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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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COVID-19 VACCINE…WHAT'S THE PLAN?

Deena Speights-Napata, Executive Director

On October 16th the Maryland Department of Health submitted its COVID-19 Vaccination Plan to the US Centers for Disease Control (CDC). The plan includes several key elements that describe how Maryland will distribute and disseminate COVID-19 vaccine once it arrives in Maryland. As we anxiously await the arrival of vaccine to senior care facilities, nursing homes, clinics, and health departments, we are particularly focused on Maryland pharmacies and their role in receiving vaccine and vaccinating citizens.

Critical facts that pharmacists will be considering as their role in immunizing is processed:

1. COVID-19 vaccine is a two dose vaccine. Can pharmacists anticipate being able to track and administer two doses per patient, and what will the storage and inventory requirements be? Are appropriate numbers of staff available, particularly during peak hours of demand?

2. The allocation of the vaccine will go first (Phase 1) to states with the highest number of "priority" populations and the jurisdictions with the greatest prevalence of the disease. Vaccine distributed in Phase 1 will be distributed by two major pharmacy chains, CVS and Walmart. Currently Maryland has a low prevalence compared to 41 other states with a higher prevalence, which could mean that Maryland will receive fewer doses of the vaccine in comparison to other states, which ultimately means fewer doses to divide among the priority populations in Maryland. According to the data included in Maryland's plan, the highest number of priority population numbers in Maryland are the high risk health care worker and people with comorbid and underlying health conditions. This would be a good time for pharmacies to assess their customer base to determine if their customer demographics include these populations. Or, will most Maryland pharmacies only seek participation in COVID-19 vaccination during the general public phase rolled out in phase 2?

(Continued on Page 2)

During the current State of Emergency, Maryland Board of Pharmacy Inspectors are conducting virtual routine inspections and will continue until further notice. Please note, however, that **the narcotic audit component of the annual inspection will be conducted separately and IN PERSON.** If your pharmacy has had a virtual annual inspection, an Inspector will be in contact with your pharmacy within the next few months to schedule an onsite narcotic audit. The narcotic audit should not take any longer than half an hour to an hour to complete. We appreciate your time and cooperation. Please contact the board at 410-764-4755 if you have any questions or concerns.

3. All vaccine sites receiving vaccine during Phase 2 must be preregistered in the state's immunization registry, called Immunet. Once preregistered, all vaccine orders will be uploaded by using the CDC vaccine tracking system, connected locally to the MDH Center for Immunization vaccine tracking system. In most cases vaccine orders distributed directly from CDC will be at least 100 doses at a time.

4. As outlined in Maryland's plan, our state communication efforts will focus on vaccine safety, vaccination of priority groups, and vaccination of the general population. How will these groups be located? How can Maryland pharmacies present themselves as being equipped to meet the needs of specific groups?

5. Training to administer the COVID-19 vaccine will be provided by the MDH Center for Immunization through webinars, website postings, and CDC written training materials. Training topics will include vaccine storage and handling, vaccine administration, vaccine ordering process, and vaccine reporting requirements. Pharmacies may want to begin researching how to access the necessary training and decide which pharmacy staff need to be trained.

There are many factors to consider that impact the process of vaccine distribution and administration. Perhaps the most important is the one we tend to talk the least about, and that is making sure that once available, people actually get the vaccine.

That may very well be the hardest plan of all.

The Maryland Board of Pharmacy is delighted to recognize the pharmacists who have served the State of Maryland for 50 years. Thank you for your dedication and service to the Maryland public.

Leroy Bradley
Stanley Caplan
George T. Dooley
Kathryn K. Fader
Stanley W. Gutowski, Jr.
Susan M. Higgins
Paul R. Holly
S. Ramakrishnan Iyer
Martin Kalmanson
Ira D. Klein
Pamela H. Lappen
Dorothy Levi
Mark A. Levi
Michael Luzuriaga
Leo A. Mierzwicki I
Stuart N. Morris
Arthur N. Riley
David S. Roffman
Ivan I. Rotkovitz
Frederic Weiss

The Coronavirus Pandemic, the Opioid Crisis, and Pharmacists' Role in Making Maryland Safer

Andy Owen, Director of Communications and Legislative Affairs, Opioid Operation Command Center

Each quarter, the Maryland Opioid Operational Command Center and the Maryland Department of Health issue a joint report on the state of the opioid crisis in Maryland. The *OOCC 2020 Second Quarter Report*, released in September, makes it clear that conditions created by the coronavirus pandemic have led to increased substance misuse across the state and elsewhere. Pharmacists play a critical role in mitigating the effects of the opioid crisis by distributing important harm-reduction supplies and by helping to educate the public about the dangers of opioid misuse.

There were 1,326 unintentional intoxication deaths from all types of drugs and alcohol reported in Maryland during the first two quarters of 2020 – an increase of 9.1 percent from the 1,215 intoxication deaths reported in the first half of 2019. Opioids were involved in 1,187 intoxication deaths during this timeframe, representing almost 90 percent of all such fatalities.

"Access to life-saving emergency services, substance use treatment, and recovery support has been disrupted by the coronavirus pandemic," said OOCC Executive Director Steve Schuh. "When you add the despair caused by economic uncertainty, you have a very difficult set of circumstances for Marylanders suffering from substances use disorders."

While the first half of 2020 saw increases in fatalities related to nearly all classes of substances, the synthetic opioid fentanyl played the biggest role. There were 1,100 deaths involving fentanyl through the second quarter of 2020, accounting for 92.7 percent of all opioid-related deaths and 83.0 percent of all intoxication-related deaths. Fentanyl-related deaths increased by 11.9 percent compared to the same period last year.

Notably, there was an 8.1 percent increase in deaths involving prescription opioids in the first two quarters of 2020 when compared to the same period in 2019.

Pharmacists' ability to make harm-reduction supplies available to patients without a prescription can make a significant contribution to the state's fight against the opioid and substance misuse crisis. Maryland has a standing order that allows pharmacists to dispense naloxone to anyone who might be at risk for opioid overdose or who might be able to assist someone experiencing opioid overdose. A person-specific prescription is *not* required to provide naloxone to these individuals.

The Code of Maryland Regulations also allows the sale of sterile syringes to individuals without prescriptions so long as there is an indication of need. In 2007, the Maryland Board of Pharmacy voted unanimously to recognize the prevention of disease as an acceptable indication of need, a position that the board reaffirmed in 2017. All pharmacists are encouraged to understand these regulations and to practice accordingly.

It is always worth keeping in mind that retail pharmacies serve as an ideal forum for public education. Awareness programs such as Washington County's "Go Purple" campaign, which educates youth and the community about the dangers of prescription pain medication, often present perfect opportunities for retail pharmacists to share posters, brochures, and other informational materials with their customers.

If you are interested in learning more about pharmacists' role in addressing the opioid and substance misuse crisis in Maryland, please contact the OOCC at Help.OOCC@Maryland.gov.

COVID-19 and the Impact on Maryland Minority Groups

Gina Migneco, PharmD

As of September 2020, the state of Maryland has over 120,000 confirmed cases of COVID-19, including 3,800 deaths. The statistics updated daily by the Maryland Department of Health show disproportionate incidence among minority groups, with Hispanics/Latinos accounting for 22% of all COVID cases in the state, despite making up only 10.6% of the population and African Americans accounting for 41% of Maryland COVID deaths, despite making up only 31% of the population.[1]

Social determinants of health, such as access to healthcare, availability of quality education, and economic stability, play a significant role in the disproportionate effects of COVID-19 felt by minority groups. Those who are minorities are disproportionately represented in essential work settings such as healthcare facilities and grocery stores, putting them at greater risk for exposure to the virus.[2] Minorities are also more likely to be uninsured and access to healthcare may be limited by other factors including lack of transportation or time off work.[3] These, in addition to the many other inequities in social determinants of health, put minority groups in a position of increased risk for coronavirus exposure and mortality.

The Maryland Department of Health Office of Minority Health and Health Disparities is working with its Minority Outreach and Technical Assistance partners to disseminate information about how minorities can access available resources. Efforts include increasing the number of testing sites in minority communities, funding community partners to conduct community conversations, and providing accurate information about COVID-19 through a variety of platforms.[4] With the executive order from Governor Hogan in May, pharmacists gained the ability to order and administer COVID-19 tests which expanded the availability and access to testing. While some measures have been taken, continued efforts must be made to further support the health and wellbeing of minority communities in Maryland through the COVID-19 crisis.

References:

1. Maryland Department of Health. Coronavirus Disease 2019 (COVID-19) Outbreak. (2020). Retrieved from https://coronavirus.maryland.gov/
2. U.S. Bureau of Labor Statistics. Labor force characteristics by race and ethnicity, 2018. (2019). Retrieved from https://www.bls.gov/opub/reports/race-and-ethnicity/2018/home.htmexternal icon
3. ER Berchick, JC Barnett, RD Upton. Current Population Reports, P60-267(RV), *Health Insurance Coverage in the United States: 2018.* U.S. Government Printing Office, Washington, DC. 2019.
4. Maryland Department of Health. Coronavirus 2019 (COVID-19) and Minority Communities. (2020). Retrieved from https://phpa.health.maryland.gov/Documents/COVID_minority_health.pdf

This article was a submission from a licensee.

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 January 1st.

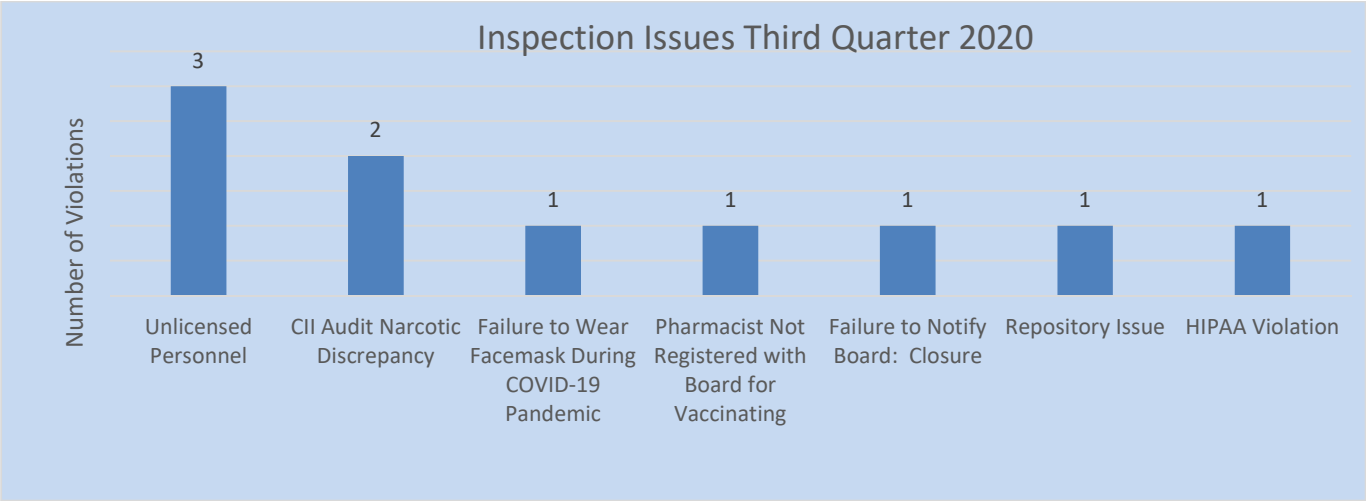
The Board does not guarantee that articles submitted will be published. Authors will be contacted as to whether the submission will be used.

Inspection Issues Second Quarter 2020

The Maryland Board of Pharmacy investigates complaints that come to the Board from various sources. Complaints may 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 breakdown of the issues that have come to the Board from the inspection of pharmacies across the state in the third quarter of 2020.

1. Unlicensed Personnel **(3 cases)**
2. CII Audit Narcotic Discrepancy **(2 cases)**
3. Failure to Wear Facemask during COVID-19 pandemic **(1 case)**
4. Pharmacist not registered with Board for vaccinating **(1 case)**
5. Failure to Notify Board: Closure **(1 case)**
6. Repository Issue **(1 case)**
7. HIPAA Violation **(1 case)**



DISCIPLINARY ACTIONS

PHARMACISTS	LIC. #	SANCTION	DATE
Diana Y. Lalchan	18754	Revocation	8/21/2020
Christina M. Getz	16709	Probation	9/22/2020

PHARMACY TECHNICIANS	LIC. #	SANCTION	DATE
Michae Denise Ross	T20794	Summary Suspension	7/23/2020
Iyonna M. Anthony	T21741	Summary Suspension	7/24/2020
Whitney Heck	T21795	Summary Suspension	8/14/2020
Kadiah Kamara	T18809	Revocation	9/16/2020

ESTABLISHMENTS	LIC. #	SANCTION	DATE
ASPCares	P06661	Probation	10/2/2020

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid- Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the

fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly be- lieved the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner educa- tion alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their compe- tency should be verified as a prerequisite to prescrib- ing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm. Fenta**NYL** patches should only be prescribed for pa- tients who are opioid-tolerant with persistent, moderate- to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and docu- ment the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, inter- active alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identi- fying information with the individual's written consent, as part of a court order, or under a few limited excep- tions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, train- ing, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders.".

BOARD COMMISSIONERS

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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. They are currently being held via teleconference. 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

November 18, 2020
December 16, 2020
January 20, 2020

Location: **1-877-521-8687**
Conference ID: 9060042

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	Director of Compliance	Manager of Program Intake, Assessment & Evaluation	Licensing Manager
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