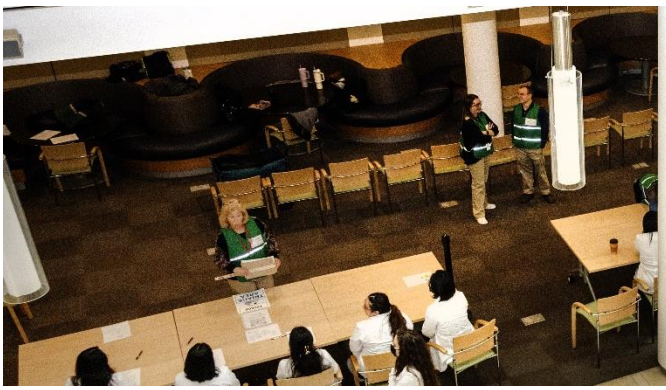
Event Corner: Emergency Preparedness: Educational Presentation & POD Exercise, University of Maryland, Baltimore, School of Pharmacy

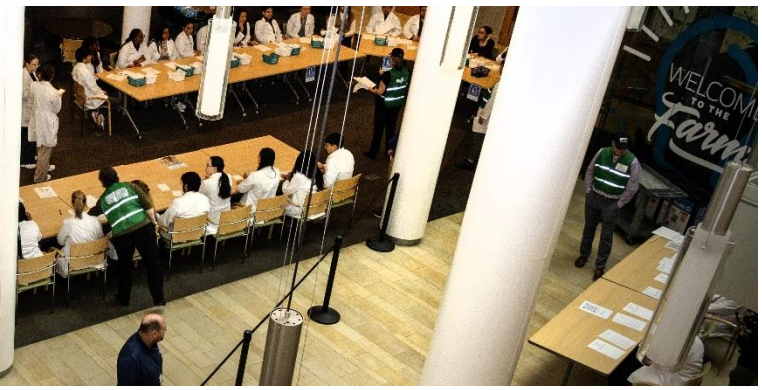
On March 1, 2024 Jennifer Thomas PharmD, Chair of the Emergency Preparedness Task Force (EPTF) spoke to the students at the University of Maryland School of Pharmacy on the National Incident Management System, the Incident Command System and the UMB Emergency Operations Plan including the Pharmacy School's role in this plan. Following this the Students were engaged in discussion of a disaster event scenario and how they might organize a response. As part of this activity students tested a QR code accessed mobile device app that produced a Medication Screening Form capable of indicating the proper antibiotic to dispense after assessing the patient's drug allergies and medical status. In the last segment of this presentation Mallory Simcox, From MD Responds explained what the organization is, what it does and how and why students should join our state Medical Reserve Corps.

The following week, on March 6, 2024, the EPTF conducted a Point of Dispensing (POD) exercise in response to a "This is Only a Drill" aerosolized anthrax exposure. During the exercise the 87 students in the class used the mobile medication screening app to actually determine the appropriate antibiotic to dispense to the students assuming the role of "patient". Students in the role of "providers" ensured not only that the appropriate antibiotic was dispensed but that patient questions were answered and the necessary drug information and instructions were provided.



EPTF members would like to express their thanks to UMB School of Pharmacy faculty, staff and students for their participation with special thanks to Drs. Cherokee Layson-Wolf, Nicole Brandt, Amy Ives and Wendy Castillo for their engagement to make these events possible. EPTF also acknowledges our partnerships with Kim Eshleman and Joe White from the Baltimore City Health Department; Karen Hopper, Mallory Simcox and Albby Chen from Maryland Responds; Chris Kozub from the Maryland Office of Preparedness & Response and finally Thomas Franklin from the Howard County Health Department who developed the mobile app for the Medication Screening Form and worked with EPTF member Larry Hogue to refine and improve the app through beta-testing at two Maryland Schools of Pharmacy.





Veterinarian's DEA number not required for non-controlled dangerous substance prescriptions

Javier Vázquez, PharmD, MS

The Board is aware that some pharmacies may have internal policies to verify a prescriber's DEA number for non-controlled dangerous substance (non-CDS) prescriptions. However, this internal process may cause delays or refusals to fill prescriptions for non-CDS veterinary drugs because not all veterinarians possess a DEA number. In these instances, the Board encourages pharmacies to engage in discussions with the veterinarian prescriber to find mutually agreeable solutions. As with all prescriptions, it is important for pharmacists to communicate directly with the patient and the prescriber in order to alleviate concern, prevent misunderstanding and strengthen the professional relationship.

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

DISCIPLINARY ACTIONS (9/1/2023 – 4/12/2024)

PHARMACISTS	LIC. #	SANCTION	DATE
Abdulmojeed Lawal	09734	Reprimand/Probation/Fine	1/17/2024
Vaibhav N. Patel	18673	Reprimand/Probation/Fine	1/25/2024
Chukwuedozie H. Okotcha	19775	Reprimand/Probation/Fine	2/26/2024
Stephanie A. Holt	24878	Revocation	3/4/2024

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Stacy Shanholtz	T04346	Summary Suspension	11/29/2023
Christine M. Gary	T16214	Summary Suspension	12/5/2023
Mary Jo Floyd	T24883	Summary Suspension	12/14/2023
Jamie M. Bailey	T18331	Reinstatement Denied	12/20/2023
Gloria S. Martinez	T20955	Summary Suspension	1/5/2024
John Schwenninger	T27045	Summary Suspension	1/5/2024
Brittany C. Hudgins	T21147	Summary Suspension	1/17/2024
De'Jania Bradford	Applicant	Denied	1/18/2024
Alexis Capriles	T20474	Fine (Stayed)	3/19/2024
Keshia Brown	T18518	Revocation	3/26/2024
Laila Carrillo	T29079	Summary Suspension	4/3/2024

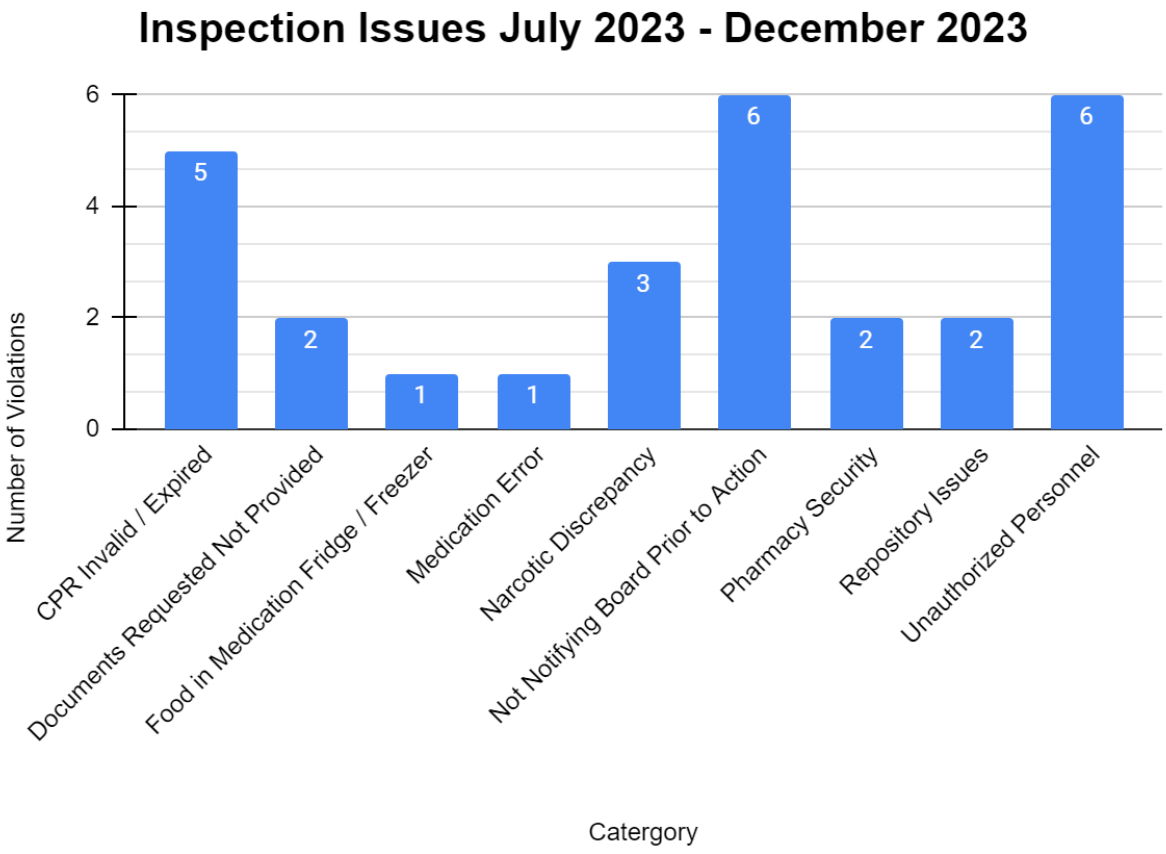
ESTABLISHMENTS	LIC#	SANCTION	DATE
Midtown Pharmaceuticals, LLC	P07965	Revocation	11/9/2023
DrugGlobe, Inc	PW0528	Revocation	1/17/2024
Extracare Pharmacy	P04023	Reprimand/Probation/Fine	1/17/2024
Patient Care Pharmacy	P07157	Reprimand/Probation/Fine	1/25/2024
Union Hospital of Cecil Co. Pharmacy	P00796	Fine	1/29/2024
KMS Medical and Supply, LLC	Unlicensed	Fine	1/31/2024
Crown's Pharmacy and Clinic	P08241	Reprimand/Probation/Fine	2/26/2024
Best Pharmacy	P07954	Probation/Fine	3/19/2024

Inspection Trends July 2023 - Dec 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 annually at minimum and distributors be inspected biannually.

The following represents a breakdown of the issues that have come to the Board from the inspection of pharmacies across the state from July 2023 - Dec 2023.

1. CPR Invalid / Expired
2. Documents Requested Not Provided
3. Food in Medication Fridge / Freezer
4. Medication Error
5. Narcotic Discrepancy
6. Not Notifying Board Prior to Action
7. Pharmacy Security
8. Repository Issues
9. Unauthorized Personnel



National Association of Boards of Pharmacy
National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION, 2Q 2024

Health Care Providers Urged by CDC to Be on Alert for Measles Cases

Between December 1, 2023, and January 23, 2024, the United States Centers for Disease Control and Prevention (CDC) recorded 23 confirmed cases of measles, with seven linked to international travel and two outbreaks exceeding five cases each. Unvaccinated children and adolescents were most affected. CDC is advising pharmacists and other health care providers to be vigilant for patients with febrile rash illness who recently traveled abroad, especially to countries with measles outbreaks. Measles patients are contagious four days before and four days after the onset of their rash. A heightened global measles threat underscores the importance of these measures. Additional information for health care providers is available on the CDC website.

ISMP Safety Brief: Prevent Additional Patient Harm and Deaths From Accidental Daily Methotrexate Dosing

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.
Methotrexate is a folic acid antagonist that was originally approved to treat a variety of cancers. Used for oncologic indications, methotrexate is administered in cyclical frequencies and in variable doses based on body surface area and the type of cancer being treated. The labeled indications for methotrexate later expanded to include the treatment of non-oncologic conditions, including psoriasis and rheumatoid arthritis. For most non-oncologic indications (eg, rheumatoid arthritis), a low dose of methotrexate is administered weekly – for example, 7.5 mg per week when initiating treatment for rheumatoid arthritis.

Accidental daily dosing of oral methotrexate has occurred all too frequently. This type of wrong frequency error has originated in all stages of the medication-use process, from prescribing to self-administration. These errors have resulted in serious methotrexate overdoses that led to mouth sores, stomatitis, serious skin lesions, liver failure, renal failure, myelosuppression, gastrointestinal bleeding, life-threatening pulmonary symptoms, and death.
Methotrexate Errors

The death of a patient reported in the media is a stark reminder of the harm that can occur. A patient had been admitted to a rehabilitation facility following a fall at home. A prescription for methotrexate 20 mg daily was sent to the pharmacy instead of a prescription for methotrexate 20 mg weekly. The pharmacy dispensing system allowed the pharmacist to bypass a high-dose alert. As a result, the patient received 20 mg of methotrexate daily for a week (a total of 100 mg). The patient became ill and died about a week later. Now, both the prescriber and pharmacist are facing criminal charges.

Since 1996, errors with daily oral methotrexate for non-oncologic use have been reported to ISMP and published in dozens of **ISMP Medication Safety Alert!** newsletters. For example, in one case, methotrexate 15 mg once weekly was prescribed for treatment of an autoimmune disorder in an elderly patient. The community pharmacy dispensed a three-month quantity of medication but provided instructions on the label to take 15 mg (six 2.5 mg tablets) once daily. The error was discovered three weeks later during patient counseling with a pharmacist when the patient requested a refill. The error resulted in severe harm, which led to a long hospital stay and treatment with the rescue agent leucovorin calcium.

Safe Practice Recommendations

Most of these wrong frequency errors with methotrexate can be prevented by implementing known risk-reduction strategies. It is time for technology vendors, regulators, standards-setting organizations, health care organizations, and practitioners to make the system improvements outlined in Best Practice #3 in the ISMP Medication Safety Best Practices for Community Pharmacy, including:

- Use a weekly dosage regimen default for oral methotrexate in electronic systems when medication orders are entered.
- Require verification and entry of an appropriate oncologic indication in order entry systems for daily orders. Ideally, computer systems would require a hard-stop verification of an appropriate oncologic indication for all daily oral methotrexate orders.
- Create a forcing function (eg, electronic stop in the sales register that requires intervention and acknowledgement by a pharmacist) to ensure that every oral methotrexate prescription is reviewed with the patient or a family member when a prescription is presented or refills are processed.
- Provide specific patient and/or family education for all oral methotrexate prescriptions.

To learn more about how to identify medication safety risks before they cause harm, consider attending an ISMP Medication Safety Intensive workshop designed for those working in community and specialty pharmacies. For more details about the program, please visit the ISMP workshop web page

FDA Issues Final Guidance Document on Developing Monoclonal Antibodies for Treating COVID-19

Food and Drug Administration (FDA) has released a final guidance document offering recommendations to sponsors on developing monoclonal antibody products targeting SARS-CoV-2 intended to prevent or treat COVID-19. Additionally, the guidance document lists the criteria needed for FDA to issue emergency use authorizations. The Development of Monoclonal Antibody Products Targeting SARS-CoV-2 for Emergency Use Authorization document replaces the Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency guidance document that was published on February 22, 2021.

Tranexamic Acid Injection Added to ISMP's List of High-Alert Medications

Tranexamic acid injections have been added to the Institute for Safe Medication Practices' (ISMP's) 2024 List of High-Alert Medications in Acute Care Settings. "High-alert" medications have an increased risk of causing significant harm to patients when they are incorrectly administered. ISMP recommends that practitioners implement safeguarding measures to minimize the risk of error when dispensing these drugs.
The list was updated based on an ISMP 2023 survey in which 100 practitioners, including pharmacists, nurses, pharmacy technicians, and others, reviewed the ISMP 2018 List of High-Alert Medications in Acute Care Settings to determine if those drugs were still considered high-alert medications in 2023 and submitted feedback on new additions.

FDA Issues Draft Interim Guidance Documents on Bulk Drug Substances in Compounding Under Sections 503A and 503B of FD&C Act

Food and Drug Administration (FDA) has issued two draft interim guidance documents that address the use of bulk drug substances in compounding under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under Section 503A of the FD&C Act, compounders can only use bulk substances that are included in the United States Pharmacopeia, the National Formulary monograph, or if it is on a list promulgated as a regulation pursuant to Section 503A(b)(1)(A)(i)(III) of the FD&C Act. Under Section 503B of the FD&C Act, bulk substances can only be used in compounding if they are used to compound a drug that is on FDA's drug shortage list at the time of compounding, distribution, and dispensing or on FDA's 503B bulk list. According to the documents, drug substances that are nominated after (or on the date of) the finalized date cannot be used until FDA has reviewed the nomination to determine if the substance has sufficient supporting information to be included on the bulk list.

Poison Control Centers Report Sharp Increase in Calls Related to Semaglutide Medications

Pharmacists and stakeholders should be aware of a significant increase in calls to poison control centers related to semaglutide products used for diabetes and weight loss. From January to November 2023, poison centers reported nearly 3,000 calls involving semaglutide, a more than 15-fold increase since 2019. The majority of calls resulted from dosing errors, with patients accidentally taking double doses or incorrect amounts. Compounded versions, arising due to demand exceeding supply, have contributed to the issue. These compounded forms, frequently sold in different dosages, may lead to potential risks. Despite calls rising, it is challenging to distinguish between calls related to patented drugs and their compounded versions.

Pharmacist Intervention Is Associated With Lowering Patients' Blood Glucose Levels

Pharmacist intervention was associated with lowering patients' HbA1C levels by 1% after recommending that primary care providers switch medication treatments for their patients, according to research presented at the American Society of Health-System Pharmacists' midyear meeting. Using information in patients' electronic health records, pharmacists provided 180 recommendations for 102 patients with diabetes and cardiovascular disease at the Memphis VA Medical Center in Tennessee. Primary care providers followed 23 of those recommendations, which included switching patients from sulfonylureas to a GLP-1 receptor agonist or an SGLT-2 inhibitor, hyperlipidemia interventions, hypertension interventions, and recommendations for tobacco cessation. The average HbA1c levels of 7.7% decreased to 6.7% among the 23 patients who were switched to a different treatment suggested by a pharmacist. However, there are some limitations, such as infrequent patient visits, that may impact how quickly the pharmacist recommendations are accepted.

Pharmacists Ranked Third Most Trusted Medical Professionals in 2023 Gallup Survey

Pharmacists are ranked as the third most trusted medical professionals among various occupations in Gallup's 2023 Annual Rating of Honesty and Ethics survey. From November 9 to December 2, 2022, 58% of Americans ranked pharmacists as having high honest and ethical standards, which is slightly lower than their 2021 and 2020 ratings. In 2022, medical doctors were ranked slightly higher than pharmacists, with 62% of Americans saying doctors have "very high" or "high" honesty and ethical standards; nurses earned the highest ethical rating at 79%. All three health-related professions scored lower compared to their scores before the COVID-19 pandemic

BOARD COMMISSIONERS

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Secretary: **Kristopher Rusinko**	Home Infusion Representative
Treasurer: **Peggy Glascoe Geigher**	Consumer Representative
Akash Patel	Chain Drug Store Representative
Daphanie Robinson	Pharmacy Technician Representative
Karla Evans	Acute Care Hospital Representative
Karen Slagle	Independent Representative
Kristen Fink	At-Large Representative
Kevin Morgan	Chain Drug Store Representative
Brenda Oliver	Consumer Representative
Jennifer Hardesty	Long Term Care Representative
Javier Vázquez	Acute Care Hospital Representative
Adetoro Oriaifo	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 CEs to all licensees.

2024 PUBLIC BOARD MEETINGS

Third Wednesday of each month

April 17, 2024
May 15, 2024
June 19, 2024
July 17, 2024

Maryland Board of Pharmacy
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