March 2015

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Pharmacy Administrative Rule Changes

The following rule changes will become effective at *sine die* of the 2015 Idaho legislature, which is typically around April 1. Rule dockets are available on the Idaho State Board of Pharmacy's website and will be engrossed into rule shortly after *sine die*.

Rules 010, 011, and 130: Are amended to allow for the definition of and the substitution of biological products with interchangeable biosimilars as allowed by Food and Drug Administration and printed in the "Purple Book."

Rules 011, 021, 074, and 600: Are amended to allow the Board to define, register, charge a registration fee, and regulate a new class of drug outlet that was recently created by the federal Drug Quality and Security Act (DQSA): the outsourcing facility. Federally registered outsourcing facilities that are currently registered as Idaho mail-service pharmacies should pay particular attention to these rules.

Rules 144, 239, 240, and 241: Regulate the practice of compounding. The current sterile compounding rule is expanded by defining dosage forms that require sterility, defining compounder responsibilities, regulating hoods and aseptic environmental control devices, requiring certain sterile product preparation equipment, establishing substantial documentation requirements, and requiring expanded policies and procedures. A new general compounding rule is promulgated that regulates both sterile and nonsterile compounding, including establishing limited exceptions, listing general compounding standards, reiterating federally prohibited and limited compounding parameters, establishing record-keeping requirements, defining accuracy requirements, and requiring policies and procedures. Another new rule regulates hazardous drug preparation, including ventilation, the use of ventilated cabinets to reduce worker exposure, labeling requirements, required equipment, required supplies, contamination prevention, hazardous waste disposal, training requirements, and requiring policies and procedures. Additionally, a new rule regulating the labeling of certain compounded drug product was promulgated. Compounders of any form or frequency should pay particular attention to these rules.

Rules 031, 041, and 340: Close loopholes in the law concerning foreign pharmacy graduates, technicians-in-training, and nonresident pharmacist practice.

Rule 140: Incorporates 2014 statutory labeling changes into rule and allows for an alternative warning when dispensing to animals.

Rule 146: Allows a pharmacy to repackage a drug previously dispensed to a patient by another pharmacy, pursuant to many requirements.

Rule 206: Allows controlled substance (CS) registrants the flexibility to conduct their annual inventories within seven days of their prior year's inventory and to reset the clock on their annual inventory any time, as long as the inventory is within the one-year window, plus seven days.

Rules 304, 631.04, and 611: Are combined to create a standard pharmacy authorized entry rule.

Rule 330: Is amended to allow an immunizing pharmacist's emergency kit to contain auto-inject epinephrine, vials of epinephrine, **or** ampules of epinephrine with various supplies.

Rule 604 and 605: Update security requirements, including credentialing for entry to secured delivery rooms and door hinges.

Rule 710: Updates retail telepharmacy with remote dispensing site law, including technician staffing, video and audio communication systems, security, and continuous improvement programs.

Rules 270 and 615: Rule 270 is struck in full and replaced by Rule 615, which regulates the distribution of prescription drugs by wholesalers, manufacturers, outsourcing facilities, and pharmacies similarly, including defining authorized distributions, listing requirements to furnish distributions, establishing invoice requirements, establishing reporting and monitoring requirements, and listing prohibited acts. Pharmacies who distribute (not dispense) prescription drugs, including compounded drug product, are now more regulated like wholesalers and should pay particular attention to Rule 615.

Rule 809, Prescription Drug Pedigrees: Is struck pursuant to federal preemption within the DQSA.

Changes Pharmacists May Make to Schedule II Prescription Drug Orders Correction

The Board supports a Drug Enforcement Administration (DEA) statement whereby a pharmacist may use his or her professional judgment in addressing a prescription drug order for a Schedule II CS that is incomplete or deemed incorrect, pursuant to the following updated Board policy. A pharmacist may change or add the dosage form, drug strength, drug quantity, and directions for use only after consultation with and agreement of the prescriber. After consultation with and agreement of the prescriber, a pharmacist may also add a missing date or change an obvious prescriber's error when writing the date, such as the prior year when a new year has just begun. On a multiple Schedule II prescription drug order, the "earliest date on which a pharmacy may fill each prescription" is an "instruction;" therefore, a pharmacist can change such dates with prescriber authorization. The date that cannot be changed on a Schedule II prescription is the date that the prescription drug orders were issued. Additionally, to satisfy the requirements of Section 37-2725(6), Idaho Code, which requires an alpha and numeric quantity on Schedule II prescription drug orders, after consultation and agreement with the prescriber, a pharmacist may add or change the alpha and/or numeric quantity. Also, a patient's address and a prescriber's DEA registration number may be added to a prescription drug order or corrected without consulting the prescriber after verifying from another reliable source. Finally, the patient's name may be corrected, such as changing a maiden name to a married name or correcting a misspelled name, but the patient's name, the physician's name, and the drug name may otherwise never be added or changed.

Upcoming CPE

Please note that Board-approved continuing pharmacy education (CPE) is granted for attendees of the jurisprudence (law) CPE at the conferences or

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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*.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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conventions listed below without a registration fee; however, presentation times are subject to change. Additionally, one hour of Board-approved, live, law CPE is issued for attendance at Board meetings.

When:	March 8, 2015, live, jurisprudence (law) CPE, 8:30 AM
Where:	Idaho State University (ISU) Meridian Campus, 1303 E Central Drive, Meridian, ID
What:	ISU CPE Seminar. Accreditation Council for Pharmacy Education (ACPE)-accredited CPE. For more information, visit *http://pharmacy.isu.edu/live/ce/location.html.*
When:	March 15, 2015, 8:30 AM
Where:	ISU Pocatello Campus, Pond Student Union, 1065 S Cesar Chavez Ave, Pocatello, ID
What:	ISU CPE Spring Seminar. ACPE-accredited CPE. For more information, visit *http://pharmacy.isu.edu/live/ce/location .html.*
When:	April 9, 2015, 8 AM - 5 PM
Where:	ISU Pocatello Campus, Pond Student Union, 1065 S Cesar Chavez Ave, Pocatello
What:	Idaho State Board of Pharmacy meeting
When:	April 11-12, 2015. Live, jurisprudence (law) CPE on Saturday at 9 AM
Where:	St Luke's Regional Medical Center, 190 E Bannock St, Boise, ID
What:	Idaho Society of Health-System Pharmacists' Spring Conference. ACPE-accredited CPE. For more information, visit *http://ishp.shuttlepod.org.*
When:	April 12, 2015, 8:30 AM
Where:	Best Western Plus Coeur d'Alene Inn, 506 W Appleway Ave, Coeur d'Alene, ID
What:	ISU Spring Seminar. ACPE-accredited CPE. For more information, visit *http://pharmacy.isu.edu/live/ce/location.html.*
When:	May 28-31, 2015. Board meeting on Thursday. Live, jurisprudence (law) CPE on Sunday.
Where:	Coeur d'Alene Resort, 115 South Second Street, Coeur d'Alene
What:	Idaho State Board of Pharmacy Meeting and Idaho State Pharmacy Association's Northwest Pharmacy Convention. ACPE-accredited CPE. For more information, visit *www .wsparx.org.*

Passing of Former Idaho Board of Pharmacy Executive Director

The Board is lamenting the loss of former Idaho State Board of Pharmacy Executive Director Doyle C. Miner, who passed away on December 18, 2014. Doyle held several prominent public positions throughout his lifetime. He was a city councilman in St Anthony, ID; a state representative from Madison and Fremont Counties where he was co-chairperson of the Joint Finance Appropriations Committee; and a co-owner of Thriftway Drug with stores in St Anthony, Rexburg, ID, and Blackfoot, ID. Doyle served as executive director of the Board from August 7, 1980 until August 31, 1982. He will be missed.

Recent Board Discipline

J.B., PharmD: License and CS registration revoked pursuant to voluntary surrender.

J.B., PharmD: Ordered to complete 18-credit hour CPE course, Patient Safety and Medication Error Prevention for Pharmacy, for failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling.

B.S., PharmD: Ordered to complete 18-credit hour CPE course, Patient Safety and Medication Error Prevention for Pharmacy, for failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling.

M.G., RPh: Fine of $2,000 for operating an unregistered pharmacy.

4.C.P., Pharmacy: Fine of $2,000 for failing to renew its registration.

E.W., Technician-in-Training: Fine of $500 for falsifying an application.

P.P., PharmD: $1,500 fine and 60 additional CPE for failing to provide proof of completion of any CPE for a two-year period.

K.B., MD: CS registration restricted as to not order, handle, administer, or dispense any CS.

R.A., DDS: CS registration revoked pursuant to Idaho State Board of Dentistry order.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

The *Idaho State Board of Pharmacy News* is published by the Idaho 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.

Mark D. Johnston, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager