SUMMER 2025 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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An Update on The Status of FDA DSCSA Regulatory Implementation

Deena Speights-Napata, Executive Director

The FDA, in partnership with the Partnership for DSCSA Governance (PDG), has completed two of three townhalls with trading partners to obtain feedback on their progress with DSCSA implementation. Over the past year the Maryland Board of Pharmacy has been represented in PDG townhalls and FDA meetings on DSCSA implementation by the board executive director. The first two townhalls have already taken place and the last one will occur on September 24, 2025.

- March 26, 2025: Progress toward end of manufacturer exemption
- June 25, 2025: Progress toward end of wholesale distributor exemption
- September 24, 2025: Progress toward end of dispenser exemption

> The DSCSA regulation requires digital product verification systems that manufacturers, repackagers, wholesale distributors, **and dispensers** must have in place. These systems must include the quarantine and investigation of a product determined to be suspect and the quarantine and disposition of a product determined to be illegitimate. Verification also includes protocols for processing saleable returns.

Townhall participants shared their views on DSCSA regulation implementation, which included:
-Appreciation for the FDA phased exemption period which allowed for more time to improve their product traceability procedures
-Data connections between manufacturers and distributors are taking place with more effort being required on new data connections
-Trading partners are actively working on improving business procedures with the goal of identifying and eliminating errors in data processing.

In Maryland there are currently one hundred thirty-six licensed distributors including manufacturers and virtual manufacturers who distribute their own products. Of these, forty-two facilities distribute prescription drug product. On site annual inspections of these facilities conducted over the past year showed documentation of DSCSA implementation in product tracing requirements, and orT3 equipment. FDA defines T3 equipment as “the systems and processes used to manage and exchange DSCSA (Drug Supply Chain Security Act) Transaction Information, Transaction History, and Transaction Statement, collectively known as the "T3" documentation.

This includes software and hardware that enables pharmacies and other authorized trading partners to receive, verify, and store T3 data for prescription drugs. The fact that this level of transaction documentation history and computer software and hardware exists in Maryland facilities is encouraging and demonstrates our distributors are pursuing alignment with DSCSA regulatory requirements.

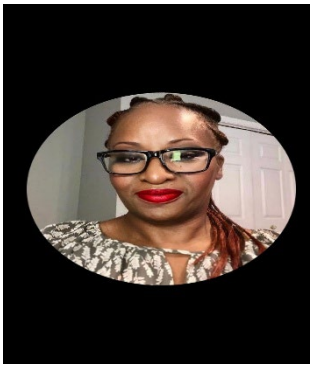
While significant process has been made over the past year, trading partners who participated in the townhall agree improvement is needed in managing data errors. Participants indicated that continued focus is needed on improving data analysis to identify root causes of the errors and develop a process to address them. Another area of focus will be on staff training and development of data quality and information exchange.

In the future, townhall participants identified several areas of focus:

1. More granular visibility of data quality at the package level, specifically on the serial number level
2. Increased clarity on staffing, including becoming clearer on adequate staffing numbers and training needs
3. Increased focus on DSCSA requirements including the prohibition on returning saleable product to a trading partner different from the original trading partner the product was received from. This focus is of particular significance to dispensers. In Maryland there are currently **1,184 pharmacy dispensers.**

The information provided in this article includes my observations as a townhall participant and my Maryland Board of Pharmacy data research, as well as information from a PDG townhall summary document.

Meet Our Board Staff



Julie Gaskins, Legislative Liaison

Julie has an impressive and diverse litigation background, including her time at the prestigious firm Williams & Connolly, founded by the legendary attorney Edward Bennett Williams. She worked on a wide array of complex cases, such as product liability, torts, medical cases, public corruption, and media and entertainment law, in addition to ERISA disputes, arbitration, administrative law, commercial litigation, class actions, consumer defense, and FDA regulation.

She refined her expertise in Real Estate at Miles & Stockbridge before moving into public service. As a Legal Assistant with the Circuit Court for Baltimore City, she supported judges on asbestos cases.

Julie re-entered the private sector as a Litigation Paralegal with Jezic & Moyse following the COVID-19 pandemic. She showcased her leadership and organizational abilities by handling numerous cases from inception to completion in this position.

Julie then returned to public service, initially as a Paralegal in the Policy Unit of the Maryland Board of Physicians, and subsequently as a Compliance Analyst in its Probation Unit, prior to moving to the Board of Pharmacy.

Julie is pursuing a Bachelor’s degree in Criminal Justice at the University of Baltimore, with an anticipated completion date of 2027.

In her personal time, she enjoys traveling with her son and their dog, as well as reading mystery novels.

Brendan Sullivan, Jr., a distinguished attorney at Williams & Connolly known for his defense of Oliver North in the Iran-Contra hearings, uttered one of Julie's cherished quotes: "I'm not exactly a potted plant…" This statement perfectly captures the essence of Williams & Connolly's enduring legacy—a steadfast dedication to justice and an unyielding pursuit of excellence, attributes that Julie consistently demonstrates in her professional endeavors.

Close to two decades ago, around 2008, the Maryland Board of Pharmacy hosted a successful in-person Continuing Education (CE) Brunch attended by pharmacists and technicians. Due to the positive engagement with the licensees, the Board continued to host an annual CE event each fall that came to be known as the CE Breakfast. Most recently, the October 2024 CE Breakfast offered four hours of live continuing education credits, including topics needed to fulfill CE requirements in the State of Maryland, like one hour on medications errors. The Board has continually evaluated feedback received from licensees regarding the format and timing of the event. To provide a wider variety of opportunities for licensees to participate throughout the year, a new strategy was implemented this summer.

On Wednesday July 30th, the Board hosted the first of a new online continuing education series for our Maryland licensees. This online series, titled "Learning in Small Doses" aims to offer a wide range of topics of interest in "smaller doses" through the year that will help licensees gain a deeper understanding of the profession, gain new knowledge and keep up to date as healthcare continues to evolve.

The event opened with Deena Speights-Napata, Executive Director of the Maryland Board of Pharmacy, providing a brief introduction. After the meeting was opened, Dr. Javier Vázquez, Board member and Chair of the Public Relations Committee, welcomed all participants and introduced our first presenter.

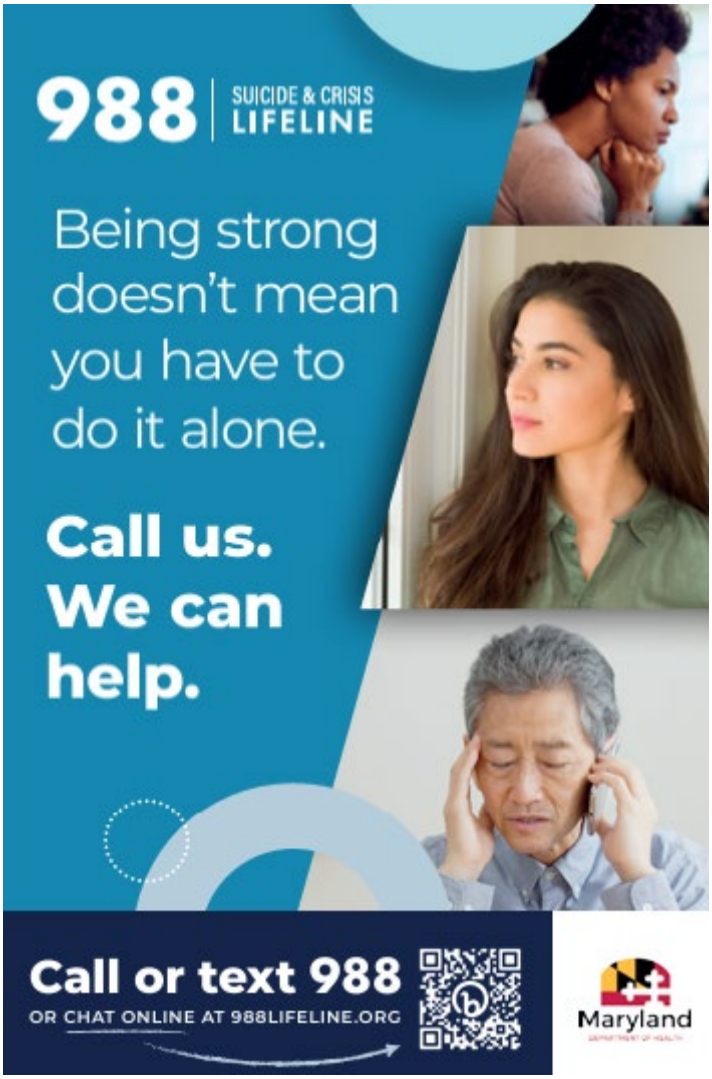
The first speaker was Robert White, MA, LCPC, who currently serves as the Director of the Pharmacist Rehabilitation Service (PRS), and is faculty at the Department of Psychiatry at the University of Maryland School of Medicine. His topic focused on the concept of intervention strategies for people suffering from substance use disorders and how to get them into treatment. In addition, he took the opportunity to remind our licensees of the services provided by the Pharmacist Rehabilitation Service Program, highlighting the treatment, monitoring and advocacy services available to our licensees.

For the second hour of the event, we were honored to welcome two pharmacy technicians that currently hold advanced roles in their respective organizations and took the opportunity to highlight the work they do at their sites. Angela Fulwood, CPhT, CSPT, kicked off the session to discuss her role as a Sterile Compounding Pharmacy Technician at the University of Maryland

Medical Center, Downtown Campus. This was followed by Amanda Webber, CPhT, MHA, who currently serves as the Drug Diversion Program Analyst of MedStar Health.

The Board would like to thank all three speakers for sharing their experiences and knowledge with our licensees. In addition, we would like to thank all who attended and contributed to the discussions. In addition, we would like to express appreciation to the Board staff who worked tirelessly to make this event happen!
The next Learning in Small Doses event is scheduled this fall, on October 29th. Remember to **SAVE THE DATE** and be on the lookout for more information coming soon!

We would like to end this article with an open invitation. If you are a subject matter expert interested in serving as a speaker at future Learning in Small Doses events and help expand the CE offerings, please reach out to the Board to learn more about opportunities to share your knowledge with our licensees. You can help us shape the future of the continuing education sessions.



Marylanders of all ages are struggling with mental health and substance use challenges. If someone is experiencing — or knows someone experiencing — anxiety, depression, thoughts of suicide or problems with drugs or alcohol, encourage them to call, text or chat 988 to get support 24/7.

Share these resources with your agency or practice. Help spread the word about the 988 Suicide & Crisis Lifeline.

Learn more at 988.maryland.gov or access the MDH 988 Toolkit for free materials to promote the 988 Suicide & Crisis Line in Maryland.

Opening/Closing Inspection To-Do List

Here's a helpful summary checklist to help make the inspection process seamless!

GENERAL PHARMACY OPENING INSPECTION

☐Possess a Class A (or equivalent) prescription balance and weights (if applicable)
☐Possess a refrigerator(s) solely used for drug storage
☐Possess refrigerator temperature monitoring device
☐Possess additional equipment to prepare and dispense Prescriptions consistent with the pharmacy's scope of operations
☐Pharmacy has cold AND hot running water
☐Have online professional resources
☐Possess the current edition of the Maryland Pharmacy Laws and Regulations
☐Possess a security system that prevents entry when the prescription area is closed

STERILE PHARMACY OPENING INSPECTION

☐ Certify all primary engineering controls (PECs) per ISO Class 5 (i.e.: Biological Safety Cabinets, Laminar Air Flow and Compounding Aseptic Isolator)
☐ Perform air sampling for conformance to ISO Class 5 (PECs), ISO Class 7 and ISO Class 8 (cleanroom and anteroom, as appropriate) by a qualified operator
☐ Possess appropriate waste containers
☐ Possess a Class A (or equivalent) balance and weights
☐ All equipment and controlled environment (including but not limited to walls, ceilings, counters, light fixtures, and floors) are made of non-porous, non-shedding cleanable surfaces
☐ Possess a library of current reference sources that is accessible
☐ Possess current edition of the *Maryland Pharmacy Law and Regulations*
☐ Possess a security system that prevents entry when the prescription area is closed
Possess policies and procedures (as appropriate) for:

☐ Compounding	☐ Disposal	☐ Training and Competency	☐ Quality Assurance Program	☐ End-product Evaluation
☐ Storage, handling and delivery of products	☐ Beyond Use Dating	☐ Proper Labeling	☐ Cleaning Schedule	☐ Environmental Monitoring
☐ Record Keeping	See COMAR 10.34.19.12 for full list			

Maintain Records for:
☐ Cleanroom testing
☐ Refrigerator and freezer, if applicable

PHARMACY CLOSING INSPECTION

☐Notify the Board of Pharmacy **AT LEAST 14 days** prior to anticipated closing date
☐Remove or cover pharmacy signage within 30 days of cease to operate date
☐Notify drug suppliers in advance with the exact closing date
☐Notify the public with the closing date
☐Compile a full list of closing CDS inventory
☐Documentation of non-CDS drug tramsfers
☐Compile all DEA-222 forms and/or Purchase Orders/Invoices used to transfer CDS after closing
☐Return Maryland Pharmacy permit and Maryland CDS registration
If patient records are transferred:
☐ Notify the public of its new location
If patient records are NOT transferred:
☐ Notify the public of its location
☐ Notify the public how the records are maintained
☐ Notify the public how the records can be accessed

WHOLESALE DISTRIBUTORS CLOSING INSPECTION

☐ Notify the Board of Pharmacy **AT LEAST 30 days** prior to anticipated closing date
☐ Notify distributors, manufacturers, drug and device suppliers, pharmacies, and prescribers AT LEAST 30 days prior to anticipated closing date
☐ Compile a full list of prescription drug inventory
☐ Compile full list of devices disposed of, transferred, or returned
☐ Compile a full list of person or business entity to whom prescription drugs were returned or transferred (include name, address, phone number, and DEA registration number)
☐ Submit a letter signed under oath if prescription drugs or devices are destroyed

☐ Submit a letter under oath if any pedigree or other documents are transferred
☐ Return distributor permit

2nd QUARTER (5/1/2025 – 7/10/2025) DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
Thomas M. Bolton	12598	Reprimand-Probation-Fine	6/09/2025
Matthew Bathula	18771	Summary Suspension	6/12/2025

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Rose M. Breen	T31003	Summary Suspension	6/12/2025
Sonja Evans	T09115	Summary Suspension	7/01/2025
Lee A Switzer	T29856	Summary Suspension	7/09/2025

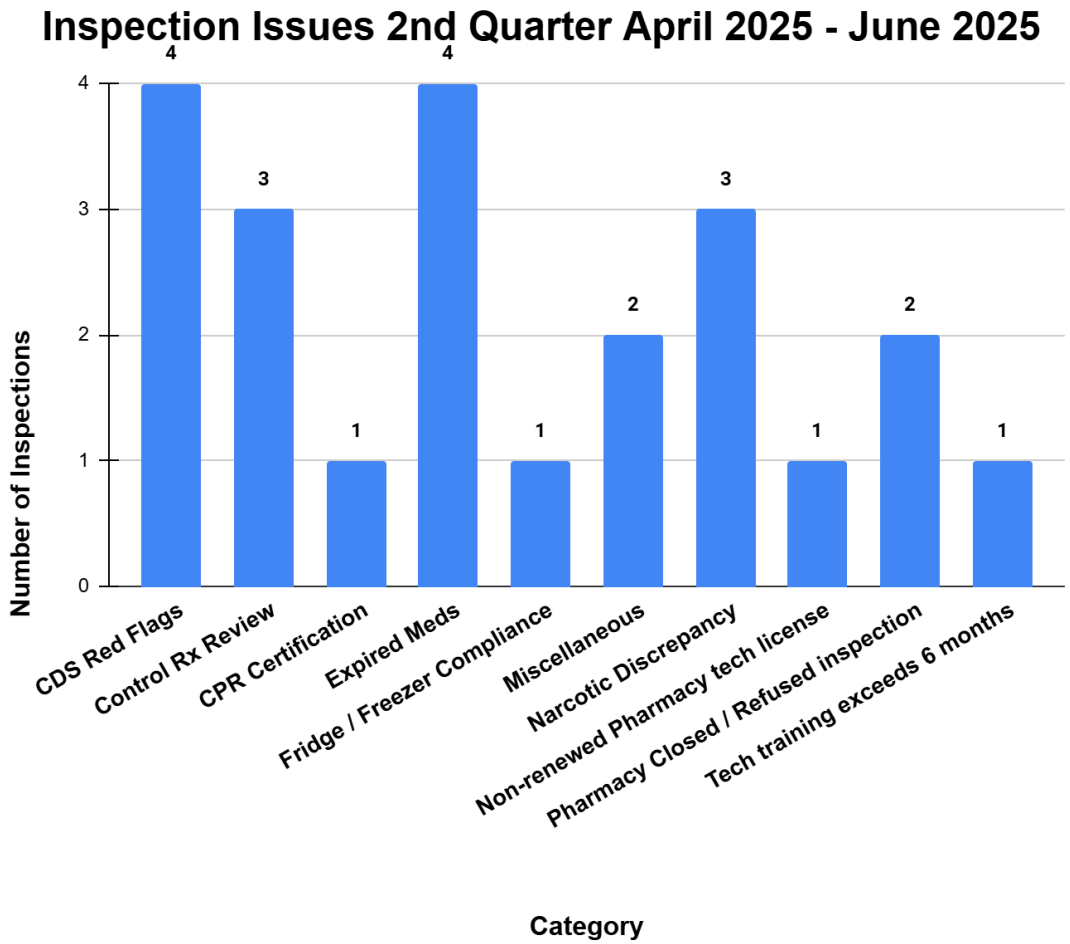
ESTABLISHMENTS	LIC#	SANCTION	DATE
Sagent Pharmaceuticals	D07324	Fine	5/19/2025
Beckmans Greene Street Pharmacy	P00939	Surrender	6/01/2025
Anazaohealth Corporation	D05656	Fine	6/02/2025
Anazaohealth Corporation	P06892	Fine	6/02/2025
Carroll Drugs of Manchester	P05569	Reprimand-Probation-Fine	6/09/2025

Inspection Trends April 2025 – June 2025

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 April – June 2025.

1. CDS Red Flags
2. Control Rx Review
3. CPR Certification
4. Expired Meds
5. Fridge / Freezer Compliance
6. Miscellaneous
7. Narcotic Discrepancy
8. Non-renewed Technician Registration
9. Pharmacy Closed / Refused Inspection
10. Technician training exceeds 6 months



National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION, 3Q 2025

USP Reports 98 Drug Shortages in 2024, Average Duration Now Over Four Years

There were 98 drug shortages in 2024, with 89% of those drugs first reported in shortage in 2023, according to the new **drug shortage report** published by United States Pharmacopeia (USP). The *USP Annual Drug Shortages Report: Long-Standing Drug Shortages Persist in 2024* notes that the average duration of a drug shortage was more than four years, while five drugs have been in shortage for more than 10 years. Three sterile injectables currently in shortage were manufactured in the North Carolina facility hit by Hurricane Helene in September 2024. Low prices, manufacturing complexity, geographic concentration of manufacturing, and quality concerns were cited as factors that cause drug shortages.

ISMP Safety Briefs: Wrong Drug Errors Are Possible

InFLIXimab-dyyb is the nonproprietary name for both Inflectra® and Zymfentra®.

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.

Food and Drug Administration (FDA) has approved two brand-name biologics with the same nonproprietary name and four-letter suffix, inFLIXimab-dyyb; however, they are not biosimilars or interchangeable with each other. Inflectra is a biosimilar of the reference product Remicade®. As such, it is available as a 100 mg lyophilized powder, single-dose vial for reconstitution and dilution. It is approved for adults and pediatric patients six years of age and older with Crohn's disease or ulcerative colitis. It is also approved for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis in adults.

Zymfentra is not a biosimilar of or interchangeable with Remicade. It is available in 120 mg/mL, single-dose prefilled syringes and prefilled pens. It is approved for adults as maintenance treatment for moderately to severely active Crohn's disease or ulcerative colitis following treatment with an intravenously administered inFLIXimab product. ISMP has previously alerted practitioners that there are branded and unbranded versions of adalimumab (eg, Hyrimoz® [adalimumab-adaz] and adalimumab-adaz) that share the same nonproprietary name and four-letter suffix. However, this is the first time ISMP has seen two brand-name products share the same nonproprietary name and four-letter suffix (ie, inFLIXimab-dyyb).
Specialty pharmacies may stock both drugs: Zymfentra, which is the subcutaneous injection that can be self-administered by the patient, and Inflectra, which is a lyophilized powder that requires preparation and intravenous administration by a provider but may be required to be "bagged" under the pharmacy benefit and dispensed to the patient or provider. If the lyophilized powder (Inflectra) is sent to the patient instead of the subcutaneous formulation (Zymfentra), there is a risk of misuse by the patient. Conversely, if a clinic received Zymfentra instead of Inflectra, they could potentially administer the subcutaneous injection to the patient via the incorrect route (intravenously) or administer it via the correct route, but it would be the incorrect formulation.

Safe Practice Recommendations

ISMP has notified FDA and Celltrion, Inc, the manufacturer of both products, about the potential for mix-up. However, per FDA-approved review documents, Zymfentra can have the same nonproprietary name and suffix as Inflectra because both are the same drug, only with a different strength, dosage form, and route of administration. To reduce the risk of errors, confirm with computer and drug information vendors that these are listed as separate products in electronic systems. Consider using the brand name when prescribing these medications. In electronic prescribing systems, ensure order sentences are associated with the correct product. In the pharmacy, verify that the dosage form and route of administration are appropriate for the prescribed and dispensed product. Educate staff about the product differences, noting that they are not interchangeable with each other, and about the potential to mix them up. At the point of sale, open the bag and have the patient check to make sure they are receiving the correct medication. If the medication is shipped to the patient, instruct them to carefully inspect the medication upon receipt, comparing the medication name and quantity to what is listed on the pharmacy label. Encourage patients to contact the pharmacy if they have any questions or concerns.

PSM Urges to Check Lot Number and Serial Number on Ozempic Injection Products

The Partnership for Safe Medicines (PSM) is **urging health care providers** to check the lot number and serial number of Ozempic® (semaglutide) 1 mg injection products, as counterfeit versions of the product have been found in the supply chain. Even though counterfeit injection products and authentic Novo Nordisk products have the lot number PAR0362, the counterfeit Ozempic products will also have the serial number 51746517. Food and Drug Administration (FDA) is investigating the risks associated with using these counterfeit products. Any adverse events or side effects related to using the product should be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Compounded Topical Finasteride Products Associated With Serious Risks, Warns FDA

Compounded topical finasteride products have been associated with serious potential risks, warns Food and Drug Administration (FDA) in a **news release**. Between 2019 and 2024, 32 reports were submitted to the FDA Adverse Event Reporting System regarding patients experiencing symptoms such as erectile dysfunction, anxiety, suicidal ideation, and brain fog associated with using compounded versions of this medication. FDA has approved two oral finasteride products for different medical conditions: Proscar® and Propecia®. No topical products containing finasteride alone or in combination with other ingredients are FDA approved. FDA recommends that health care providers inform patients about the potential risks associated with using compounded topical finasteride.

New FIP Guide Expands on Role of Pharmacists in Providing Vaccination Services

The International Pharmaceutical Federation (FIP) has published an updated version of its **vaccination reference guide for pharmacists**. The 2025 version of the *FIP Knowledge and Skills Reference Guide for Professional Development in Vaccination Services* expands on the roles of pharmacists in reducing vaccination hesitancy, improving vaccine uptake, and maintaining proper storage, handling, and distribution procedures for vaccines. The guide also identifies areas where pharmacists can enhance their skills and knowledge to continue to be leaders in providing vaccination services, including advances in vaccine technology and supply chain management, navigating digital health systems and leveraging technology, preparing for future health emergencies, and more.

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.

2025 PUBLIC BOARD MEETINGS

Third Wednesday of each month

Aug 20, 2025
Sept 17, 2025
Oct 15, 2025
Nov 19, 2025
Dec 17, 2025

Maryland Board of Pharmacy
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BOARD OF COMMISSIONERS

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Secretary: **Javier Vazquez**	Acute Care Hospital 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
Matthew Shimoda	At-Large Representative
Amir Masood	Chain Drug Store Representative
Adetoro Oriaifo	At-Large Representative
Neil Leikach	Independent Representative
Vacant	Consumer Representative
Vacant	Long Term Care Representative

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Executive Director
Deena Speights-Napata

Director of IT, Budget & Procurement	Director of Compliance	Call Center Manager	Licensing Manager	Director of Inspections
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