February 2015

Delaware State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Cannon Building • 861 Silver Lake Blvd, Suite 203 • Dover, DE 19904
http://dpr.delaware.gov/boards/pharmacy/index.shtml

Pharmacy Issues

Driving Under State of Emergency

As a review, state agencies, including the Delaware State Board of Pharmacy and the State of Delaware Department of Safety and Homeland Security, worked on regulation governing travel restrictions during a state of emergency. This regulation addresses first responders, essential personnel, and the three levels of driving bans. Under the regulation, pharmacists could travel during a Level 1 and 2 driving ban. Any pharmacist driving while under a Level 2 ban must carry appropriate identification of his or her professional license. Pharmacists would be banned from driving under a Level 3 driving ban. The level of the driving ban would be described and stated at the time of the state of emergency.

Controlled Substance Issues

Changes a Pharmacist Can Make to a Schedule II Controlled Substance Prescription

The recent reformulation of Vicodin® 5/325 mg to Vicodin 5/300 mg has initiated questions from Delaware health care practitioners and pharmacists of exactly what action the pharmacist is permitted to take to dispense the Vicodin 5/300 mg product.

Drug Enforcement Administration (DEA) has stated the following.

> On November 19, 2007, the DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)…may not be modified orally."
>
> The instructions contained in the Rule's preamble are in opposition to DEA's previous policy which permitted the same changes a pharmacist may make to schedules III-V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber . . .
>
> DEA expects pharmacists to use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.

Until DEA resolves this matter in an amended rule, the State of Delaware Division of Professional Regulation Office of Controlled Substances recommends the following.

When a Schedule II controlled substance (CS) combination product is prescribed, and the strength of the CS component is correct but the non-CS component **strength is not correct,** the pharmacist **may obtain verbal authorization from the practitioner to change the strength of the non-CS component of the combination product.** Thus, in the above scenario, Vicodin 5/300 mg may be amended based on a verbal authorization from the prescribing practitioner. This practitioner consultation and authorization must be documented on the prescription.

Please note that if the CS component strength is not correct, practitioner verbal authorization is not sufficient. A new prescription must be obtained from the practitioner for the correct strength.

Robberies in the Pharmacy

Recently, Delaware pharmacies have been faced with robberies. As a reminder from past *Newsletters,* a robbery in the pharmacy setting might be one of the most frightening experiences in a pharmacist's life. It is important that you be prepared should you ever be exposed to such an experience.

First, it is important to understand the difference between a theft and a robbery. A theft is basically the taking of another's property without force. On the other hand, a robbery occurs

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

when force is used during the taking of another's property. Thus, if someone takes something off the pharmacy counter, a theft has occurred. If someone takes something off the counter brandishing a weapon, then a robbery has occurred.

When faced with a situation of robbery in your pharmacy, your safety and the safety of your staff is the main objective. You have the responsibility to your employees, patients, and loved ones to avoid anything that would result to violence on the part of the robber. Therefore, complying with the demands of the robber is the most prudent course to follow. There is no property in your pharmacy that is worth the risk of harm to yourself, your patients, or your staff.

What to Do During a Robbery

- Cooperate fully with the robber.
- Do not argue or make insulting comments.
- Do not attempt to thwart the robbery or apprehend the criminal yourself.
- Do exactly what you are told to do, nothing more and nothing less.
- Try to remain calm and avoid sudden movements that might cause further conflict.
- Try to notice identifiable aspects of the robber; ie, clothing, hair length and color, size, build, tattoos, scars, and other body features.

What to Do Following a Robbery

- Immediately obtain treatment for anyone injured during the commission of the crime.
- When the situation is safe, sound your pharmacy alarm, contact 911, and alert other store personnel.
- Lock the doors immediately to prevent reentry.
- If it is safe, try to see the vehicle and/or direction taken by the robber.
- Request that customers remain in the store to provide statements to authorities.
- Protect the crime scene by not letting others come into areas with which the robber came into contact.
- Do not trust your memory; record all factual information.
- Do not discuss the facts of the robbery with anyone on the scene until after the authorities have taken your statement.
- Alert your company officials and follow company policies.

By remaining calm and being observant during the commission of the robbery, you can increase the likelihood of a safe outcome for yourself and staff, as well as the apprehension of the robber.

Newly Licensed Pharmacists

25 Issued from October 1, 2014 to December 31, 2014

Mina Lee – A1-0004689; William M. Glenn – A1-0004690; Frances E. Ulmer – A1- 0004691; Ridhi Mehta – A1- 0004692; Laura A. Garza – A1-0004693; Dawit M. Yifru – A1- 0004694; Maria Jeanne Lanser – A1-0004695; Marx A. Twumasi – A1-0004696; Duncan Joseph Runyon – A1-0004697; Erika N. Bronk – A1-0004698; Jae Hyun Park – A1-0004699; Tovonnia Wachet Collins – A1-0004700; Uday J. Gohel – A1-0004701; Sally M. Abbonizio – A1-0004702; Jennifer M. Demeno – A1-0004703; Michael P. Conti – A1-0004704; Maureen A. Worrell – A1-0004705; Mary Melissa Williams – A1-0004706; Jackline GZ. Tawfik – A1-0004707; Margaret Waithira Githara – A1-0004708; Marie A. Callahan – A1-0004709; Jill S. Extract – A1-0004710; Sarah Ahmed – A1-0004711; Mark E. Ciarlone – A1-0004712; Kalee J. Olson – A1-0004713

Distributor Permits

32 Issued from October 1, 2014 to December 31, 2014

Hygen Pharmaceuticals, Inc – A4-0001480; Dubin Medical, Inc – A4-0001499; 3M ESPE Dental Products – A4-0001620; Medline Industries, Inc – A4-0001994; Smith Medical Partners, LLC – A4-0002121; Bausch and Lomb, Inc – A4-0002123; Bausch and Lomb, Inc – A4-0002124; Bausch and Lomb, Inc – A4-0002125; McKesson Medical Surgical, Inc – A4-0002126; WellGistics, LLC – A4-0002127; Eq Detroit, Inc – A4-0002128; Tolmar Pharmaceuticals, Inc – A4-0002129; Tolmar Pharmaceuticals, Inc – A4-0002130; DMS Pharmaceutical Group, Inc – A4-0002131; Medi-Nuclear, LLC – A4-0002132; Prescript Pharmaceuticals, Inc – A4-0002133; Smith Medical Partners, LLC – A4-0002134; BMTM Services, Inc – A4-0002135; MWI Veterinary Supply dba Invesco – A4-0002136; Medline Industries, Inc – A4-0002138; Hi-Tech Pharmacal Co, Inc – A4-0002139; A4-0002140 – Bound Tree Medical, LLC – A4-0002140; Smiths Medical ASD, Inc – A4-0002141; Asclemed USA, Inc – A4-0002142; Ceva Animal Health, LLC – A4-00002143; Exela Pharma Sciences, LLC – A4-0002144; DV Medical Supply, Inc – A4-00002145; Norbrook, Inc – A4-0002147; Sun Pharmaceutical Industries, Inc – A4-0002148; Proficient Rx, LP – A4-0002149; H.D. Smith, LLC – A4-0002151; A4-0002151; Specialty Therapeutic Care, LP – A4-0002152

In-State Pharmacy Permits

One Issued from October 1, 2014 to December 31, 2014

Target Store T-1146 – A9-0000650

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.

David W. Dryden, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager