



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.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215
Tel: 410-764-4755
Fax: 410-358-6207
Toll Free: 800-542-4964
TTY: BALTO-383-7555



HIGH FIVE! Our Top Five Answers To Your Top Five Questions

Deena Speights-Napata, Executive Director

Every month, the board call center receives literally hundreds of phone calls, emails, and voice mails seeking answers to lots of questions, the majority of which concern individual license or registration status.

However, we also get our fair share of repeat questions...important questions that many of you are asking every week. So in this article I would like to share the top five questions we have received this year, and the answers we provided. They are listed in no specific order:

Q: What is the board's position on USP 797 and 800?

A: The Board has not adopted USP-800 into its regulations at this time; however, provisions that overlap with USP-797 will continue to be enforced. Please see the Board's regulations, COMAR 10.34.19, for requirements relating to sterile compounding.

Q: Can my pharmacy sell CBD products that are derived from industrial hemp?

A: Because industrial hemp is not covered by the Maryland Pharmacy Act, the Board of Pharmacy does not have a position on this issue. For further information on the legal status of CBD products derived from industrial hemp in Maryland, licensees and permit holders should contact the Maryland Office of Controlled Substances Administration (OCSA) at 410-767-6500.

Q: What type of injections may a pharmacist administer? OR Is it permissible for me to administer X injection as a pharmacist in Maryland?

A pharmacist may administer an influenza vaccination to any individual who is 9 years or older without a prescription. Pharmacists may also administer vaccinations listed in the Center for Disease Control and Prevention's (CDC) Recommended Immunization Schedule to individuals that are between 11 and 17 years old and have a prescription from an authorized prescriber. Finally, when dealing with adult patients, a pharmacist may administer vaccinations that are either a) listed in the CDC's Recommended Immunization Schedule, or b) listed in the CDC's Health Information for International Travel without a prescription. Please see the Board's regulations, COMAR 10.34.32, for information on additional requirements relating to protocols, recordkeeping, continuing education, reporting, and CPR certification.

For more information on Maryland's recommended adult and childhood immunization schedules, please review the information provided on the Maryland Center for Immunization website, accessible by using this link:

<https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/childhood-adult-immunization-schedule.aspx>

(Continued from page 1)

Q: Can my pharmacy sell prescription drugs directly to a practitioner for office use?


A: Yes. Under Md. Code Ann., Health Occ. § 12-6C-01(u)(2)(vi), pharmacies are permitted to sell minimal quantities of prescription drugs to licensed health care practitioners for office use. It should be noted, however, that if such sales exceed 5% of a pharmacy's annual sales, the pharmacy would be considered a wholesale distributor pursuant to Md. Code Ann., Health Occ. § 12-6C-01(v)(2)(xii) and would require an additional wholesale distributor permit. Lastly, additional requirements apply to sales of controlled dangerous substances.


Q: What is the maximum number of dosage units of a scheduled substance that may be dispensed at one time to a patient?


There is no state or federal law limiting the quantity of a controlled dangerous substance that can be prescribed or dispensed on a single prescription. However, third-party reimbursement entities do limit quantities they will cover, and the CDC guidelines, and presumably REMS training, also have recommended limitations. As with every prescription, standards of care apply, taking into consideration the particular facts and circumstances of the prescription at issue.



Amended Regulations

 **COMAR 10.34.05.05 - Pharmacy Security.** The Board amended this regulation to require pharmacists to report significant losses of controlled substances, in addition to the existing requirement of reporting theft. Under the amended regulation, pharmacies must report thefts of non-controlled prescription drugs to the Board, and must report thefts or significant losses of controlled substances to 1) the Board, 2) local police, 3) the Office of Controlled Substances Administration, and 4) the U.S. Drug Enforcement Administration. The regulation amendments became effective on May 20, 2019.

 **COMAR 10.34.09.02 - Fees.** This regulation amended an existing regulation to waive fees for pharmacy technician training programs submitted to the Board when the didactic portion of the program is comprised entirely of a didactic program that has been previously approved by the Board. The regulation amendments became effective on May 20, 2019.

 **COMAR 10.34.30 - Change to Permits.** This amendment to COMAR 10.34.30 codifies the Board's policies and procedures regarding name change, ownership change, location change, and other changes made by a licensee to information contained in a previously submitted application. The amendment also codifies the Board's policy of requiring applicants to re-submit all application materials and fees if an incomplete application has not been completed within one year after submission. The amendments became effective on May 20, 2019.

Medication-Assisted Treatment in Opioid Use Disorders

By Greg Kim, PharmD & Rhonda Toney, MBA, BSPHarm, FASHP

Medication-Assisted Treatment (MAT) is the use of Food and Drug Administration (FDA)-approved medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders. For many patients with Opioid Use Disorders (OUDs), the use of combined therapy is superior to withdrawal management combined with psychosocial therapies, or psychosocial therapy alone.

Currently, there are three FDA-approved medications for use in MAT: naltrexone, methadone, and buprenorphine. While naltrexone (an opioid antagonist) can be prescribed in any medical setting, methadone and buprenorphine require special licensing, certifications, or waivers in order to be prescribed or dispensed.

Opioid Treatment Programs (OTPs) are state-and federally-regulated facilities that are licensed to dispense opioid agonist treatment, and are the only facilities that are permitted to use methadone in individuals with OUD. Office based opioid treatment (OBOT) is limited to buprenorphine, and can be prescribed outside of OTPs by providers (physicians, nurse practitioners, physician assistants) with acquired buprenorphine certifications, to be filled as ordinary prescription medications. OBOT may not be suitable for individuals that have active alcohol, sedative, hypnotic, or anxiolytic use disorders, due to the potential for adverse reactions with buprenorphine treatment.

Methadone, buprenorphine, and naltrexone each have specific dosing requirements, precautions, and adverse effects that require consideration by the healthcare team when treating patients. In addition, special considerations are required when converting patients from one product to the other. Pharmacists are in a position to assist in counseling patients and consult with other healthcare providers to ensure proper use of these medications.

The appropriate use of MAT may increase the likelihood of successful treatment for individuals with OUDs, and may play a vital role in reducing morbidity and mortality rates. Additional information about MAT may be found at <https://www.samhsa.gov/medication-assisted-treatment>.

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 November 1st.

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

Medication Safety – a Full-time job?

By Neil Leikach, RPh, and Dixie Leikach, RPh, MBA

Safety is the top priority in a pharmacy setting. For pharmacy permit holders, there are various categories relating to safety - physical safety, job safety, and medication safety. The Maryland Board of Pharmacy has regulations governing medication safety in Maryland which requires each permit holder to establish an ongoing quality assurance program that “systematically and routinely reviews the medication delivery system of a pharmacy for the purpose of minimizing the occurrence of medication errors.” (COMAR 10.34.26.01). For most pharmacies, the QA program is developed by the entity that owns the pharmacy. However, the pharmacist supervising the pharmacy’s operations must be knowledgeable about the QA program to ensure its effective implementation.

A pharmacy’s QA program must, at minimum, identify and investigate each medication error through a root-cause analysis, and engage in remedial actions to lessen the reoccurrence of another similar medication error. In addition, the permit holder must conduct periodic reviews of its QA records every 3 months for overall weaknesses in the medication delivery system, and every 6 months to identify high-alert medications. (COMAR 10.34.26.04)

Because medication error prevention is so vital to the delivery of safe and effective healthcare, where would a pharmacist find additional information and training? The Board of Pharmacy newsletter frequently contains information regarding medication error prevention. In fact, conducting root cause analyses was the topic in the last Board of Pharmacy newsletter! Furthermore, each pharmacist is required to complete one hour of continuing education in medication safety during each renewal period. As most states require this type of continuing education, these programs tend to be widely available.

Additional resources may also be found on the Institute for Safe Medication Practices (ISMP) website at ISMP.org. ISMP provides a range of information topics available on the website at no charge such as the quarterly “Medication Safety Action Alert Agenda”, published by ISMP. There are also other associations and non-profits that may provide additional education and resources on preventing medication errors.

Pharmacists play an important role in preventing medication errors, no matter the practice site. Our professional responsibility requires us to, at a minimum, adhere to the Board’s regulations governing patient safety improvement by training pharmacy staff on medication error prevention, obtaining required continuing education on this topic, and utilizing professional resources when appropriate to ensure that patients receive safe and effective medications.

REMINDER

Continuing Education Breakfast

Sunday, October 20, 2019

Sheraton Baltimore North
903 Dulaney Valley Road, Towson, MD 21204
7:30 am – 1:00 pm

\$10 Registration Fee (in-person or live webinar)

Registration found on home page of Board website:

<https://health.maryland.gov/pharmacy/Pages/index.aspx>

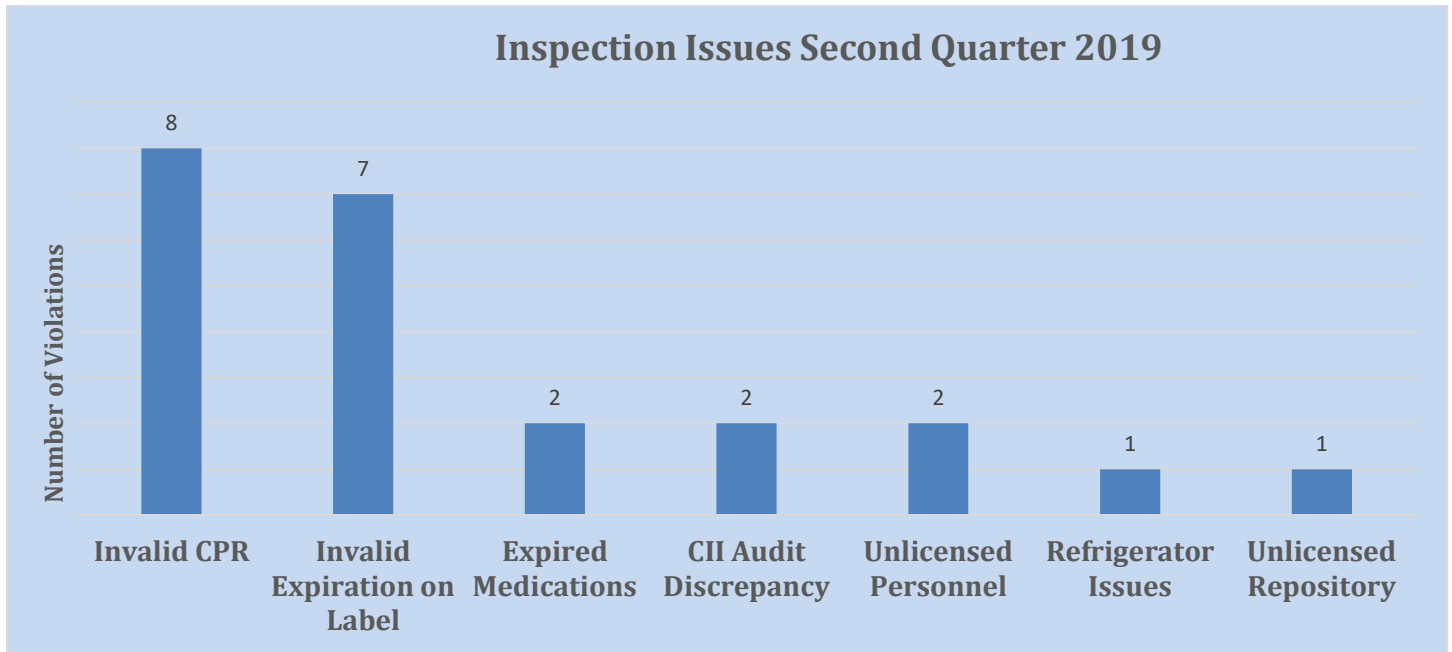
ACPE-approved for four credits!

Topics will include opioid policy implementation, prescribing hormonal contraceptives, new FDA approved drugs, and more!

Inspection Issues Second 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 second quarter of 2019:



Events Corner



L to R: Neil Leikach, Nakia Jordan, Leo Gray



MPhA Attendees

The Maryland Pharmacists Association held its Annual Convention in Ocean City, MD from June 21-24th. The Maryland Board of Pharmacy staff was represented by Nakia Jordan, Manager of Program Intake, Assessment & Evaluation, and Leo Gray, Public Affairs Specialist. They distributed the Spring edition of the newsletter along with the Pharmacy Rehabilitation Services pamphlet. Also in attendance was Emergency Preparedness Taskforce member and Board Commissioner Neil Leikach and Taskforce member Lawrence Hogue. The Board appreciates the chance to interact with its licensees.

DISCIPLINARY ACTIONS

<u>PHARMACISTS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Richard D. Hiller	10814	Revocation	5/15/2019
Pamela K. Karnbach	13350	Probation	5/15/2019
William Chester	15241	Summary Suspension	7/12/2019
Ketankumar Patel	10301	Probation	7/16/2019
Pradeep Pandya	16176	Denial	9/17/19

<u>ESTABLISHMENTS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Poplar Grove Pharmacy	P05639	Summary Suspension	4/15/2019
Associated Pharmacies	D02899	Fine	4/23/2019
Safe Chain Solutions	Unlicensed	Fine	5/28/2019
Independent Pharmacy Cooperative	D01202	Fine	5/30/2019
Novant Health Pharmacy	P06896	Fine	5/31/2019
CVS Pharmacy #1881	P05299	Fine	6/18/2019
Akina Pharmacy	P06197	Fine	6/26/2019

<u>PHARMACY TECHNICIANS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Krystal Rennie	T06154	Probation	5/20/2019
Deanna Higgs	T00892	Denial	5/28/2019
Charles Mbachu	T20290	Suspension	6/7/2019
Katrice Matthews	T01945	Summary Suspension	6/14/2019
Tasia Ingram	T12189	Revocation	6/19/2019
Ciara Maples	T17954	Revocation	6/19/2019
Tiffany Michaud	T18902	Revocation	6/19/2019
Kiyomi Nichols	T18111	Revocation	6/19/2019
Sirron Richardson	T13890	Revocation	6/19/2019
Dejon Robinson IV	T18333	Revocation	6/19/2019
Jennifer M. Smith	T04339	Revocation	6/19/2019
Pedro Villalobos	T15438	Revocation	6/19/2019
Earl Montague III	T17435	Summary Suspension	7/12/2019
Matthew G. Sherman	T17274	Summary Suspension	9/9/2019

National Association of Boards of Pharmacy

National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers' access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a [Drug Safety Communication](#), provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

“Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse,” the agency said in the communication. “Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.” In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the [News and Events section](#) of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a [DEA press release](#), this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened

victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- ♦ maintaining quality manufacturing compliance,
- ♦ strengthening and refining regulations on compounding from bulk drug substances,
- ♦ finalizing the agency's memorandum of understanding with the states, and
- ♦ issuing revised draft guidance for compounding by hospital and health systems.

“We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs,” then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a [statement](#) published on the FDA website. “We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . .”

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other

compounding-related measures not outlined in the statement

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a [press release](#) from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries. “Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis,” Senate Minority Leader Chuck Schumer said in the press release. “We must hold China accountable for their role in the fentanyl trade. China’s new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers.”

In a December meeting with President Donald Trump, China’s President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be “the largest source of illicit fentanyl and fentanyl-like substances” in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports

of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement. Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a [press release](#) posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy (NABP) Drug Disposal Locator Tool, available in the AWARD Prescription Drug Safety section of the NABP website, www.nabp.pharmacy/initiatives/AWARD. With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map. Additional information about the FDA campaign can be found at <https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine>.

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 Chain Drug Store Representative
 Acute Care Hospital Representative
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 Home Infusion Representative
 Consumer Representative
 Independent Pharmacist 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.

2019 PUBLIC BOARD MEETINGS

Third Wednesday of each month
 October 16th, 2019
 November 20th, 2019
 December 18th, 2019

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

Executive Director
Deena Speights-Napata

Deputy Director & Operations Manager <i>Edward Fields</i>	Director of Compliance <i>Trina Leak</i>	Manager of Program Intake, Assessment & Evaluation <i>Nakia Jordan</i>	Acting Licensing Manager <i>Doris James</i>
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 4201 Patterson Avenue
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