VOLUME XVIII, ISSUE 5 FALL/WINTER EDITION

Quarterly Newsletter

New Administration in the White House!

Deena Speights-Napata, Executive Director

What's the impact on pharmacy?

A new administration will take over the White House in January 2025, and with that change there will most assuredly be policy and practice changes that may broadly impact the administration and provision of health services on the national and local level. Just as COVID impacted pharmacies in fundamental ways, changes that are in the forecast for public health policy and social policy will most likely impact medical care and dispensing systems across the country.

There has been some speculation about how pharmacy practice might be affected. Following are some of the national changes being talked about and my thoughts on the potential impact these changes may have on the local practice of pharmacy.

Expansion of access to care for veterans:

Expansion in care for veterans may likely increase the number of facilities authorized to provide care which may lead to an increase in pharmacies providing prescriptions, immunizations, and other services to veterans that have not typically been serviced in traditional pharmacies. An increase in physician prevention and treatment services could likely result in an increase in medications prescribed, which may put additional pressure on pharmacies to increase staffing and drug inventory. Also, due to the types of medication some veterans are typically prescribed, the pharmacy may be required to provide increased pharmacists on hand to provide medication management services, or more technicians available to provide more immunizations and other services.

Reforming or Restructuring of the FDA and CDC:

FDA: There has been some speculation that the new administration may revise the limited use authorization designation used during the COVID pandemic and initiate tougher standards for the drug pre-market approval process. Delays in drug authorizations will impact the availability of drugs in the pharmacy for use by the consumer. Some sources also believe that there will be

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 increase in pharmacies and hospitals in which sterile compounding inspection and monitoring activity occurs.

CDC: There is speculation that the administration and manufacturing of vaccines will be reformed. Also, the new administration has suggested that the CDC budget will be reduced. Many speculate that CDC budget cuts will result in reduced funding to local health departments that administer vaccines and provide health services, which could mean that pharmacies will see an increase in consumers that will need prescriptions filled and vaccinations administered they may have previously received through the local health department.

Replacing the Affordable Care Act:

Replacing the Affordable Care Act with an insurance program that provides coverage for fewer consumers will result in an increase in the number of chronically ill patients without health insurance coverage. Less insurance coverage for the chronically ill adversely impacts low income populations and most likely will result in fewer prescriptions being prescribed and filled. Under the ACA mandatory drug rebates were increased by 50%, including brand name drug rebates. Medicaid coverage increased under ACA and Medicare compensation rates increased. Replacing ACA may result in decreased coverage for populations currently receiving health care benefits. Pharmacies may see a decrease in patients visiting the pharmacy.

Increase in apprenticeships and alternative work pathways:

This program may serve to benefit pharmacies by providing them with greater options for being the receptacle for hosting apprentice programs. In conjunction with the state pharmacy board, pharmacies may be able to offer shorter technician training programs to an increased number of trainees, and in partnership with the pharmacy schools, provide opportunities for more pharmacy internships.

Please email the board and let me know your thoughts.

Prescriptions by Physician Assistants – Change in Requirements

Effective October 1, 2024, prescriptions issued by physician assistants (PA's) no longer require the name of the PA's supervisory physician written on the prescription. This change is the result of the enactment of the PA Modernization Act (Chap. 920, 2024), which is codified at Md. Code Ann., Health Occupations Article § 15-302.2(a)(5). Please reference the statute for the full text of the new law.

Therefore, a prescription issued by a PA must include the PA's name, business address, business telephone number and signature. The prescription must also contain the PA's DEA number if the prescription is issued for a controlled dangerous substance. This information, of course, is in addition to the other standard and required prescription elements.

In order to verify the prescriptive authority of a PA, pharmacists may query the Practitioner Profile Portal on the Maryland Board of Physicians website (mbp.state.md.us).

Important Notice: We've received reports of fraudulent calls from individuals posing as Board staff. Please exercise caution when receiving unsolicited calls.

Fraudulent investigative agents have been calling pharmacists, using their license information to scare them into sending them money.

The criminals call the victims through a masked phone number, posing as the Board phone number (410-764-4755), and identify themselves as agents or law enforcement officials from other agencies. The impersonators inform their victims that their license has been used for illegal activity, and that enforcement action will be taken against them unless they pay a fine. In most cases, the impersonators instruct their victims to pay the "fine" via wire transfer to a designated location, usually overseas. If victims refuse to send money, the impersonators often threaten to arrest them or search their property. Another scheme involves criminals contacting some victims who purchased their drugs using a credit card to scare them into thinking they committed fraud with their credit cards. License information is public information. Just because they have limited license information does not mean they are from the Board of Pharmacy.

Anyone receiving a telephone call from a person purporting to be a special agent from the Board of Pharmacy, DEA Investigator, or other law enforcement official seeking money should refuse the demand and report the threat to the Board at mdh.mdbop@maryland.gov

Continuing Education Breakfast 2024

The annual Continuing Education Breakfast met in person at the BWI Airport Marriott, in Linthicum Heights. This event is offered to give licensees an opportunity to hear excellent speakers while receiving nationally certified credit. The event was planned by the Public Relations Committee of the Board of Pharmacy and was offered for free.

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 Dixie Leikach, the President/CEO of PEER (Pharmacy Ethics, Education and Resources), and the Managing Network Facilitator for CPESN MD (Community Pharmacy Enhanced Services Network of Maryland). Her topic focused on medication safety and ethical decision making in Pharmacy. Presenting next was Kyle Robb, Pharm.D, who is the Director of State Policy & Advocacy at the American Society of Health-System Pharmacists in Bethesda, MD. Dr. Robb presented information reading regulatory considerations related to the concept of “white and brown bagging” methods of drug distribution.

Following annual traditions at the Continuing Education Breakfast, the Maryland Board of Pharmacy recognized the licensees who have held a pharmacist license for 50 years or more. Each licensee received a citation from the governor, thanking them for their service. The citations were presented by the Board’s President, Dr. Kristopher Rusinko. This year we recognized the 2024 recipients.

Following this ceremony, Mac Gbenro Jr, Program Manager in the Center for Innovative Care Delivery and Center for Health Information Technology at the Maryland Health Care Commission (MHCC) provided a brief

communication regarding the implementation of HB1127 and the upcoming reporting requirements of noncontrolled prescription drug dispenses to the Sate Designated Health Information Exchange.

After a brief break, Dr. Nicole Culhane, who currently serves as the Assistant Dean of Experiential Education and is a Professor in the Clinical and Administrative Sciences department at Notre Dame of Maryland School of Pharmacy, lead a delightful discussion focused on empowering pharmacy learners through the art of precepting and delivering feedback.

Rounding out the presenter line up for the day was Lori Mayall, Senior Associate General Counsel at Gilead Sciences, Inc. and leads the company's Anti-Counterfeiting/Global Product Security group. She described an intricate counterfeiting case from the perspective of the manufacturer and the impact to the national supply chain and product integrity.

Executive Director Deena Speights-Napata closed out the Continuing Education Breakfast with a reminder about how to obtain the credits for the event. The Public Relations Committee would like to thank to 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!

Technician Administration of Certain Vaccines

Effective November 11, 2024, the Board finalized the adoption of regulations that allow registered pharmacy technicians to administer certain vaccines as a delegated pharmacy act under the direct supervision of a pharmacist. A summary is provided below; however, please reference the Board's regulations, COMAR 10.34.34, for comprehensive requirements.

In order to qualify to administer vaccines, a technician must complete an ACPE-approved practical training program that includes: (1) hands-on injection technique; (2) clinical evaluation of indications and contraindications of vaccines; and (3) recognition and treatment of emergency reactions to vaccines. In addition, the technician must possess an active CPR certification obtained through in-person classroom instruction.

Technicians who administer vaccines must first submit written notification to the Board on a form developed by the Board. The "Pharmacy Technician Administration of Vaccinations Notification Form" may be found on the Board's website (https://health.maryland.gov/pharmacy). A technician may not administer a vaccine until the technician receives written confirmation from the Board accepting the technician's notification form.

A technician may only administer influenza, Coronavirus (COVID-19) or pneumonia vaccines to an individual at least 18 years old, or respiratory syncytial virus (RSV) or herpes zoster vaccines to an individual at least 50 years old. The supervising pharmacist must confirm that a pharmacy technician has met the requirements of the Board's regulations before delegating the administration of vaccines to the technician.

Ensuring Patient Safety with Access to Complete Medication History

New Reporting of Noncontrolled Prescription Drug Dispenses to Begin in 2025

Do You Know?

Maryland is preparing to make available dispense information for noncontrolled prescription drugs. Prescribers and pharmacists will access the information through the State-Designated Health Information Exchange, CRISP, to support the treatment and care coordination of patients. New information on noncontrolled prescription drug dispenses will supplement dispense information on controlled dangerous substances currently made available by the Maryland Prescription Drug Monitoring Program (PDMP). Certain individuals authorized by law to dispense noncontrolled prescription drugs to a patient or a patient's agent in Maryland are anticipated to begin reporting in 2025.

Value

Enabling access to patients' comprehensive medication histories informs clinical decision making and improves patient safety by helping identify potential drug interactions and minimizing risk of medication errors and adverse drug events. Nationally, adverse drug events result in over 1.5 million visits to a hospital emergency department annually (according to the Centers for Disease Control and Prevention). Incomplete information on past and current medications at the time of admission can lead to interrupted or inappropriate drug therapy during and after hospitalization. Having access to accurate and up-to-date medication history supports the medication reconciliation process, especially during transitions of care.

Maryland Law

The Maryland Health Care Commission (MHCC) is tasked with supporting the implementation of Maryland law requiring dispensers to report dispenses of noncontrolled prescription drugs to CRISP (Chapter 296/House Bill 1127, Public *Health – State Designated Exchange – Health Data Utility*, 2022). CRISP is required to make the information available for treatment and care coordination purposes. The MHCC has proposed regulations (COMAR 10.25.18), which include a provision for MHCC to publish a *Noncontrolled Prescription Drugs Dispenser Data Submission Manual* (manual). A preliminary draft of the manual was developed with input from stakeholders, including health care providers and pharmacists. The draft manual provides information and guidelines for reporting data on noncontrolled prescription drug dispenses to CRISP; this includes reporting timeframes and frequency, electronic specifications, and technology failure protocols. To minimize dispenser challenges, submission of noncontrolled prescription drugs will closely align with PDMP reporting requirements.

About MHCC

Please contact mhcc.noncds@maryland.gov for more information about upcoming dispenser reporting of noncontrolled prescription drugs. The Maryland Health Care Commission is an independent regulatory agency – learn more by visiting mhcc.maryland.gov or searching MHCCMD on Facebook or Twitter.

MARYLAND Health Care Commission

UMES 11th Annual Point-of-Dispensing (POD) Drill for Students' Training on Emergency Preparedness and Response: An Interprofessional Education Collaborative during National Preparedness Month in September 2024

Hoai-An Truong, PharmD, MPH, FNAP, FAPhA, FNAP, Professor, Director of Public Health and
Lana Sherr, PharmD, Associate Professor and Assistant Dean for Professional Affairs

School of Pharmacy and Health Professions, University of Maryland Eastern Shore

In a continued effort to increase awareness of disaster responses, especially with recent hurricanes, and emergency preparedness training for future generations of pharmacists and healthcare professionals, University of Maryland Eastern Shore (UMES) School of Pharmacy and Health Professions celebrated National Preparedness Month in September 2024 with the 11th Annual Point-of-Dispensing (POD) drill on September 11, 2024. This 11th annual UMES SOP signature pharmacy, interprofessional and public health preparedness event is a sustained collaboration with the Somerset County Health Department (SCHD) and with support from the Maryland Board of Pharmacy Emergency Preparedness Task Force (EPTF), the Maryland Department of Health – Office of Preparedness and Response (OPR), and the Eastern Shore Collaborative for Interprofessional Education (ESCIPE), an inter-institutional initiative of the UMES and Salisbury University. Special thanks to SCHD team Danielle Weber, Christopher Osment and other staff, from EPTF – Jennifer Thomas, Don Taylor and other EPTF members, and from OPR – Christopher Kozub. The September 2024 POD drill was also a third reunion for an in-person exercise since the last virtual POD drill in 2021.

Students and staff of UMES, with Emergency Preparedness Taskfore

Historically, the POD drill exercise was inaugurated in 2013 and continued through 2019 with a focus on mass prophylaxis or dispensing of ciprofloxacin and doxycycline for anthrax. This was a seven-year collaborative partnership of the above-mentioned partners that enabled faculty to convert to virtual POD drill in 2020-2021, as well as prepared students for volunteer roles at mass vaccination clinics during the COVID-19 pandemic. Specifically, ongoing interprofessional collaboration among faculty in pharmacy and physical therapy brought together about 60 students for preparedness and response training. This 2024 real-world application- or skills-based training focused on the preparation and implementation of a mass vaccination clinic for the influenza vaccination. During the POD drill, students exchanged roles as providers versus patients in three rounds and rotated through five stations, including: greeting, registration, consultation, vaccination, and observation. Students also received just-in-time-training, which occurred immediately prior to the start of the drill exercise for all students. During multiple rounds of the POD drill over a three-hours period, interprofessional faculty and students worked side-by-side in a variety of roles to provide greetings, registration, consultation, vaccination, and observation throughout the exercise. Faculty provide feedback after the POD drills, while students were asked about their POD drill and interprofessional education experiences. Overall, it was a positive real-world experience for all those involved and increased awareness among students for disaster and emergency preparedness and response.

Notre Dame POD Drill

October 8, 2024

"What if you were suddenly made aware that terrorists had released aerosolized anthrax over the East coast – how would you react and what would you do? This was the question that was posed to a group of approximately

130 student pharmacists, student nurses and physician assistant students at Notre Dame of Maryland University on October 8, 2024. In the lecture that followed, which was presented by the Maryland Board of Pharmacy's Emergency Preparedness Task Force (EPTF), the planned reactions and responses were explained. Following the talk students were able to participate in an actual Point of Dispensing (POD) exercise. POD exercises are designed to demonstrate how a given facility, in this case Notre Dame, could rapidly provide medical assets to their professional community after a public health emergency such as an Anthrax exposure

This event built upon the experiences gained at last year's exercise which employed, for the first time at any school of pharmacy's POD drill, QR codes and mobile device technology for completing the required Medication Screening Form

Notre Dame Students active in the POD

EPTF member G. Lawrence Hogue, who organized this exercise, said that this drill was particularly noteworthy in that the QR codes provided much faster processing times and most importantly more error-free results than compared to the paper screening forms utilized in the past.

EPTF members worked closely with participating Notre Dame faculty to assist them with operations so that the faculty would be able to independently manage their POD if the need should arise in the future. In addition, students who took part in the exercise, having seen how they could be of great assistance, should be more willing to volunteer to help in an actual emergency.

Hogue and the EPTF members were very appreciative of Notre Dame Dean Matthew Shimoda for his cooperation and enthusiasm, Kim Eshleman and Joe White from the Baltimore City Health Department for their engagement, Karen Hopper and Mallory Simcox from MD Responds for their emphasizing the value of becoming a Medical Reserve Corps member and especially to Thomas Franklin from the Howard County Health Department who was instrumental in creating the mobile device app that was employed for this event.

Board Employees Recognition of Years of Service


State of Maryland

Certificate of Service

Awarded to *Trina Leak*

In appreciation of Ten years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR


State of Maryland

Certificate of Service

Awarded to *Shanelle Young*

In appreciation of Fifteen years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR


State of Maryland

Certificate of Service

Awarded to *Leroy Jackson*

In appreciation of Ten years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR


State of Maryland

Certificate of Service

Awarded to *Lawrence Tates*

In appreciation of Ten years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR


State of Maryland

Certificate of Service

Awarded to *Deena Speights-Napata*

In appreciation of Fifteen years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR


State of Maryland

Certificate of Service

Awarded to *Amanda Vollmerhausen*

In appreciation of Ten years of faithful service to the people of Maryland

Date June 2024

GOVERNOR LT. GOVERNOR

DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
James G. Walker	09983	Probation/Fine	7/23/2024
Patrick Donohue	21664	Suspension	8/19/2024
Moshin Naeem	23822	Revocation	8/21/2024

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Gloria Martinez	T20955	Revocation	12/18/2024
Laila Carrillo	T29079	Revocation	8/21/2024
Jessica L. Parsons	T26422	Revocation	8/21/2024
Christine M. Gary	T16214	Revocation	10/16/2024
Brittany C. Hudgins	T21147	Revocation	10/16/2024
Tiffany S. Carter	T25569	Revocation	10/21/2024
John Schwenninger	T27045	Revocation	12/18/2024
Amber L. Coffren	T26600	Revocation	11/20/2024

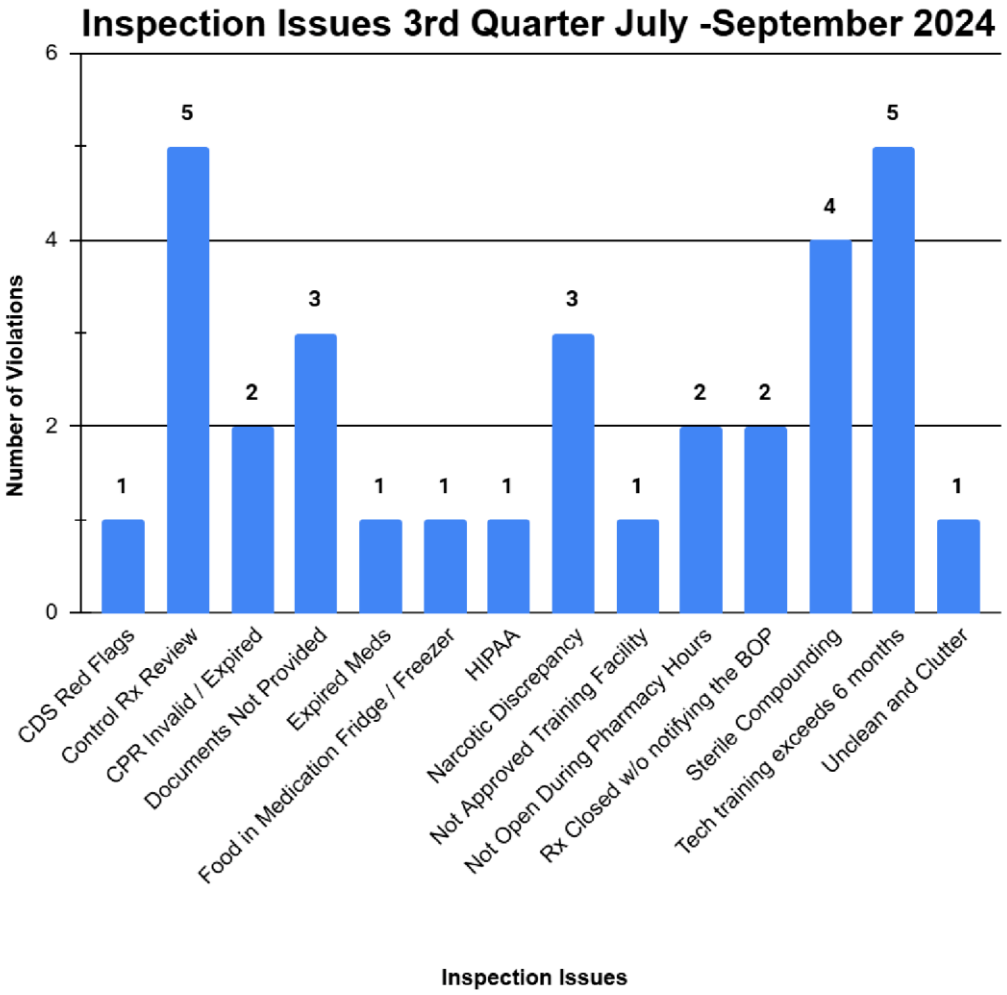
ESTABLISHMENTS	LIC#	SANCTION	DATE
Getinge USA Sales, LLC	D07025	Fine	4/15/2024
Ethicon, Inc.	D07179	Fine	7/2/2024
Walker Pharmacy, Inc	P07936	Probation/Fine	7/23/2024
St. Jude Children's Research Hospital	P05396	Fine	8/8/2024
AHF Pharmacy	P08909	Fine	8/19/2024
Custom Prescriptions of Lancaster	P05572	Fine	9/12/2024
American Life Pharmacy	P08890	Fine	9/23/2024
Qualgen, LLC	D05760	Probation	10/22/2024
Fisher Scientific and Fisher Healthcare	D06316	Fine	10/29/2024
Safechain Solutions	D03211	Reprimand/Fine	12/11/2024
Hill Top Pharmacy	P08600	Surrender	12/04/2024

Inspection Trends -Third Quarter July - Sept 2024

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 on biannually.

The following represents a breakdown of the issues that have come to the Board from the inspection of pharmacies across the state in the third quarter of 2024.

1. CDS Red Flags
2. CDS Rx Review
3. CPR Invalid / Expired
4. Documents Not Provided
5. Expired Medication
6. Food in Medication Fridge / Freezer
7. HIPAA Issues
8. Narcotic Discrepancy
9. Not Approved Tech Training Facility
10. Not Open During Pharmacy Hours of Operation
11. Establishments Closed w/o notifying the BOP
12. Sterile Compounding/USP 797 Issues
13. Tech training exceeds 6 months
14. Unclean and Clutter



National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION, Q1 2025

Guidance for Imported Fluid Products Published by ISMP

Following Food and Drug Administration's approval of a temporary importation list for fluid products in response to Hurricane Helene, the Institute for Safe Medication Practices (ISMP) has released guidelines to help health care organizations evaluate safety and assess potential risks when using these imported products. ISMP's Imported Fluid Product Checklist outlines factors that should be considered when reviewing potential risks with imported products, such as lacking a scannable barcode on a medication or fluid. ISMP also encourages organizations to visit the Baxter Medical Education page to view the list of products currently approved for importation.

ISMP Safety Briefs

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.
PRIORIX Diluent Administered Without Vaccine

PRIORIX ® is a measles, mumps, and rubella vaccine manufactured by GSK. It is available in cartons containing 10 single-dose vials of lyophilized antigen component and 10 single-dose prefilled ungraduated syringes of sterile water diluent. The prefilled diluent syringes have luer tips to accommodate the attachment of needles to reconstitute the vials of lyophilized antigen and to administer the vaccine. Recently, a patient arrived at a clinic for the vaccine. It was a busy day in the clinic, and when the nurse went to retrieve and prepare the PRIORIX vaccine, they only removed a syringe of sterile water from the carton, leaving the vial of lyophilized antigen in the carton. They reported they did not see the vial containing the lyophilized antigen, as it was "hidden" by the inside flap of the carton. The nurse administered the diluent alone and did not uncover the error until finding an extra vial of lyophilized antigen in the carton a couple of hours later.

To prevent preparation and administration errors with vaccines

that come with prefilled diluent syringes, ISMP recommends establishing a process to keep vaccines and their corresponding diluents together, if storage requirements do not differ. Implement barcode scanning prior to preparing and administering vaccines. Configure the system to require scanning of both the vaccine and corresponding diluent barcodes. Provide vaccine-specific auxiliary labels to facilitate relabeling of the diluent syringe after the vaccine is reconstituted and withdrawn from the vial. Store the

labels with the specific vaccine products. Document the National Drug Code number, lot number, and expiration date of each container in the vaccination record or log before administration to confirm the appropriate selection or preparation of both components. Documenting the actual administration of the vaccine should always occur after the vaccine is administered.

Inhalation Medication Entered Incorrectly Causes Error

A pharmacist reported that a medication was entered incorrectly into their pharmacy dispensing system from an electronic prescription. The prescriber had ordered "mometasone 100 mcg-formoterol 5 mcg inhalation." However, the pharmacy technician entered "mometasone 100 mcg inhalation." Fortunately, a pharmacist intercepted the error while verifying the prescription and corrected the mistake. In their investigation, the pharmacy found that distractions likely contributed to the error. The technician who entered the prescription was completing multiple tasks at one time, including answering phone calls, assisting patients at the pharmacy counter, and helping to onboard new employees.

To minimize errors, prescribers should align electronic prescriptions with National Council for Prescription Drug Programs standards and Surescripts guidelines for accurate drug matching.

The pharmacy should also investigate why the pharmacy dispensing system may not automatically match the correct drug and strength (or other information on the prescription) and communicate issues related to the electronic prescription with prescribers and their pharmacy computer system vendor and/or internal information technology staff. Design pharmacy space and workflow to minimize distractions, especially during data entry, filling, and pharmacist verification. Borrow a concept from the airline industry and create a "sterile cockpit" at each workstation to minimize unnecessary distractions and interruptions. Designate an orientation/staff development leader and safety coaches and provide protected time for onboarding to ensure that new hires are competent in the areas and systems they are assigned to work. Ideally, ISMP recommends that those who train new staff have a reduced workload to accomplish orientation goals safely and thoroughly.

Dr. Lorna Breen Heroes' Foundation to Co-Host Healthcare

Leadership Collaborative Event

The Dr. Lorna Breen Heroes' Foundation, the national coalition of health workers for "ALL IN: Wellbeing First for Healthcare," is inviting organization leaders to participate in its second annual Healthcare Leadership Collaborative event on March 18, 2025. The event is co-hosted by Johns Hopkins Carey Business School's Human Capital Development Lab and Johns Hopkins Medicine Office of Well-Being. During this event, leaders will discuss strategies for transforming the workforce culture and fostering effective leadership for health care workers.

As of September 1, 2024, 375 hospitals and 34 licensure boards have verified that their credentialing applications do not include any intrusive mental health questions and stigmatizing language – a goal of the "ALL IN: Wellbeing First for Healthcare," known as the Wellbeing First Champion Challenge.

The foundation recommends that state boards of pharmacy, licensure boards, hospitals, health systems, and insurance companies use the coalition's licensing and credentialing toolkits to remove any intrusive mental health questions from their applications, forms, and addendums. Additionally, the foundation has developed a downloadable social media toolkit to motivate other licensure boards and hospitals to join the challenge.
NABP supports the Wellbeing First Champion Challenge and other efforts to improve pharmacists' mental health and well being and will continue to work with its member boards of pharmacy on this and other efforts that can help create a more resilient and healthier pharmacy workforce.

FDA Reconsiders Removing Eli Lilly Weight Loss and Diabetes Drug From Shortage List

Food and Drug Administration (FDA) is reconsidering its decision to remove tirzepatide injection, a glucagon-like peptide-1 medication, from the official shortage list. The decision comes after FDA was sued by compounding pharmacies and a trade organization representing compounding pharmacies, arguing that the drug from Eli Lilly is still in short supply. FDA's motion to stay the court proceeding and remand the case back to itself was granted. The agency has requested that plaintiffs provide additional information on the drug to assess its availability. As of October 2, 2024, dulaglutide, semaglutide, and liraglutide injections continue to be in shortage.

Exemption to Connected Trading Partners Granted by FDA

Food and Drug Administration (FDA) is issuing an exemption from the enhanced drug distribution security requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act, through the Drug Supply Chain Security Act, for eligible trading partners.
This exemption applies to any product transacted by eligible trading partners (who have successfully completed or made documented efforts to complete data connections with their immediate trading partners but still face challenges exchanging data).
This exemption is part of the agency's broader efforts to avoid supply chain disruptions and ensure that patients will not face delays in receiving the medicines they need.
The duration of the exemption varies depending on the eligible trading partners:

- *Manufacturers and repackagers: May 27, 2025*
- *Wholesale distributors: August 27, 2025*
- *Dispensers with 26 or more full-time employees: November 27, 2025*

Trading partners who utilize these exemptions do not need to notify FDA.

Impersonation Scam Directed at Pharmacists, DEA Warns

Drug Enforcement Administration (DEA) is warning pharmacists and doctors of fraudsters impersonating DEA agents and demanding sensitive information or payment. Legitimate DEA agents will only communicate with individuals about investigations or legal actions in person or via an official letter. Scam tactics may include using an urgent and aggressive tone, threatening arrest, referencing National Provider Identifier numbers and/or state license numbers, and more. Individuals receiving a call from someone claiming to be with DEA are encouraged to report the incident to the Federal Bureau of Investigation.

CDC Alerts Health Care Professionals to Risks of Ordering Prescription Medications Online

Individuals ordering what they believe to be prescription medications from online pharmacies are taking a potential public health risk, according to a new statement released by Centers for Disease Control and Prevention (CDC). The statement, aimed at public health officials, clinicians, and patients, mentioned a recent indictment against individuals orchestrating illegal online pharmacies. CDC also listed a few tips to consider when purchasing from an online pharmacy, such as visiting Food and Drug Administration's website to locate a state-licensed online pharmacy, always carrying naloxone, and calling 911 in the case of an emergency.

NABP encourages consumers to only buy medications from verified, licensed websites that comply with applicable laws and NABP patient safety and pharmacy practice standards. Verify before you buy using the Safe Site Search Tool at safe.pharmacy

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

Prescriber licensing requirements for pharmacy claims submitted to the Maryland AIDS Drug Assistance Program (MADAP)

December 5, 2024

Pharmacies that submit claims to MADAP for processing and payment must ensure that the claim is submitted using a prescriber who is licensed per COMAR 10.18.06.02 pursuant to 10.09.03.02(C) which states that, *"A doctor of medicine or osteopathy shall be licensed and legally authorized to practice medicine and surgery and to dispense drugs in the state in which the service is provided."*

Currently, claims submitted with a prescriber who does not meet MADAP prescriber licensing requirements will receive a NCPDP rejection code of 25 that says *"M/I PRESCRIBER IDENTIFICATION"*. This soft rejection serves as an alert for the pharmacy to resubmit the claim using credentials of a prescriber who meets MADAP program licensing requirements as indicated above.

Since March 2024, MADAP has been contacting pharmacies that have submitted claims with prescribers who do not meet MADAP program licensing requirements as a follow up attempt to:

- Remind the pharmacy of the prescriber licensing requirement, and
- Provide the pharmacy with an opportunity to reprocess the claim(s) under a prescriber who meets MADAP program licensing requirements pursuant to COMAR 10.09.03.02(C).

Claims that are not rectified, will be subject to audit. Any claims identified as not meeting MADAP's prescriber licensing requirements will result in claim reversal and recoupment of previous claim payment by MADAP.

In 2025, MADAP will implement a hard stop rejection for pharmacy claims submitted with prescribers who do not meet program licensing requirements. Once this hard stop is activated, MADAP will not make courtesy calls to pharmacies. Claims will only process without rejection when submitted with a prescriber who meets MADAP licensing requirements.

Should there be any questions or concerns regarding this matter, please contact Michelle Groff at 443-934-5494 or via email at michelle.groff@maryland.gov.

BOARD OF COMMISSIONERS

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Secretary: **Javier Vazquez**	Acute Care Hospital Representative
Treasurer: **Peggy Glascoe Geigher**	Consumer Representative
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Daphanie Robinson	Pharmacy Technician Representative
Karla Evans	Acute Care Hospital Representative
Karen Slagle	Independent Representative
Kristen Fink	At-Large Representative
Amir Masood	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
Neil Leikach	Independent 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 who attend in person. 2025 PUBLIC BOARD MEETINGS

Third Wednesday of each month

Jan 15, 2025	Apr 16,2025
Feb 19, 2025	May 21, 2025
Mar 19, 2025	June 18, 2025

Maryland Board of Pharmacy
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Maryland Board of Pharmacy

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