VOLUME XV, ISSUE 1 SPRING/SUMMER 2020

Board of Pharmacy News

In This Issue

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists and registering pharmacy technicians and student interns, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

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In The Age of COVID-19

Deena Speights-Napata, Executive Director

During this uncertain season of unknown outcomes and far too little security, the Maryland Board of Pharmacy wants all of our licensees and customers to know that we are committed to you. Throughout the past month the board has proactively addressed the hundreds of phone calls, emails, and letters we've received from pharmacists, technicians, physicians, politicians, health care financing groups, insurers, health administrators, and lobbyists concerning COVID-19 questions and concerns you have brought to our attention.

The board has effectively used its small committee structure and public board arena to address the issues that matter to you. We've literally spent hours hashing over issues being addressed for the first time ever; lunches haven't been eaten, children haven't been played with, and many of us have been putting in lots of overtime to provide you with what you need...answers. Today this column is dedicated to those we thank for asking us good questions that make us work even harder to provide good practical solutions.

Here are some of our answers….

COVID-19 Policy and Practice

Remote Processing

In order to support the Governor and Secretary of Health with their directives to telework and social distance to the extent possible, the Board will not enforce requirements regarding the direct supervision of pharmacy technicians by a licensed pharmacist if the technicians are engaged in remote processing of delegated pharmacy acts. Remote processing of delegated pharmacy acts includes prescription or order entry, other data entry, and may also include insurance processing and other administrative functions. Pharmacists currently have the ability to engage in remote processing, which may also include clinical functions such as drug utilization review, authorizing release of medications from automated medication systems, providing drug information, and other similar pharmaceutical services. Remote processing does not include the physical handling of any prescription drugs or devices

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Virtual Inspections

In April 2020 the board implemented virtual facility inspections to support the state COVID-19 social distancing policies, and to protect board staff. Most elements of the inspection process have been completed utilizing videoconferencing and submission of licensing documents using email and faxing. This practice has allowed board staff to monitor and evaluate pharmacy practices while not endangering staff, customers, technicians, and pharmacists.

Can pharmacists who are licensed in other states practice in Maryland in a community pharmacy during the declared state of emergency?

At this time, the answer is no. The executive order on health care matters signed by Governor Hogan on March 16 allows for persons licensed as health care practitioners in other states to practice in "health care facilities" in Maryland if certain criteria were met. The definition of "health care facility" used in the order does not include community pharmacies. Therefore, at this time pharmacists that do not hold a Maryland license are not permitted to practice in Maryland in a community pharmacy.

FDA Temporary Compounding Policy

Maryland-licensed pharmacies that want to implement this temporary policy will be required to submit their request in writing to the board for consideration. Board authorization is required before any pharmacy may provide compounded products under the auspices of this FDA policy guidance.

Requests and inquiries should be submitted to mdh.mdbop@maryland.gov

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Refills

The Maryland Pharmacy Act, Sec. 12-506(c), allows a pharmacist, during a state of emergency, to refill a prescription for which a refill has not been authorized if: (1) the pharmacist is unable to obtain authorization from the prescriber; (2) the refill is not for a controlled dangerous substance; (3) the quantity dispensed does not exceed a 30-day supply or unit of use; and (4) the pharmacist notifies the prescriber of the refill within 7 days.

Licensing

Pursuant to an Executive Order issued by Governor Hogan on March 12, 2020, all licenses, registrations, and permits issued by the Board set to expire during the state of emergency and catastrophic health emergency shall be extended to the 30th day after the date the state of emergency is terminated and the catastrophic health emergency is rescinded. No late fees or reinstatement fees will be imposed during this time period. To the extent it is able, the Board will accept and continue to process renewal applications during the state of emergency and catastrophic health emergency.

In keeping with the Governor's policy extending expiration dates for licenses, and maintaining the ability of the pharmacist workforce to administer influenza and other CDC-recommended vaccinations, the Board will not take enforcement action based on expired or inactive CPR certifications held by pharmacists registered to administer vaccinations if the CPR certification becomes inactive or expires during the state of emergency. Upon the termination of the state of emergency, the Board will allow affected pharmacists 30 days to update their live CPR certification.

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Licensing (cont'd)

The Board will not impose the 30-day notice requirement associated with a change of business hours for a permitted pharmacy or wholesale distributor pursuant to COMAR 10.34.30.05(A). The Board will instead require advanced notice as soon as practicable if an establishment location is forced to change its hours or temporarily close. Please note that all other requirements still apply, such as notice to patients, transfer of prescriptions, and documentation of transfers of any drug inventory

License Testing Locations:

As of March 31, 2020, 130 Pearson testing sites have reopened across the country, with plans to reopen the remaining locations sometime in April. PLEASE NOTE: The Board has recently learned that none of the reopened Pearson VUE testing centers are located in Maryland, Virginia, or the District of Columbia. Please contact Pearson directly for plans about opening testing centers in these jurisdictions.

Due to limited capacity and significant demand, it may take longer than usual to receive a test date. Rescheduling a date offered by Pearson may also result in lengthy delays, so they are recommending every effort be made to avoid rescheduling a test. For further information, please check the Pearson and/or NABP websites.

Criminal Background Checks and "Live" CEs

The Board has received a number of inquiries related to criminal background checks, specifically related to difficulties in fingerprinting. Although all CJIS MVA locations remain closed, the CJIS Fingerprinting Storefront located at 6776 Reisterstown Road, Baltimore, is now open for fingerprinting (please note, fingerprinting is currently BY APPOINTMENT ONLY at this facility). In addition, the Board understands a number of private fingerprinting facilities remain open. Please check the CJIS website for further information, at https://www.dpscs.state.md.us/publicservs/fingerprint.shtml

Pursuant to Governor Hogan's March 12, 2020 Executive Order, all licenses set to expire during the state of emergency have been extended until 30 days after the state of emergency is terminated. The Board, however, understands that many pharmacists may want to renew their licenses during the state of emergency. The Board also understands that many "live" continuing education courses and conferences have been canceled for the foreseeable future. As such, the Board has determined that it will waive the requirement that two (2) hours of continuing education be obtained via live instruction for pharmacists who renew their licenses during the state of emergency.

Graduating Pharmacy School Interns

Pharmacy students who are graduating from pharmacy school and are currently registered with the Board as registered interns may continue to work under the registration after graduation. Pursuant to Governor Hogan's Executive Order, dated March 12, 2020, in the event that a pharmacy intern's registration expires during the state of emergency, the intern may continue to work on the expired registration until 30 days after the state of emergency is terminated.

Pharmacy Inspection Reminder

On several inspections it was noted that prescription-only items were stocked in the OTC area.

Reminder that the Maryland Pharmacy Act, **Section 12-403(12)** states**:** [A pharmacy for which a permit has been issued] Shall store all prescription or nonprescription drugs or devices properly and safely subject to rules and regulations adopted by the Board.

A Proud Time for Pharmacy

A Letter from Kevin Morgan, President, Maryland Board of Pharmacy

Dear Pharmacists, Technicians, and Board of Pharmacy Staff,

The last day that I was at the Board of Pharmacy office was on March 13th, which honestly feels like a year ago. Since that date everything has changed.

I am beyond amazed seeing what pharmacists and technicians are doing in the face of these most challenging times. Circumstances that none of us have ever seen before, or could have predicted, have our professionals working right on the frontlines. They are not only doing what they were trained to do as a health care professional, but literally standing as essential pillars in our communities. As businesses, organizations, and events are closed/cancelled and rescheduled, we have heard from our government leaders that pharmacies are vital to providing crucial medications and services to society during this COVID-19 pandemic.

As this crisis evolved, pharmacists, technicians, and pharmacies were forced to adjust to the challenges of providing care. Everything from limiting the number of customers in their stores to expanding drive-thru capabilities and initiating curbside pick-up! No matter the hurdles our professionals have encountered we have found innovative ways to successfully help our patients. This is a testament to our ingenuity and dedication to putting the needs of the patient first.

In the beginning government officials, communities, organizations, businesses and families were preparing for the absolute worst. Much like you would prepare for an impending hurricane, we store supplies, board the windows, fill sand bags and move to higher ground. Then even if the hurricane makes a direct hit to your area it is the community that is well prepared that fairs out the best.

My fellow pharmacy professionals have proven that they had the ability to prepare rapidly and completely while providing wonderful guidance to our patients as part of their COVID-19 plan. This gives me great confidence that as the response to this virus continues to progress over the coming weeks and months that our profession has shown great skill in quickly modifying and reworking efforts to the ever changing landscape.

I am proud to let everyone know that the Board of Pharmacy staff have been exceptional throughout this crisis. What the Board is going through right now requires extreme levels of communication, collaboration, preparation and execution. The board staff continues to support the public and the pharmacies of Maryland with very little disruption.

If you went to the office now you would find it nearly empty, but the work goes on. It would be impossible to list all of the actions that the administrative and IT teams did to make this all possible. Phones are answered all day, questions are responded to timely and licenses are processed without delay. Most of our staff transitioned to working remotely. The licensing department was able to make this move seamlessly. The investigative and call center teams have all been able to make the necessary changes to work remotely. Our inspection group has developed a virtual inspection process to ensure that the Board continues to audit pharmacies and support the public.

I am also inspired by my fellow commissioners. This public health crisis has impacted their personal and professional lives but everyone on this commission has remained engaged with the Board's work almost daily. They have worked long hours to ensure that the BOP was doing everything possible to serve the State and to keep pharmacies operational along with ensuring public safety.

(Continued from page 4)

There is constant communication with the Nursing and Physicians boards, Office of Controlled Substance Administration, Maryland Department of Health, National Association of Boards of Pharmacy, as well as several other state and national associations.

Staff is compiling all of the questions that come into the call center and prioritizing those that concern the COVID-19 crisis. We are addressing the questions and providing answers quickly sometimes in hours as well as monitoring communication from the Governor, CDC, DEA, other states and associations to provide the most up to date guidance for our licensees.

Lastly, as I reflect on what the pharmacists, technicians, Board of Pharmacy staff and fellow commissioners have all done to support Maryland residents, I have never been more proud to be a pharmacist. It is an added honor to have the opportunity to serve you as the President of the Maryland Board of Pharmacy during this time.

Please be safe and I look forward to passing along my appreciation when permitted in person.

Thank you,

Kevin M. Morgan, PharmD
President
Maryland Board of Pharmacy

New Board Member Announcements

Kristen Fink

The Maryland Board of Pharmacy would like to welcome **Kristen Fink, PharmD, BCPS, CDE** as our new At-large Representative. Kristen graduated pharmacy school from Duquesne University and went on to complete a Managed Care Pharmacy Practice Residency at Kaiser Permanente. Following her Residency, Dr. Fink spent 10 years in clinical practice as a Primary Care Clinical Pharmacy Specialist at Kaiser Permanente. Dr. Fink is currently the Director of the PGY1 Residency Program and PGY1 Managed Care Residency Program and Academic Affairs Coordinator for the Kaiser Permanente Mid-Atlantic Region. We welcome you, Kristen, to the Maryland Board of Pharmacy.

Peggy Glascoe Geigher

The Maryland Board of Pharmacy would also like to introduce **Peggy Glascoe Geigher, MPA** as our new Consumer Representative. Peggy spent 25 years in medical education at the Association of American Medical Colleges – first as an Assistant Director, then as the National Program Manager for the Summer Health Professions Education Program. Peggy was accepted into the National Urban Fellows Program where received an MPA from the City University of New York. She retired in 2018. We welcome you, Peggy, to the Maryland Board of Pharmacy.

Drug Administration Practices: To Crush or Not To Crush?

Tenielle Watkins, PharmD and Ellen H.Yankellow, PharmD

One of the most common questions that pharmacists receive is the age old, “Can this medication be crushed?”

While crushing medications may seem like an accommodating and compassionate decision to help facilitate medication administration for children, patients with dysphagia, enteral tubes, or those with a history of difficulty swallowing tablets and capsules, potential consequences must always be thoroughly considered. There are often comparable liquid formulations available. When in doubt, do not crush, open, chew, or split any medication; ask a pharmacist first!

How could crushing a medication pose a problem? There are unpleasant and potentially dangerous complications that can result from crushing medications that are not formulated to support being crushed. Most common examples of formulations that should not be crushed include extended, controlled, or timed-release, long-acting, delayed-release, enteric coated, film coated, and abuse-deterrent. Other examples are medications that are teratogenic or chemotherapeutic.[2]

When an immediate-release medication is administered, our bodies are typically able to “immediately” begin acting to absorb, distribute, metabolize, and excrete that medication.[3] Long-acting or extended, controlled, and timed-release medications are formulated to slow this process in the body, allowing for a small amount of the medication to be released consistently over a longer period of time. If these medications are crushed or opened for administration, contents that were originally meant to be processed in the body over time are forced upon the body all at once. This can lead to increases in side effects and adverse events[4], including too much medication in the body at once (overdose). Consequences can range from mild to severe and short-term to permanent.

Delayed-release and enteric coated formulations are designed to prevent medications from being absorbed by the body until they reach a certain location or environment (pH) within the digestive tract. This may be desirable to help protect certain areas of the digestive tract from being damaged by the drug, or conversely, to prevent the body from breaking down the medication before it reaches the location where it needs to work (e.g. stomach, intestines, etc.)

Film-coatings are typically used to improve stability (protect the ingredients from light, moisture, gas), increase ease of swallowing, make a product more visually appealing, and/or to cover medications that have extremely unpleasant tastes or smells.[5] Crushing medications formulated with a film-coating may result in degradation of the ingredients, make medications more difficult to swallow, or expose noxious flavors or scents underneath. Potential consequences include loss of efficacy, decreased tolerability, and reduced patient adherence.

Avoiding the crushing of teratogenic and chemotherapeutic agents is largely to provide protection for those handling the drugs prior to administration (nursing, pharmacy, caretakers), and to reduce contact between the active ingredients and delicate tissues of the digestive tract. Crushing abuse deterrent medication formulations produces a range of results including production of a gel-like substance or release of an unpleasant taste/odor.

The Institute for Safe Medication Practices (ISMP) maintains a publicly accessible website that reflects a list of oral dosage forms that should not be crushed.[2] Examples of medications from each category discussed above can be located on this list.

References

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2. Institute for Safe Medication Practices. Oral Dosage Forms That Should Not Be Crushed. https://www.ismp.org/recommendations/do-not-crush . Updated November 1, 2018. Accessed August 20, 2019.
3. Perrie Y, Rades T. FASTtrack Pharmaceutics, Drug Delivery and Targeting. Pharmaceutical Press; 2012.
4. Cornish P. "Avoid the Crush": Hazards of Medication Administration in Patients with Dysphagia or a Feeding Tube. CMAJ. 2005;172(7):871-2.
5. Elder D. Design, Formulation and Manufacture of Film-Coated Drug Products. European Pharmaceutical Review. October 25, 2017. Issue 5. https://www.europeanpharmaceuticalreview.com/article/68115/design-formulation-manufacture/ . Accessed August 25, 2019.

Inspection Issues First Quarter 2020

The Maryland Board of Pharmacy investigates complaints that come to the Board from various sources. Complaints come from consumers, healthcare professionals, pharmacy boards outside of Maryland, federal agencies, and from Board inspections of pharmacies, sterile compounding facilities, and distributors in Maryland. The Board requires that all pharmacies be inspected on an annual basis and distributors be inspected on a biannual basis.

The following **represents** a break out of the issues that have come to the Board from the inspection of pharmacies across the state in the first quarter of 2020:

DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
George Afari Tawiah	16742	Suspension	1/23/2020
Louis Onwuanaibe	17332	Revocation	3/2/2020

ESTABLISHMENTS	LIC. #	SANCTION	DATE
Henry Ford Pharmacy Advantage Southfield	P06219	Fine	1/2/2020
Key Compounding Pharmacy	P04568	Pre-Charge Consent Order	2/3/2020
East Pines Pharmacy & Medical Equipment	P04821	Reprimand & Fine	2/14/2020

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Andrea Baker	T05345	Revocation	1/15/2020
Shantel Howard	T18720	Revocation	1/15/2020
Cynthia R. Price	T09577	Revocation	1/15/2020
Tyrone Watkins	T12012	Revocation	1/15/2020
Wales Davis	T08120	Suspension	1/23/2020
Charlie Dunkerly	T20112	Summary Suspension	2/6/2020
Joseph Danielson	T20330	Revocation	2/19/2020
Jordan Edelman	T21870	Revocation	2/19/2020
Chameka Michelle Hendricks	T17269	Revocation	2/19/2020
Anber R. Simon	T13799	Revocation	2/19/2020
Donetta Washington	T22493	Surrender	2/19/2020
Kadiah Kamara	T18809	Summary Suspension	4/17/2020
Victoria Scanlon	T09244	Summary Suspension	4/24/2020
Candyce A. Penn	T17544	Summary Suspension	5/6/2020
Aubrey Holland	T21747	Summary Suspension	5/6/2020

Pharmacist Administration of Vaccinations

Each year pharmacists administer thousands of vaccinations to patients in our State. The contributions of pharmacists to improve the health of our citizens is recognized and appreciated.

The requirements to administer vaccinations are summarized in the Code of Maryland Regulations, 10.34.32.03. If you possess a registration authorizing you, as a licensed pharmacist, to administer vaccinations you must comply with all of the requirements including the possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

If you are no longer providing immunizations, you must still maintain an active certification card for basic cardiopulmonary resuscitation or you should return your registration authorizing you to administer vaccinations to the Maryland Board of Pharmacy.

Board of Pharmacy is currently accepting submissions from readers for upcoming newsletter articles. Desired subjects covered may include public health or general educational topics. Submissions should be 500 words or less, in Microsoft Word document format.

Send any submissions to mdh.mdbop@maryland.gov by July 1st.

The Board does not guarantee that articles submitted will be published. Authors will be contacted as to whether the submission will be used.

National Association of Boards of Pharmacy
National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain: Developing the Evidence,* also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines

based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

BOARD COMMISSIONERS

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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.

2020 PUBLIC BOARD MEETINGS

Third Wednesday of each month

May 20th, 2020
June 17th, 2020
July 15th, 2020

Location: 4201 Patterson Avenue
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