Maryland Board of Pharmacy The Pharmacy

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The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists; registering pharmacy technicians; issuing permits to pharmacies and distributors; setting pharmacy practice standards through regulations and legislation; receiving and resolving complaints; and educating the public.

Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, MD 21215 Tel: 410-764-4755 Fax: 410-358-6207





FROM THE EXECUTIVE DIRECTOR'S DESK LaVerne G. Naesea

From time to time it is important to lend space in this newsletter to sister agencies in order to provide important information to licensees, permit holders and registrants. After recently meeting with Kate Jackson, fairly new to her post as Manager for the Prescription Drug Monitoring Program (PDMP), the importance of reminding most pharmacies and pharmacists that dispense Controlled Dangerous Substances (CDS) prescriptions about their legal obligation to register with and/or report to the PDMP became quite clear. There are exceptions, however, please read the below article submitted by the PDMP to learn if you are in compliance with Maryland's PDMP laws.

The Maryland Prescription Drug Monitoring Program (PDMP) was authorized by law in 2011 (Health-General Article, § 21-2A, Annotated Code of Maryland) with the goal to reduce the non-medical use, abuse, and diversion of prescription drugs while preserving the professional practice of healthcare providers and patient access to optimal pharmaceutical care.

The law requires persons and entities that dispense Schedule II - V controlled dangerous substances (CDS) to a patient or the patient's agent in Maryland ("dispensers") to **electronically report information to the PDMP within 3 business days of dispensing a CDS prescription.** This requirement has been in effect since August 2013, but we want to remind all pharmacies that they must continue to report to the PDMP and new pharmacies must begin reporting if CDS prescriptions are dispensed.

If your pharmacy is required by law to report and is not currently doing so, please reference the Dispenser's Implementation Guide for instructions. **Dispensers failing to submit prescription monitoring data can be subject to civil penalties** (COMAR10.47.07.07(A))

http://www.hidinc.com/assets/files/mdpdmp/MD%20PDMP_Dispensers%20 Implementation%20Guide.pdf

Note: If you are in the process of submitting dispensing records back to the mandated start date of August 20, 2013, and you have records that are more than 180 days old, please contact the HID Help Desk in order to ensure that the batch is accepted: mdpdmp-info@hidinc.com or 1-855-729-8920 (M-F, 9am – 5pm ET)

The PDMP law includes **exceptions to the reporting requirement** for certain specialty pharmacies, opioid maintenance programs, veterinarians and other persons or entities that dispense CDS. Details on these exceptions are available on the Maryland PDMP website (http://bha.dhmh.maryland.gov/PDMP/ SitePages/Home.aspx) and state regulations (COMAR 10.47.07.03).

If you have any questions about the requirement and exceptions of reporting, or PDMP policies, please e-mail dhmh.pdmp@maryland.gov or call 410-402-8686.

WHOLESALE DISTRIBUTOR RENEWAL PERIOD TO BEGIN

The renewal period for Distributor permits in Maryland begins March 16, 2015 and runs through May 31, 2015. In order for a renewal application to be processed and a permit issued before the current permit expires, a complete application, including all attachments and the renewal fee (\$1750.00) must be received by the Maryland Board of Pharmacy (the "Board) at least two weeks (May 15, 2015) prior to expiration of the current license. Operating an establishment without an active permit is punishable by a fine not to exceed \$500,000. (See Md. Code Ann., Health Occ. § 12-6C-11 and Code of Maryland Regulation ("COMAR") 10.34.11.10.) Please note the following application types:

1. Wholesale Distributor application - To be completed by entities engaged in the wholesale distribution of prescription drugs or devices into or within Maryland (not including third-party logistics providers), see Md. Code Ann., Health Occ. § 12-6C-01(v); and

2. Manufacturers and Virtual Manufacturers Distributing Only Their Own Prescription Drugs and Devices application (abbreviated form) - To be completed by manufacturers that distribute into or within Maryland, only their own FDA-approved prescription drugs and/or devices, or outsourcing facilities registered with the FDA under 503(b) that meet state and federal regulatory requirements.

On November 23, 2013 the Drug Supply Chain Security Act (DSCSA) was signed into federal law which outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed. In addition to other changes, the new federal law prohibits states from licensing Third Party Logistics (3PL's) providers as Distributors. Therefore, 3PL's issued Maryland Wholesale Distributor permits may continue to operate as <u>3PL's</u> in Maryland after their wholesale distributor permit expires.

COMPLIANCE CORNER - Working Conditions Survey

David H. Jones, RPh, FASCP, Board Commissioner

The Maryland Board of Pharmacy (the "Board") extends a sincere thank you to all the pharmacists and technicians who responded to the Working Conditions Survey (the "Survey"). Board Staff and Commissioners appreciate the feedback. This survey was designed to assist the Board in promotion of quality healthcare and patient safety.

As stated in the Survey, the Board sought to gather information about working conditions that may lead to risks for medication errors and thus to risks to public health and safety. The Board recognizes that there are pressures and stressors in all pharmacies that might impede optimal professional practice. These potential impediments were the focus of many of the Survey questions.

The Survey time frame has ended, and the Board is beginning the process of reviewing the responses received. When the Survey data have been analyzed, any essential Board action will be determined.

In the interim, please be reminded that it remains the ongoing professional responsibility of all pharmacists and pharmacy technicians to perform all activities to protect and improve patient safety. These include adherence to all legal mandates that relate to filling and dispensing all prescriptions and to essential patient counseling. These requirements are defined in State legislation and regulation and are universal standards of professional practice. To avoid patient harm, pharmacists, pharmacy technicians, and pharmacy management are jointly responsible for assuring that any and all issues that inhibit or restrict the performance of essential practice requirements are addressed through quality improvement actions.

The essential concern of the Board has been and will be the protection and enhancement of public safety. This goal, of course, is that shared by all pharmacists and pharmacies throughout Maryland. Again, the Staff and Commissioners of the Board thank all who participated in this Survey to "Help Us Help You" in protecting public health.

TRANSFER OF PRESCRIPTIONS

YuZon Wu, Compliance Unit Manager

A pharmacist from Pharmacy A may permanently transfer a prescription order to a pharmacist in Pharmacy B for Non-Scheduled prescription drugs if the prescription is lawfully refillable. The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order. COMAR 10.34.04.03-05.

The transfer of Schedule III-V prescription drugs for the purpose of refill dispensing is permissible between pharmacies on a one time basis. However, the transfer of Scheduled III-V drugs between pharmacies that electronically share a real-time, online database may transfer up to the maximum refills permitted by laws and the prescriber's authorization. 21 CFR § 1306.25.

The transfer of Schedule II prescription drugs is prohibited. The pharmacist providing and/or receiving the transfer must comply with all State and Federal regulations related to procedures of documentation of such transfer as defined in COMAR 10.34.04 and 21 CFR § 1306.25.

Around November 2011, Maryland Medicaid amended their regulations (COMAR 10.09.03.01B(34)) to allow pharmacies, at the request of the Medicaid patients, to transfer a prescription provided that the pharmacies/pharmacists comply with all the applicable State and Federal regulations.

COMAR 10.09.03.01B(34):

.01 Definitions.

- B. Terms Defined.
 - (34) "Prescription" means an order by a prescriber, or a prescriber's order transferred from one pharmacist to another, for Program covered pharmacy services in accordance with applicable federal and State laws conveyed in one of the following forms:
 - (a) An original order signed by the prescriber and written on tamper-resistant paper which shall contain industry-recognized features designed to prevent:
 - (i) Unauthorized copying of a prescription form;
 - (ii) Erasure or modification of information written on the prescription by the prescriber; and
 - (iii) Use of counterfeit prescription forms;
 - (b) A fax of an original order signed by the prescriber sent directly from the prescriber to the pharmacy provider;
 - (c) An electronic order; or
 - (d) An oral order from the prescriber to the pharmacist if the:
 - (i) Pharmacist promptly writes or prints out and files the prescription;
 - (ii) Prescription is not for a Schedule II controlled dangerous substance; and
 - (iii) Prescription is not for certain drugs that have been determined by the Secretary to present an emerging threat in the State because of increasing abuse and diversion.

DISCIPLINARY ACTIONS				
PHARMACIST	LIC. #	SANCTION	DATE	
Gary Shafer	07911	Voluntary Surrender	11/19/14	
Olesegun Adediran	16036	Reprimand/Probation	01/22/15	
PHARMACY TECHNICIAN	REG. #	SANCTION	DATE	
Lacey Street	T12171	Revoked	08/20/14	
Treneda Allen	T05558	Suspended	10/29/14	
Beverly Winn	T10372	Suspended	10/29/14	
Khadiyhah Strauder	T02082	Non-Renewed	11/05/14	
Adam Evans	T11604	Suspended	12/16/14	
Twyla Hughes	T06392	Probation	12/17/14	
Vandever Rash	T14348	Suspended	12/30/14	
ESTABLISHMENT	PERMIT #	SANCTION	DATE	
Apothecure, Inc.	P04701	Revoked	09/19/14	
MedPro Distributors	None	Fine	10/02/14	
Nelcha Pharmacy	PW0457	Suspended	11/25/14	
Spot on Specialties		Fine	01/25/15	
Lupin Pharmaceuticals	D01631	Fine	02/18/15	

MESSAGE FROM DHMH: MEASLES UPDATE & GUIDANCE

The following important update regarding the current measles outbreak in the United States, is excerpted from a February 4, 2015 notification prepared by Lucy Wilson, M.D., Sc.M, Chief of the Center for Surveillance, Infection Prevention and Outbreak Response, at the Department of Health and Mental Hygiene.

U.S. MULTI-STATE MEASLES OUTBREAK DECEMBER 2014—JANUARY 2015

The United States is currently experiencing a large, multi-state outbreak of measles linked to an amusement park in California. From December 28, 2014 to January 28, 2015, 67 people from 7 states in the U.S. (AZ, CA, CO, NE, OR, UT, WA), and 2 people in Mexico, have been reported to CDC as having measles related to this outbreak. Some of them have been hospitalized. Most of them were unvaccinated; others did not know their vaccination status. A minority of them were vaccinated. Cases have occurred in people of all ages. The outbreak likely started from a traveler who became infected overseas with measles, then visited the amusement park while infectious. However, no source has been identified. Comparison of the genomic sequences from 9 patients for which information was available show that all 9 are identical to the measles B3 virus type that caused the large measles outbreak in the Philippines in 2014.

Measles can cause health complications in up to 30% of cases, ranging from ear infections and diarrhea to pneumonia and encephalitis, and rarely, death. Children younger than 5 years of age and adults older than 20years of age are at higher risk measles complications. About 1 in 4 unvaccinated people in the U.S. who get measles will be hospitalized; about 1 in 500 may die.

MEASLES IN MARYLAND

Currently, Maryland does not have any measles cases associated with the multi-state outbreak. Maryland has not had a confirmed case of measles since 2013. Historically, Maryland has had high measles

vaccination rates. Based on the DHMH Annual School Immunization Survey, an estimated 98% of kindergartners had documentation of 2 doses MMR vaccine for the 2013 school year. Also, based on the 2013 National Immunization Survey, an estimated 95% of 2 year olds were vaccinated with at least one dose of MMR vaccine.

GUIDANCE FOR HEALTHCARE PROVIDERS AND HEALTHCARE SETTINGS

Healthcare providers should be vigilant about measles. Ensure all patients are up to date on measles, mumps, rubella (MMR) vaccine. Consider measles in patients presenting with febrile rash illness and clinically compatible measles symptoms (cough, coryza, and conjunctivitis), and ask patients about recent travel internationally or to domestic venues frequented by international travelers, as well as a history of measles exposures in their communities. Promptly isolate patients with suspected measles to avoid disease transmission and immediately report the suspect measles case to the health department. People who work in healthcare settings should have documented evidence of immunity to measles according to the Advisory Committee on Immunization Practices. Measles outbreaks in healthcare settings can disrupt care of patients and put them at higher risk for severe disease. This is especially important for patients who have underlying medical conditions, including weakened immune systems. Refer to "Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices" (www.cdc.gov/mmwr/pdf/rr/rr6007.pdf).

For more information on measles in general & the measles outbreak, refer to the CDC measles websitewww.cdc.gov/measles

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY FOUNDATION UPDATE

System-Based Causes of Vaccine Errors Reprinted from National Pharmacy Compliance News

Immunizations are widely recognized as one of Practice Recommendations. Involve the patient the most successful and cost-effective health intervention ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included Haemophilus influenza type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis absorbed, and inactivate poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acelllular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HopB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing agedependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

This column was prepared by the Institute for Safe Medication Practices (IMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports.

EMERGENCY PREPAREDNESS TASK FORCE

The Maryland Board of Pharmacy (MDBOP) sponsors an Emergency Preparedness Task Force (EPTF) that works closely with the State Office of Preparedness and Response to prepare for any emergencies that may occur. The EPTF has enabled pharmacists to be recognized as being vital members of the State's emergency teams. The MDBOP has been instrumental in writing the State Emergency Preparedness Plan which includes roles for pharmacists, pharmacy technicians and pharmacy establishments.

In order to assure that trained personnel are available, regardless of where an emergency may occur, the Board is recruiting volunteer representatives from various locations throughout Maryland.

If you able and willing to serve on the EPTF, as a representative for your specific area of Maryland, please contact Janet Seeds at <u>janet.seeds@maryland.gov</u> or 410-764-5988. All interested persons will be contacted.

Also, to register as an Emergency Volunteer, please go to www.mdresponds.org. Click onto 'register now'. This will assist the Office of Preparedness and Response in fulfilling requests for deployment of pharmacy personnel during emergencies.

BOARD OF PHARMACY SPONSORS BOOTH AT BABY BOOMER EXPO

Janet Seeds, Public Information Officer

Over 10,000 individuals attended the 2014 Baby Boomer Expo on October 22 -23, 2014 at the Timonium Fairgrounds. Maryland Board of Pharmacy staff and student interns provided informative brochures and incentives to those visiting its booth. Questions that were not immediately responded to during the event were forwarded to appropriate Board and staff members who prepared follow-up responses.



A written consumer survey was completed by many visitors to the Board's booth to gain a better understanding of their knowledge of the Board of Pharmacy and its mission. During the two-day event, hundreds of visitors were enlightened to the fact that the Board of Pharmacy regulates pharmacists, pharmacy technicians, pharmacies and wholesalers to help ensure that the public is protected. The Board of Pharmacy will continue its efforts to educate the public about it how protects Maryland's pharmacy patients.

All in all, Board participation at the Baby Boomer Expo was quite successful, with many individuals leaving with greater confidence about how the medications they take are monitored and information about how to contact the Board if needed. The consumer survey also provided vital

information to help the Board evaluate its efforts in informing the community about the Board and determine new ways to gain public exposure.

CONTINUING EDUCATION BREAKFAST PROGRAM

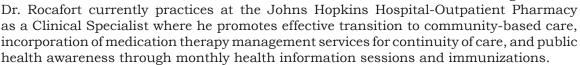
Janet Seeds, Public Information Officer

The Board of Pharmacy's Annual Continuing Education Breakfast Program was held on Sunday, October 19, 2014 at the Maritime Institute. The topic was, "Emerging Care Practices: Immunizations/Telemedicine" and the presenters were excellent.



Dr. Paul Vitale, PharmD, spoke about *Emerging Care Practices* during a very lively and entertaining presentation. Dr. Vitale has been a practicing pharmacist licensed in Maryland and the District of Columbia for over 35 years. He is currently an Associate Professor of Clinical and Administrative Sciences at the Notre Dame of Maryland University School of Pharmacy.

Dr. P. Tim Rocafort, PharmD, BCACP, Assistant Professor of Pharmacy Practice and Science at the University of Maryland School of Pharmacy presented valuable information about patient care in the community setting. He presented a session entitled, *Calling the Shots: Immunization Updates 2014*, incorporating the roles of telemedicine, as well as immunizations during his talk.







During the program, seven (7) pharmacists were honored for holding active licenses in Maryland for 60 years. Gilbert Cohen and Rudolph F. Winternitz were present and received Governor's Citations. Other honorees, Paul L. Goldstein, Mayer Handelman, Florence E. Raimondi, David F. Rombro, and Jonas J. Yousem were unable to attend the recognition ceremony.

Prior to the event, each honoree was asked to respond to questions related to their 60 years careers as pharmacists in Maryland. Excerpted responses included:

- Being a pharmacist has been: more than I hoped or dreamed for; provided me and my family a comfortable and grateful life.
- The biggest change seen in the practice of pharmacy over the years: is education; we only had to attend 4 years, now pharmacists attend 6-8 years and learn more; The position of trust of pharmacists today I feel has been brought about by the intensive education of graduates. We are thought of as the drug experts by the public and all health care professions; Computers [have changed the practice of pharmacy over the years]; In my day, pharmacists graduated and opened their own pharmacy or continued to work in the family business. Today pharmacists tend to work for corporations; In those days, pharmacists filled prescriptions and were paid immediately; today most prescriptions are paid through third parties; The number of female pharmacists has changed; in my class there were only four women, now most of graduates seem to be women. Also, there was only one School of Pharmacy then. What began as the Father Milton School of Pharmacy became the University Of Maryland School Of Pharmacy; With the onset of corporate pharmacy, the pharmacists do a lot less compounding than before. I feel that this 'advancement' gave away some of our abilities; Having been a part of the Pharmacists Education and Advocacy Council since 1982, I have helped many in our profession work through the disease of drug and alcohol abuse. Helping someone regain his life and return to our profession has been a very gratifying and significant experience.
- Advice offered to support newly licensed pharmacists: If a pharmacist just fills the prescription, he has just done his job. I have always felt that the patient is another human being and we must treat him/her as such. There, but for the grace of God, go I.

Regretfully, several registered individuals failed to attend the Board of Pharmacy's annual education session. Nonetheless, it was well received by the 150 in attendance. Those who registered with the CPE Monitor received 2.5 continuing education credits.



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Maryland Board of Pharmacy

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At-Large Representative
Acute Care Representative
Chain Representative
Consumer Representative
Independent Representative

BOARD MEETINGS

Public Pharmacy Board meetings begin at 9:30~a.m. 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.

2015 PUBLIC BOARD MEETINGS DATES

Third Wednesday of each month

April 15, 2015 May 20, 2015 June 17, 2015

Location: 4201 Patterson Avenue, Baltimore, MD 21215