



# 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.*

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## COVID-19 Updates: What You Need to Know

*Deena Speights-Napata, Executive Director*

Over the past few months, the board has been actively engaged in providing COVID-19 vaccine distribution and vaccine administration information to its licensees. The Board of Pharmacy has made every effort to ensure our licensees are aware of local health department vaccination clinic efforts across Maryland, to publicize which populations are being vaccinated when, and to provide information on the process by which one may register to administer the vaccine.

Most of this information is available on our website. The board has also communicated information through blast emails and by responding to the numerous individual email inquiries received at the board. The following sections are answers to the questions we receive most often:

### **Can Maryland registered Pharmacy Technicians administer the COVID vaccine?**

Yes, under certain circumstances:

The Maryland Secretary of Health issued an Amended Directive and Order, dated January 21, 2021, allowing certain registered pharmacy technicians to administer COVID vaccinations. Pursuant to the Amended Order, pharmacy technicians must complete the CDC Administration of COVID vaccines training and work under the supervision of qualified supervisory personnel. Registered pharmacy technicians working under the authority of the Secretary's Amended Order are not required to obtain a vaccination registration issued by the Board.

### **Which Maryland Pharmacies are scheduled to administer COVID vaccine?**

Currently Giant, Walmart, Rite Aid, and Safeway pharmacy chain stores were scheduled to receive the COVID vaccine by February 1<sup>st</sup>. Each of these chains are required to submit a vaccine request to the Maryland Department of Health Immunet system. All registered COVID vaccination clinics will be listed on the MDH Immunet website page as the information is received. The location for the page can be found at the following link: [https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/quick\\_ref\\_guides.aspx](https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/quick_ref_guides.aspx)

(Continued from Page 1)

**Will I receive two doses of the COVID vaccine?**

Yes. Maryland will automatically provide enough vaccine for two doses to be administered to each vaccine recipient. A COVID vaccine provider may not use its second dose allocation on first dose recipients.

**Can I receive a COVID vaccine in a county or priority group that is not my own?**

No. COVID vaccine providers are required to verify the residency and/or age or COVID vaccine phase status of every person registered to receive the vaccine.

**How can pharmacists volunteer at COVID clinics?**

The Department of Health and local health departments (LHD's) in various counties are seeking qualified pharmacist volunteers to administer vaccines, and specifically COVID-19 vaccines, at anticipated vaccination sites.

**Question:** Pharmacists who are interested in volunteering have asked how they can meet the Board's vaccine reporting and recordkeeping requirements when volunteering in this capacity.

**Answer:** Pharmacists who volunteer for an LHD to administer vaccines at an LHD-designated site are on behalf of the LHD, and thus may rely on the LHD to report vaccines administered by the pharmacist volunteer to Immunit and the CDC, and to maintain the requisite administration records in compliance with HIPAA and Maryland medical records laws.

For more information regarding how to become a pharmacist volunteer, please contact the Maryland Responds Medical Reserve Corps at [mdresponds@health.maryland.gov](mailto:mdresponds@health.maryland.gov).

**Where Can I Receive a COVID Test?**

There are several Maryland mass testing sites currently in operation. They include Six Flags America in Prince Georges County, the Baltimore Convention Center in Baltimore City, and Timonium Fairgrounds in Timonium. There also several other locations that include chain pharmacies, Medstar hospital and urgent care centers. For a comprehensive listing please visit: <https://coronavirus.maryland.gov/pages/symptoms-testing>

For specific information on COVID vaccine doses given by county and race, please visit: <https://coronavirus.maryland.gov/#Vaccine>

**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](mailto:mdh.mdbop@maryland.gov) by April 1<sup>st</sup>.

# Mental Health Matters: How to Cope with Stress during COVID-19?

*Salin Nhean, PharmD, BCPS, AAHIVP and Sheryl C. Nwankwo, PharmD*

The coronavirus disease 2019 (COVID-19) pandemic has taken a mental toll on everyone, including patients and healthcare professionals. As the virus continues to spread throughout communities, frontline healthcare workers are particularly vulnerable to the detrimental mental effects as they balance patient care responsibilities and concerns about their well-being and that of their family and friends. According to a survey of 1,119 healthcare workers, 93% were experiencing stress, 86% anxiety, 77% frustration, and 76% exhaustion and burnout.<sup>1</sup> Seventy-six percent of healthcare workers were worried about exposing their child to COVID-19, and about 50% were concerned about exposing their spouse, partner, and older family members.

Although often overlooked, pharmacists and pharmacy technicians are one of the frontline healthcare workers providing much-needed services during the pandemic, such as COVID-19 screening, disseminating drug information regarding investigational agents, maintaining continuity of care through medication dispensing and home medication delivery, managing medication shortages, collaborating with the interdisciplinary team to optimize care for patients with COVID-19, and more.<sup>2</sup> It is critical that healthcare workers, including pharmacists and pharmacy technicians, recognize symptoms of stress, take steps to improve mental health, and know where to get help if needed.

## Recognizing symptoms of stress:

- Trouble sleeping
- Lack of motivation
- Feeling overwhelmed and burned out
- Feeling irritation, anger, or denial
- Trouble concentrating
- Feeling sad or depressed
- Feeling helpless or powerless
- Feeling nervous or anxious

## How to cope with stress as a healthcare professional?<sup>3,4</sup>

It is important to remember that you have a support system at work and home. Communicate openly with supervisors and coworkers about work stress. It is often helpful to recount things that you have accomplished and accept situations you have no control over. Recognize that you play an important role in fighting this pandemic and that you are doing the best you can with the resources available.

Other tactics that may assist pharmacy staff with coping with stress include limiting your exposure to media coverage and social media, implementing mindfulness activities e.g., breathing exercises, grounding, meditation, and reaching out to friends and family.

## Resources

1. National Suicide Prevention Lifeline: 800-273-8255
2. National Domestic Violence Hotline: 800-799-7233 and 800-787-3224 (TTY)
3. Disaster Distress Helpline (overwhelming sadness, depression, anxiety): 800-985-5990

## Conclusion

The COVID-19 pandemic has placed healthcare professionals under immense stress and pressure as they balance between caring for patients and themselves. It is important for them to recognize symptoms of stress and formulate strategies to care for their mental health.

(Continued on page 4)

## References:

1. Mental Health America. The mental health of healthcare workers in COVID-19. <https://mhanational.org/mental-health-healthcare-workers-covid-19>. .
2. Elbeddini A, Wen CX, Tayefehchamani Y, To A. Mental health issues impacting pharmacists during COVID-19. J Pharm Policy Pract. 2020;13:46.
3. Centers for Disease Control and Prevention. Healthcare personnel and first responders: how to cope with stress and build resilience during the COVID-19 pandemic. Updated December 16, 2020.
4. World Health Organization. Mental health and psychosocial support during COVID-19.

## Virtual CE Event



Thanks to Don Taylor for providing the lecture about the Emergency Preparedness Taskforce's history and response to the current Covid-19 pandemic, and thanks to everyone who attended. Your interaction helped make the event a success. We only had slots for 100 licensees and they filled up very quickly.

If you missed this virtual CE event, a second one will be held, date and speaker to be announced in a later email. The number of slots will be increased to 180. The announcement will also be posted on the Board of Pharmacy home page:

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

## New Board of Pharmacy Staff

### Lakeshia Griggs

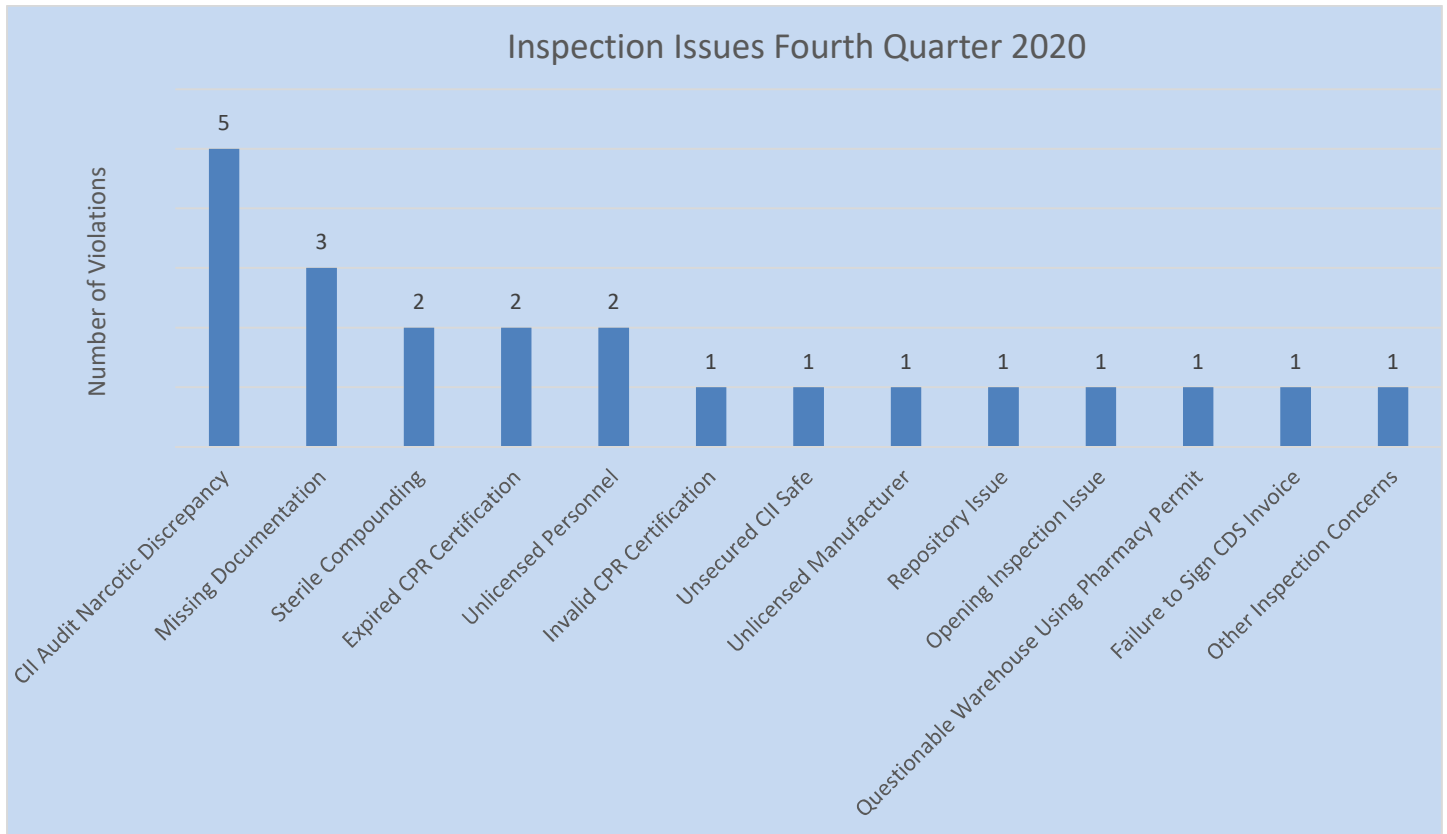
Lakeshia Griggs also joined the Board of Pharmacy staff in January 2021 as a Health Occupations Investigator. Lakeshia most recently worked for Allstate as a Claims Investigator for two years and with State Farm Insurance as an insurance agent for several years. She holds a Bachelors Degree from Kennesaw State University in Criminal Justice, and a Masters Degree in Criminal Justice from South University.

**welcome!**

# Inspection Issues Fourth Quarter 2020

The Maryland Board of Pharmacy investigates complaints that come to the Board from various sources. Complaints 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 fourth quarter of 2020:



## DISCIPLINARY ACTIONS

<u>PHARMACISTS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Stephen M. Chalker	23113	Revocation	11/20/2020
John Anthony Wolk	09874	Reprimand, Probation, Fine	12/11/2020

<u>PHARMACY TECHNICIANS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
Waqas M. Abaid	T04325	Summary Suspension	11/6/2020
Victoria L. Scanlon	T09244	Revocation	11/20/2020

<u>ESTABLISHMENTS</u>	<u>LIC. #</u>	<u>SANCTION</u>	<u>DATE</u>
ASPCares	P06661	Reprimand & Probation	10/2/2020
Pharmacy Solutions Inc.	P06838	Reprimand & Fine	10/2/2020
Austin Pharmacy and Austin Pharmacy & Medical Supplies	P01511 & P05668	Probation & Fine	12/11/2020



# National Association of Boards of Pharmacy

## National Pharmacy Compliance News

*Reprinted from the National Association of Boards of Pharmacy FOUNDATION*

### **DEA Publishes New Version of Pharmacist's Manual**

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA [website](#).

### **Time to End VinCRISTine Syringe Administration**



*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](http://www.ismp.org) or by email to [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org) to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (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](http://www.ismp.org).*

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of trans-dermal fentaNYL patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fentaNYL 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 fentaNYL patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fentaNYL patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

Unfortunately, some practice sites are still using syringes to administer IV vinCRISTine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vinCRISTine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vinCRISTine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals*, which were launched in 2014<sup>1</sup>. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vinCRISTine labeling.<sup>2</sup>

ISMP has frequently referred to wrong route administration of vinCRISTine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vinCRISTine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vinCRISTine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vinCRISTine doses to be diluted in a minibag.

### **References**

1. [www.ismp.org/guidelines/best-practices-hospitals](http://www.ismp.org/guidelines/best-practices-hospitals)
2. [www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids](http://www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids)

## ***What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products***



*This column was prepared by FDA, an agency within the*

*US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on [March 23, 2020](#), FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

### **Key Terms for Biosimilar and Interchangeable Products:**

- ✦ **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- ✦ **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- ✦ **Reference Product:** A reference product is the

single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

### **Are Biosimilars the Same as Generic Drugs?**

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

### **What is the Purple Book?**

The [Purple Book](#) database contains information on FDA- licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research.

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation(eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

## Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the “Orange Book.” The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

## Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA’s rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

## Where Can I Find Additional Resources?

- † [fda.gov/biosimilars](https://www.fda.gov/biosimilars)
- † [purplebooksearch.fda.gov](https://purplebooksearch.fda.gov)
- † [fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act)

- † [fda.gov/media/135340/download](https://www.fda.gov/media/135340/download)

## Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, [Insanitary Conditions at Compounding Facilities Guidance for Industry](https://www.fda.gov/oc/insanitary-conditions-compounding-facilities-guidance-for-industry), provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.



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 Consumer Representative  
 Independent Pharmacist Representative  
 Acute Care Hospital 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 CEs to all licensees.

### 2021 PUBLIC BOARD MEETINGS

#### Third Wednesday of each month

March 17, 2021

April 21, 2021

May 19, 2021

**Location: 1-877-521-8687**

**Conference ID: 9060042**

### CONTACT DIRECTORY

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#### Executive Director

*Deena Speights-Napata*

<b>Deputy Director &amp; Operations Manager</b>  <i>Edward Fields</i>	<b>Director of Compliance</b>  <i>Trina Leak</i>	<b>Manager of Program Intake, Assessment &amp; Evaluation</b>  <i>Nakia Jordan</i>	<b>Licensing Manager</b>  <i>Doris James</i>
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# Maryland Board of Pharmacy

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