

SUMMER 2017

Maryland Board of Pharmacy news

FROM THE EXECUTIVE DIRECTOR'S DESK --- *Deena Speights-Napata*

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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, 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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FRIENDLY COMMUNICATION JUST AS IMPORTANT AS ACCURATE COMMUNICATION

I've always been someone who enjoyed analyzing numbers. Oh don't misunderstand, I don't have a PhD in mathematics or statistics, and neither does anyone on my staff. But after working as Deputy Director of the Data Analysis unit of Maryland Medicaid for four years, I learned quite a bit from a staff of PhDs and data analysts and programmers that taught me the value of data analysis. I'm so thankful that here at the Board of Pharmacy I have a quality staff of data collectors that provide me with the numbers I like to look at, at least once or twice every fiscal year.

For example, when I look at the number and types of customer complaints our board received during FY 2017 (July 2016-June 2017) resulting from customer experiences inside a pharmacy establishment, I find that 90% of those complaints were standard of care complaints. Standard of care complaints as we define it primarily include communication complaints and medication error complaints. In our case, upon review, most of the standard of care complaints are communication complaints.

Ironically, when I look at the customer service complaints we receive internally through a 5 question survey we administer monthly, I also find that out of the 2 or 3 below average ratings we receive from customers each month, close to 95% of them have to do with the way in which information was conveyed and the tone of the staff agent, not what was conveyed. Based on these findings we know that, one, we are doing a good to great job of handling customer service issues inside the office 95% of the time, but when we don't handle the situation well, it is because of how we communicate and not what we communicate. Likewise, customers in pharmacies have indicated a level of dissatisfaction with how they were talked to and how the pharmacy experience was overall. We do have a fair amount of medication error complaints but in many instances when follow up is conducted to obtain the facts surrounding medication error complaints, mixed in with the complaint are colorful details describing the words and actions of the pharmacist or technician describing how they responded to the customer complaint. The customer gave just as much weight to how they were talked to by the pharmacist or technician, as they did the actual medication error.

The Maryland Board of Pharmacy takes complaints seriously. That's mainly because our mission is to protect the public, and our vision is to establish a standard of care. That's why in this past fiscal year 94% of complaints submitted to our board resulted in an investigation, and out of those we investigated, 30% resulted in some type of board action.

So here's my advice: Let's be nicer to one another. It can be learned behavior. Our staff here at the board receives customer service training at every monthly staff meeting. Our call center staff has weekly meetings in which they discuss customer communication and participate in role play. This staff also received certification from the Maryland Department of Health in customer service thinking. We have prioritized not only effective communication, but friendly communication.

Our pharmacists and technicians provide a vital service, which can be stressful. Our staff of inspectors have seen it firsthand, and we recognize the pressures associated with the practice of pharmacy. 72% of the inspections we completed last year were in retail and community pharmacies. We have observed first hand some of the challenges associated with the practice of pharmacy, and so have some of the customers who are serviced. The board would like to be supportive in helping pharmacists and technicians perform their duties in an environment that results in fewer instances of communication problems and medication errors. Let's begin by communicating with a smile. That would be beneficial to everyone.

Visit the Board at <http://health.maryland.gov/pharmacy> or email mdh.mdbop@maryland.gov

As of July 1, 2017,
the Department of Health and Mental Hygiene (DHMH)
has been changed to the
Maryland Department of Health (MDH)

Reminder about the MARYLAND PRESCRIPTION DRUG MONITORING PROGRAM

On April 26, 2016, Governor Hogan signed into law HB 437 which includes the following legal changes:

1. Mandatory PDMP Registration for CDS Prescribers & Pharmacists

Beginning July 1, 2017, prescribers and dispensers licensed to prescribe and/or dispense CDS in Maryland must be registered with the PDMP through CRISP at <https://crisphealth.org>. For registration help, call 1-877-952-7477.

2. Mandatory PDMP Use by CDS Prescribers & Pharmacists

Beginning July 1, 2018:

- Prescribers must, with some exceptions, query and review their patient's PDMP data prior to initially prescribing an opioid or benzodiazepine AND at least every 90 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine. [**The Winter Newsletter mistakenly stated 30 rather than 90.**] Prescribers must also document PDMP data query and review in the patient's medical record.
- Pharmacists must query and review patient PDMP data prior to dispensing ANY CDS drug if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition.
- Information regarding Mandatory Use is available on the DHMH PDMP website, <http://bha.dhmh.maryland.gov/PDMP>. DHMH will provide additional information and reminders closer to, but before, the implementation date.

3. CDS Prescribers & Pharmacists May Delegate PDMP Data Access

Prescribers and pharmacists may delegate healthcare staff to obtain CRISP user accounts and query PDMP data on their behalf. Delegates may include both licensed practitioners without prescriptive authority and non-licensed clinical staff that are employed by, or under contract with, the same professional practice or facility where the prescriber or pharmacist practices.

To learn more, visit the DHMH PDMP website for updated information, important compliance dates and frequently asked questions: <http://bha.dhmh.maryland.gov/PDMP>. For more information about the opioid addiction and overdose epidemic in Maryland and what healthcare providers can do to help, visit http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/.

***Change impacting pharmacy staff access of PDMP data!**

CRISP and DHMH (Maryland Department of Health and Mental Hygiene) are pursuing several enhancements to Maryland's Prescription Drug Monitoring Program (PDMP) as use of the program continues to grow dramatically. One of the major exciting enhancements is a new and improved PDMP User Interface called 'PDMP Search'. This Interface will replace the Clinical Query Portal to access PDMP data in the next couple of months. PDMP Search is currently being rolled out incrementally to users who have access to only PDMP data at present in the Query Portal - this includes most Maryland pharmacists and pharmacist delegates!

In preparation of the new release, we want to ensure a seamless transition by confirming that all pharmacists are able to access the new website for PDMP as some organizations lock down new websites in the workplace.

The link to the web address for accessing PDMP Search is : <https://ulp.crisphealth.org/> ‘

We appreciate your support of the PDMP by making sure that the link above is available at all pharmacy locations prior to April 10th, 2017.

We have also emailed this new URL to each registered PDMP-only user, including your pharmacists, but know that website access may be controlled at the administrator or corporate level.

For any questions about this change, please contact the CRISP support team at 1.877.952.7477 or support@crisphealth.org.

**Pharmacies are being approved as Repositories for
Drug Disposal Sites and/or the Re-Dispensing for Indigent Patients Program**

Go to dhmh.maryland.gov/pharmacy/Pages/drug-repository.aspx and click onto the Maryland Prescription Drug Repository Program Application. Your pharmacy will be notified about approval.

BIOSIMILARS COMPARISON CHART

David Jones, R.Ph.

Biosimilars Comparison Chart					
Biosimilar Brand Name	Manufacturer	Biosimilar Generic Name	Originator Brand Name	Purple Book Designation	Interchangeable
Xarxio®	Sandoz	Filgrastim-sndz	Neupogen®	B	N
Inflectra®	Pfizer	Infliximab-dyyb	Remicade®	B	N
Erelzi®	Sandoz	Etanercept-szss	Enbrel®	B	N
Amjevita®	Amgen	Adalimumab-atto	Humira®	B	N
Renflexis®	Samsung Bioepis	Infliximab-abda	Remicade®	B	N
Insulin "Biosimilars" *		Presented for information only*			
Basaglar®	Lilly/BI	Insulin glargine	Lantus®	Not evaluated	Does not apply

Revised 04-25-17

Purple Book Reference I = Interchangeable; B = Biosimilar.

* Note: Insulins are not considered true biosimilars for regulatory reasons, but alternative agents are becoming available.

For any questions about biosimilars and interchangeability, refer to the FDA Purple Book website at www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm423462.pdf

BIOSIMILARS DRUGS: What are They and What's Up?

David Jones, R.Ph.

Biological drugs, or biopharmaceuticals, have been a part of therapy since at least the introduction of insulin. Traditionally, these have all been brand name, or originator, drugs exclusively. This has now changed.

The biopharmaceutical marketplace changed after the Biologics Price Competition and Innovation Act (BPCIA) of 2009, which provided for the equivalent of generic products for biological drugs. This was enacted as part of the Patient Protection and Affordable Care Act. BPCIA established an abbreviated licensure pathway for such alternative biologicals. BPCIA includes the Biologics License Application (BLA), approximately equivalent to the New Drug Application (NDA) for small molecule drugs (SMD). Once approved following the BLA,

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exclusivity for newly approved biosimilars may be in place for up to one year. Per FDA interpretation, insulins are excluded from this legislation and from associated review and substitution issues.

The biologicals are proteins and differ from traditional drugs, or SMD, in a number of ways. Biological agents are developed from genetically engineered living cells. The molecular structure of biologicals is very large, heterogeneous and complex. Differences in the manufacturing process can mean significant differences in therapeutic outcomes and potential for risks. There may always be batch to batch variations in the end-result molecule. These drugs are sensitive to heat, light, denaturing and risk for degradation. The review and approval process for biologic agents is based on the BLA. The FDA “*Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*” (more familiarly called the “Purple Book”) will be a compendium for the biologic agents similar to the generic reference, the “Orange Book” for SMD.

A number of alternative products to the originator drug are now available and many more are under FDA review or in the pipeline. All of these alternative agents must be considered under two categories – biosimilars and interchangeable biological products.

A biosimilar is defined as highly similar to the original drug. There are no clinically relevant differences between the biosimilar and the reference product.

Interchangeable biologic products are biosimilar to the reference molecule by definition. However, they also have the same clinical effect and defined outcomes as the brand name drug. Interchange from the reference drugs to these alternatives provides the same clinical benefits and risk profile as the reference product. A biosimilar does NOT necessarily translate to an interchangeable product. The Purple Book will designate approved biosimilars that are also interchangeable. At the time of this writing, no products have been accepted in the Purple Book as interchangeable. As of early June 2017, just two of the five approved biosimilar products are currently marketed. These are filgrastim-sndz (Zarxio[®] by Sandoz) and infliximab-dyyb (Inflectra[®], Pfizer)

Examples of biologic drugs include, but are not limited to, insulin, adalimumab, infliximab, interferon, etanercept, epoetin, filgrastim, and rituximab. Again, insulins are not included in BCPIA legislation or regulations.

Biosimilars offer prescribers and pharmacists options in product selection and dispensing. There is potential for cost savings for the entire health care system. Prescribers must write for the specific biosimilar or pharmacists must contact the prescriber in order to dispense a biosimilar for the referenced product. Automatic interchangeability does not currently exist for any biological product.

Note: A comparison chart of currently available biosimilars is attached for reference. Always refer to the Purple Book for most up-to-date information.

References:

FDA website, accessed June 16, 2017.

Note: This website includes references to the “Purple Book”

<https://fda.gov/downloads/drugs/guidance/ucm44661> (for general Q&A regarding biosimilars)

Special Report: Understanding Key Differences Between Biosimilars and Small Molecule Drugs, May 2013.

GaBIONline.net, accessed June 16, 2017(For basic information about generics and biosimilars)

A FEW FAQs for Pharmacy School Graduates

What's the difference between an initial vs reciprocity pharmacist application?

Initial applications are for those who want to become a Maryland Licensed Pharmacist and do not hold any Pharmacist Licenses in any other state. These are often for anyone who just recently graduated from Pharmacy School or recently came to the United States. A reciprocity application is for those who already have a Pharmacist License in another state and wish to obtain a Maryland Pharmacist License.

Initial applicants:

- Graduates of an ACPE approved pharmacy school
- Graduates of a foreign pharmacy school

Reciprocity applicants:

Pharmacists who are licensed in another state and have earned 520 pharmacy practice hours

What is the general licensing application process and steps to obtain an initial pharmacist license?

You must first download Initial Pharmacist Application. Fill out the application and attach all required documents including your proof of age (which can be a passport, driver's license, and birth certificates), the correct affidavit form, and application fee. Once you submit your application go to NABP's website in order to register to take the NAPLEX and/or MPJE. You must pay to take the exam before the Board can release an ATT (Authorization To Test). Once all prequalification(s) are met then NABP will e-mail you directly with your ATT. You will then schedule to take the exam through Pearson Vue's website at www.pearsonvue.com/nabp.

What forms and documents are required to apply as a new Maryland pharmacist, as a U.S. graduate?

The following is required in order to obtain a new licensure in Maryland as a U.S. graduate:

Maryland Board of Pharmacy Initial Application titled "New Pharmacist License Application Instructions: U.S. Graduates and Foreign Graduates" completely filled out with hand written signatures.

- Proof of Age – Birth Certificate, Driver's License, Passport, and other government issued ID.
- Pharmacy School Affidavit (Attachment 1) with school seal.
- NAPLEX passing score
- MPJE passing score

When will I get my Authorization to Test (ATT)?

You must first apply and pay to take the exam(s)(NAPLEX and/or MPJE) through NABP and submit an application to the Maryland Board of Pharmacy with required documents. The board will then review your application which can take 2-4 weeks. If you have met all requirements of the Boards application to become eligible for the exam(s), approval will be sent to NABP, who will provide you with the ATT(s). Remember we CANNOT release an ATT to you if you have not paid to take the exam(s).

What is a score transfer?

A score transfer is when you pass the NAPLEX exam in another state that is not Maryland, and have that exam score transferred to us through NABP in order for you to use the same NAPLEX score for the Maryland Board of Pharmacy Initial Pharmacist Application.

I am applying as a Score Transfer, which application will I use?

Score Transfers will apply as an initial pharmacist. It is recommended that you submit an additional note stating that you are transferring your NAPLEX score to Maryland. Your transferred NAPLEX score will be used towards your application process. However, you will need to take the Maryland MPJE.

Download our most up-to-date application forms at health.maryland.gov/pharmacy.



DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at www.deadiversions.usdoj.gov/drugreg/index.html.

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

This column was prepared by the Institute for Safe Medication Practices (ISMP). 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. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacap/Index.asp>.

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs,

notes the CDC publication. The publication is available at www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf.

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcpp.net>.

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at www.fda.gov/downloads/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/UCM434174.pdf.

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has

“determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles,” said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technician is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at www.ptcb.org in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm." For more information about the campaign, visit www.BuySafeRx.pharmacy.

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

The Maryland Board of Pharmacy is going completely electronic, so all of the licensees that requested printed copies of the Newsletters have been deleted. The process **MUST** be done again.

If you need a printed copy of the Newsletter, please send your address to Janet Seeds, janet.seeds@maryland.gov. This issue of the newsletter is being sent to all licensees and stakeholders electronically.

DISCIPLINARY ACTIONS

PHARMACIST	LIC. #	SANCTION	DATE
Sheshagiri Palakurthi	17557	Probation	05/17/17
Helen O’Sullivan	11463	Suspended	07/19/17
TECHNICIAN	REG. #	SANCTION	DATE
Jasmine Smith	T13015	Revoked	02/15/17
Kiyomi Nichols	T18111	Suspended	02/16/17
Zacharie Famoso	T19032	Suspended	07/06/17
Crystal Abrims	T14353	Suspended	07/17/17
Britne Saunders	T16259	Suspended	07/17/17
Delsy Lima	T18334	Suspended	07/17/17
ESTABLISHMENTS	PERMIT #	SANCTION	DATE
Professional Arts Pharmacy	P01022	Fine & Reprimand	06/01/17
Marley’s Drug, Inc.	P07484	Fine	06/19/17
St. Mary’s Medical Park	None	Fine	06/28/17
Alco Pharmacy	PW0249	Fine	06/19/17
Superior Lane Pharmacy	P06480	Revoked	07/19/17
Sav-Rx Pharmacy	P06333	Fine	07/20/17

MEDICAID OPIOID PRESCRIBING POLICIES

The following policies took effect July 1, 2017 for both Medicaid Fee-for-Service and all 8 Managed Care Organizations (MCO):

Non-opioids are considered first line treatment for chronic pain. The CDC recommends expanding first line treatment options to non-opioid therapies for pain. In order to address this recommendation, the following evidence-based alternatives are available within the Medicaid program: NSAIDs, duloxetine for chronic pain; diclofenac topical; and certain first line non-pharmacological treatment options (e.g. physical therapy). Some MCOs have optional expanded coverage that is outlined in the attached document.

Prior authorization will be required for long-acting opioids, fentanyl products, methadone for pain, and any opioid prescription that results in a patient exceeding 90 morphine millequivalents (MME) per day.¹ A standard 30 day quantity limit for all opioids will be set at or below 90 MME per day. The CDC advises, “clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosages to ≥ 50 MME/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.” Moving forward, in order to prescribe a long acting opioid, fentanyl products, methadone for pain and opioids above 90 MME daily, a prior authorization must be obtained every 6 months.

The prior authorization will require the following items: an attestation that the provider has reviewed Controlled Dangerous Substance (CDS) prescriptions in the Prescription Drug Monitoring Program (PDMP); an attestation of a Patient-Provider agreement; attestation of screening patient with random urine drug screen(s) before and during treatment; and attestation that a naloxone prescription was given/offered to the patient/patient’s household member. Patients with Cancer, Sickle Cell Anemia or in Hospice will be excluded from the prior authorization process but they should also be kept on the lowest effective dose of opioids for the shortest required duration to minimize risk of harm. *HealthChoice MCOs may choose to implement requirements or limitations beyond the State’s policy.*

Providers should screen for Substance Use Disorder. Before writing for an opiate or any controlled substance, provider should use a standardized tool(s) to screen for substance use. Screening, Brief Intervention and Referral to Treatment (SBIRT) is an example of a screening tool.² Caution should be used in prescribing opioids for any patients who are identified as having any type of or history of substance use disorder. Providers should refer any patient whom is identified as having a substance use disorder to a substance treatment program.

Screening, Brief Intervention and Referral to Treatment (SBIRT), is an evidenced-based practice used to identify, reduce and prevent problematic use, abuse and dependence on alcohol and drugs. The practice has proved successful in hospitals, specialty medical practices, emergency departments and workplace wellness programs. SBIRT can be easily used in primary care settings and enables provider to systematically screen and assist people who may not be seeking help for a substance use problem, but who drinking or drug use may cause or complicate their ability to successfully handle health, work or family issues. The provision of SBIRT is a billable service under Medicaid. Information on billing may be accessed here: http://mmcp.dhmf.maryland.gov/MDOupdates/Documents/pt_43_16_edicaid_program_updates_for_spring_2017.pdf

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Patients identified with Substance Use Disorder Should be Referred to Substance Use Treatment. Maryland Medicaid administers specialty behavioral health services through a single Administrative Services Organization – Beacon Health Options. If you need assistance in locating a substance use treatment provider, Beacon Health Options may be reached at 800-888-1965. If you are considering a referral to behavioral health treatment for one of your patients, additional resources may be accessed at http://maryland.beaconhealthoptions.com/med_hc_professionals.html.

Naloxone should be offered to patients that meet certain risk factors. Both the CDC and Centers for Medicaid and Medicare Services have emphasized that clinicians should incorporate strategies to mitigate the risk of overdose when prescribing opioids.³ We encourage providers to prescribe naloxone – an opioid antagonist used to reverse opioid overdose – if any of the following risk factors are present: history of substance use disorder; high dose or cumulative prescriptions that result in over 50 MME; prescriptions for both opioids and benzodiazepine or non-benzodiazepine sedative hypnotics; or other factors, such as drug using friends/family.

Providers should use the PDMP every time they write a prescription for CDS. Administered by DHMH, the PDMP gives healthcare providers online access to their patients’ complete CDS prescription profile. Practitioners can access prescription information collected by the PDMP *at no cost* through the CRISP health information exchange, an electronic health information network connecting all acute care hospitals in Maryland and other healthcare facilities. Providers that register with CRISP get access to a powerful “virtual health record” that includes patient hospital admission, discharge and transfer records, laboratory and radiology reports and clinical documents, as well as PDMP data.

For more information about the PDMP, visit the DHMH website: <http://bha.dhmh.maryland.gov/pdmp/Pages/Home.aspx>. If you are not already a registered CRISP user you can register for **free** at https://crisphealth.force.com/crisp2_login. PDMP usage is highly encouraged for all CDS prescribers and will become mandatory (by law) in July 1, 2018.

If a MCO is implementing any additional policy changes related to opioid prescribing, the MCO will notify providers and beneficiaries.

¹Instructions on calculating MME is available at: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_doa-a.pdf

²A description of these substance use screening tools may be accessed at: <http://www.integration.samhsa.gov/clinical-practice/screening-tools>

³CDC guidance: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>; and CMS guidance: <https://www.medicare.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf>

INTRODUCING THE NEWEST BOARD STAFF MEMBERS....

Darchelle Lanteon-Edmonds has joined the Maryland Board of Pharmacy as the Licensing Specialist Lead. She comes to us after being employed for 10 years at DLLR at the Real Estate Commission.

Lisa Sanderoff is the new Investigation Supervisor. She is coming to the Board of Pharmacy with over 20 years of pharmacy management experience. Her most recent position was as a pharmacy manager with Naturecare.

NAVIGATING PRIVATE HEALTH INSURANCE COVERAGE FOR MENTAL HEALTH AND SUBSTANCE USE DISORDER EMERGENCIES

Maryland Insurance Administration

- To start the process of obtaining authorization for an inpatient admission, **call the number on the back of the patient's health insurance ID card first.**
- The insurance company will ask what facility you have in mind for the patient or what treatment is required. The insurance company will tell you the documents they need to make a determination.
- If a patient is in imminent danger to self or others, and the determination is made by the patient's physician or psychologist and a member of the medical staff of the facility who has admitting privileges, then a health insurance company cannot deny the first 24 hours of an admission based on medical necessity. Notify the company as soon as possible.
- For an **emergency inpatient admission** for treatment of a mental health or substance use disorder, **the insurance company must make a decision within 2 hours** of receiving the requested documents.
- If the insurance company denies the request for a admission, call **1-800-492-6116**. The Maryland Insurance Administration is available 24 hours a day for complaints in emergencies when care has not yet been rendered. In an emergency, the Maryland Insurance Administration will make a decision within 24 hours.
- If the Maryland Insurance Administration does not regulate the health insurance plan, your complaint will be sent to the agency that does.
- An insurance company is not allowed to retaliate against a provider for filing appeals with the insurance company or complaints with the Maryland Insurance Administration.
- The Health Education and Advocacy Unit in the Office of the Attorney General can assist with filing an appeal or complaint: 410-528-1840 (in Baltimore) or 1-877-261-8807.

IF THE INSURANCE COMPANY DOES NOT FOLLOW THE LAW, OR DENIES AN EMERGENCY ADMISSION, CALL THE MARYLAND INSURANCE ADMINISTRATION AT 1-800-492-6116

REMINDER to Check and Update your Contact Information

Please check your contact information (e-mail address, residential address, name, employer) by completing and submitting the Name/Address/Employer change form at: dhmh.maryland.gov/pharmacy (see left column, under Online Service)

ATTENTION PHARMACY TECHNICIANS

Pharmacy Technicians with National Certification **MUST** also be registered with the Maryland Board of Pharmacy in order to work as Pharmacy Technicians in Maryland [COMAR 10.34.34.04].

Overview and Treatment of Chronic Hepatitis C (HCV) Infection

By: Valerie D. Barnes, PharmD, MS, BCPS

Hepatitis C Virus (HCV) is a contagious viral infection that leads to inflammation of the liver. The course HCV infection varies in severity, ranging from a mild and limited infection to a serious, chronic illness. The Centers for Disease Control and Prevention (CDC) reported in 2014 that an estimated 30,500 cases of acute HCV infection were reported in the United States and an estimated 2.7 to 3.9 million people have chronic Hepatitis C. Several studies have shown that chronic HCV infection can have a significant negative effect on patients' health and quality of life. HCV is the main cause of end stage renal disease as well as the reason for most liver transplants, liver-related deaths, and hepatocellular carcinomas in the US.

Over the past 5 years, the treatment options and outcomes for HCV have been revolutionized by innovation in the pharmaceutical industry. In 2014, a class of medications known as direct-acting antiviral agents (DAAs) became available which provided a breakthrough in the treatment effectiveness and tolerability of chronic HCV infection. Prior to 2014, the mainstay of HCV treatment included a lengthy 24 to 48 week course of treatment with Pegylated interferon and ribavirin (IFN/RBV). This treatment produced mediocre cure rates at best, with most clinical studies demonstrating a sustained viral response (SVR), or clinical cure, in only 50% of treated patients or less. In clinical trials, DAAs produced SVR rates in >90% of treated patients, offering the first real hope of large scale cure and possible eradication of chronic HCV infection.

Transmission of HCV Virus

HCV is primarily transmitted through large or repeated exposure to infected blood. Less frequent transmission methods include sex with an infected person, sharing personal items contaminated with infected blood (i.e. razors, toothbrushes), or invasive healthcare procedures when devices or medications are contaminated.

Signs and Symptoms of Infection

Infection with HCV is often asymptomatic. When symptoms are present, they may be mild, nonspecific and not bothersome enough to prompt a visit to a healthcare professional. However, approximately 20% to 30% of persons newly infected with HCV will experience fatigue, abdominal pain, poor appetite or jaundice. Other possible symptoms include fever, dark urine, clay-colored stool, nausea, vomiting and joint pain.

Who should be tested?

All persons with an increased risk for contracting HCV should be screened and tested for the virus. In 2012, the CDC established additional screening guidance to include a large section of the US population known as Baby Boomers, individuals born between 1945 and 1965. The CDC recommends that Baby Boomers be tested for HCV at least once in their lifetime, regardless of risk factors as data has shown that persons born between 1945 and 1965 are 5 times more likely to have hepatitis C. Other persons considered to be high risk who should be tested include those who:

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*The Maryland Board of Pharmacy would like to thank
Pharmacists' Education & Advocacy Council (PEAC)
for their years of substance abuse treatment services to our licensees.*

- Inject or injected illegal drugs at any point in their life
- Received clotting factors prior to 1987
- Received a blood or organ transplant prior to July 1992
- Ever received a long term hemodialysis treatment
- Have known exposure from a HCV positive individual (e.g. healthcare needle stick, organ recipient from an HCV positive donor)
- Are HIV positive
- Have signs and symptoms of liver disease
- Are born to HCV positive mothers
- Receive a tattoo in an unregulated setting
- Are incarcerated

Treatment

The introduction of direct-acting antivirals (DAAs) has largely improved the success rate of HCV treatment and markedly reduce the occurrence adverse effects compared to previous IFN/RBV based regimens. There are several DAA treatment regimens available and the choice of treatment and the treatment duration depend on many factors such as genotype, previous treatment experience, presence of cirrhosis, and drug-drug interactions amongst other considerations.

Table 1 provides a listing of currently available DAAs, their brand names and the HCV genotypes for which they are approved to treat by the Federal Drug Administration (FDA). The selection of HCV medication may vary from patient to patient based on patient-specific factors. Additionally, some DAA regimens may be given in conjunction with Ribavirin to either improve effectiveness or shorten the duration of treatment. Most DAA regimens have a recommended treatment duration of 12 weeks but there are exceptions. Sofosbuvir/ledipasvir is FDA approved for 8 weeks of treatment in patients who have mild liver disease and a HCV viral load less than 6 million copies. For those patients not able to tolerate Ribavirin or who prefer a Ribavirin free regimen, treatment duration with certain DAA medications may extend to 24 weeks of treatment. There are no significant adverse effects associated with DAA treatment. The most common patient complaint from therapy is headache, fatigue and nausea.

Table 1. FDA approved Direct Acting Antiviral Agents for treatment of HCV

Medication Ingredients	Brand Name	Genotypes treated
Sofosbuvir	Sovaldi	1,2,3,4
Sofosbuvir/ledipasvir	Harvoni	1,4,5,6
Sofosbuvir/velpasavir	Epclusa	1,2,3,4,5,6
Sofosbuvir/velpasavir/voxilaprevir	Vosevi	1,2,3,4,5,6
Paritaprevir/ritonavir/ombitasvir/dasabuvir	Viekira Pak	1
Sofosbuvir/simeprevir	Olysio	1
Daclatasvir/sofosbuvir	Daklinza Sovaldi	+ 1,3
Elbavir/grasoprevir	Zepatier	1,4

Continued on page 14

During treatment with DAAs, some clinical monitoring may be required by the healthcare provider. An important milestone in HCV treatment occurs 12 weeks post-treatment completion when the healthcare provider will draw lab work to determine if the HCV virus is still detectable in the blood. An undetectable viral load at 12 weeks after treatment has completed is considered a clinical cure from HCV. It is important to note, however, that there is no long-term immunity obtained to HCV virus once a cure has been achieved. Persons remain at risk for HCV reinfection if they engage in high risk behaviors.

Newer DAAs continue to be developed by the pharmaceutical industry. One medication, Vosevi, was just FDA approved July 2017. These new generation DAAs allow for treatment of the few patients who did not successfully clear the HCV virus from treatment with early generation DAAs.

References

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2. Sebhatu P, Martin MT. Genotype 1 hepatitis C virus and the pharmacist's role in treatment. *Am J Heal Pharm.* 2016;73(73):764-774. doi:10.2146/ajhp150704.
3. Chung RT, Naggie S, Kim AY, et al. INTRODUCTION | Recommendations for Testing, Managing, and Treating Hepatitis C. Recommendations for Testing, Managing, and Treating Hepatitis. <http://www.hcvguidelines.org/full-report/introduction>. Published 2016. Accessed July 1, 2016.
4. Higleyman L. FDA Approves Gilead's Epclusa Combo Pill for All Hepatitis C Genotypes. *HIVandHepatitis.com*. <http://www.hivandhepatitis.com/hcv-treatment/approved-hcv-drugs/5759-fda-approves-gileads-epclusa-combo-pill-for-all-hepatitis-c-genotypes>. Published 2016. Accessed July 1, 2016.
5. Feld JJ, Jacobson IM, Hézode C, et al. Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection. *N Engl J Med.* November 2015. doi:10.1056/NEJMoa1512610.

ATTENTION PHARMACIES

Electronic Inspection Process Fully Operational

The Board has completed a six month project to integrate the inspections of all pharmacy permit holders to a fully electronic process. This new electronic process allows the pharmacy inspectors to be more efficient when conducting onsite inspections. Rather than manually entering 31 steps, they can now electronically complete the entire inspection in only 6 steps. The inspection data flows directly to the Boards database of licensees and eliminates the need to print additional paper copies, and also scans the inspection reports into the database with a simple click.

SAVE THE DATE

Continuing Education Breakfast

“How Medical Marijuana and Opioids Impact Pharmacy”

Sunday, October 22, 2017

7:30 am – 12:45 pm

Conference Center at the Maritime Institute
692 Maritime Boulevard, Linthicum Heights, MD 21090

\$10 Registration Fee

Pharmacists, Technicians, and Interns can register at
health.maryland.gov/pharmacy
by clicking on the link on the right column.

BOARD COMMISSIONERS

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At-Large Representative

BOARD MEETINGS

Public Pharmacy Board meetings begin at 9:30am on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings and awards 2 LIVE CEs to all licensees.

2016 PUBLIC BOARD MEETINGS

Third Wednesday of each month

August 16, 2017
September 20, 2017
October 18, 2017

Location: 4201 Patterson Avenue
Baltimore, MD 21215

CONTACT DIRECTORY

Customer Service Center 410-764-4755 ▪ mdh.mdbop@maryland.gov ▪ health.maryland.gov/pharmacy ▪ 1-800-542-4964

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