Summer/Fall 2014

Maryland Board of Pharmacy news

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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 and registering pharmacy technicians, 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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Sterile Compounding

The new Health Occupations Article, Title 12, Subtitle 4A, Annotated Code of Maryland, Sterile Compounding Permits (HO §12-4A), passed during the 2013 Legislative Session as House Bill 986, requires the Maryland Board of Pharmacy to regulate and monitor entities that prepare sterile compounded drug for patients.

Thanks to all who participated in the Sterile Compounding Survey which closed October 1, 2014

The following is provided for your information prior to implementation on January 1, 2015:

1. Sterile Compounding Permits will begin to be issued on January 1, 2015 pursuant to the effective date of the implementing regulations, COMAR 10.34.19;
   - To prepare for January 1, 2015, the Board has posted the Sterile Compounding Permit Application on its website for download.
   - **Please be advised that the Board will not accept any applications or fees until January 1, 2015. Any applications or fees received before January 1, 2015 will be returned to the sender.**
   - Sterile compounding facilities with completed applications on file with the Board by **February 18, 2015** will not be subject to Board action for sterile compounding without a permit, until such time that the Board makes a final determination on the application.
2. Sterile compounding entities that plan to operate (or to continue operating) in Maryland after January 1, 2015, should prepare to meet new requirements of HO §12-4A and revised regulations, COMAR 10.34.19 as adopted in the *Maryland Register*.
3. All Maryland licensed sterile compounding pharmacies are required to continue to meet USP 797 standards and Maryland sterile compounding regulations currently in effect;
4. The Board will continue conducting annual inspections of sterile compounding pharmacies for compliance with state and federal laws, in addition to USP 797; and
5. Board wholesale distributor permits are required for outsourcing facilities that are registered with the FDA to allow them TO DISTRIBUTE STERILE DRUG PRODUCTS in Maryland.

Please visit the Board's website to view the Frequently Asked Questions (FAQ's)

FROM THE EXECUTIVE DIRECTOR'S DESK

LaVerne G. Naesea

CHANGING OF THE GUARD — REORGANIZING TO ENHANCE SERVICE & EFFICIENCY

The Board moved from the third to the first floor of its Patterson Avenue office building in 2007 in preparation for new staff to support new mandates. Just prior to that move, the former Independent Commissioner Harry Finke began serving eight years on the Board. He told me upon our first meeting that he "had some ideas" that would enhance the practice of pharmacy. Then he was off and running -- quickly assuming Board leadership roles as Chair of the Disciplinary Committee and subsequently as Chair of the Practice Committee. He was elected by his Board peers to the office of Board Secretary (a position he held until the end of his term) and aggressively supported various Board initiatives including greater oversight and accountability of dispensing practitioners and non-resident pharmacies. Harry was also instrumental in the development of policies that allowed the Board to regulate pharmacy technicians and to directly inspect pharmacies and wholesale distributors.

During his tenure, Harry served as a reviewer for the MPJE state exam questions, liaison to the Pharmacist Rehabilitation Committee and as the alternate delegate at NABP national and district meetings. He displayed passion and commitment in the many hats that he wore during his tenure, often proclaiming, that many Board proposed regulatory changes were *important to protect the public!!* Harry's 2nd term ended in May 2014. He actually did leave a legacy of enhanced pharmacy practice and improved patient safety, so undoubtedly, he will continue to serve and protect the public and pharmacy profession in his private life.

Over the past two years, eight new Commissioners have joined the Board of Pharmacy. In addition to Jermaine Smith, David Jones and Charmaine Rochester, Independent Pharmacist representatives, Bruce Zagnit and Roderick Peters, Consumer representative, Trinita Robinson, and Acute Care Pharmacist representatives, Sajal Roy and Dan Ashby have taken up Harry's public protection banner. The many Board successes in strengthening patient safety and enhancing pharmacy practice during Harry's tenure had however begun to place a strain on Board operations. Licensing specialists who process applications were unable to keep pace with the doubled-plus volume; complaint investigations resulting from the Board's added inspection responsibilities doubled the caseload, and the over 200 daily phone calls and other forms of communications from licensees and the general public, only served to exacerbate already strained operations. Thus, the arrival of *new blood* could not have been timelier.

It's been said more than once about the Board of Pharmacy that change comes very slowly, often trying everyone's patience as desired outcomes are met. This appears not to be the case this time, however. Following orientation and a mini retreat, the virtually brand new Board joined with staff in examining operational adjustments needed to improve efficiency and customer service. New operational plans are being aggressively implemented in order to capitalize on the gains previously made in achieving the Board's vision of *setting a standard for pharmaceutical services, which ensures safety and quality health care for the citizens of Maryland.*

One recent change undertaken to enhance operations has included simplifying most front-end processing of applications to reduce duplication of effort by Administration and Licensing staffs. This has resulted in quicker reviews and processing. Some readers have also received benefit of a recent Board effort when they contacted the Board through its new Customer Service Unit. This new pilot initiative brought together key staff from three key program areas – Licensing, Compliance and Administration – with a goal to resolve 80% of inquiries after one contact. The unit representatives are trained to directly address inquiries or forward and track an inquiry until a resolution is documented. Though still a pilot, the Customer Service Center is working! The numbers of repeat phone contacts and other communications have significantly decreased. More important, Board customers have provided positive feedback after interacting with the unit representatives and staff morale at the Board has improved.

Within the next six months, the Board will begin issuing sterile compounding permits and pharmacy intern registrations. The State approved six new positions at the Board to support this effort. The Board has also begun to reorganize staff to better meet on-going responsibilities and these new mandates. The Board plans to move again to the fifth floor before the end of the year. An older project to scan most paper licensing records into the Board's database is in full drive. This initiative will free up space when the Board moves and better accommodate the staff reorganization.

The beauty of change is that new ideas flourish. I have seen this happen at least five times during my fourteen years with the Board. I suspect that's how this Board has survived, revived and thrived these past 112 years!!!

DECENTRALIZED PHARMACIES

Anna Jeffers, Legislation & Regulations Manager

The Board of Pharmacy has received a number of questions about decentralized or outlying pharmacies in institutional settings. Specifically, hospitals have asked whether these decentralized pharmacies may operate under one hospital pharmacy permit or are there requirements for separate licensure and inspection? Hospitals are required to obtain separate licenses for any pharmacies on their campuses that do not qualify as decentralized pharmacies. The term "decentralized pharmacy" means one that provides services for patients in an institutional setting and is:

1. Dependent on another institutional pharmacy for
   a. Administrative control
   b. Overall pharmacist staffing and supervision
   c. Drug procurement; and
2. Located in the same building or pavilion as the institutional pharmacy noted above.

Thus, if there is centralized administrative control, including staffing and supervision and drug purchasing and distribution oversight, there is no need for separate licenses if the decentralized pharmacy is located in the same building or pavilion as the pharmacy having administrative control. Pharmacy inspectors would need to be aware of and inspect all such locations. It is important to note that all decentralized pharmacies must still otherwise comply with requirements for the operation of a pharmacy, to include having a pharmacist on the premises at all times the decentralized pharmacy is in operation.

If the centralized administrative and purchasing control does not exist, or if the outlying pharmacy is located in a separate building or pavilion from the centralized pharmacy, separate licensure is required.

The Board of Pharmacy will post a summary of this information on the Board's website under Frequently Asked Questions. Please refer to COMAR 10.34.03 for specific requirements.

ORDER/DIRECTIVE TO REPORT MERS CASE INFORMATION AND TAKE MEASURES TO PREVENT TRANSMISSION OF MERS

Joshua M. Sharfstein, M.D., Secretary of Health and Mental Hygiene

Whereas the World Health Organization ("WHO") and Centers for Disease Control and Prevention ("CDC") have issued health advisories concerning the spread of an infectious and/or contagious condition known as Middle East Respiratory Syndrome ("MERS"), which is caused by the MERS-coronavirs ("MERS-CoV");

Whereas MERS-CoV is capable of causing extensive loss of life or serious disability and therefore is a deadly agent as defined in §18-901(c) of the Health-General Article of the Maryland Code;

Whereas prompt reporting of MERS cases and the proper use of infection control measures are required for effective control of MERS-CoV;

Whereas MERS can at present be medically contained by the Department and appropriate health care providers;

Now, therefore, I, Joshua M. Sharfstein, Secretary of Health and Mental Hygiene, pursuant to §§2-104, 18-103(a), 18-904 and 18-905 of the Health-General Article of the Maryland Code, finding it necessary for the control of communicable disease, for the maintenance of an effective disease surveillance system, and for the investigation of actual or potential exposures to MERS-CoV, hereby order and direct as follows:

1. All health care providers, as defined in §18-901(g) of the Health-General Article, and all nursing homes, as defined in § 19-1401(e) of the Health-General Article, and ambulatory care facilities, as defined in § 19-3B-01 of the Health-General Article, shall:

   a. Become familiar with the current CDC case definition of MERS as set forth at the CDC MERS-CoV website at http://www.cdc.gov/coronavirus/mers/case-def.html;

   b. Consult with the local health department for the jurisdiction in which the practitioner, provider, or facility is located for assistance with MERS case detection, classification, testing, and prevention, as necessary;

   c. Submit immediate telephonic and written morbidity and other reports to the local health department for the jurisdiction in which the practitioner, provider, or facility is located;

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d. Follow the current CDC infection prevention protocols as posted on the CDC website and take such additional infection control measures as are necessary to prevent person-to-person transmission of MERS;

e. Educate and instruct a suspected MERS case on appropriate infection control measures to prevent transmission of MERS-CoV to others;

f. Not release a suspected MERS case until the immediate reporting requirements in section 2(c), above, and the education and instruction in section 2(e), above, have been completed and the local health department concurs with the release; and

g. Immediately notify the local health department for the jurisdiction in which the practitioner, provider, or facility is located by telephone of any suspected MERS case who, in the practitioner or provider's judgment, is unwilling or unable to comply with the instructions in section 2(e), above, for preventing transmission of MERS-CoV to others;

2. All Local Health Departments shall:

a. Immediately notify the DHMH, Office of Infectious Disease Epidemiology, and Outbreak Response of any suspected MERS cases;

b. Determine, under CDC guidelines and in consultation with the DHMH Office of Infectious Disease Epidemiology and Outbreak Response, which persons might be contacts of a suspected MERS case;

c. Provide support to suspected MERS cases and contacts of suspected MERS cases in complying with instructions for preventing transmission of MERS-CoV;

d. Notify the DHMH Office of Infectious Disease Epidemiology and Outbreak Response at 410-767-6700 immediately if, in the local health department's judgment, an individual suspected of having MERS fails to comply with instructions for preventing transmission of MERS-CoV; and

e. Maintain the confidentiality of information collected pursuant to Section 1, above, as required by Title 4 and § 18-904(d) of the Health-General Article;

3. Any sheriff, deputy sheriff, or other law enforcement officer of the State or any subdivision shall assist with the enforcement of any portion of this directive and order, if directed to do so, as anticipated in § 18-905(a)(3) of the Health-General Article.

THIS DIRECTIVE AND ORDER IS ISSUED UNDER MY HAND THIS 16TH DAY OF JUNE, 2014, AND IS EFFECTIVE IMMEDIATELY.

COMPLIANCE CORNER – DEA Issues Final Rule on Tramadol Schedule

YuZon Wu, Compliance Unit Manager

On July 2, 2014, the United States Drug Enforcement Administration (DEA) published its Final Rule in the Federal Register (Vol. 79, No. 127 /Wednesday, July 2, 2014), placing Tramadol into Schedule IV effective August 18, 2014. Tramadol is a centrally acting opioid analgesic first approved for use in the United States (U.S.) by the U.S. Food and Drug Administration (FDA) in 1995 under the trade name ULTRAM®. Since then, the FDA approved marketing of generic combinations and extended release Tramadol products.

As of August 18, 2014, manufacturers are required to print the designation "C-IV" on the label of each commercial container distributed. Any person who handles (i.e.: manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) Tramadol must be registered with the DEA. Any person who currently handles Tramadol and wishes to continue to handle Tramadol but is not registered with the DEA, must submit an application and obtain an approved DEA registration by August 18, 2014. Any person who does not desire or is not able to obtain a DEA registration must surrender all quantities of currently held Tramadol to a person registered with the DEA on or before August 18, 2014.

Any facility that handles Tramadol, must possess a DEA registration and CDS registration and must take an inventory of all stocks of tramadol on hand as of August 18, 2014. Thereafter, facilities are required to maintain inventory records on hand at least every two years (biennial inventory) as stipulated in Title 21, Code of Federal Regulations § 1304.03, 1304.04, 1304.11; U.S.C.827 and 958; and Code Of Maryland Regulations 10.19.03 and Criminal Law Article, §5-202, Annotated Code of Maryland.

LETHAL MIXTURES – BENZODIAZEPINES AND OPIODS, INCLUDING BUPRENORPHINE

Bethany DiPaula, PharmD and Raymond C. Love, PharmD

Drug overdose has been steadily increasing and is now the leading cause of death by injury in the US.[1] In 2010, 75% percent of prescription overdoses involved opioid analgesics.[2] When benzodiazepines are combined with opioids, patients may experience reduced oxygen saturation and respiratory depression along with an increased risk of mortality.[3]

SAMHSA's May 2014 Drug Abuse Warning Network (DAWN) Report notes that emergency department visits involving alprazolam have doubled from 2005 to 2010 and then remained stable in 2011.[4] The majority (81%) of these emergency department visits involved the nonmedical use of alprazolam in combination with another drug. Narcotic pain relievers were the most commonly cited second drug accounting for 32% of cases with alprazolam and 57% of cases with alprazolam and 2 or more drugs. This concurrent use or abuse of alprazolam and narcotics puts patients at significant risk of fatal overdose.[4] Physicians should consider the following in managing patients prescribed opioids (including buprenorphine) on a chronic basis:[5]

1. Whenever possible, benzodiazepines should be avoided in patients who are regularly maintained on opioids. When benzodiazepines are required, they should only be used on a short term basis.

2. Regular urine screens, which assess for natural and semi-synthetic opioids, should be monitored. Positive screens should be verified with a confirmation test, such as gas chromatography mass spectrometry (GCMS).

3. The Maryland Prescription Drug Monitoring Program (PDMP) data should be reviewed for any patient prescribed a controlled substance, particularly opioids or benzodiazepines. When a discrepancy is identified, the discovering physician should make notification to other prescribers.

4. Written treatment agreements should be utilized to clarify treatment expectations and to specifically educate about the risk for overdose including when opioids and benzodiazepines are combined.

Buprenorphine is rarely associated with overdose death. However, care must be taken with benzodiazepines in combination with buprenorphine. Buprenorphine is a partial opioid agonist that is generally considered safer than full agonists in overdose. When combined with benzodiazepines, buprenorphine's natural ceiling effect for toxicity may be diminished, resulting in significant respiratory depression.[6, 7] Patients are at greatest risk for serious toxicity and death when buprenorphine is used in high doses, injected, or combined with sedatives such as benzodiazepines.[8, 9] One study found that benzodiazepines were associated with 82% of fatal buprenorphine poisonings.[10] The exact mechanism for increased respiratory toxicity is unclear, but it appears to be more pharmacodynamic than pharmacokinetic.[7] Buprenorphine and benzodiazepines affect respiration by several different mechanisms. Benzodiazepines increase upper airway resistance, while opioids reduce central and peripheral respiratory drive.[7, 9] While naloxone is the treatment of choice for opioid overdose, buprenorphine overdoses may not be responsive to this standard agent. If a patient does not respond to a naloxone dose of 4 mg, it is unlikely that they will respond to higher doses. In these cases, the focus of care should switch to supportive treatment.[11] Because of buprenorphine's long half-life, patients may require continuous infusion as opposed to bolus administration and should be closely monitored.[11] When buprenorphine is combined with benzodiazepines, the benzodiazepine antagonist flumazenil can be effective in reversing respiratory depression.[9]

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4. Substance Abuse and Mental Health Services Administration, (SAMHSA). The DAWN report: Emergency department visits involving nonmedical use of the anti-anxiety medication alprazolam. Rockville, MD: SAMHA, Center for Behavioral Health Statistics and Quality; May 22, 2014.

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This article was prepared at the request of the DHMH Behavioral Health Administration. To learn about recognizing 'red flags' to help prevent drug diversion at pharmacies visit the homepage of the Board's web site at http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx (see News Updates on right side of Homepage).

DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	STATUS	DATE
Sharon Baker	12454	Probation	06/18/14
Sean Park	17609	Probation	07/16/14
Michael Partyka	13968	Fine	08/20/14
PHARMACY TECHNICIANS	**REG. #**	**STATUS**	**DATE**
Lindy Lewis	T12856	Summary Suspension	06/13/14
Jennifer Gurule	T00842	Summary Suspension	06/13/14
Kaitlyn Ciaravella	T08163	Revoked	06/18/14
Katrice Joe	T04389	Revoked	06/18/14
Derek Richardson	T13453	Suspended	06/23/14
LeAnn Harmon Weamer	T01901	Summary Suspension	07/23/14
Louis McMichael	T13180	Summary Suspension	07/23/14
Joon Lee	T04754	Fine	08/01/14
Becky Riden	T03064	Revoked	08/20/14
ESTABLISHMENTS	**PERMIT #**	**STATUS**	**DATE**
Celgene Corporation	D02255	Fine	05/30/14
Lee Medical International	None	Fine	06/12/14
McKesson Corporation	D00031	Fine	08/20/14

EMERGENCY PREPAREDNESS TASK FORCE

The Maryland Board of Pharmacy (MDBOP) has an Emergency Preparedness Task Force (EPTF) that works closely with the State of Maryland to prepare for any emergencies that may occur. This task force has enabled pharmacy to be recognized as being a vital part of the emergency teams. The MDBOP has been instrumental in writing the State Emergency Preparedness Plan to include pharmacy's role.

In order to maintain the EPTF more efficiently, the Board would like to secure representatives from various locations throughout Maryland. This would allow for the best scenario; to have trained personnel available, regardless of where an emergency may take place.

If you would be willing to serve on the EPTF, as a representative from your specific area of Maryland, please contact Janet Seeds at janet.seeds@maryland.gov 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 in fulfilling requests for deployment in the case of an emergency.

Medication Errors and Working Conditions Survey

The Board of Pharmacy is researching pharmacists working conditions and how they may be related to the occurrence of medication errors in pharmacy practice. Medication errors are generally recognized as having an impact on morbidity and mortality, thus effecting patient safety.

Although there has been some research nationwide on this issue, the Board is surveying pharmacists and technicians to determine the nature of pharmacy working conditions in Maryland. Your participation is of vital importance for the Board to obtain an accurate picture of working conditions in Maryland.

The survey is compiled on "Survey Monkey" and is anonymous. No personal information, contact information, IP address, or other identifying information will be collected.

The survey should take less than 10 minutes to complete and is anticipated to be available in October. A link to the survey is on the homepage of the Board's website at: http://dhmh.maryland.gov/pharmacy/SitePages/policy.

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Maryland Board of Pharmacy

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Patricia Gaither, Administration & Public Support Manager **Rhonda Goodman,** APS Assistant	Fiscal, Budget, Procurement, Travel, Personnel and Public Information
LEGISLATION AND REGULATIONS	
Anna Jeffers, Legislation and Regulations Manager **Anasha Page,** Administrative Assistant	Legislation and Regulations and Pharmacy Practice Issues
COMPLIANCE	
Yu Zon Wu, Compliance Manager; **Courtney Jackson,** Compliance Secretary	Practice/Patient Complaints, Disciplinary Actions, Inspections, Complaint Investigations and Pharmacists Rehabilitation
LICENSING	
Latoya Waddell, Licensing Manager; **Vacant,** Licensing Secretary	Licensing, Permits, Registrations, Reciprocity, Certifications, Scores and Verifications
MANAGEMENT INFORMATION SERVICES	
John Johnson, MIS Manager	Database statistics and Rosters, Website Host and On-line Renewals

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President: **Lenna Israbian-Jamgochian**	Chain Representative
Secretary: **Lynette Bradley-Baker**	At-Large Representative
Treasurer: **Mitra Gavgani**	Home Infusion Representative
Daniel Ashby	Acute Care Representative
David Jones	Long Term Care Representative
Roderick Peters	Independent Representative
Trinita Robinson	Consumer Representative
Charmaine Rochester	At-Large Representative
Sajal Roy	Acute Care Representative
Jermaine Smith	Chain Representative
Zeno W. St. Cyr, II	Consumer Representative
Bruce Zagnit	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.

PUBLIC BOARD MEETINGS DATES

Third Wednesday of each month

November 19, 2014
December 17, 2014
January 21, 2015

Location: 4201 Patterson Avenue, Baltimore, MD 21215