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Virginia Board of Pharmacy News

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Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233
Phone: 804/367-4456 • *www.dhp.virginia.gov/pharmacy*

Renewal of Pharmacist Licenses and Pharmacy Technician Registrations

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2016. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Virginia Board of Pharmacy. Renewal notifications have been sent to the email addresses on record. If you did not renew your license or registration by the second week in November, a paper renewal notice was mailed to your address of record. 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 both the public address and address of record (private) as well as phone numbers and email addresses the Board has on record. Fees for renewals received by the Board by December 31, 2016, are as follows: pharmacist current active license – $90; pharmacist current inactive license – $45; and pharmacy technician registrations – $25. If you desire to change your pharmacist license status from active to inactive, submit a written request to the Board providing your license number and the $45 fee. An additional late fee of $30 for current active pharmacist licenses, $15 for current inactive pharmacist licenses, and $10 for pharmacy technicians must be submitted for renewals received by the Board after December 31, 2016. Renewals are processed the next business day following receipt; however, it may take seven to 10 business days following renewal to receive the updated license or registration by mail. Holidays may further delay processing and receipt by mail. If you do not receive your license or registration 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 2016 calendar year. 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 2016 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause 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 and be required to submit the original CE documents as proof of compliance. Refer to Guidance Documents 110-4 and 110-42 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm* for more information related to CE.

Frequently Cited Inspection Deficiencies During Routine Pharmacy Inspections – 2016

The deficiencies referenced below may be reviewed in Guidance Document 110-9, available at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Perpetual Inventory (Deficiency 15 – 18VAC110-20-240): The failure to maintain a perpetual inventory as required is the most frequently cited deficiency. Regulation 18VAC110-20-240 states that each pharmacy shall maintain a perpetual inventory of **all** Schedule II drugs received and dispensed, with reconciliation at least monthly. This includes Schedule II drugs that are slow moving and expired. 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. The perpetual inventory record must accurately indicate the physical count of each Schedule II drug on hand at the time the inventory is being performed. To comply with the requirement, an explanation for any difference, including overages and shortages, between the physical count and the theoretical count must be notated. A required biennial inventory may be used for the monthly

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FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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reconciliation requirement of the perpetual inventory. More information on performing inventories may be found in Guidance Document 110-16, available at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Incoming Pharmacist-in-Charge Inventory Not in Compliance (Deficiency 14 – §54.1-3434): This deficiency is cited when the incoming pharmacist-in-charge (PIC) inventory was not performed, when the inventory was performed more than five days after the effective date of change, or when the inventory performed did not include all required drugs. The effective date of change for a PIC is the date that is indicated on the application sent to the Board. An inventory is considered to be substantially incomplete when the inventory does not include all drugs in Schedule II-V. Expired drugs must be included in the incoming inventory; however, if these drugs are left off and the inventory is otherwise complete, Deficiency 113 is cited. The Board accepts the Drug Enforcement Administration requirements for estimated counts or measure of Schedule III, IV, and V drugs unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made.

Biennial Inventory Not in Compliance (Deficiency 13 – §54.1-3404 and 18VAC110-20-240): This deficiency is most frequently cited when the individual completing the inventory does not indicate if it was taken prior to the opening of business or at the close of business. In a pharmacy that is open 24 hours, the pharmacist must indicate on the inventory if receipt or distribution of drugs occurred before or after the inventory was taken. This deficiency is also cited when the inventory was performed over 30 days late, did not include all drugs in Schedule II-V, or was not signed and dated by the person completing the inventory.

Refrigerator and Freezer Temperatures and Requirements

Regulation 18VAC110-20-150 states that if the pharmacy stocks drugs requiring cold storage temperature, adequate refrigeration facilities equipped with a monitoring thermometer shall be maintained. Refrigerators and freezers used to store drug products are required to maintain the product temperature between the limits as defined on the product label. Regulation 18VAC110-20-10 defines storage temperature and provides the following conditions for "cold" temperature.

> "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

During an inspection, the inspector will use a calibrated thermometer to measure the temperature of any refrigerators or freezers that contain drugs. If the variance in temperature is either above or below 4°F, Deficiency 8 will be cited on the inspection report. Drugs may be embargoed for items with critical storage requirements, such as Zostavax®. If drugs are embargoed and the manufacturer is able to confirm to the Board that the drugs may still be used for dispensing, the embargo may be released. If the pharmacy wishes to send the embargoed drugs for destruction, a request to the Board must be submitted and approved to lift the embargo prior to destruction.

New Website Launched to Help Combat Prescription Drug and Heroin Addiction in Virginia

On November 1, 2016, Governor Terry McAuliffe announced the launch of *www.VaAware.com,* a new website that was developed as an information tool for Virginia's fight against prescription drug and heroin abuse. This website was developed as part of a recommendation of the Governor's Task Force on Prescription Drug and Heroin Abuse in Virginia and contains specific pages for parents, health care providers, law enforcement members, and those individuals seeking help with addiction.

"This website is an important tool to help those struggling with addiction and their family members find resources available in Virginia, and to provide a resource to health care and public safety professionals seeking the latest information in our efforts to end this epidemic," said Governor McAuliffe. "Deaths from prescription drug overdoses doubled in Virginia over the past 15 years, while heroin-related deaths tripled from 2011 to 2015. We must all do our part to bring positive change to the lives of Virginians battling substance abuse, and I am proud of our state agencies for their teamwork and dedication to this important initiative."

The website is the result of a collaboration between four Virginia agencies: the Department of Health Professions (DHP), the Department of Health, the Department of Criminal Justice Services, and the Department of Behavioral Health and Development Services. The site is hosted and maintained by the DHP, the umbrella agency for the Board of Pharmacy, Virginia Board of Medicine, and Virginia Board of Nursing as well as other health professional boards.

"We are happy to support this important resource as Virginia fights the opioid epidemic," said DHP Director David Brown. "The website will also be useful for health professionals, with best practices, guidelines and continuing education links on pain management, addiction and proper prescribing of opioids."

The Board encourages its licensees to visit the website, *www.VaAware.com,* and spread the news of the availability of this valuable resource to their patients, caregivers, and community.

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Caroline Juran, Executive Director - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager