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Virginia Board of Pharmacy News

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Safeguards Against Diversion of Controlled Substances

Section 54.1-3434 of the Virginia Drug Control Act states that a pharmacist-in-charge (PIC) of a pharmacy "shall provide safeguards against diversion of all controlled substances." There are several requirements in law and regulation with which the PIC must comply:

- Ensure all security measures are in compliance and operational, eg, locks to enclosures are functional, access to the key(s) and alarm code is restricted to pharmacists who practice at the location, and the emergency key and alarm code are securely stored.
- Ensure the biennial inventory of all drugs in Schedules II, III, IV, and V, including any expired drugs in Schedules II-V, is performed within two years of the previous biennial inventory.
- Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include all Schedule II drugs in the monthly perpetual inventory requirement, including any drugs on hand that were not dispensed during that month and any expired drugs. To comply with the requirement to perform the required "reconciliation" of the perpetual inventory, an explanation for any difference between the physical count and the theoretical count must be noted. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable, provided such alerts are reviewed at least monthly. If using an electronic system, any discrepancies must be noted with an explanation for any differences between drugs received and drugs dispensed.
- Notify the Virginia Board of Pharmacy of any theft or unusual losses of drugs as soon as discovered. Within 30 days of the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity, and strength of the lost drugs. Maintain this listing for two years from the date of the recorded transaction.

Within Guidance Document 110-16, the Board also offers the following suggested best practices:

- Perform state and federal criminal background checks on all personnel with access to controlled substances (CS);
- Require periodic urine drug screening of all personnel with access to CS;
- Prohibit personnel from bringing smocks or bags into the prescription department;
- Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to CS;
- Ensure all personnel with access to CS are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, including armed robberies and loss of CS;
- In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at risk for diversion and appropriately reconcile all discrepancies;
- Do not delegate the management of drug inventory to solely one individual;
- Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
- Install surveillance cameras to prevent and/or identify theft or loss of CS;
- Have full and timely access to all reports relating to inventories, invoices, and audits; and
- In addition to the reporting requirements in Section 54.1-2400.6, notify the Board of any separation of an employee for known or suspected drug diversion.

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National Pharmacy Compliance News

September 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.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation.* Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when

mixed with water and sequesters excess opioids and other drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further,,USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The Standard plan is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically.

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Review Guidance Document 110-27 for additional responsibilities of the PIC and Guidance Document 110-16 regarding the performing of inventories at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Education of USP Chapter <800>

In December 2017, the Board amended Guidance Document 110-36, Compliance with USP Standards for Compounding, to include frequently asked questions (FAQs) on complying with United States Pharmacopeia (USP) Chapter <800>. The guidance document is intended to assist licensees with coming into compliance with this chapter, which will take effect on December 1, 2019. On July 2, 2018, pharmacy inspectors began educating pharmacists on the requirements of USP Chapter <800> during routine pharmacy inspections and how this chapter may affect their pharmacy practice. No deficiencies will be cited for noncompliance prior to December 1, 2019. As a reminder, it is strongly encouraged that pharmacists review USP Chapter <800> and become familiar with the requirements, complete additional training on the subject if necessary, and begin working toward compliance with this new chapter. Guidance Document 110-36 may be accessed at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Revised Inspection Form and Changes to Guidance Document 110-9

A comprehensive review of the Board's routine pharmacy inspection report was recently performed. Revisions resulted in a shorter inspection form with a greater focus on issues referenced in Guidance Document 110-9. The portion related to sterile compounding remains the same. A section on USP Chapter <800> was added to assist inspectors in educating pharmacists on select general concepts of the new standards. USP Chapter <800> cannot be enforced until the chapter has taken effect in December 2019; this portion of the inspection report is for educational purposes only.

Additionally, the Board significantly revised Guidance Document 110-9 regarding the enforcement of certain deficiencies. Beginning July 1, 2018, if deficiencies #3, 4, 6, 8, 9a, 11, 12a, 13, 30, or 31 are cited during a routine pharmacy inspection, a monetary penalty will not be imposed; however, the deficiency must be corrected. If a "repeat" deficiency of the same violation is observed by the inspector during the next subsequent routine or focused inspection, then the Board will impose the recommended monetary penalty. A "repeat" deficiency is a deficiency that was cited during the routine or focused inspection performed **immediately prior to the current routine inspection** and after July 1, 2018.

Example #1:

- Routine inspection performed on July 1, 2018 – Deficiency #3 was cited. No monetary penalty will be imposed.
- Routine inspection performed on July 1, 2020 – Deficiency #3 was cited as a repeat deficiency. The monetary penalty will be imposed.

Example #2:

- Routine inspection performed on July 1, 2018 – Deficiency #3 was cited. No monetary penalty will be imposed.
- Routine inspection performed on July 1, 2020 – Deficiency #3 was **not** cited.
- Routine inspection performed on July 1, 2022 – Deficiency #3 was cited. No monetary penalty will be imposed since it was not cited during the inspection immediately prior to this inspection.
- Routine inspection performed on July 1, 2024 – Deficiency #3 was cited. The monetary penalty will be imposed since it is a repeat deficiency from the inspection immediately prior to this inspection.

Refer to Guidance Document 110-9 for additional information at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.* An explanation of the enforcement procedure is provided on the last page of the Guidance Document.

Update on Pharmaceutical Processors

A pharmaceutical processor is a facility that operates under pharmacist oversight and has obtained a permit from the Board, pursuant to Section 54.1-3408.3, to cultivate cannabis plants for the production and dispensing of cannabidiol (CBD) oil or THC-A oil. A physician registered with the Board may issue a written certification for the oils to a patient for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the physician to benefit from such use. The written certificate provides an affirmative defense for possessing the oils. Patients, along with parents and guardians of minors or incapacitated adults, must also register with the Board. The online registration application process for physicians, patients, and parents/guardians was implemented on July 30, 2018.

The pharmaceutical processor permits will be awarded through a competitive application process, as the law authorizes the Board to issue or renew in any year a maximum of five pharmaceutical processor permits, one for each health service area established by the Virginia Board of Health. The application process for the pharmaceutical processor permits will occur in three stages: the submitting of initial applications, awarding of conditional approval(s), and granting of pharmaceutical processor permit(s). The Board

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received 51 applications prior to the June 8, 2018 request for application deadline. An ad hoc committee has been appointed by the Board chairman to evaluate the applications. Because of the large number of applications and voluminous submissions received, the ad hoc committee's tentative in-person meeting on July 30-31 was rescheduled to September 4-5, 2018, to allow additional time for the committee to complete a thorough review of the applications prior to the in-person discussion. The Board will now tentatively consider the committee's recommendations on September 25, 2018. The Board will then inform those applicants to be awarded conditional approval to complete criminal background checks. The Board will review the criminal background results and finalize the awarding of the conditional approval tentatively on October 25, 2018, or November 28, 2018, depending on the receipt of all background results.

On September 25, 2018, the Board will also adopt permanent regulations for the pharmaceutical processor program to replace the emergency regulations. Additional information, including FAQs, laws, and regulations, may be accessed at *www.dhp.virginia.gov/pharmacy/PharmaceuticalProcessing/default.htm.*

A list of registered physicians capable of issuing a written certification may be accessed via the online "License Lookup" feature at *https://dhp.virginiainteractive.org/Lookup/Index* and searching the occupation of "Registered Physician for CBD/THC-A Oil" in the state of Virginia.

New Board Appointees and Election of Chairman and Vice Chairman of the Board

Governor Ralph Northam announced the following Board member appointments on July 27, 2018:

- Glenn Bolyard of Glen Allen, VA 23059, member, appointed July 27, 2018, for a term of four years beginning July 1, 2018, and ending June 30, 2022, to succeed Jody Allen;
- Melvin L. Boone, Sr, of Chesapeake, VA 23320, citizen member, appointed July 27, 2018, for a term of four years beginning July 1, 2018, and ending June 30, 2022, to succeed himself;
- Cheryl H. Nelson of Richmond, VA 23238, member, appointed July 27, 2018, for a term of four years beginning July 1, 2018, and ending June 30, 2022, to succeed herself;
- Kristopher S. Ratliff of Marion, VA 24354, member, appointed July 27, 2018, for a term of four years beginning July 1, 2018, and ending June 30, 2022, to succeed Michael Elliott; and
- Patricia Lynn Richards-Spruill of Suffolk, VA 23434, member, appointed July 27, 2018, for a term of four years beginning July 1, 2018, and ending June 30, 2022, to succeed Sheila Elliott.

The Board welcomes the recently appointed members and extends gratitude to Jody Allen who served eight years on the Board, and Michael Elliott and Sheila Elliott who each served four years on the Board. The Board also extends appreciation to Ryan K. Logan and Michael I. Elliott for their dedication and leadership while serving as chairman and vice chairman, respectively, during the previous year, and congratulates Rafael Saenz and Cynthia Warriner who were recently elected chairman and vice chairman, respectively.

Virginia Medical Reserve Corps

Contributed by Christine Fletcher, pharmacy consultant for the Office of Emergency Preparedness, Virginia Department of Health

The Virginia Medical Reserve Corps (MRC) is a force of dedicated volunteers who stand ready to support the community in the event of a public emergency. The mission of MRC is to engage volunteers to strengthen public health, emergency response, and community resiliency. MRC units are community-based and function as a way to localize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies and promote healthy living throughout the year. MRC volunteers supplement existing emergency medical and public health resources.

While a significant number of pharmacists and pharmacy technicians have indicated a willingness to provide emergency assistance when renewing their health professions licenses, the majority have not fully completed the registration and orientation process to become deployable emergency response volunteers. Pharmacy personnel possess specialized training and experiences critical for accurately and efficiently dispensing drugs. Pharmacists and pharmacy technicians can greatly assist their communities in many ways by joining their local MRC unit.

Completing the volunteer registration and orientation process is easy and can be done online and in person. To get started, visit *www.vamrc.org* or visit Virginia Medical Reserve Corps on Facebook.

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