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Virginia Board of Pharmacy News

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Updated Pharmacy-Related Regulations

New Regulation Allows Dispensing Schedule VI Prescriptions in Quantities Up to the Total Amount Prescribed, with Certain Restrictions

In March 2017, the Virginia Board of Pharmacy adopted a proposed amendment resulting from a petition for rulemaking to allow for the dispensing and refilling of Schedule VI prescriptions, with certain restrictions, in quantities up to the total amount prescribed. The public comment period on final regulations occurred October 1, 2018, through October 31, 2018. The revised Regulation 18 Virginia Administrative Code (VAC) 110-20-320(B) became effective October 31, 2018. Subsection B of the regulation now states (emphasis added):

> A prescription for a drug listed in Schedule VI **may** be refilled as authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in § 54.1-3410 C or subdivision 4 of § 54.1-3411 of the Code of Virginia. **Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519 of the Code of Virginia, a pharmacist, using professional judgment and upon request by the patient, may dispense or refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration.**

Board Amends Rules on Emergency Drug Kits, Stat-Drug Boxes, and the Use of Automated Dispensing Devices

In March 2017, the Board also acted on another petition for rulemaking to amend Regulations 18VAC110-20-540 Emergency Drug Kit, 18VAC110-20-550 Stat-Drug Box, and 18VAC110-20-555 Use of Automated Dispensing Devices, to clarify requirements for the use of electronic devices as emergency drug kits and stat-drug boxes. The petition stated that the requirement in Board regulation differed from federal regulation because the Board requirement for a controlled substance (CS) registration did not distinguish between using automated dispensing devices for first dose, non-routine administration, versus routine drug administration.

The Board voted unanimously to accept the petition for rulemaking by amending Regulation 18VAC110-20-555 to conform to federal regulations by clarifying that a CS registration is not required to use an automated dispensing device in a nursing home when the drugs are only accessed as a stat-drug box. However, a CS registration is required when using an automated dispensing device in a nursing home and accessing the drugs for routine administration. The Board further clarified in the regulation the quantity of drugs in Schedules II-V that may be stocked in the device. The revised Regulations 18VAC110-20-540, 18VAC110-20-550, and 18VAC110-20-555 became effective October 31, 2018. To review Regulations 18VAC110-20-540, 18VAC110-20-550, and 18VAC110-20-555 within the Regulations Governing the Practice of Pharmacy document, visit *www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.*

Renewal of Pharmacist Licenses and Pharmacy Technician Registrations

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2018. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Board. Renewal notifications have been sent to the email addresses on file with the Board and to the official mailing address of record for those persons who have not provided the Board with an email address. Either an established login and password from a previous renewal cycle may be used to gain access, or licensees may use the license number and personal identification number provided in the renewal notification. Licensees are encouraged to renew online. Additionally, please be sure to review for accuracy both the public address and address of record (private) as well as phone numbers and email addresses that the Board has on record. Fees for renewals received by the Board by December 31, 2018, are as follows: pharmacist current active license – $90; pharmacist current inactive license – $45; and pharmacy technician registrations – $25. To change a pharmacist license status from active to inactive, follow the online instructions for changing the status and submitting the $45 renewal fee for inactive status. An additional late fee of $30 for current active pharmacist licenses, $15 for current inactive pharmacist licenses, and $10 for pharmacy technicians must

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National Pharmacy Compliance News

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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be submitted for renewals received by the Board after December 31, 2018. Renewals are processed the next business day following receipt. However, it may take seven to 10 business days following the Board's receipt of a renewal to receive the updated license or registration by mail. Holidays may further delay processing and receipt by mail. If a license or registration is not received via mail within 14 days of submitting the renewal, please contact the Board by email at pharmbd@dhp.virginia.gov.

In addition to submitting the renewal fee, each current active pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2018 calendar year. Please note that there is no specific topic required for CE in 2018. Each year, pharmacists are required to obtain 15 contact hours of qualifying CE per calendar year and pharmacy technicians must obtain five contact hours of qualifying CE per calendar year. Individuals who have not obtained the appropriate amount of CE during 2018 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good causes only. Such requests must be made in writing and prior to renewing the license. Any individuals who request an extension will have their CE audited the following year. Refer to Guidance Documents 110-4 and 110-42 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm* for more information related to CE.

Returning a Dispensed Drug to Stock

As a reminder, regulation allows for a pharmacy to return a dispensed drug to stock for re-dispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. The expiration date may be manually written or printed on the label. Additionally, the restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210. To review the relevant regulations in the Regulations Governing the Practice of Pharmacy document, visit *www.dhp.virginia.gov/pharmacy/pharmacy_laws_ regs.htm.*

Fraudulent Prescription Alert: Promethazine With Codeine

The Board recently received notice from Drug Enforcement Administration (DEA) of fraudulent prescriptions for promethazine with codeine. Fraudulent prescriptions have been seen in Delaware, the District of Columbia, Maryland, Pennsylvania, and Virginia. Contact local law enforcement or call 911 if suspected fraudulent prescriptions are received. If the fraudulent activity involves a licensee of the Department of Health Professions (DHP), also file a complaint with the DHP Enforcement Division at *www.dhp.virginia.gov/enforcement/complaints.htm.*

Use of Mobile Devices in the Issuance of EPCS

DEA issued the following statement on August 16, 2018, regarding the use of mobile devices for issuing electronic prescriptions for controlled substances (EPCS) due to confusion surrounding this issue:

> At this time, the DEA does not preclude the use of a mobile device, for the issuance of an electronic prescription for a controlled substance, **if** the encryption used on the device meets the latest security requirements set out in Federal Information Processing Standards (FIPS 140-2). The DEA will allow the use of a mobile device as a hard token, that is separate from the computer or device running the EPCS application, **if** that device meets FIPS 140-2 Security Level 1 or higher. The device used to create the prescription cannot be the same device that serves as the hard token in the two-factor authentication.
>
> A practitioner who uses a mobile or other electronic device for EPCS, and who does not wish to carry a hard token on a separate device, must use biometrics, and a password or a challenge question. See 21 C.F.R. §§ 1311.115 and 1311.116.
>
> A practitioner may issue an electronic prescription for a Schedule II, III, IV, or V controlled substance when all of the requirements under 21 C.F.R. Part 1311 (Subpart C) are met.
>
> Please note that while this document reflects DEA's interpretation of the relevant provisions of the Controlled Substances Act (CSA) and DEA regulations, to the extent it goes beyond merely reiterating the text of law or regulations, it does not have the force of law and is not legally binding on registrants. Because this document is not a regulation that has the force of law, it may be rescinded or modified at DEA's discretion. For more information contact DEA Policy & Liaison Section at ODLP@usdoj.gov.

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