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Pharmacy Issues

Board Licensing Outsourcing Facilities

On June 18, 2014, the Delaware State Board of Pharmacy unanimously agreed to license "outsourcing pharmacies" as described under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). On November 27, 2013, the president signed into law the Drug Quality and Security Act, legislation that contains important provisions relating to federal and state oversight of compounding of human drugs. The new legislation creates a new section 503B in the FD&C Act under which a facility that compounds sterile drugs can register to become an "outsourcing facility." An outsourcing facility can qualify for exemptions from Food and Drug Administration (FDA) approval requirements and the requirement to label products with adequate directions for use, but it still must comply with current good manufacturing practice requirements. The registration of pharmacies as outsourcing facilities will help FDA identify and more effectively regulate these facilities. FDA intends to continue to partner with states in the oversight of drug compounding.

Controlled Substance Issues

Controlled Substance CE for Pharmacists

The Board and the Office of Controlled Substances continue to receive numerous notices of missing/theft of controlled substances (CS) from pharmacies. In some cases, the sheer number of associated CS missing/diverted is staggering. Pharmacists-in-charge are reminded that they are the persons responsible for reporting, pharmacy operations and training of personnel, and proper adherence with state laws and regulations. On February 14, 2014, House Bill 154 with Amendments was signed into law by the governor. 24 *Del. C.* §2512 requires that "the Board shall not renew any license to any applicant unless and until the applicant has offered proof that the applicant has completed continuing professional education relating to: (1) the distribution, dispensing or delivery of controlled substances, as defined in this chapter; or (2) the detection and recognition of symptoms, patterns of behavior, or other characteristic of impairment and dependency resulting from the abusive or illegal use of controlled substances; and (3) other topics as the Board deems appropriate." At its regularly scheduled meeting held on June 18, 2014, the Board determined that the mandated CS-related continuing education (CE) credits would not go into effect and be due until the two-year term of October 1, 2014 to September 30, 2016. The Board will be working on regulations pertaining to the above issue in upcoming meetings.

Dispensing Naloxone

Naloxone for nasal administration can be dispensed by a pharmacist with a prescription for patients at risk of an opioid overdose. Naloxone is indicated for the reversal of respiratory depression or unresponsiveness caused by an opioid overdose. Naloxone is not a CS and can be prescribed by anyone with a medical license or prescriptive authority. It may be delivered intranasally with the use of a nasal adaptor/mucosal atomizer device. The Division of Professional Regulation and the Delaware Department of Health and Social Services support a comprehensive approach to increase access to naloxone by persons at high risk of opioid overdose and friends or family of persons at high risk of opioid overdose. Historically, naloxone has been administered by emergency medical personnel or in a hospital environment. However, rates of overdose and death from prescription opiates and heroin are increasing nationwide. Pharmacists providing opioid overdose education and naloxone to patients at risk can help save lives and reduce opioid overdose mortality.

Indications for naloxone include:

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

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4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription
5. Receiving any opioid prescription for pain, plus:
   a. Rotated from one opioid to another because of possible incomplete cross-tolerance
   b. Smoking, chronic obstructive pulmonary disease, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness
   c. Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
   d. Known or suspected concurrent alcohol use
   e. Concurrent benzodiazepine or other sedative prescription
   f. Concurrent antidepressant prescription
6. Patients who may have difficulty accessing emergency medical services (eg, distance, remoteness)
7. Voluntary request from patient or caregiver

Instructions for use and ordering information are available through the Board office.

DEA Publishes Final Rule Rescheduling Tramadol to Schedule IV

The United States Drug Enforcement Administration (DEA) published its Final Rule in the *Federal Register* placing tramadol into Schedule IV, effective August 18, 2014. Effective August 18, 2014, all manufacturers will be required to print the designation "C-IV" on every bottle, and it is unlawful for commercial containers of tramadol to be distributed without that designation. In addition, all DEA registrants will be required to take an inventory of all tramadol stock in compliance with 21 C.F.R. §1304.11(d).

Newly Licensed Pharmacists

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Heather M. Sheridan Revel – A1-0004557; Richard S. Boahene – A1-0004558; Carl D. Tepper – A1-0004559; David L. Snow – A1-0004560; Victor G. Spearman – A1-0004561; Monica Ngo – A1-0004562; Kelly A. Klakowicz – A1-0004563; Karen Beth Main – A1-0004564; Hugh A. Smith – A1-0004565; Lisa A. Odenwelder – A1-0004566; Martin F. Blood – A1-0004567; John Mathew – A1-0004568; Linus Louis – A10004569; Mitul T. Vora – A1-0004570; Staci J. Welch – A1-0004571; Antonina Nikolaidis – A1-0004572; Valerie Fay Rentfro – A1-0004573; Ann Marie Gill – A1-0004574; Paul J. Burrichter – A1-0004575; Adam J. Talbot – A1-0004576; Messiah K. Moore – A1-0004577; Conroy S. Whitely – A1-0004578; Utkarsh B. Doshi – A1-0004579; Allison R. Turner – A1-0004580; Daniel R. Rogers – A1-0004581; Tri Minh Nguyen – A1-0004582; Gounathan Adly – A1-0004583; Kristine A. Ziemba – A1-0004584; Padraic E. Keen – A1-0004585; Rosemary A. Spiccioli – A1-0004586; Liza D. Nguyen – A1-0004587; Bruce Roberts – A1-0004588; Amber L. Myers – A1-0004589; Charlotte J. Lopacki – A1-0004590; Russell E. Farmer – A1-0004591; Maggie Yan Yu Chan – A1-0004592.

Distributor Permits

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True Science Holdings, LLC – A4-0001845; Bryant Ranch Prepack – A4-0001872; A-S Medication Solutions – A4-0002080; Kroger Limited Partnership II – A4-0002081; Vertical Pharmaceuticals, LLC – A4-0002082; Kroger Limited Partnership I – A4-0002083; MWI Veterinary Supply Co dba Invesco – A4-0002085; INO Therapeutics, LLC – A4-0002086; HealthSource Distributors, LLC – A4-0002087; The Proctor & Gamble Distributing, LLC – A4-0002088; The Proctor & Gamble Distributing, LLC – A4-0002089; The Proctor & Gamble Distributing, LLC – A4-0002090; The Proctor & Gamble Distributing, LLC – A4-0002091; The Proctor & Gamble Distributing, LLC – A4-0002092; The Proctor & Gamble Distributing, LLC – A4-0002093; The Proctor & Gamble Distributing, LLC – A4-0002094; Exel, Inc – A4-0002095; Freedom Pharmaceuticals, Inc – A4-0002096; Mission Pharmaceutical Company – A4-0002097; Amatheon, Inc – A4-0002098; Kenco Bracco – A4-0002099; DCS Logistics, Inc – A4-0002100; Priority Air Express, LLC – A4-0002102; Abbott Laboratories, Inc – A4-0002103; FFF Enterprises, Inc – A4-0002104; A.P.I. Solutions, Inc – A4-0002105; Total Pharmacy Supply, Inc – A4-0002106; Sun Pharmaceutical Industries, Inc – A4-0002107; Smith & Nephew, Inc – A4-0002108; Sun Pharmaceutical Industries, Inc – A4-0002109.

In-State Pharmacy Permits

Five Issued from April 1, 2014 to June 30, 2014

Rite Aid #4916 – A3-0000664; Harris Teeter Pharmacy – A3-0000966; Delaware CVS Pharmacy – A3-0000968; Genoa Healthcare of Delaware, LLC – A3-0000969; Synergy Rx Express – A3-0000970.

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