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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.

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Board of Pharmacy News

Practice of Pharmacy Hot Topics

Deena Speights-Napata, Executive Director

When I arrived at the Board of Pharmacy four years ago, there were very few sizzling hot topics being discussed in the pharmacy community. Since then several programs and practices like Tech Check Tech, contraception prescribing, virtual pharmacy inspections, and COVID-19 testing have found a foothold in Maryland. Exciting times!

While the board is pleased with its role in making these programs happen, we are also looking forward to how the following hot topics may impact the practice of pharmacy locally and nationally:

COVID-19 Treatments and Vaccine Development

The US Department of Health and Human Services (HHS) has made significant financial investment in the development of a COVID vaccine (5 manufacturers currently funded) and effective COVID treatments (7 manufacturers currently funded). In addition, partnerships are being established with companies to produce raw chemicals necessary for the creation of the vaccine, and contracts are being created to ensure production of supplies like glass vials and accelerated platforms for vaccine production. Boards of Pharmacy, Pharmacist organizations, and other pharmacy stakeholders should begin discussing now how these developments will impact the practice of pharmacy. Will pharmacists be administering the COVID vaccine in pharmacies? If so, will the distribution and stockpile of vaccines be sufficient to support equal distribution across all practices of pharmacy and geographical locations? Will pharmacists be required to complete training in COVID vaccine administration? Will it require special certification?

COVID-19 concerns around virus spread and infection have dramatically impacted the exam testing environment for future pharmacists and technicians. Reduced capacity testing centers and waiting lists have become the new norm. As leaders, we will need to come up with creative strategies for addressing these hardships that are delaying the ability for our new graduates to practice pharmacy at a time when they are desperately needed. Schools of Pharmacy across the country are working to implement strategies that will allow them to have limited classroom instruction and widespread virtual instruction. Many educational officials are concerned about the use of virtual instruction, and debate about whether student learning is maximized through this process. Time will tell—are we ready for the new virtually educated to graduate?

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Our board continues to receive inquiries from pharmacists about the administration of vaccines (TB and Hepatitis B in most instances), COVID-19 testing procedures, controlled substances licensing procedures, electronic prescriptions, and the list goes on and on. What I've noted over the past four years is that there has been an increase in the number of instances in which issues being faced by pharmacists in pharmacies and hospitals transcend the scope of knowledge of the pharmacist and increasingly require a knowledge of clinical practices outside of pharmacy. To that end, how will we effectively begin to cross educate and integrate clinical learning to address the issues that transcend individual clinical practice? Also important will be how pharmacists will more effectively become involved in government and private sector initiatives that will continue to impact the practice of pharmacy?

If COVID-19 has taught us anything, it's that pharmacists must be ready to move forward and lead as situations create the demand for knowledge, communication, and leadership.

Don't get left behind!

INSPECTION REMINDERS

PHARMACY ANNUAL INSPECTIONS

As of March 2020, the Maryland Board of Pharmacy began conducting virtual annual inspections. All relevant materials collected during an annual inspection are faxed or emailed to the board inspector, who collects and processes the information provided. A closing video conference call is held to discuss inspection findings and offer recommendations. Starting in July 2020, board inspectors will continue to conduct virtual annual inspections. They will also begin conducting live, in-person, narcotic count verifications and labeling. Opening and closing inspections will also be conducted in person.

Please remember that currently, the Governor's Executive Order requires pharmacy staff and customers to wear masks and encourages social distancing.

STERILE COMPOUNDING PHARMACY PERMIT REQUIREMENTS

All sterile compounding pharmacies holding a Maryland Permit are required to provide accurate reports of the pharmacy's status in order to remain in good standing with the Board. In accordance with **COMAR 10.34.19.18**:

A pharmacy shall:

- A. Document and perform routine testing as required by USP 797 Standards for the appropriate risk levels of sterile compounded preparations; and
- B. Report to the Board within 5 calendar days:
 - (1) Adverse events that have been discovered including corrective actions taken or proposed;
 - (2) Deficiencies related to the sterile compounding process;
 - (3) Disciplinary actions in other states or by other state agencies;
 - (4) Changes in accreditation status;
 - (5) Disciplinary actions taken against a pharmacist who is an owner, operator, or employee of the pharmacy; and
 - (6) Disciplinary actions taken against any other known permit, or any other authorization, held by the pharmacy permit holder.

Any deviations from USP <797> compliance are to be followed up with timely, appropriate actions. In the event that microbial contamination of concern is detected, immediate actions must be taken to ensure control and surveillance over the controlled environment. As a part of the pharmacy's quality assurance program, those actions must be documented.

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The Maryland Board of Pharmacy requires that all pharmacies submit Adverse Event Report forms for the initial event and all follow-up testing, up to and including an acceptable passing report within five (5) days of receiving test results. The form is located on the Board's website and can be submitted to mdpharmacyboard.compounding@maryland.gov. Failure to report in the appropriate time and/or extended periods of inaction after an adverse event will be reviewed by the Board and could result in disciplinary actions.

When Maryland calls, Pharmacists Respond!

Leo Gray, Board Staff

Emergency Preparedness and Response has been at the forefront of the COVID-19 pandemic. Now, more than ever, hospitals need PPE and necessary medication to care for the staggering number of patients infected with the virus. Because of this, the Emergency Preparedness Taskforce activated on April 24th to assist in the Pharmacy response. The EPTF is a group of licensed Maryland pharmacists who volunteer to oversee the state stockpile of emergency medication. The Office of Preparedness and Response (OP&R), the Department of Health office in charge of the State's emergency response, requested their activation.

With the change to an all-hazards approach to disaster, emergencies and threats, the EPTF has been working in conjunction with the OP&R in planning and response to help protect Maryland citizens' safety and welfare. Timely distribution of medical assets to facilities within Maryland that request State assistance has been a central part of the planning effort.



EPTF Members Post-wash (L to R): Hoai-An Truong, Bart Regan, Leo Gray, Jennifer Thomas, Chaltu Wajkira, Julia Anderson, Don Taylor, Arnie Honkofsky



EPTF members in action (L to R): Bart Regan, Dixie Leikach, Julia Anderson, Neil Leikach, Phil Cogan

Since activating, the EPTF has provided assistance in inventorying incoming medication shipments and preparing outgoing shipments to local Maryland healthcare facilities. The process has been operating smoothly thanks in large part to the contributions of volunteer pharmacists.

The EPTF was originally conceived as a response to the 9/11 attack on the Twin Towers. The last time it activated was in response to the H1N1 virus. The taskforce is supported by the Maryland Board of Pharmacy, and any licensed Maryland pharmacist may apply to participate. The current members include: Don Taylor, Neil Leikach, Arnie Honkofsky (former MDBOP commissioner), Jennifer Thomas, Phil Cogan, Bart Regan, Hoai-An Truong, Chaltu Wajkira, Julia Anderson, Dixie Leikach, Larry Hogue, and Board staff Nakia Jordan and Leo Gray.



Remdesivir shipments, packaged and ready to go!

If you are a licensee interested in applying to the Emergency Preparedness Taskforce, please send an email to: mdh.mdbop@maryland.gov. For other Emergency Response opportunities, please visit MD Responds.

Expansion of COVID-19 Testing to Maryland Pharmacies

Temitope Oyeleke, PharmD

On May 19th, 2020, Governor Hogan issued an executive order¹ to authorize pharmacists to order and administer tests for the novel coronavirus (COVID-19) in accordance with Centers for Disease Control and Prevention (CDC) Screening Guidance. Maryland joined the group of 23 other states² that have approved pharmacies as COVID-19 testing sites. This order includes the authority to collect or supervise the collection of specimens for the purpose of COVID-19 testing. It also allows a laboratory to perform a COVID-19 test pursuant to a written or electronic authorization of a licensed pharmacist.

Currently, participating pharmacies are providing swab tests to adults meeting CDC criteria by appointment only. Patients are being required to stay in their cars and are directed to the pharmacy drive-thru window or a designated parking area. They are then provided with a test kit and given instructions. A pharmacist observes the self-swab process to ensure it is done properly. Once completed, the patient deposits their sample in a collection container. Tests are then processed at an external lab.

Pharmacies dramatically expand the availability and access of testing for Maryland residents. Maryland has nearly 1,200 pharmacies so testing has become more widely available for many people. Pharmacists are frontline employees and can now serve our communities in an additional capacity.

Temitope Oyeleke, PharmD is a pharmacist practicing in the Baltimore area and can be reached at temitopeoyeleke@gmail.com

References

1. Exec. Order No. 20-05-19-01, 3 C.F.R. 1-3 (2020). Print.
2. National Alliance of State Pharmacy Associations. "COVID-19: Testing." *Naspa.us*. N.p., 29 May 2020. Web. 31 May 2020.
3. "The Office of GOVERNOR LARRY HOGAN." *Governor of Maryland*. N.p., 2020. Web. 01 June 2020

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 October 1st.

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

From the Maryland Board of Pharmacy:

The coronavirus pandemic has taken a major toll on healthcare workers and the communities they serve.

Your sacrifices, hard work and dedication to the pharmacy profession have provided and continue to provide a sense of care and safety to our patients and their families.

The Maryland Board of Pharmacy and staff cannot overlook the long hours, service and flexibility you put in to maintain a clean, safe environment.

While mandatory “shelter in place” and other restrictions are followed all over the world, pharmacy professionals are humbly performing duties that fulfill the daily healthcare needs of the public.

During these unsettling and uncertain times, your healthcare responsibilities cannot be underestimated.

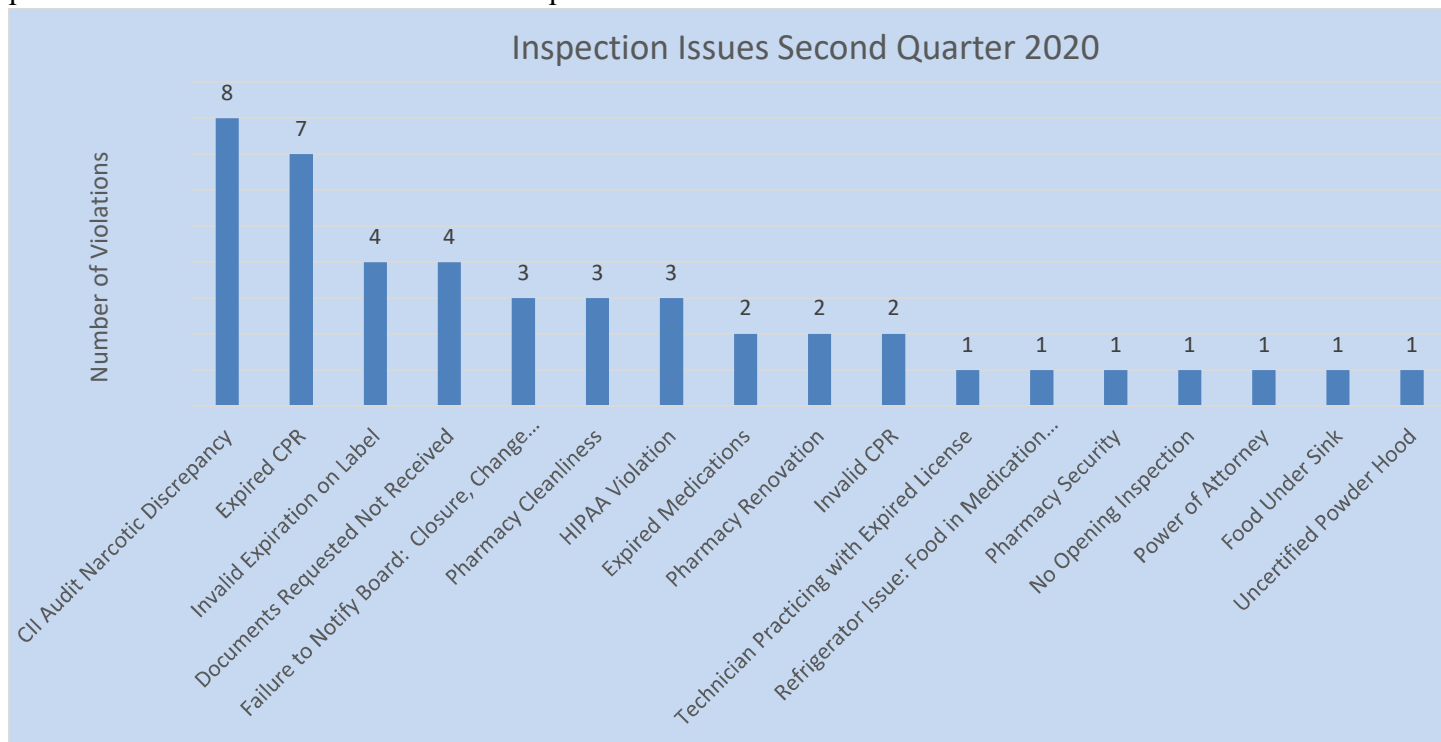
And, for this, we are forever grateful.

Thank You to Our Heroes!

Inspection Issues Second Quarter 2020

The Maryland Board of Pharmacy investigates complaints that come to the Board from various sources. Complaints may come from patients, 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 breakout of the issues that have come to the Board from the inspection of pharmacies across the state in the second quarter of 2020:



DISCIPLINARY ACTIONS

<u>PHARMACY TECHNICIANS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Tara M. Alban	T21018	Revocation	5/20/2020
Michae Denise Ross	T20794	Summary Suspension	7/23/2020
Iyonna M. Anthony	T21741	Summary Suspension	7/23/2020

National Association of Boards of Pharmacy

National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION

HHS Secures More Than 500,000 Courses of Remdesivir for US Hospitals to Treat COVID-19 Patients

The United States Department of Health and Human Services (HHS) has secured more than 500,000 treatment courses of the drug remdesivir for US hospitals through September for the treatment of the coronavirus disease 2019 (COVID-19). Through an agreement with Gilead Sciences, US hospitals will be able to purchase the drug in amounts allocated by HHS and state health departments.

“To the extent possible, we want to ensure that any American patient who needs remdesivir can get it,” said HHS Secretary Alex Azar in a press release. “The Trump Administration is doing everything in our power to learn more about life-saving therapeutics for COVID-19 and secure access to these options for the American people.”

The newly secured supplies of the drug will be allocated to state and territorial health departments based on COVID-19 hospital burden, and health departments will allocate it to hospitals. According to the HHS press release, the delivery of the purchased remdesivir will go directly to the hospital, per the state health department’s allocation decision, rather than going first to the state health departments for subsequent delivery to hospitals.

Reminder: Four-Part Webinar Series on Confluence of the COVID-19 Pandemic and the Opioid Epidemic Begins July 20

NABP President Timothy D. Fensky to Speak on Initiative During August 10 Presentation

A webinar series on the intersecting impacts of the COVID-19 pandemic with the national opioid epidemic is being hosted by the Collaborative for Effective Prescription Opioid Policies (CEPOP) group and Mothers Against Prescription Drug Abuse (MAPDA). The series of four one-hour webinars will seek to share information on this topic, with the goal of fostering more effective and sustainable policy action.

The series begins Monday, July 20, 2020, at 3 PM EST, and goes through August 17. CEPOP and

MAPDA participants and national leaders will be invited to provide their perspectives as preeminent voices within this field. A question and answer segment will also be provided for participants during the moderated sessions.

NABP President Timothy D. Fensky, RPh, DPh, FACA, will present during the August 10 webinar session, “Addressing Access and Utilization of Opioid Overdose Reversal Medications.” Fensky will share his presidential initiative for the 2020-2021 year, which focuses on promoting pharmacist-provided, medication-assisted treatment for patients diagnosed with opioid use disorder.

Additional details, including how to register, are available from the CEPOP website.

New HHS Web Page Shares COVID-19 Testing Plans for Each State, Jurisdiction

Working with subject matter experts from HHS and the Federal Emergency Management Agency, the governors in each state designated teams to develop testing plans to combat the COVID-19 pandemic. These testing plans are available on the HHS Testing Plans web page. The web page includes the total number of individuals planned to be tested by month and detailed testing strategies being implemented by each state and jurisdiction.

Testing plans for July-December were due to the Centers for Disease Control and Prevention (CDC) and HHS Office of the Assistant Secretary for Health on July 10. To support these testing targets, supplies that are in short supply, such as swabs and transport media, will be distributed by the federal government to each jurisdiction. In addition, the government will support the laboratory reagents needs of each state and advise commercial suppliers on their allocation. CDC will work with each state to provide technical assistance for plan implementation, including flexible testing strategies and contact tracing.

ASHP Survey Provides Key Insights Into Current Hospital, Health-System Pharmacy Practice

Formulary management, pharmacogenomics, opioid stewardship, and pharmacist prescribing authority are some of the key areas explored through an annual survey conducted by the American Society of Health-System Pharmacists (ASHP). Pharmacy directors of more than 5,000 US hospitals responded to the survey, and the results

provide key insights on hospital and health-system pharmacy practice. Of the hospitals that participated in the survey:

89% give pharmacists the authority to write medication orders; among these, 94% of pharmacists are able to modify or initiate therapy by policy or protocol, whereas 6% are authorized to prescribe medications;

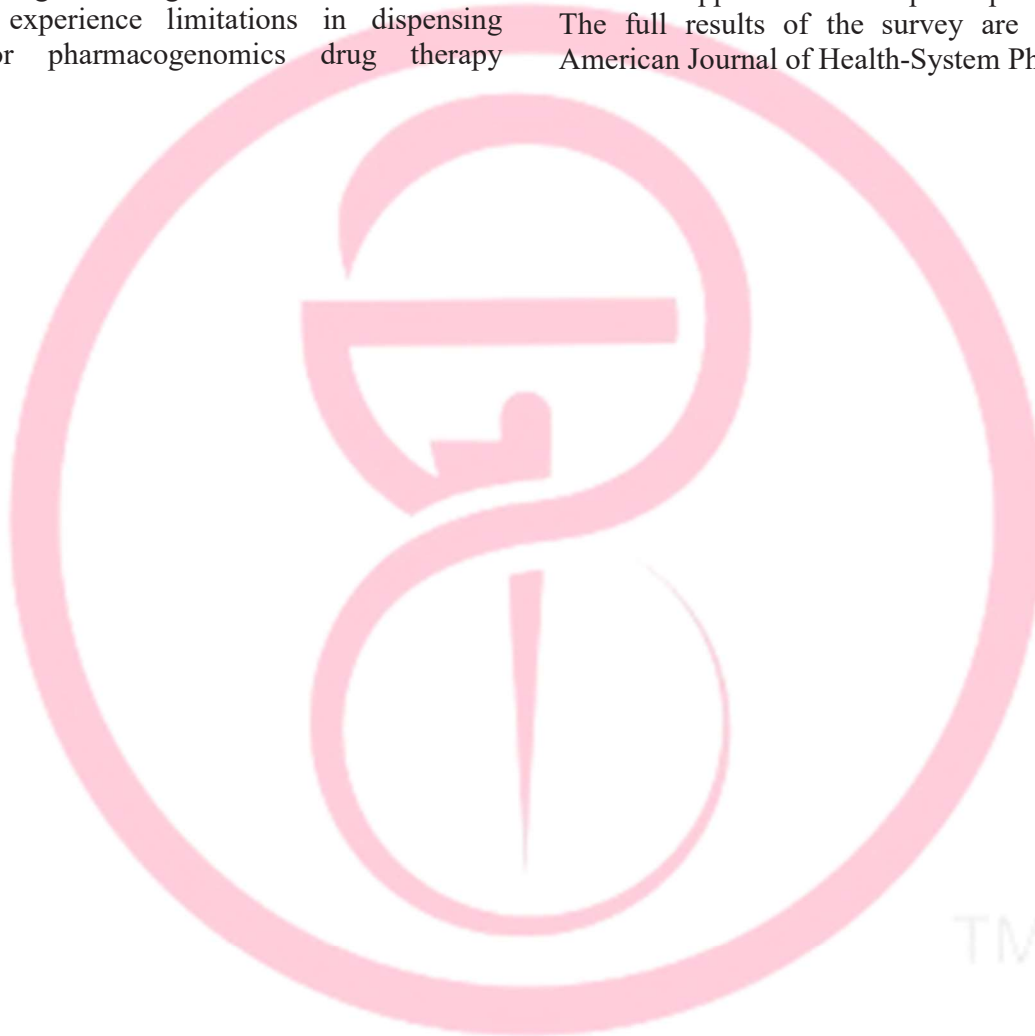
5.4% reported their recommendations for scheduling of pharmacogenomics testing for determining drug and dosage; 90% indicated that their pharmacists experience limitations in dispensing products for pharmacogenomics drug therapy

management;

65% indicated that their pharmacists function as leaders for accountability concerning the hospital's opioid stewardship programs; and

85% have been using a prescription drug monitoring database, compared to 63.5% in 2018.

In all, results from the survey show that pharmacists continue to assume greater responsibility and are taking a leading role in addressing the opioid crisis, advancing compounding pharmacy safety, and leveraging clinical decision support tools to improve prescribing practices. The full results of the survey are published in the American Journal of Health-System Pharmacy.



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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. They are currently being held via teleconference. The Board encourages all interested parties to attend the monthly Board Meetings and awards 2 LIVE CE's to all licensees.

2020 PUBLIC BOARD MEETINGS

Third Wednesday of each month

August 19, 2020
September 16, 2020
October 21, 2020

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

CONTACT DIRECTORY

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