

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 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.

The Maryland Board of
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Reflections From The Maryland Board of Pharmacy OUTGOING PRESIDENT



As I approach the end of my second term representing Home Care/Home Infusion Seat on the Board and outgoing President, it would only be fair if I formally signed off to those whom I took the oath to serve and those who supported me through my journey on the Board.

As I reflect on the last 8 years, I have had the privilege of serving alongside an elite group of Board members; Pharmacist and Consumer members alike; and a dedicated team of staff, leadership, Councils and Executive Directors. Some even went out of their way early on to teach me ropes of the road. I could not have made it through the learning curve without them and cannot thank them enough.

All my fellow board members hold full time positions and/or have additional professional commitments while serving as a Board member. They never hesitate to serve and in most cases sacrifice their personal time to carry out their responsibilities as a Board member. They take part in committee meetings, case resolution conferences, disciplinary hearings, conferences and legislative meetings at local and national stage. To be part of this group is special and I have learned something from each one. As a Maryland resident, I am beyond grateful for their service. It has been an honor to serve with these leaders.

Prior to joining the board, my exposure to the operation of the Board was mostly through the licensing process. Little did I know that my journey ahead was to be defined by the staff, primarily. Shortly before becoming a Board member, I had the opportunity to serve as a stakeholder on a taskforce and began to appreciate the depth of expertise in the legislative front, brilliance of the legal team and sheer commitment despite the limited resources and high demands at all levels of the staff. I have a high degree of respect for their expertise and attention to details. As I scan through our progress, my heart fills with joy and pride for the amazing staff, hardworking investigators and inspectors, dedicated management team, exceptional legal team and leadership of our Executive Director for their accomplishments.

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Moving through almost every committee, chairing multiple committees at some point and eventually serving as the President of the Board, I have been the first hand witness to a journey towards improvement by all involved. Our improvements in the response time to inquiries and turn around for processing applications are only a small sample of the mountain of challenges that the Board and Staff collectively have overcome in the last few years.

Not too long ago, during a turbulent time with constant regulatory updates, subsequent overload of new tasks, exhaustion and significant transitions within the team, we took the time to redefine our image and transform our operations. As a true Infusion pharmacist, I described my personal goal for transformation as “Infusing Passion into everything we do from handling a concern from public, to phone call from a licensee,...”. As they say, be careful what you ask for. Before I knew, our consultant had those two words, Infusing Passion, plastered all over the place. Over the next couple of years, we invested in our technology for office and field staff, updated our organization structure, moved to a new space, created a new call center, said many goodbyes, and welcomed many new faces. We have come a long way and with ongoing focus on public safety and customer experience, we continue to evolve. Our passion lives on and fuels our commitment to make every task, every effort and every resource count for the safety of Maryland residents.

This journey to excellence would not be possible if it were not for those who showed up at our public meetings and/or wrote letters to share their experiences. You challenged the Board to do better and dig deeper. I extend my most sincere appreciation to you, our constituents, stakeholders, and partners who kept your watchful eyes on us during my time and urge you to continue to keep the lines of feedback and communication open. You have invigorated my passion for public health and service; You are the reason we are here to serve. You have the ears of staff and the Board.

Last but not least, I could not have had this enriching and fulfilling experience if it was not for the support of my “village”. I have been fortunate to have the constant and unconditional support from my family at home and the Johns Hopkins Medicine. I am surrounded by a special group of leaders, an amazing boss, peers and staff at Johns Hopkins Home Care Group who have selflessly encouraged me and cheered on while covering for me during my absences on Wednesdays. My husband and two children have been beyond patient and flexible. Their pride in my contributions to public safety has been a great validation and true source of inspiration. I am forever in debt and grateful to my entire support system and village.

I believe the Board is in trusted hands with the current Board members and more importantly with a strong leadership of our Executive Director and passionate team of staff who will carry on the torch for years to come. I could not be more proud of our journey and happy to pass the baton on to my fellow Board Member and President Elect, Kevin Morgan.

Thank you for the opportunity to serve, learn and grow.

Sincerely,

Mitra Zare Gavgani, Pharm D

Opioid Overdose Crisis

Revised February 2018

Every day, more than 115 Americans die after overdosing on opioids.¹ The misuse of and addiction to opioids — including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.²

How did this happen?

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive.^{3,4} Opioid overdose rates began to increase. In 2015, more than 33,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl, a powerful synthetic opioid.¹ That same year, an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers, and 591,000 suffered from a heroin use disorder (not mutually exclusive).⁵ Here is what we know about the opioid crisis:

- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.⁶
- Between 8 and 12 percent develop an opioid use disorder.⁷⁻⁹

- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin.⁷⁻⁹
- About 80 percent of people who use heroin first misused prescription opioids.⁷

This issue has become a public health crisis with devastating consequences including increases in opioid misuse and related overdoses, as well as the rising incidence of neonatal abstinence syndrome due to opioid use and misuse during pregnancy. The increase in injection drug use has also contributed to the spread of infectious diseases including HIV and hepatitis C. As seen throughout the history of medicine, science can be an important part of the solution in resolving such a public health crisis.

What are HHS and NIH doing about it?

In response to the opioid crisis, the U.S. Department of Health and Human Services (HHS) is focusing its efforts on five major priorities:

1. improving access to treatment and recovery services
2. promoting use of overdose-reversing drugs
3. strengthening our understanding of the epidemic through better public health surveillance
4. providing support for cutting-edge research on pain and addiction
5. advancing better practices for pain management

The National Institutes of Health (NIH), a component of HHS, is the nation's leading medical research agency helping solve the opioid crisis via discovering new and better ways to prevent opioid misuse, treat opioid use disorders, and manage pain. To accelerate progress, NIH is exploring formal partnerships with pharmaceutical companies and academic research centers to develop:

1. safe, effective, non-addictive strategies to manage chronic pain
2. new, innovative medications and technologies to treat opioid use disorders

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3. improved overdose prevention and reversal interventions to save lives and support recovery

In a plenary address during the National Rx Drug Abuse and Heroin Summit in April 2017, NIH Director Dr. Francis Collins describes the NIH opioid research initiative headed up by the National Institute on Drug Abuse (NIDA). In a May 2017 New England Journal of Medicine special report, NIDA Director Dr. Nora Volkow and Dr. Collins outline how science can provide solutions to the opioid crisis and as they offer a 3 pronged strategy for research partnerships.

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ATTENTION LICENSED PHARMACISTS

To register and re-new as an immunizer, **CPR MUST BE LIVE.**

The Maryland Pharmacy Law Book, Code of Maryland Regulations, Chapter 32.03.2(b) states, that the registration form shall include verification from the licensed pharmacist of the following: ***“Possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction”*** such as American Red Cross, American Heart Association, or local fire departments.

Check Google for LIVE CPR classes.

DISCIPLINARY ACTIONS

<u>PHARMACIST</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Emmanuel Fapohunda	13846	Suspended	11/16/2017
Emmanuel Bertrand	13099	Probation	01/19/2018
<u>PHARMACY TECHNICIAN</u>	<u>REG. #</u>	<u>SANCTION</u>	<u>DATE</u>
Devin Smith	T03931	Suspension	11/20/2017
Mary Burlock	T15658	Suspended	11/30/2017
Sherika Pinkney	T04262	Probation	11/30/2017
Maegan Jackson	T07985	Revoked	01/02/2018
Jazzmine Anderson	T16514	Revoked	02/21/2018
Britne Saunders	T16259	Revoked	02/21/2018
<u>ESTABLISHMENT</u>	<u>PERMIT #</u>	<u>SANCTION</u>	<u>DATE</u>
Tailor Made Compounding	P07527	Fine	11/13/2017
Germantown Professional Pharmacy	P06662	Fine	11/15/2017

Update for Pharmacists Regarding the Naturopathic Formulary

On January 24, 2018, the Maryland Board of Physicians (Board of Physicians) approved a naturopathic formulary for use by Maryland licensed naturopathic doctors (NDs). With a few exceptions (oxygen, auto-injectable epinephrine, diaphragms, and cervical caps), the formulary may not include prescription drugs or devices or controlled substances.

The Board of Physicians began licensing NDs on March 1, 2016. In 2017, the Naturopathic Doctors Formulary Council (NDFC) formed to develop and recommend to the Board of Physicians a formulary. The NDFC includes seven members, including a pharmacist.

To verify the license of an ND, please visit the Board of Physicians' website at www.mbp.state.md.us and click on 'Look up a license.'

The naturopathic formulary is located at https://www.mbp.state.md.us/licensure_ahapp_nat_form.aspx on the Board of Physicians' website.

Please watch for future updates as the Board of Physicians and the Board of Pharmacy work together on a set of Frequently Asked Questions (FAQs) regarding the naturopathic formulary.



FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA’s website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC’s *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, “Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015,” can be accessed on the CDC website at www.cdc.gov/mmwr/index.html in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient’s family member or close friend, which may be found in the August 2017 document, “AMA Opioid Task Force naloxone recommendations,” available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.

FAQs about Technicians' Renewal

1. What are the requirements needed to renew my registration?

In order to renew you will need to submit a renewal application with the appropriate board fee along with 20 hours of approved continuing pharmaceutical education (CEs) within the 2-year period immediately preceding the registrant's renewal application.

If this is the first time you are renewing your Pharmacy Technician Registration the Board of Pharmacy will only require 10 hours of CEs

2. Can I renew my pharmacy technician registration online?

Yes, you can renew your pharmacy technician registration online. If you have any questions about online renewals please visit our FAQ sections for Online Renewals.

3. I would like to reinstate my pharmacy technician registration. What are the requirements?

Depending on how long your registration has been expired your requirements will vary. Please read the requirements listed under the time frame your registration has been expired below:

It has been less than 2 years since my registration expired.

In order to reinstate your pharmacy technician registration, you will need to submit a reinstatement application, 20 continuing education credits, and the appropriate board fee.

It has been more than 2 years since my registration expired.

In order to reinstate your pharmacy technician registration, you will need to submit a reinstatement application, 20 continuing education hours/credits, appropriate board fee and provide proof of passing a Board approved training programs exam or National certification

Pharmacy Technician forms can be downloaded from the Board's web site.

CONGRATULATIONS, PHARMACISTS!!!

As of March 2, 2018, 91.37% of all pharmacists have registered with **CRISP** for the **Prescription Drug Monitoring Program (PDMP)**.

For the 1011 pharmacists still needing to register, please register at:

<https://crisphealth.org/services/prescription-drug-monitoring-program-pdmp/pdmp-registration/>

NABP Services unavailable March 20th through April 2nd

The National Boards of Pharmacy (NABP) is finalizing a new upgraded online system that will increase communication efficiency between NABP and the state boards of pharmacies, pharmacists, students, and technicians.

To install the new system NABP services will be unavailable from March 20, 2018 at 5 PM CT until approximately April 2, 2018 at 12 PM CT.

During this time NABP testing applications, score reports, practice tests, licensure transfer applications, CPE Monitor, and publication ordering will not be available.

If you have questions or concerns please contact the Maryland Board of Pharmacy at [410-764-4755](tel:410-764-4755).

RECRUITMENT for Approved Repository Locations throughout Maryland

Go to health.maryland.gov/pharmacy/Pages/drug-repository.aspx and click onto the Maryland Prescription Repository Program Application. This program is designed to provide for the proper disposal of prescription of drugs, as well as to assist needy individuals.

There is no board fee associated with this program. Your pharmacy will be notified about approval.

REMINDER to Check and Update your Contact Information

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

STUDENT TECHNICIAN EXEMPTION FORM

NOW on Board Website

<https://health.maryland.gov/pharmacy/docs/BOP-Forms/APPS/technicians/Pharmacy%20Student%20Technician%20Exemption%20Form%20Final.pdf>

New Lockbox Vendor

We are happy to announce that MD State Government has partnered with a new vendor for Lockbox Services. The old vendor was Citibank.

The overnight and priority payment address has changed. The new overnight and priority mail address is below:

**Wells Fargo Bank
Attn: State of MD – Board of Pharmacy
Lockbox 2051
7175 Columbia Gateway Drive
Columbia, MD 21046**

Regular mail payment and application address will remain the same with the change to Wells Fargo.

If you have any further questions please refer to The MD Board of Pharmacy website or contact our office at 410-764-4755.

Pharmacy Renewal Time!!

Spring is renewal time for all pharmacies licensed by the Maryland Board of Pharmacy (Board). All pharmacy permits expire on May 31, 2018. The renewal period for Maryland pharmacy permits is from March 14, 2018 through May 31, 2018. Renewal notices will be mailed in early March. The online renewal process will be available in mid-March. Visit the Board website at <https://health.maryland.gov/pharmacy/Pages/index.aspx> for more information.

In order to avoid a late fee, a completed renewal application, including all attachments and the appropriate renewal fee, **must** be postmarked or received by the Board no later than May 1, 2018. Operating a pharmacy without a renewed permit is punishable by a fine not to exceed \$50,000. COMAR 10.34.11.09D.

INVOLVEMENT IN MPhA Mid-Year CONFERENCE

Rhonda Toney, Board Commissioner and Public Relations Committee Vice-Chair

The Maryland Board of Pharmacy attended the 2018 Mid-Year Meeting of the Maryland Pharmacists Association. Pictured here is Janet Seeds, the Public Information/Education/ Communication/Training Coordinator responding to a pharmacist's concern.



Pictured here is Neil Leikach, Maryland Board of Pharmacy Independent Commissioner Representative and Chairman of the Emergency Preparedness Committee who is recruiting pharmacists to serve on the Emergency Preparedness Tash Force at MPhA's 2018 Mid-Year Meeting.

Deena Speights-Napata, MDBOP Executive Director, was invited to share at the MPhA Mid-Year Meeting on Sunday, February 18, 2018. She brought greetings on behalf of the Maryland Board of Pharmacy and provided an update on the Contraceptives Regulation, COMAR 10.34.40, pharmacists prescribing contraceptives, to the pharmacists and technicians who attended the Mid-Year Meeting.



A Consumer's Perspective on the Role of Board Members



On December 4, 2017, Zeno St. Cyr II, Consumer Member of the Maryland Board of Pharmacy presents to over 150 participants at the annual Health Occupations Boards and Commissions Orientation Program about the roles and responsibilities of Board members.

BOARD COMMISSIONERS

President: **Mitra Gavvani**
 Secretary: **Zeno W. St. Cyr, II**
 Treasurer: **Kevin Morgan**

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Efstratios (Steve) Bouyoukas
Karla Evans
Jennifer Hardesty
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Brenda Oliver
Roderick Peters
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Home Infusion Representative
 Consumer Representative
 Chain Drug Store Representative

Acute Care Hospital Representative
 Chain Drug Store Representative
 Acute Care Hospital Representative
 Long Term Care Representative
 Independent Pharmacist Representative
 Consumer Representative
 Independent Pharmacist Representative
 At-Large Representative
 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.

2018 PUBLIC BOARD MEETINGS

Third Wednesday of each month

March 21, 2018

April 18, 2018

May 16, 2018

Location: 4201 Patterson Avenue

Baltimore, MD 21215

CONTACT DIRECTORY

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