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News

North Carolina Board of Pharmacy

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Item 2294 – Board Member Election – Southeastern District

The North Carolina Board of Pharmacy will be conducting an election to fill the Southeastern District member position in spring 2015. Robert (Joey) McLaughlin currently holds this seat. Mr McLaughlin will complete his second consecutive five-year term on April 30, 2016, and thus is term-limited. Accordingly, this will be an "open" seat for election.

The Southeastern District comprises Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Johnston, Jones, Lenoir, New Hanover, Onslow, Pamlico, Pender, Pitt, Robeson, Sampson, Scotland, and Wayne counties. A pharmacist with an active license and who resides in one of these counties as of March 15, 2015, is eligible to run.

Nominations are open through March 15, 2015. A pharmacist may be placed on the ballot by submitting a notice of intent to run signed by the would-be candidate and 10 North Carolina licensed pharmacists who reside in the Southeastern District. The election will be held in April and May 2015, and any necessary run-off election held in May and June 2015. More detail will follow. The successful candidate would assume office on May 1, 2016, after commissioning by the governor.

Board membership is a substantial commitment to the protection of the public health and safety. With that position of trust comes a number of responsibilities. To help interested pharmacists learn more about the process, membership expectations, training requirements, and matters that are the Board's responsibility (and just as importantly, matters that are **not** part of the Board's public safety protection mission), Board staff will host a candidate interest forum. Any pharmacist interested in Board membership is strongly encouraged to attend.

The candidate interest forum is scheduled for Thursday, January 8, 2015, at 7 PM at the Best Western Plus Coastline Inn in Wilmington, NC. The address and directions may be found at *www.coastlineinn.com/maps_directions.html*. For ease of planning, please email Kristin Moore at the Board office at kmoore@ncbop.org if you plan to attend, or call 919/246-1050, ext 209.

Item 2295 – Licenses, Permits, and Registrations Not Renewed for 2015 Are Now Late

All persons or entities licensed by, permitted by, or registered with the Board are reminded that all licenses, permits, and registrations expired on December 31, 2014. By operation of law, a person or entity is not deemed to be engaged in the "unlicensed practice of pharmacy" until 60 days after expiration. But any license, permit, or registration not renewed by March 1, 2015, will be moved to inactive status.

Instructions on the electronic renewal process are found on the Board's website, *www.ncbop.org*.

Item 2296 – Epinephrine Auto-Injectors in Schools

A provision of the 2014 North Carolina budget bill requires all North Carolina public and public charter schools to have on hand a minimum of two epinephrine auto-injectors. The provision went into effect on November 1, 2014.

Board staff has provided a guidance document for school systems and pharmacies concerning the requirement that answers a number of specific questions about implementation. It may be found at *www.ncbop.org/faqs/Pharmacist/GuidanceEpinephrineAutoInjectorStatuteDec2014.pdf*.

At the time of this writing, the Board is approaching the final stages of a rulemaking that, pursuant to a

continued on page 4

DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

continued from page 1

request from the state health director, would allow epinephrine auto-injectors for public schools to be dispensed by registered nurses who practice at local health departments. More information on this rulemaking is found in Item 2292 of the October 2014 *Newsletter* and, along with information about all rulemakings underway by the Board, at *www.ncbop.org/rulemakings.htm*.

Item 2297 – Amendments to Rules Governing Pharmacy Compounding

As a result of changes to the law governing pharmacy compounding enacted as part of the federal Drug Quality and Security Act, as well as in response to recommendations from the Board's Pharmacy Compounding Work Group, the Board has completed its work on a set of amendments to its compounding rules.

The effort is the culmination of over a year of work, consultation with numerous stakeholders, and thoughtful input during the notice and comment process. The Board gave final approval to the amendments at its November 2014 meeting. As of this writing, the amendments were awaiting approval from the Rules Review Commission, which was expected in mid-December 2014, with an effective date of January 1, 2015. Pharmacists should monitor the Board's website, *www.ncbop.org,* for updates.

Item 2298 – Recordkeeping Requirements for DME Permit Holders

During inspections of durable medical equipment (DME) facilities in fall 2014, some permit holders expressed confusion about a handful of the specific rules that govern the creation, maintenance, and access to orders and records for devices and medical equipment. Board staff has provided a clarifying "FAQs" document, which may be found at *www.ncbop.org/faqs/FAQDMERecordKeeping.pdf.*

Board staff appreciates the advice and input received from the DME Subcommittee in developing this clarifying document.

Item 2299 – Pharmacist Manager Drug Loss Report Filing Responsibilities

Board investigative staff often receive two questions concerning drug loss reports: (1) who is responsible for filing the report with the Board; and (2) when the report must be filed.

Who? NCGS 90-85.25(b) states that **"the pharmacist in charge** of a pharmacy shall report within 10 days to the Board any disaster, accident, theft, or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy" (emphasis added). As is clear in the statute, the pharmacist manager – and not loss prevention, the district manager, the corporate office, etc – bears this responsibility. (Note further that a drug loss report is to be submitted when it involves **either** a controlled substance (CS) or a non-CS.)

When? This question is also clearly answered in the statute. If a pharmacy experiences a burglary, robbery, diversion, or other event in which a medication, (controlled or non-controlled) is lost, damaged, stolen, or otherwise improperly leaves the pharmacy's control, then the Board Drug Disaster & Loss Report shall be filed **"within 10 days"** of that event. Furthermore, if the event involves a CS, the pharmacist manager shall file Drug Enforcement Administration (DEA) Form 106, Report of Theft or Loss of Controlled Substances as well.

The Board Drug Disaster & Loss Report is available for download at *www.ncbop.org/Forms/DrugDisasterandLossReport.pdf*. The DEA Form 106 Report can be found at *www.deadiversion.usdoj.gov*. If you have any questions about the forms, or who and/or when the loss reports are filed, please call 919/246-1050 and ask for Joshua Kohler, director of investigations and inspections, or Cindy Parham, investigations and inspections coordinator.

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