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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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Maryland Board of Pharmacy Represented at the NGA Pharmaceuticals Summit

Deena Speights-Napata, Executive Director

On December 3rd and 4th the National Governors Association sponsored the "NGA Pharmaceuticals Summit" in Washington, DC. Over 30 states were represented at the summit. The focus of the summit was on state government costs for pharmaceuticals and factors impacting those costs. I participated along with our state Medicaid director of pharmacy services, and state director of Medicaid initiatives.

Over half of the states in attendance stated that the primary drug cost challenge is supporting the costs of specialty drugs. Those specifically mentioned were drugs associated with the treatment of diabetes and cystic fibrosis. For community pharmacies, the issue is primarily the insurance approval process for specialty drugs, which can take several weeks. The delay results in customer dissatisfaction, particularly if the drug cost is not approved. In addition to this issue, there are instances in which the generic drug is approved instead of the brand drug prescribed. This too often contributes to customer dissatisfaction. Often independent pharmacies do not have specialty drugs in stock, causing at least an additional 1-2-day delay, even after the insurance reimbursement is approved.

Other challenges include:

- Fiscal budgeting challenge for managing unpredictable drug costs
- Extensive FDA Approval Process
- Ineffective drugs
- Reimbursement rates

Some of the solutions currently being worked on to control drug costs include regulating pharmacy benefit managers (PBMs), pushing for more transparency in drug pricing, support of wholesale drug importation through Canada, and support of drug affordability review boards.

(Continued from page 1)

Regulation of PBMs: Current federal regulation addresses consumer protection and regulation of PBM licensing and reporting of rebates, and prohibiting of price spreading and claw backs.

Transparency in drug pricing: Legislation is currently in place in CA, NY, VT, OR, and MT. Legislative proposals are being worked on in CT, Maine, AW, and TX.

Wholesale Drug Importation: CA and Maine currently working on developing a pilot program.

Drug Affordability Review Boards: Currently in place in Maine, Maryland will have its first Prescription Drug Affordability Board meeting on January 13, 2020. Led by former Secretary of Health Van Mitchell, the board consists of 4 other members: Ebere Onukwugha, an associate professor in the University of Maryland School of Pharmacy; George S. Malouf Jr., an ophthalmologist; Gerard F. Anderson, director of the Johns Hopkins Center for Hospital Finance and Management; and Joseph Levey, a professor in the Johns Hopkins Bloomberg School of Public Health.

Board Statement Regarding Pharmacists' Refusal to Fill Prescriptions

Recently, the Maryland Board of Pharmacy (the "Board") has received complaints from patients and healthcare providers related to pharmacists refusing to fill prescriptions, mostly for opioids and other controlled dangerous substance medications. Further, many of the patients report that pharmacists are not being clear about the reasons for the denial, nor are they informing patients about possible alternative medications or other healthcare options. From a patients' perspective, they are finding it increasingly frustrating to be denied without explanation while presenting what they believe is a legitimate prescription.

The Board generally recognizes and supports a pharmacist's right to refuse to fill a prescription provided that the refusal is based on professional judgment, experience, and knowledge. Indeed, a pharmacist must refuse to fill a prescription that the pharmacist believes has not been issued for a legitimate medical purpose as part of the pharmacist's corresponding responsibility.

However, pharmacists, as healthcare providers, are viewed by patients to have unique and reliable expertise regarding medications and drug therapy. Therefore, a pharmacist who refuses to fill a patient's prescription should consider providing other reasonable and expected health services in tandem. This may include, for example, counseling a patient regarding why the patient's prescription is clinically inappropriate and not being filled, and requires communicating the same to the patient's healthcare provider.

Importantly, refusing to fill a prescription requires a specific, individualized assessment of the patient and/or the prescription. Methods such as reviewing PDMP/CRISP data and consulting with the prescriber should be considered in the individualized assessment of each prescription. The Board recommends that pharmacists review the Board's laws and regulations regarding refusal to fill, specifically Md. Code Ann., Health Occ. § 12-501 and COMAR 10.34.10.08, and ensure that they are adhering to all legal requirements when refusing to fill prescriptions. In making these determinations, pharmacists play a crucial role in effectively responding to the opioid epidemic that is sweeping Maryland and the nation.

The Board also wishes to stress the importance of pharmacists and other pharmacy staff acting professionally in their interactions with patients at all times. Treating patients respectfully, protecting their confidentiality, and ensuring they understand their options- even when refusing to fill a prescription- will help to strengthen the pharmacist-patient relationship and improve overall health outcomes.

For the Board,

Deena Speights-Napata. M.A.
Executive Director

Maryland Code, Health Occupations § 12-501

(a) A pharmacist may refuse to dispense or refill a prescription if the decision is based on professional judgment, experience, knowledge, or available reference materials.

(b) (1) Except as provided in paragraph (2) of this subsection, if a pharmacist refuses to dispense or refill a prescription, the pharmacist shall, to the extent practicable, notify the authorized prescriber that the prescription or refill was refused within 72 hours after the refusal.

(2) Paragraph (1) of this subsection does not apply if a pharmacist is unable to determine the name of the authorized prescriber.

COMAR 10.34.10.08- Refusing to Dispense a Controlled Substance

A. If, based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe, or should have reason to believe, that a prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist may not dispense the controlled dangerous substance until the pharmacist:

(1) Consults with the prescriber; and

(2) Verifies the medical legitimacy of the prescription.

B. If, after consulting with the prescriber, and based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe that the prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist shall:

(1) Refuse to dispense the drug; and

(2) Report the incident to the regulatory board that license the prescriber.

The Board of Pharmacy is currently accepting article submissions 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 March 1st.

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

Insights at the Continuing Education Breakfast

By Leo Gray, Public Affairs Specialist

Board staff at CE Breakfast sign-in table

The Continuing Education Breakfast took place at the Sheraton in Towson, on a rainy October morning. Braving the weather were 400 pharmacists and pharmacy technicians who attended in person, with approximately 200 attendees via webinar. Attendees received four ACPE-accredited continuing education credits, along with breakfast. The breakfast is coordinated by the PR Committee and Dr. Ellen Yankellow welcomed everyone and introduced each of the speakers. An introduction to the event was given by Deena Speights-Napata, Executive Director.

Robin Rickard, Deputy Director of the Opioid Overdose Command Center, was the first of four speakers. She spoke on the work of the Opioid Overdose Command Center to date, and their ongoing role in the opioid crisis. The OOCC was established in 2017, after Governor Hogan declared a state of emergency. Their current operating mode is three-pronged: Prevention & Education, Enforcement, and Treatment & Recovery. To learn more about the OOCC and their role in preventing the spread of opioid addiction, visit https://beforeitstoolate.maryland.gov/

Dr. Lynn McPherson, Professor at University of Maryland School of Pharmacy, armed with her wit, presented an overview of drugs approved by the FDA this year. For each drug, she discussed pertinent information, including indication(s), usual dosing, contraindications, major warnings/precautions, major drug interactions, and the drug's place in therapy, based on known efficacy, safety, cost, and convenience factors.


Ellen Yankellow introducing Dr. Lynn McPherson

The Board recognized 50-year pharmacists during the break. In the past, the Board has recognized pharmacists who have held their licenses for 60 years, but frankly, there haven't been many of them the past few years. So, a shift was made to pharmacists who have held their licenses for 50 years, and honored all of the pharmacists in between 60 and 50 years to make up the difference. There were 100+ 50 to 60 year pharmacists contacted personally over the phone and then via email by Leo Gray, Public Affairs Specialist. Of these, approximately 30 were in attendance for recognition by Kevin Morgan, Board President. Before and after the recognition, they milled about, greeting one another, and celebrated their long histories of practicing pharmacy in Maryland.

After the recognition, Dr. C. Daniel Mullins, also a Professor at University of Maryland School of Pharmacy, gave a talk on the work he is doing with the PATIENTS program. PATIENTS stands for The PATient-centered Involvement in Evaluating effectiveNess of TreatmentS (PATIENTS) Program. Their intent with the program is that all patients and stakeholders are heard, inspired, and empowered to co-develop patient-centered outcomes research (PCOR). You can read more about the PATIENTS program here: https://patients.umaryland.edu/

Rounding out the slate of dynamic speakers was Charmaine Rochester-Eyeguokan, our final Professor from University of Maryland School of Pharmacy, to shed light on the processes pertaining to the recent change in Maryland law which granted pharmacists the ability to prescribe certain hormonal contraceptives. She discussed the six components that make up the regulatory chapter, the Self Screening Risk Assessment, visit summary and optional forms created to facilitate the process.

Pharmacy Renovations

Many pharmacies have been engaging in renovations. The Maryland Board of Pharmacy (the "Board") would like to take this time to remind you that ***if you are making renovations to your pharmacy the Board needs to be notified by email (mdh.mdbop@maryland.gov) or in writing.*** This does not apply to facilities located outside the state of Maryland.

Please notify the Board within 30 days if you:

- Make changes in pharmacy blueprint
- Disrupt or alter the security of pharmacy
- Update rooms to be compliant with USP standards (does not include HVAC updates)

When submitting a renovation notice to the Board please include:

- Pharmacy's Permit number
- A description of the renovations being made (include a blueprint if relevant)
- A timeline of the renovations with estimated completion date
- If sterile compounding: actions mitigating product contamination during construction

These actions require a Board inspector to come out and inspect changes made to the pharmacy.

Note for Sterile Compounding:

- If the renovations involve the pharmacy's sterile compounding area, a Board inspection will be required before sterile compounding resumes.
- If the renovations call for the pharmacy to create a temporary sterile compounding area, a Board inspection will be required before sterile compounding begins in the termporary area.

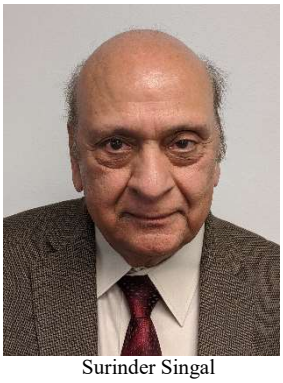
Once the work is complete, please call the Board to schedule an inspection. The relevant inspection forms can be found on the Board's website at the bottom of the Establishments page for your review:

https://health.maryland.gov/pharmacy/Pages/Establishments.aspx

How to prepare for inspection:

- Have all documents ready for the inspection including: items requested in the inspection reports, a print out of the security log showing active use, certification reports, and/or environmental sampling reports if applicable.
- The pharmacy cannot be approved for full sterile compounding until an environmental sampling demonstrating that the pharmacy has control over the cleanroom environment is provided to the Board.

Please contact the Board if you have any questions. Thank you.


Surinder Singal

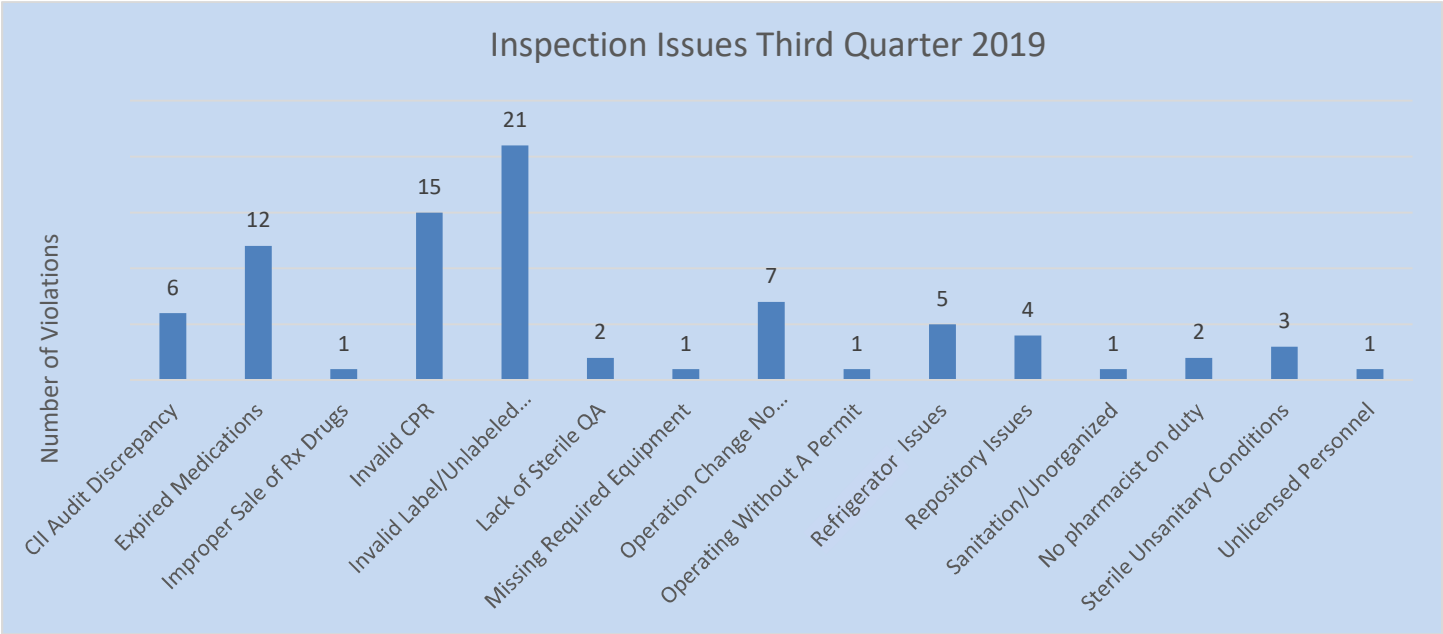
New Commissioner Announcement

The Maryland Board of Pharmacy would like to introduce **Surinder Singal, M.S.**, as our new Independent Board Commissioner. Surinder graduated from George Washington University in 1978. Surinder was appointed by Governor Hogan to serve the remainder of the vacancy of the Independent Board Commissioner position. He has owned and operated small pharmacies in Calvert and Anne Arundel Counties for the last 30 years. We welcome you, Surinder, to the Maryland Board of Pharmacy.

Inspection Issues Third Quarter 2019

The Maryland Board of Pharmacy requires all Maryland pharmacies to be inspected annually; these inspections can reveal a number of different issues, some of which result in Board investigations.

The following graph represents the inspection issues in the third quarter of 2019:



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, Chapter 32, 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.

Events Corner

L to R: Kevin Morgan, Board President, Deena Speights-Napata, Executive Director, Mitra Gavgani, former Board president

L to R: Kevin Morgan, Board President, Deena Speights-Napata, Executive Director, Roderick Peters, former Board Commissioner

L to R: Kevin Morgan, Board President, Deena Speights-Napata, Executive Director, Zeno W. St. Cyr, II, former Board Commissioner

Former Board Member and Staff Recognition Luncheon

On September 18th, the Board of Pharmacy recognized contributions from former Board commissioners and current Board staff at a luncheon. The event was held in Room L-1 at 201 W. Preston Street. The former Board commissioners recognized were former Board President Mitra Gavgani, who served as Home Infusion Representative until April 30th, 2018, Zeno W. St. Cyr, II, who served as a Consumer Representative for two terms to June 30th, 2018, and finally, Roderick Peters who served for one term as an Independent Pharmacist Representative, which expired on April 30th, 2018.

Point of Dispensing Exercise at Notre Dame University

On November 5th, members of our Emergency Preparedness Taskforce ran a Point of Dispensing (POD) exercise with students of Notre Dame University. POD exercises simulate real-life disaster scenarios in which Maryland's emergency supply of medication would need to be accessed and distributed.

EPTF member Chaltu Wakijra and EPTF member and former Chair Don Taylor, working with Notre Dame students

EPTF member and former chair Don Taylor, overseeing Notre Dame students

EPTF member Larry Hogue, with Notre Dame students

EPTF member Larry Hogue, answers questions from Notre Dame students

DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
Jason S. Chvat	15795	Probation	11/4/2019
William R. Chester	15241	Suspension	11/4/2019
Ketankumar Patel	10301	Probation	7/16/2019
Steven Levin	22295	Probation	11/8/2019
Pradeep Pandya	16176	Denial	9/17/2019
Stefany Overbeck	13193	Suspension	9/19/2019
Elizabeth Okang	12578	Probation	9/23/2019
Oluseyi Ilori	16660	Probation	9/26/2019
Ndiouga Dieng	12622	Suspension	9/27/2019
Hossein Zamani	18128	Suspension	10/16/2019

ESTABLISHMENTS	LIC. #	SANCTION	DATE
Famili-Care Pharmacy	P06331	Revocation	11/20/2019
Germantown Professional Pharmacy & Compounding	P06662	Surrender	10/16/2019
Hallandale Pharmacy	P07560	Fine	12/11/2019
Henry Ford Pharmacy Advantage Southfield	P06219	Fine	12/11/2019
Izeen Pharma, Inc.	D06251	Revocation	9/18/2019
Glory Pharmacy	P07638	Probation	9/26/2019
Woodand Hills Pharmacy	P06088	Probation	11/8/2019

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Kristin Guinn	T21639	Summary Suspension	9/9/2019
Sherne L. Jones	T21282	Suspension	9/27/2019
Gabrielle Benson	T16144	Revocation	10/16/2019
Miles Fink	T17314	Revocation	10/16/2019
Joevany Martinez	T16956	Probation	10/16/2019
Shantel Howard	T18720	Summary Suspension	10/23/2019
Donnetta Washington	T22493	Summary Suspension	10/23/2019
Joseph Danielson	T20330	Summary Suspension	11/6/2019
Jordan Edelman	T21870	Summary Suspension	11/6/2019
Jaime L. Baker	T22609	Summary Suspension	11/18/2019
Earl Montague III	T17435	Revocation	12/18/2019

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister .gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

Creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;

Developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and

Promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health.These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

BOARD COMMISSIONERS

President: **Kevin Morgan**	Chain Drug Store Representative
Secretary: **Kristopher Rusinko**	At-Large Representative
Treasurer: **Jennifer Hardesty**	Long Term Care Representative
Daniel Ashby	Acute Care Hospital Representative
Efstratios (Steve) Bouyoukas	Chain Drug Store Representative
Karla Evans	Acute Care Hospital Representative
Vacant	Consumer Representative
Neil Leikach	Independent Pharmacist Representative
Vacant	At-Large Representative
Brenda Oliver	Consumer Representative
Surinder Kumar Singal	Independent Pharmacist Representative
Ellen H. Yankellow	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.

2020 PUBLIC BOARD MEETINGS

Third Wednesday of each month
February 19th, 2020
March 18th, 2020
April 15th, 2020

Location: 4201 Patterson Avenue
Baltimore, MD 21215

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Executive Director *Deena Speights-Napata*			
Deputy Director & Operations Manager *Edward Fields*	**Director of Compliance** *Trina Leak*	**Manager of Program Intake, Assessment & Evaluation** *Nakia Jordan*	**Licensing Manager** *Doris James*

Maryland Board of Pharmacy

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