New Law Exam for Pharmacist Licensure

The Virginia Board of Pharmacy has historically administered its own jurisprudence examination, the Virginia Federal and State Drug Law Examination (FSDLE). However, as a result of the increasing number of complex issues facing the Board and its limited resources, it was determined that resources used to administer the FSDLE would be better utilized in addressing other issues. Therefore, the Board will cease administering the FSDLE on June 30, 2016. Beginning July 1, 2016, Virginia will become the 49th jurisdiction to require examination candidates seeking pharmacist licensure to successfully pass the Multistate Pharmacy Jurisprudence Examination® (MPJE®) administered by the National Association of Boards of Pharmacy® (NABP®). As of May 1, 2016, candidates will have the option of scheduling to take the FSDLE prior to July 1, 2016, or registering with NABP to take the MPJE on or after July 1, 2016. Those wishing to take the MPJE may register online by visiting *www.nabp.net;* click on Programs, then scroll down and click MPJE, and click Registering for the MPJE on the sidebar. Those who register for the MPJE will not be able to schedule their exam until July 1, 2016.

Additional information on the transition to the MPJE may be found at *www.dhp.virginia.gov/pharmacy/news/MPJE_transition.pdf.*

Disposal of Drugs by Authorized Collectors

Recently enacted Regulation 18VAC110-20-211 authorizes narcotic treatment programs, hospitals, clinics with an on-site pharmacy, and pharmacies to accept for return a previously dispensed drug for the purpose of destruction once authorized by Drug Enforcement Administration (DEA) as a collector. Drugs may be collected from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The process used to collect and destroy drugs, along with any required record keeping, shall comply with applicable federal and state law.

Pharmacies that are already registered with DEA as an authorized collector are now listed on the Board's website at *www.dhp.virginia.gov/pharmacy/news_consumer.htm.* The list of authorized collectors is intended to assist the public in identifying a location where persons may dispose of unwanted medications. Pharmacists who want to participate in drug collection efforts should first register with DEA and then submit the "Registration For A Facility To Be An Authorized Collector For Drug Disposal" form found on the Board's website at *www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm#Pharmacies.* The Board will then add the location's information to its online listing of authorized collectors. If an authorized collector chooses to cease acting as a collector, the pharmacist-in-charge (PIC) or medical director shall notify the Board within 30 days.

To review Regulation 18VAC110-20-211 within the *Regulations Governing the Practice of Pharmacy,* visit *www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.*

Transitioning Security Systems From 2G to 3G or 4G

Many wireless security systems communicate via cellular networks using 2G, 3G, and 4G technology. Some of these security systems were installed with a 2G-compatible Global System for Mobile communication device that can only communicate via the 2G wireless network. Therefore, when the 2G sunset occurs on January 1, 2017, these security systems will no longer be able to communicate alarm signals.

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/Press Announcements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

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of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References
1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/Resources ForYou/HealthProfessionals/ucm211957.htm*.

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:
(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

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

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com*, under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*.

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

FDA's Division of Drug Information, CDER, presents a series of continuing education 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. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/ WorkingatFDA/FellowshipInternshipGraduateFaculty Programs/PharmacyStudentExperientialProgramCDER/ ucm228391.htm*.

Pharmacies with older alarm systems may still be operating on a 2G frequency and may have received notifications from their alarm company regarding the need to upgrade their system from 2G to 3G or 4G technology. The amount of work necessary to upgrade the security system will depend on the security system in place and could involve only a minor modification, or it could involve a significant modification or possibly a replacement of the security system. Pharmacists practicing in an environment using cellular technology must contact their alarm company directly to determine what actions, if any, will be necessary to upgrade the pharmacy's security system. Per Board guidance, if the upgrade requires only a change to the circuit board, then a remodel application will not need to be submitted to the Board office. However, please be aware that if the upgrade involves any other type of action, including replacement of the alarm panel, then a remodel application must be submitted to the Board office along with the appropriate fee, as the modified or new alarm system must be reinspected. Additionally, the Board advises pharmacists to maintain documentation on file that indicates if 3G or 4G technology is currently being used, if and when an upgrade was performed, and what action was necessary to upgrade the security system. This documentation should be readily available for review by an inspector. At all times, the security system shall comply with Regulation 18VAC110-20-180.

Pharmacists Dispensing Naloxone via Standing Orders

Pharmacists are encouraged to collaborate with a prescriber for implementing a standing order to dispense naloxone to patients at risk of overdose or to those persons who may benefit from having naloxone readily available to assist another person with a possible overdose. As a reminder, in addition to dispensing naloxone pursuant to a valid patient-specific prescription, pharmacists may now dispense naloxone via a standing order pursuant to §54.1-3408(X) of the Code of Virginia. The law was amended in 2015 to authorize a pharmacist to dispense naloxone for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber, and in accordance with a protocol developed by the Board of Pharmacy in consultation with the Virginia Board of Medicine and Virginia Department of Health. The protocol was recently amended in March 2016 to include a third naloxone option, the Narcan® Nasal Spray 4 mg that was recently approved by Food and Drug Administration, and may be found at *www.dhp.virginia.gov/pharmacy/ news/NaloxoneProtocolForPharmacists.pdf*.

The law also authorizes a person to possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. It further authorizes law enforcement officers as defined in §9.1-101 and firefighters who have completed a training program to possess and administer naloxone in accordance with this protocol.

When dispensing naloxone, pharmacists shall provide counseling in opioid overdose prevention, recognition, response, and administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf life, and safety. The recipient cannot waive receipt of this counseling unless the pharmacist is able to verify successful completion of the REVIVE! Opioid Overdose and Naloxone Education training program for Virginia. Verification of completing the training program may be made by viewing the recipient's card issued to him or her at the conclusion of the REVIVE! training program. Pharmacists shall also provide the recipient with a copy of the brochure developed by the Virginia Department of Behavioral Health & Developmental Services, which may be downloaded from *www.dbhds .virginia.gov/library/substance%20abuse%20services/ osas-revive-pharmacy-dispensing-brochure.pdf*.

To read §54.1-3408(X) within *The Pharmacy Act and the Drug Control Act With Related Statutes,* visit *www.dhp.virginia.gov/pharmacy/pharmacy_laws_ regs.htm*. To access additional information on the REVIVE! Opioid Overdose and Naloxone Education training program for Virginia, visit *www.dbhds.virginia .gov/individuals-and-families/substance-abuse/revive* and scroll to the bottom of the page.

PIC Responsibilities

The PIC of a pharmacy is responsible for providing safeguards against diversion of controlled substances (CS) as well as ensuring that the practice of pharmacy is in overall compliance with the laws and regulations. Highlighted here are a few reminders for those serving in the role of PIC:

♦ Regulation 18VAC110-20-190 states that the prescription department of each pharmacy shall be provided with enclosures that meet certain requirements to protect the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty. Please ensure the enclosure is locked and alarmed at all times when a pharmacist is not on duty. "On duty" is defined in 18VAC110-20-10 to mean that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed. Simply locking the front door to the business does not sufficiently comply with the requirement to lock the enclosure to the prescription department.

♦ Regulation 18VAC110-20-190(D) states that a "PIC or pharmacist on duty shall not permit access to the prescription department or [CS] by a pharmacist, pharmacy intern, or pharmacy

technician whose license or registration is currently suspended or revoked." The current status of a license or registration may be verified using the License Lookup feature on the Board's website at *https://dhp.virginiainteractive.org/Lookup/Index.*

♦ Changes to Guidance Document 110-27, PIC Responsibilities, were approved at the December 2015 full Board meeting. The amendments clarified when an incoming PIC inventory should be taken and the designation of the effective date for the change in PIC that is recorded on the application. Guidance Document 110-27 also offers Board suggestions for best practices to safeguard against diversion of CS and summarizes actions to take when leaving the PIC position.

To review Regulation 18VAC110-20-190 within the *Regulations Governing the Practice of Pharmacy,* visit *www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.*

Guidance Document 110-27 may be viewed at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Become a Registered User of Virginia Regulatory Town Hall

Virginia's Regulatory Town Hall, found at *http://townhall.virginia.gov/index.cfm,* is a public website that is a source of information about proposed changes to Virginia's regulations. The site also provides current information regarding Board meetings, as well as a forum where the public may provide comment on proposed regulatory changes during specified comment periods. Users may also sign up for an email notification service to receive notifications regarding meetings and change of stages in proposed regulatory action. Charts outlining the steps for completing various regulatory processes may also be found at *http://townhall.virginia.gov/UM/charts.cfm.*

The Board is currently completing a periodic review of regulations in Chapters 20 and 50. Registered users of the Virginia Regulatory Town Hall will receive email notifications regarding public comment periods for any proposed changes to these regulations as they occur.

Proof of Identity

Board staff occasionally receives questions regarding the requirements in §54.1-3420.1 of the Drug Control Act regarding proof of identity when filling prescriptions. Please be aware that the law was amended in 2010 and again in 2011. The Board adopted a revised version of Guidance Document 110-11 on June 8, 2011, to provide guidance for how to comply with the law. It states:

In summary:

♦ If any person picking up or "seeking to take delivery" of a Schedule II dispensed prescription is known to the pharmacist or his agent, then the pharmacist or his agent is not required to obtain ID.

♦ If the person picking up the Schedule II dispensed prescription is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID.

♦ If anyone other than the patient for whom the prescription is written seeks to take delivery of the drug, and the pharmacist or his agent does not know the person, then the pharmacist or his agent must either make a photocopy or an electronic copy of such person's ID **or** record the full name and address of such person. The pharmacist must keep the record or copy of ID for at least one month.

To read Guidance Document 110-11 in its entirety, visit *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*