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Virginia Board of Pharmacy News

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Virginia Selected for the 2015 NABP Fred T. Mahaffey Award

The Virginia Board of Pharmacy recently received the 2015 National Association of Boards of Pharmacy® (NABP®) Fred T. Mahaffey Award. This award recognizes a board of pharmacy that has made substantial contributions to the regulation of the practice of pharmacy over the past year. Virginia was specifically recognized for its significant contributions in protecting the public by ensuring that compounding is performed in a safe and compliant manner.

Virginia was one of the first states to increase standards for nonresident pharmacies to submit a current inspection report for licensure that must indicate compliance with United States Pharmacopeia (USP) standards when performing compounding. Additionally, the Board worked closely with NABP during the initial phase and process development of the Verified Pharmacy Program™, and it continues to work closely with NABP on the development of an inspection blueprint that could be used by all state boards of pharmacy. The Board extends appreciation to NABP for recognizing Virginia's efforts to improve patient safety, and to those pharmacists, legislators, associations, USP experts, other health care providers, and members of the public who collaborated with the Board to address these concerns.

Board Member Appointments, Election Results

Congratulations to Rafael Saenz and Freeda Cathcart, who were recently appointed by Governor Terry McAuliffe to the Board. Mr Saenz and Ms Cathcart replace Empsy Munden and Dinny Li, whose terms expired June 30, 2015. The Board extends appreciation to Ms Munden and Ms Li for their dedication and leadership during the past four years. Additionally, congratulations are extended to Cynthia Warriner who is presently serving as chairman of the board, replacing Ms Munden. An election for vice chairman will be held during the full board meeting on September 29, 2015.

Practitioners Prescribing for Self or Family

Board staff occasionally receives questions from pharmacists trying to determine the validity of a prescription written by a prescriber for him or herself or a family member. Please note that a physician may only prescribe for self or family in compliance with Virginia Board of Medicine Regulation 18VAC85-20-25. This regulation does not permit the prescribing of drugs in Schedule II-V for self or family unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or if it is for a single episode of an acute illness through one prescribed course of medication. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship. Similar regulatory requirements exist for nurse practitioners and physician assistants.

For more information, refer to Guidance Document 110-7 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Increased Access to Naloxone

Lives continue to be lost at an alarming rate from prescription drug and heroin overdoses. Overdoses can result from accidental overuse of legitimately obtained prescription drugs to treat chronic pain, or they can result from abuse of prescription drugs or heroin. While Virginia has seen a slight reduction in prescription drug overdoses, the rate remains high. Heroin overdoses have also increased and have reached epidemic proportions nationally. When persons addicted to prescription opioids no longer have access to these drugs, they often turn to heroin because it produces a similar high, is cheaper, and is more readily accessible. Naloxone counteracts opioid overdoses and saves lives.

On April 15, 2015, legislation was signed into law that expanded the state's naloxone pilot program by increasing access to naloxone statewide. Specifically, §54.1-3408(X) was amended to authorize a pharmacist to dispense naloxone or other opioid antagonist used 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 Board of Medicine and Virginia Department of Health. It also authorizes a person to

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way 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. 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 an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

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. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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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. The law 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.

Pharmacists are encouraged to collaborate with a prescriber for implementing a standing order to dispense naloxone and to identify patients at risk of overdose who may benefit from having naloxone readily available. Pharmacists interested in dispensing naloxone for intranasal administration may obtain kits free of charge from the Virginia Department of Behavioral Health & Developmental Services (DBHDS) by submitting a request to REVIVE@dbhds.virginia.gov. These kits contain all required materials for administering the drug intranasally, except for the drug itself. Pharmacists must add the naloxone to the kit at the point of dispensing. When dispensing either naloxone for intranasal administration or the naloxone autoinjector, pharmacists shall provide counseling in opioid overdose prevention, recognition, and 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 that was 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 DBHDS, which may be downloaded from *http://dbhds.virginia.gov/library/document-library/osas-revive-pharmacy-dispensing-brochure.pdf.*

To view the Board of Pharmacy-approved protocol, visit *www.dhp.virginia.gov/pharmacy/news/NaloxoneProtocolForPharmacists.pdf.* To access additional information on the REVIVE! Opioid Overdose and Naloxone Education program, visit *www.dbhds.virginia.gov/individuals-and-families/substance-abuse/revive* and scroll to the bottom of the page.

Declining to Fill a Prescription

Pharmacists must use professional judgement when determining the validity of a prescription. When a pharmacist declines to fill a prescription for any reason other than for unavailability of the drug prescribed, Board Regulation 18VAC110-20-270(D) requires that the pharmacist record the following information on the back of the prescription before returning it to the patient: the word "declined;" the name, address, and telephone number of the pharmacy; the date the filling of the prescription was declined; and the signature of the pharmacist. Please note that the regulation does not require the pharmacist to record an explanation for declining to fill the prescription. If the pharmacist determines that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it in accordance with 18VAC110-20-270(E). The forged prescription may be given to a law enforcement official investigating the forgery, or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigation or other legitimate purpose.

Access to and Copies of Records by Virginia State Police

Please be aware that designated individuals within the Virginia State Police may legally access pharmacy records when performing a drug diversion investigation. In accordance with §54.1-3405, "any agent designated by the Superintendent of the Department of State Police to conduct drug diversion investigations shall, for the purpose of such investigations, also be permitted access . . . to all such records relevant to a specific investigation and be allowed to inspect and copy such records." The agent of the state police may copy and remove these patient records if they are relevant to a specific investigation, and he or she shall allow the pharmacist to examine any copies of records before he or she removes them from the pharmacy. If the agent copies records on magnetic storage media, he or she will provide to the pharmacist a duplicate of the magnetic storage media on which the copies are stored. If it is necessary to remove the original of any record from the pharmacy, a receipt will be left by the agent with the pharmacist for this removal.

Reminder for 2015 CE Requirement on Opioid Use or Abuse

Pursuant to §54.1-3314.1(J), and to address concerns with prescription drug abuse, the Board is requiring all pharmacists to obtain at least one hour of continuing education (CE) in the subject of "opioid use or abuse" during the calendar year of 2015. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2015, and not in addition to the required 15 hours. This is a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years. This requirement applies only to pharmacists, not pharmacy technicians. Please note that the requirement does not specify particular objectives that must be included in the program, nor does it identify a list of approved programs. The general requirement is of a broad nature in order to allow pharmacists the flexibility of choosing an appropriate CE program that focuses on the use or abuse of opioids. The CE must be obtained between January 1 and December 31, 2015.

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.

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