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Virginia Board of Pharmacy News

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Significant Regulatory Changes Effective December 11, 2019

As indicated in an email previously sent to licensees, the Virginia Board of Pharmacy recently completed a comprehensive review of its regulations, which resulted in many regulatory changes that became effective December 11, 2019. A periodic review of regulations is performed approximately every four years. A crosswalk summary document may be found at *https://www.dhp.virginia.gov/Pharmacy/leg/CrosswalkForPharmacyChapters2019.docx* to assist you in identifying which regulations were affected. Please review this document, along with the current regulations, which may be accessed at *https://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm.*

The most notable regulatory changes are outlined below:

- Eligible pharmacists-in-charge (PICs) must now have at least two years of experience practicing as a pharmacist in Virginia or another United States jurisdiction. This requirement does not impact a PIC who assumed the role prior to December 11, 2019.
- Beginning in 2020, of the 15 contact hours of continuing education required for annual renewal of a pharmacist license, at least three hours shall be obtained in courses or programs that are live or real-time interactive. Included in the three hours, the following may be credited:
  1. A maximum of one hour for attendance at a Board meeting or formal hearing; or
  2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.
- Regulations related to pharmacists, pharmacy technicians, and pharmacy interns were removed from Chapter 20, Regulations Governing the Practice of Pharmacy, and placed into a new chapter, Chapter 21, Regulations Governing Pharmacists, Pharmacy Interns, and Pharmacy Technicians. Regulations remaining in Chapter 20 primarily address pharmacies, medical equipment suppliers, and the practice of pharmacy;
- Regulations in Chapter 50, Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-Party Logistic Providers, were revised.

Pharmacists Play Important Role in Proper Drug Storage and Disposal

Unused or expired prescription medications are a public safety issue, leading to potential accidental poisoning, misuse, and overdose. Proper disposal of unused drugs saves lives and protects the environment. Pharmacists and pharmacy technicians play an important role in educating patients about how to safely dispose of unwanted prescription medications. Adverse effects on the environment can be minimized by promoting the use of approved drug disposal programs.

Year-round drug disposal is available to the public at Drug Enforcement Administration (DEA)-authorized collection sites across the state. Available medication disposal sites in your area can be found by visiting *http://www.dhp.virginia.gov/pharmacy/destructionsites.asp*. In addition to the authorized collection sites, DEA provides National Prescription Drug Take-Back Days each spring and fall. Collection sites are set up in local cities and counties throughout the state for safe disposal of prescription drugs, including opioids. The disposal is free to consumers and no questions are asked. Information for upcoming Take-Back Days can be found at *https://takebackday.dea.gov*.

Access to educational flyers and pharmacist resources for counseling patients on proper drug storage and disposal is available in Guidance Document 110-47 found here.

Prescribing of Gabapentin

The 2019 Virginia General Assembly passed House Bill (HB) 2557, which classified gabapentin as a Schedule V

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National Pharmacy Compliance News

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NABPF
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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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

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

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

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 a legitimate investigation or legal action is always 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.

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controlled substance as of July 1, 2019. Board staff continues to receive questions on this subject. As a reminder, while this scheduling action occurred under state law, DEA has not yet scheduled gabapentin; therefore, a prescriber is not required to hold a DEA registration in order to possess, dispense, or prescribe gabapentin. More information on this subject may be accessed here.

First Pharmaceutical Processor Permit Issued

The Board issued its first pharmaceutical processor permit for the cultivation of cannabis for the purpose of producing cannabidiol (CBD) oil and THC-A oil on January 14, 2020, to Dharma Pharmaceuticals located in Bristol, VA. The pharmaceutical processor plans to have CBD and THC-A oil products for dispensing to patients by summer. These products may legally have up to 5% tetrahydrocannabinol (THC), the psychoactive component of the cannabis plant, and may only be dispensed to Board-registered patients who have been issued a written certification by a Board-registered practitioner for treatment or to alleviate the symptoms of the patient's diagnosed condition or disease. Up to four additional pharmaceutical processor permits may be issued later this year.

More information on the pharmaceutical processor program, including updates and a general overview regarding allowances for CBD and THC-A oil may be accessed here.

Separate Prescriptive Authority License for Nurse Practitioners to Be Eliminated

Note: This information is provided for informational purposes only and does not require pharmacists to take any particular action.

The Virginia Board of Nursing has historically granted a separate license beginning with the numbers 0017 to nurse practitioners with prescriptive authority. This license was in addition to the license to practice as a nurse. Recent changes to Board of Nursing regulations no longer require a separate license for nurse practitioners with prescriptive authority. Effective March 4, 2020, all nurse practitioners will have one license beginning with the numbers 0024. Nurse practitioners who have been granted prescriptive authority will have an additional designation of "RX Authority" clearly displayed on their licenses. Nurse practitioner licenses can be verified on the License Lookup feature located on the Board of Pharmacy's website.

Virginia Immunization Information System

Pharmacists are increasingly playing a vital role in administering vaccines to patients. Most pharmacies currently document these administrations in the Virginia Immunization Information System (VIIS), Virginia's statewide immunization registry that contains immunization data of persons of all ages. VIIS is a voluntary, free, web-based system for data that documents all immunizations a person has received into one definitive, accurate record. It assists health care providers in ensuring patients do not receive unnecessary duplication of immunizations. The Board encourages all pharmacists who administer vaccines to enroll in VIIS and check a patient's immunization history before vaccinating to reduce duplicate vaccines or the administration of an invalid vaccine if given too soon after a previous dose. More information is available at *http://www.vdh.virginia.gov/epidemiology/immunization/viis/index.htm.*

E-Prescribing of Opioids Effective July 1, 2020

As a reminder, HB 2559 was passed by the 2019 General Assembly, which amended §54.1-3408.02 and §54.1-3410 and requires any prescription for a controlled substance that contains an opioid to be issued as an electronic prescription as of July 1, 2020. Several exceptions to this requirement are enumerated in §54.1-3408.02. As indicated in §54.1-3410, a pharmacist who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in §54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law.

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