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New Laws Regarding the Virginia Prescription Monitoring Program

The Virginia Prescription Monitoring Program (PMP) saw three bills passed and signed into law in 2016 that impact pharmacists and pharmacies.

House Bill (HB) 293 makes it mandatory for prescribers to query the PMP when initiating treatment with an opioid expected to last more than 14 days. The bill also extends delegate authority to individuals who are employed or engaged at the same facility and under the direct supervision of the prescriber or dispenser and (i) are licensed, registered, or certified by a health regulatory board under the Virginia Department of Health Professions (DHP) or in another jurisdiction; or (ii) have routine access to confidential patient data and have signed a patient data confidentiality agreement.

Senate Bill (SB) 287 allows information on a specific recipient to be disclosed to a dispenser for the purpose of establishing a prescription history to assist the dispenser in providing clinical consultation on the care and treatment of the recipient. Previously, a dispenser could only receive information on a specific recipient for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription. The requirement for a notice to be given to patients that information may be requested by the dispenser from the PMP remains in place. This bill also has a provision with an effective date of January 1, 2017, that requires dispensers to report the dispensing of covered substances to the DHP or its agent within 24 hours or the dispenser's next business day, whichever comes later. This is a change from the current requirement of reporting within seven days of dispensing.

HB 657 directs the director of the DHP, in consultation with an advisory panel with representatives from the Virginia Board of Medicine and Virginia Board of Pharmacy, to develop criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers. Upon analysis of data by the PMP using the criteria developed, the director may then direct the disclosure of information about the unusual prescribing or dispensing to the Enforcement Division of the DHP for investigation.

Other New Laws Affecting Pharmacy, Effective July 1, 2016

The following is a summary of select pieces of legislation passed by the Virginia General Assembly in 2016 affecting pharmacists and pharmacies:

HB 319 amended 54.1-2400 (6) to require health regulatory boards to promulgate regulations providing for the satisfaction of Board-required continuing education for those licensed or registered individuals who provide volunteer health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic. This bill has a delayed effective date of January 1, 2017.

HB 527 created a new section of law, 54.1-3435.3:1, to require nonresident medical equipment suppliers shipping hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled devices, sterile water and saline for irrigation, or solutions for peritoneal dialysis to consumers within the Commonwealth to register with the Board.

HB 528, in response to Title II of the Drug Quality and Security Act, amended several sections of law regarding supply chain requirements. The bill defines a "third-party logistics provider" in 54.1-3401 to distinguish them from wholesale distributors and requires in-state providers to be permitted by the Board. The bill also requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed. It also creates a new licensing category for registering nonresident manufacturers shipping into the Commonwealth, in lieu of registering them as nonresident wholesale distributors. Lastly, it specifies that bulk drug substances used for compounding drugs distributed by a

continued on page 4

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 appropr iate 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 interest form available 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.

continued from page 1

supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board as well as the federal Food and Drug Administration.

HB 629 creates a new section of law, 54.1-3411.2, to clarify that pharmacies may participate in voluntary drug disposal programs provided that such programs are operated in accordance with state and federal law by a pharmacy, and requires the Board to maintain a list of such pharmacies on a website maintained by the Board. This bill also provides that no person who participates in such disposal programs shall be liable for any theft, robbery, or other criminal act, given the practice site is acting in good faith and in accordance with applicable state and federal law and regulations.

SB 701 amends and creates several sections of law to authorize the Board to permit up to five pharmaceutical processors to operate under the supervision of a Virginia-licensed pharmacist to cultivate cannabis for the purpose of producing and dispensing cannabidiol oil and THC-A oil for the treatment of intractable epilepsy. The bill specifies that only a licensed practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of these oils and requires certain individuals to register with the Board. The bill provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana and requires the Board to adopt emergency regulations for overseeing pharmaceutical processors. An enactment clause on SB 701 requires the 2017 General Assembly to reconsider the bill prior to the laws and regulations becoming effective.

2016 Board Member Appointments, Election Results

Congratulations to Cynthia Warriner and Rebecca Thornbury who were reappointed by Governor Terry McAuliffe to serve a second full term on the Board. Their second term will expire June 30, 2020. Additionally, congratulations to Rebecca Thornbury, who was recently elected board chairman, and Ryan K. Logan, who was elected vice chairman. The Board wishes to extend its appreciation to Ms Warriner and Ms Thornbury for their dedication and leadership during the past year as chairman and vice chairman, respectively.

Amendments to Pharmacy Inspection Deficiency Monetary Penalty Guide and PIC Inventory Guidance

During the March 2016 Regulation Committee Meeting, the committee reviewed suggested amendments to the pharmacy inspection Guidance Document 110-9 (available for download at *www.dhp.virginia.gov/pharmacy/guidelines/110-09.doc*), which included striking references to the terms "major" and "minor" throughout the document, amending Deficiencies 25c and 26a to include gloved fingertip testing, and considerations for increasing the monetary penalty for Deficiencies 1 and 2 based on a noticeable increase in noncompliance with pharmacy owners not assigning new pharmacists-in-charge (PICs) within the required time frame. These suggested changes were recommended to the full Board in March, and the Board voted unanimously to accept the recommendations.

Additionally, the Board amended Guidance Document 110-15 to authorize staff to issue a pre-hearing consent order to impose the recommended monetary penalty for either not having a PIC fully engaged in the practice of pharmacy ($2,000) or not having a PIC in place and application filed within the required time frame ($1,000).

Deficiency 14 is still one of the most commonly cited deficiencies on routine inspections. When assuming the role of PIC of a pharmacy, perform an incoming change of PIC inventory of **all** Schedule II, III, IV, and V controlled substances, including all expired drugs, prior to opening for business on the date you first assume the role as PIC, ie, the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and there are no drugs on hand on opening date, an inventory must still be performed recording a zero balance. Additional guidance on how to perform an inventory is found in Guidance Document 110-16 (available for download at *www.dhp.virginia.gov/pharmacy/guidelines/110-16%20Performing%20inventories%209-2011.doc*).

When Is a Remodel Application Required?

Board staff occasionally receives questions as to whether a remodel application and inspection is necessary. Pursuant to Regulation 18VAC110-20-140, any structural changes to an existing prescription department or changes to a previously approved security system are considered a remodel. Structural changes include, but are not limited to, changes in walls, shelving, placement of doorways, windows, gates, and installing automated dispensing devices. Any change to a previously approved security system other than simply replacing previously installed motion sensors also requires an application and inspection.

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