



# Virginia Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Board Member Transitions to Staff**

Virginia Board of Pharmacy Member Ellen Shinaberry resigned from the Board February 10, 2018, and joined the staff as a deputy executive director. Ms Shinaberry served on the Board for the past eight years, including serving as Board chairman from July 1, 2014, through June 30, 2015, and chaired numerous committees throughout the years. She practiced as a pharmacist in community and long-term care pharmacy and has more than 25 years of hospital pharmacy experience in various leadership roles. Most recently, she served as the Blue Ridge Pharmacy information technology specialist at Sentara RMH Medical Center in Harrisonburg, VA.

The Board extends its sincere appreciation to Ms Shinaberry for her participation and leadership in protecting public safety and wishes her well in her new position.

## **Board of Medicine Emergency Regulations on Prescribing Opioids**

Board of Pharmacy staff have received several inquiries from pharmacists and patients recently regarding the Virginia Board of Medicine's emergency regulations on prescribing opioids. Please note that on August 24, 2017, the Board of Medicine amended and replaced the emergency regulations that became effective on March 15, 2017. One of the more significant amendments authorizes buprenorphine without naloxone (buprenorphine mono-product) to be prescribed to patients who have a demonstrated intolerance to naloxone. However, such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record. This is an expanded authorization for when a prescriber may prescribe buprenorphine mono-product, as the earlier emergency regulations did not previously allow the prescribing of buprenorphine mono-product for patients with an intolerance to naloxone.

To assist both prescribers and pharmacists in understanding the regulations, the Board of Medicine published a list of frequently asked questions in September 2017, which

may be accessed at <https://www.dhp.virginia.gov/medicine/docs/FAQPrescribingBuprenorphine.pdf>. While the regulations are for prescribers and do not place additional requirements on pharmacists, pharmacists are strongly encouraged to review the document to increase their knowledge and ability in assisting patients. Pharmacists should continue to evaluate the validity of all prescriptions by ensuring that the prescription was issued for a legitimate medical purpose.

The Board of Medicine's emergency regulations, effective August 24, 2017, with the changes bracketed may be accessed at [https://www.dhp.virginia.gov/medicine/leg/EmergencyText\\_082417.docx](https://www.dhp.virginia.gov/medicine/leg/EmergencyText_082417.docx). However, these emergency regulations expire on March 19, 2018, and will be replaced with permanent regulations. Once published, the permanent regulations will be accessible on the Board of Medicine's website at [https://www.dhp.virginia.gov/medicine/medicine\\_laws\\_regs.htm](https://www.dhp.virginia.gov/medicine/medicine_laws_regs.htm).

## **New Guidance Documents for Delivery of Dispensed Drugs and Drug Disposal**

On September 26, 2017, the Board adopted two guidance documents to assist licensees with processes for delivering and disposing of dispensed drugs. Guidance Document 110-46, Delivery of Dispensed Drugs, found on the Board's website at <https://www.dhp.virginia.gov/pharmacy/guidelines/110-46.docx>, highlights the importance of pharmacists ensuring that dispensed drugs are packaged for delivery in a manner that maintains appropriate storage temperature requirements in accordance with the manufacturer's recommendations. The packaging may require the use of a temperature monitoring device, particularly for drugs that are temperature-sensitive, to alert the patient if a drug has been maintained at a temperature outside of an acceptable range. Any cold packs used in the packaging materials should be appropriately placed in the container to avoid freezing and ensure that the appropriate temperature range is maintained during delivery.

Guidance Document 110-47, Guidelines for Provision of Counseling and Information by Pharmacists Regarding Proper Disposal of Unused Dispensed Drugs, was

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# National Pharmacy Compliance News

March 2018



**NABPF**  
National Association of Boards  
of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

## **FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers**

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm).

## **Amount of Prescribed Opioids Remains High, Reports CDC**

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with

prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at [www.cdc.gov/mmwr/index.html](http://www.cdc.gov/mmwr/index.html) in the Weekly Report section.

## **AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients**

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

## **Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants**

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at [www.fda.gov/Drugs/DrugSafety/ucm575307.htm](http://www.fda.gov/Drugs/DrugSafety/ucm575307.htm).

### **New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country**

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

### **Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions**

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they

comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm).

### **FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan**

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm).

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report).

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developed pursuant to House Bill 2046, passed during the 2017 Virginia General Assembly Session, and may be accessed on the Board's website at <https://www.dhp.virginia.gov/pharmacy/guidelines/110-47.docx>. It recommends that pharmacists counsel patients on the importance of properly securing dispensed drugs at home to prevent diversion from medicine cabinets and how to properly dispose of unwanted drugs, particularly those in Schedules II-V. Various disposal options for patients are listed within the document, and links to additional resources, such as a flyer for pharmacists to print and share with patients, are found within the guidance document.

### **Continuing Education in 2018**

As part of the annual 15-hour continuing education (CE) requirement, §54.1-3314.1 permits the Board to require pharmacists to obtain up to two hours of CE on a specific topic. Please note that there is no specified topic for the 2018 CE requirement. Pharmacists may obtain the required 15 contact hours in subjects of their choosing to best enhance their knowledge and improve their practice. Additionally, as a reminder, please be aware that both pharmacists and pharmacy technicians may now obtain a portion of their required CE contact hours for volunteering in a free clinic or local health department. More information on this topic may be found at <https://www.dhp.virginia.gov/pharmacy/guidelines/110-04.docx>.

### **Compliance With USP Chapter <800>**

During the September 2017 full Board meeting, the Board discussed time frames for enforcing United States Pharmacopeia (USP) Chapter <800>. Subsequent to the meeting, USP announced its intent to delay the effective date of Chapter <800> until December 1, 2019. USP stated, "The purpose of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> Pharmaceutical Compounding—Sterile Preparations, to provide a unified approach to quality compounding." Therefore, the Board revisited this topic at the December 2017 full Board meeting and adopted amendments to Guidance Document 110-36, Compliance With USP Standards for Compounding, to address the enforcement timeline and assist licensees with how to comply with Chapter <800>.

Guidance Document 110-36 states that the Board cannot enforce the standards of Chapter <800> until the chapter takes effect on December 1, 2019. However, pharmacy inspectors will begin identifying areas of noncompliance during routine pharmacy inspections during the summer of 2018 as a means of assisting pharmacists in understanding where modifications may be necessary. The inspectors will not cite deficiencies for such noncompliance, but will simply note the discussion on the inspection report. Additionally, approximately 35 questions and answers were added to the guidance document to assist pharmacists with

understanding how to comply with Chapter <800>. It is strongly recommended that pharmacists review the document, read the proposed Chapter <800>, complete additional training on the subject as necessary, and begin working toward complying with the standards no later than December 1, 2019. Guidance Document 110-36 may be accessed at [www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](https://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm).

### **Prescriptions Written for 'Office Use Only'**

A pharmacy may provide prescription drugs to a physician for office use in accordance with §54.1-3435.02 of the Drug Control Act, which states that a permitted pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as a wholesale distributor when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances (CS) do not exceed 5% of the gross annual sales of prescription drugs by the relevant permitted pharmacy; or such wholesale distributions of Schedules II-V CS do not exceed 5% of the total dosage units of the Schedule II-V CS dispensed annually by the pharmacy. Occasionally, a physician will request prescription drugs by providing the pharmacy with a prescription indicating "For Office Use Only" in the name field. This does not constitute a valid prescription because it is not issued in the name of a specific patient for a specific drug that resulted from a bona fide practitioner-patient relationship. Pharmacists must not dispense prescriptions written "For Office Use Only."

To properly transfer the requested drugs, the pharmacist must create an invoice containing the following information: the date of transfer; the name and address of the physician to whom the drugs are to be transferred; the name and address of the pharmacy from where the drugs were transferred; and the kind and quantity of drugs transferred. The transferring pharmacy maintains the original invoice for two years from the date of transfer and provides a copy to the receiving physician. Once received, the physician must indicate the date of receipt on the invoice and maintain the invoice for two years from the date of receipt. If the requested drug is classified as a Schedule II, the physician wishing to obtain the drug must execute a Drug Enforcement Administration (DEA) Form 222 as the "purchaser" and provide this form to the transferring pharmacy. The transferring pharmacy would then complete DEA Form 222 acting as the "supplier" in this instance. Copies of DEA Form 222 must then be properly forwarded as required by federal law. If maintaining a separate record of the distribution electronically in the pharmacy's computer, pharmacists must ensure that the information is not transmitted to the prescription monitoring program (PMP) with other dispensing records. Assigning a "prescription" number to the transaction may result in the distribution information being uploaded to the PMP.

## **Preventing Overdose Deaths Through Counseling and Naloxone**

Pharmacists are strongly encouraged to counsel patients receiving prescriptions for opioids, particularly those who may be at increased risk of overdose based on a high morphine milligram equivalency (MME), and to recommend the patient obtain naloxone if he or she has not already done so. Pharmacists who query the PMP may view the patient's MME on the report provided by the PMP. To read more about addiction and learn about resources that may assist you in your practice, visit the VaAware website at <http://vaaware.com>. VaAware is a collaboration between five Virginia agencies: the Department of Health, Department of Behavioral Health and Developmental Services, Department of Criminal Justice Services, Department of Health Professions, and Department of Social Services.

## **PMP Now Interoperable With North Carolina; UVA Improves Access to PMP**

On January 24, 2018, Governor Ralph Northam announced that North Carolina is the most recent state to become interoperable with Virginia's [PMP](#). This addition makes Virginia's program fully integrated with more than

half of the states in the US. Furthermore, all states bordering Virginia are now connected to Virginia's PMP.

Additionally, it was announced in January that the University of Virginia (UVA) Health System in Charlottesville, VA, became the first large medical system in Virginia under a public-private grant to initiate use of the [NarxCare](#) digital bridge. NarxCare is a platform developed by Appriss Health that is used by prescribers and pharmacists within their workflow to expedite access to the Commonwealth's PMP.

To read more about these two initiatives, visit [www.dhp.virginia.gov/dhp\\_programs/pmp/default.asp](http://www.dhp.virginia.gov/dhp_programs/pmp/default.asp).

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