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News

Idaho State Board of Pharmacy

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2016 Pharmacy Administrative Rule Changes

The following rule changes are anticipated to become effective at *sine die* of the 2016 Idaho legislature, which is expected to be around March 26.

Rules 010, 011, and 012: Provide a definition for terms related to compounding, including hazardous drugs, reconstitution, and United States Pharmacopeia (USP) Chapters <795> and <797>. In addition, the definition of pharmaceutical care services is updated to further clarify that Idaho pharmacists may order and interpret laboratory tests.

Rules 016, 060, and 116: Provide a variety of opportunities for the Idaho State Board of Pharmacy to more meaningfully respond to declared emergencies, including: 1) suspension of licensing requirements for pharmacists licensed in other states, 2) allowance of emergency refills of up to a 30-day supply; and 3) establishment of temporary or mobile pharmacy facilities.

Rule 021: Creates a streamlined approach to the registration of non-retail pharmacy outlets, creating one category of registration regardless of the number of over-the-counter products sold.

Rule 031: Ensures parity in the minimum number of experiential hours required for foreign pharmacy graduates and graduates of accredited US schools of pharmacy.

Rule 040: Updates the names of the entities that certify pharmacy technicians, and allows the Board to cancel technician registrations if a national certification is not appropriately maintained.

Rule 210: Clarifies how controlled substances (CS) may be stored. Pharmacies may keep such products in a securely locked, substantially constructed cabinet, or dispersed in whole or in part throughout their non-controlled stock. Other drug outlets must keep CS in a securely locked, substantially constructed cabinet.

Rule 310: Broadens the existing collaborative practice laws by allowing a pharmacy, not just pharmacists, to be a party to the agreement. It also clarifies that patient records under a collaborative practice agreement should be kept for three years. In addition, it establishes that statewide protocols may be issued by the director of the Idaho Department of Health and Welfare for the purposes of improving public health.

Rule 630: Creates harmony with federal law on permissible and impermissible dispensing of drugs and devices for use outside of an institutional facility.

Upcoming Board Strategic Planning Meeting

The Board will hold its 2016 strategic planning meeting on April 8, 2016, in Boise, ID. Prioritized topics that will be covered include pharmacy technicians (appropriate roles, responsibilities, education, and training) and curbing prescription drug abuse. To facilitate public input in the planning process, Board staff will hold informal "idea-raisers" approved for one hour of law continuing education (CE) at the following times and locations:

- March 16, 8 AM, Idaho State University (ISU), Room 472, Meridian, ID
- March 16, 7 PM, ISU, Room 472, Meridian
- March 17, 7 PM, ISU, Leonard Hall, Building 8, Room 123, Pocatello, ID
- March 18, 8 AM, ISU, Leonard Hall, Building 8, Room 123, Pocatello
- March 18, 6 PM, Eastern Idaho Regional Medical Center, Idaho Cancer Center Classroom, Idaho Falls, ID
- March 29, 7:30 PM, St Luke's Magic Valley Medical Center, Twin Falls, ID
- April 4, 7:30 AM, St Joseph's Regional Medical Center, Lewiston, ID
- April 4, 7:30 PM, Kootenai Health and Medical Center, Building 4, Cedar Conference Room, Coeur d'Alene, ID

Pharmacists may also submit written feedback through a survey on the Board's website, available at *http://bop.idaho.gov*.

Common Red Flags in CS Dispensing

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a CS prescription. Such a determination is to be made **before** the prescription is dispensed.

In the course of filling a prescription (new or refill), there are circumstances that may cause a pharmacist to question the validity of a prescription for a CS. These warning signs are often called "red flags." When encountering a red flag, a pharmacist's concerns do not mean that the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a CS, the pharmacist shall attempt to resolve any red flags by exercising his or her independent professional judgment.

Examples of common red flags encountered in the dispensing process include:

- The patient requests to pay with cash, especially if insurance is on the patient's record.
- The patient travels a long distance to the prescriber or pharmacy.
- There is evidence of "doctor shopping" or "pharmacy shopping."
- The patient engages in a pattern of early refills, or statements suggest abuse.
- Patients travel in groups with others filling similar prescriptions.
- The prescriptions appear altered or are missing key requirements of a valid prescription.
- The prescriptions are for highly abused "cocktails" (eg, a combination of opiate, benzodiazepine, and muscle relaxant).

When attempting to resolve a red flag, each prescription may require a different validation process, and no singular process can fit each situation that may be encountered. Common ways that pharmacists may attempt to resolve red flags include: communication with the patient or the patient's representative; communication with the prescriber or the prescriber's agent; and/or accessing the Idaho Prescription Monitoring Program (PMP) database.

When validating a prescription, if at any time the pharmacist determines in his or her professional judgment that concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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With respect to the PMP, only 60% of Idaho pharmacists are currently registered. Failing to register or failing to use the PMP is not a defense against administrative claims in a case of prescription drug abuse. To register with the PMP and leverage this valuable database as part of the resolution process, visit the PMP website at *https://idaho.pmpaware.net/login*.

Review of Pharmacist Notification Requirements

The Board is seeing an increasing trend of licensees not informing the Board of changes to personal information and/or employment as required by law. Every pharmacist, student pharmacist, and technician must inform the Board of any changes of employment and personal contact information, such as home address, phone number, etc, within **10 days** of the change (per Rule 017).

In addition, every pharmacist-in-charge (PIC) and director of a pharmacy must also notify the Board within **10 days** of any staff changes (Rule 302). Both the outgoing and incoming PIC and director must notify the Board within **10 days** of PIC and director designation changes (per Rules 302 and 622).

Employers are also required to notify the Board within **30 days** of any terminations of employees for adulteration and/or misappropriation of CS (per Section 37-117(a), Idaho Code).

Failure to properly notify the Board of changes to personal and employment information may lead to discipline for the individual, PIC and/or director, and facility.

Pharmacy Sales of CS for Office Use

The Board has encountered a number of pharmacies that have provided CS to practitioners who do not have the required CS registrations at the address the pharmacy is listing on the invoice. Practitioners can prescribe at multiple locations by having only one Drug Enforcement Administration (DEA) registration, but they can only possess CS at a registered address.

Pharmacies selling or transferring CS are required by law to ensure the purchaser/transferee holds a current DEA registration. The Board recommends that pharmacies require the practitioner to provide a copy of his or her DEA certificate, and then verify the practitioner's Board registration status and address on the Board's website at *https://idbop.glsuite.us/GLSuiteWeb/Clients/IDBOP/Public/Verification/Search.aspx*.

If the two addresses differ, the pharmacy should not complete the transaction and should inform the practitioner of the reason for denial. The practitioner can then contact the Board office with any questions. In addition, pharmacies providing CS to practitioners must submit monthly reports to the Board pursuant to Rule 615.05.

Recent Board Discipline

For a more detailed report on these cases, view the draft minutes of the January 18-19 Board meeting at *http://bop.idaho.gov/board_meeting*.

B.C., PharmD: $2,000 fine and up to six hours of CE for excessive provision of CS (eight fills of hydrocodone for the same patient, each for a 30-day supply, over a two-month period).

K.D., PharmD: $2,000 fine and up to six hours of CE for excessive provision of CS (three fills of tramadol for the same patient, each for a 17-day supply, over three days).

D.A., PharmD: $2,000 fine and up to six hours of CE for excessive provision of CS (patient filled three 30-day supplies of lorazepam in 20 days; patient filled four 30-day supplies of zolpidem in seven days).

A.J., PharmD: $500 fine and up to six hours of CE for excessive provision of CS (patient filled eight 30-day supplies of zolpidem in two months).

M.P., RPh: $500 fine for misrepresentation by licensee in securing renewal of license.

R.W., PharmD: $2,000 fine for failure to maintain accurate inventories of CS.

J.F., PharmD: 18 hours of CE for a medication dispensing error (provided a stock bottle of 100 lysodren tablets when the prescription called for eight tablets).

R.M., CPhT: $250 fine for failure to maintain national certification.

M.H., PharmD: Ordered to provide a public CE session for violation of the emergency refill rule.

B.S., RPh: Ordered to undergo an evaluation for theft of non-CS.

In addition, 36 pharmacists were proposed penalties for failing to complete their CE requirements. In most cases, the penalty was $500 for misrepresentation by the licensee in securing renewal of license, $50 per missed CE hour, and double the requirement per missed CE the following year.

It is the pharmacist's responsibility to ensure that Accreditation Council for Pharmacy Education (ACPE) statements of credit are accurately reported to the National Association of Boards of Pharmacy® CPE Monitor® service, as ACPE certificates will only be accepted if they are reported through this system. Pharmacists must also maintain statements of credit for continuing medical education or Board-approved CE in a readily retrievable fashion (ie, able to be produced to Board staff in 72 hours). No exceptions will be made during the expanded 2016 audit.

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 it carefully.

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.

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