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News

Delaware State Board of Pharmacy

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Pharmacy Issues

Medication Disposal and CPR Certification Regulations Amended

Pursuant to 24 Del. C. §2506(a)(1), the Delaware State Board of Pharmacy revised Regulations 5 and 14 of the Delaware Rules and Regulations. Effective March 11, 2015, a new rule exists that specifies disposal methods for disposing of medications under state and federal guidelines.

Under Regulation 5.1.14.3, dispensed medications returned by the public shall be properly disposed of in accordance with Delaware controlled substance laws and regulations and the federal Controlled Substances Act, Title 21 Code of Federal Regulations (CFR) §1300 to the end. Proposed disposal methods must be authorized by the Delaware Office of Controlled Substances and federal authority.

In addition, Regulation Rule 14.1.1 is amended to state that CPR certification must be obtained through hands-on education pertaining to requirements for administering injectable medications, biologicals, and adult immunizations. CPR certification cannot be obtained through an online course.

Controlled Substance Issues

Hospital DEA Number Use

The Board office frequently receives inquiries from pharmacies and prescribers regarding the use of the hospital Drug Enforcement Administration (DEA) registration number by an individual practitioner. Often office inquiries center around the use of the hospital DEA number by practitioners other than residents of the hospital. Title 21 CFR §1301.22(c) addresses this issue.

> An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:
>
> (1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
>
> (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;
>
> (3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;
>
> (4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;
>
> (5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and
>
> (6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

Pharmacists who receive prescriptions that comply with this rule may dispense medication accordingly.

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*.

Pharmacists Providing Syringes to Patients

Recently, the Board office has received questions regarding the providing of syringes by a pharmacist. The original intent of the Board submitting this amendment to the legislature was for pharmacists to be able to provide syringes to patients for prescriptive medicinal use, such as patients with diabetes. 16 Del. C. §4762(a) states:

> A licensed pharmacist, or pharmacist intern or pharmacy student under the supervision of a pharmacist, may provide hypodermic syringes or hypodermic needles, including pen needles for the administration of prescription medications by injection in the State of Delaware without a prescription, but only to persons who have attained the age of 18 years and who will self-administer prescription medications by injection or administer prescription medications to a minor child for whom they are the parent or legal guardian. When providing hypodermic syringes or hypodermic needles without a prescription, the above-mentioned pharmacist, pharmacist intern or pharmacy student must **only** provide syringes to inject and administer **prescription medication** after obtaining proof of identification that validates the individual's age.

Under this law, pharmacists may not provide syringes to the public when they have knowledge that the syringe will be used to inject substances that are not prescription medications.

Newly Licensed Pharmacists

29 Issued From April 1, 2015, to June 30, 2015

Jerry Allan Bliss – A1-0004734; Ayman M. Yousef – A1-0004735; Irene Ji Kim – A1-0004736; David G. Sherbin – A1-0004737; Tessina Tressa Thomas – A1-0004738; Susan Jennifer Dietze – A1-0004739; Heather H. Wade – A1-0004740; Ealia Kendra Washington – A1-0004741; Hajira Ebady – A1-0004742; Doris Victoria Bertolet – A1-0004743; Jeffrey E. Paup – A1-0004744; Kieu-Loan Mau Vu – A1-0004745; Peris N. Gathura – A1-0004746; Urvashi Garib-Sohan – A1-0004747; Marianne Bious – A1-0004748; Bonita Dunbar Buesmaill – A1-0004749; Ha B. Hoang – A1-0004750; Lorraine Lombos Asa – A1-0004751; Tara D. Kompare – A1-0004752; Kevin Steger – A1-0004753; Andrew Gerard Babb – A1-0004754; Bethany Rae Sharpless – A1-0004755; Amanda Louise Valentin – A1-0004756; Hannah L. Parsons – A1-0004757; Adeola Olufunmilayo Edema – A1-0004758; Anik Palit – A1-0004759; Lawrence John Krebs – A1-0004760; Rachael Nicole DiMeo – A1-0004761; Tamika Marie Greenwood – A1-0004762

Distributor Permits

28 Issued From April 1, 2015, to June 30, 2015

ProVen Pharmaceutical, LLC – A4-0001471; RGH Enterprises, Inc – A4-0001888; Boehringer Ingelheim VetMedica, Inc – A4-0001899; Sanofi-Aventis U.S., LLC – A4-0002188; Eye Care and Cure Corporation – A4-0002189; Kuehne + Nagel, Inc – A4-0002190; AcariaHealth Solutions, Inc – A4-0002191; Top Rx, LLC – A4-0002192; Paragon Enterprises, Inc – A4-0002193; Mr. Crash Cart, LLC – A4-0002194; TheraCom, LLC – A4-0002195; Integrated Commercialization Solutions, LLC – A4-0002196; ASD Specialty Healthcare, Inc – A4-0002197; Virtus Pharmaceuticals, LLC – A4-0002198; Alexso, Inc – A4-0002200; Exel, Inc – A4-0002201; HealthSource Distributors, LLC – A4-0002202; ProPharma Distribution, LLC – A4-0002203; Exel, Inc – A4-0002205; PureLife, LLC – A4-0002206; The Procter & Gamble Distributing, LLC – A4-0002207; Carlsbad Technology, Inc – A4-0002208; Par Sterile Products, LLC – A4-0002209; Crown Laboratories, Inc – A4-0002210; American Pharmaceutical Ingredients, LLC – A4-0002211; The Procter & Gamble Distributing, LLC – A4-0002213; Enclara Pharmacia Wholesale – A4-0002214; Profounda, Inc – A4-0002215

In-State Pharmacy Permits

Four Issued From April 1, 2015, to June 30, 2015

Rite Aid #11192 – A3-0000853; Longneck Pharmacy – A3-0000983; Sussex Pharmacy – A3-0000985; Accredo Health Group, Inc 0000986

The *Delaware State Board of Pharmacy News* is published by the Delaware State 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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