September 2016

News

# Idaho State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

## Proposed Rulemaking Hearing Scheduled: October 26

The Idaho State Board of Pharmacy's public hearing on its proposed rules is scheduled for **October 26, 2016,** at 1 PM MDT and will be held at the Idaho State Capitol, Room WW53, 700 W Jefferson St, Boise, ID.

The Board encourages all interested parties to review the proposed rules, available on its website, *https://bop.idaho.gov,* and provide feedback to the Board. Comments may be submitted in writing in advance of the meeting to Board Executive Director Alex Adams via email to alex.adams@bop.idaho.gov or by fax to 208/334-3536. In addition, verbal comments may be delivered in person at the meeting.

## Announcing Launch of PMP Gateway to Integrate PMP Data Into Pharmacy Dispensing Systems

In August 2016, the Board officially launched PMP Gateway, which enables the integration of prescription monitoring program (PMP) data directly into electronic medical records and pharmacy dispensing systems. This integration allows instant access to PMP data for prescribers and pharmacists without having to separately log on to the Board's PMP web portal.

The Board often hears complaints about the time burden associated with logging in to the current PMP and believes this tool will streamline access and reduce the administrative burden on end users. As more prescribers and pharmacists get instant access to the PMP, it is the Board's hope that this tool will strengthen the fight against opiate abuse. Currently 20 states use this tool, and it has greatly enhanced use of the PMP!

PMP Gateway is operated by Appriss, Inc, the Board's PMP vendor. Initial integration and ongoing maintenance fees are managed by Appriss and do not pass through the Board. Use of PMP Gateway is subject to Appriss' terms and conditions, and users must take care to ensure their use is consistent with the limits placed on prescribers and pharmacists in Idaho Code. The Board will continue to monitor appropriate use of the PMP. Only individuals who have previously registered with the Board for PMP access will be permitted to access data through PMP Gateway.

To begin the process of integrating your electronic medical record or pharmacy dispensing system, contact Teresa Anderson at teresa.anderson@bop.idaho.gov.

## Delivery of a CS for Direct Administration

Currently, Rule 503 prohibits a pharmacy from delivering a controlled substance (CS) to the patient's licensed health care provider. At the June 2, 2016 Board meeting, the Board granted a waiver request to a pharmacy that allows the pharmacy to deliver a CS to a health care provider if the CS is intended for direct administration to the patient (eg, an intrathecal pain pump). The Board's granting of a waiver on CS for direct administration is consistent with a recent expression of policy from the federal Drug Enforcement Administration.

The Board intends to update Rule 503 through the rulemaking process. In the meantime, pharmacies seeking similar waivers to enable delivery of CS to health care providers for direct administration to the patient may apply to the Board's executive director by following Board Rule 13.

## Board Designates U-47700 as a Schedule I CS

On August 3, 2016, the Board designated 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide, commonly known as U-47700, as a Schedule I CS via a temporary rule. U-47700 is a synthetic opioid that is reported to be nearly eight times more potent than morphine. It is linked to at least 50 deaths nationwide, including two in Idaho. A full copy of the Board's temporary rule will be published in the Idaho Administrative Bulletin.

## Maintaining CPE Documentation

As the Board begins its annual continuing pharmacy education (CPE) audit, it is useful to remind pharmacists of the requirements. Each pharmacist must annually complete 15 CPE hours with the following parameters:

- A **minimum** of 12 hours must be obtained through an Accreditation Council for Pharmacy Education (ACPE) or Accreditation Council for Continuing Medical Education (ACCME)-accredited provider.
- A **maximum** of three hours may be obtained through a program explicitly approved by the **Idaho** Board.

For more information on the CPE requirements, visit the Board's website, *https://bop.idaho.gov/continuing_education/index.html*.

As documentation of ACPE-accredited programs, the Board will **only** accept credits reported to CPE Monitor®, a collaborative service of the National Association of Boards of Pharmacy® (NABP®), ACPE, and ACPE providers. Board staff routinely fields allegations from pharmacists that a CPE provider did not report credit to CPE Monitor; in each instance, it has been determined that the pharmacist did not in fact complete the program, knowingly or unknowingly. It is the **pharmacist's** responsibility – not the Board's – to ensure that credit for continuing education (CE) programs is accurately reported to CPE Monitor, as CPE credit from ACPE-accredited providers will only be accepted if it is reported through this system. No exceptions will be made during the expanded 2016 audit.

Pharmacists must maintain documentation of completed CE from continuing medical education providers or a Board-approved program for a minimum of three years. The credits should be in the form of a certificate of completion. All ACCME or Board-approved

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## FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

## More Selected Medication Safety Risks to Manage in 2016

*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.*

### Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

### Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

**References**

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## USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

## FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. 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. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

## FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

## FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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CE credits must be stored in a readily retrievable fashion (ie, able to be produced to Board staff within 72 hours upon request).

## Providing CLIA-Waived Tests in Idaho

Recently, the Board updated the definition of "pharmaceutical care services" to include "ordering and interpreting laboratory tests." This rule change took effect on March 25, 2016. This rule change gives Idaho one of the broadest state laws regarding laboratory tests, allowing pharmacists to further practice at the top of their education and training and improve patient outcomes.

While the definition was broad, most pharmacies nationally focus primarily on Clinical Laboratory Improvement Amendments (CLIA)-waived tests, such as those for glucose, cholesterol, influenza, and strep throat, among others. As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." In order to provide such tests, pharmacies must obtain a CLIA Certificate of Waiver through the Idaho Bureau of Laboratories. A Certificate of Waiver, which costs $150 and is valid for two years, is needed for **each** pharmacy prior to performing CLIA-waived testing.

To assist Idaho pharmacies with this new rule, the Board has posted a free online CPE program on its website, titled "How to Obtain a CLIA Waiver and Begin Testing." The program is approved for 0.5 hours of home study CPE credit in pharmacy law and may be accessed from the Board's home page, *https://bop.idaho.gov*.

## PMP Reporting

Board Rule 204 requires specified data to be reported weekly **or more often as required by the Board.** On January 1, 2015, the Board changed the reporting requirement to **daily.** All pharmacies should now be reporting on a daily basis. Please take the extra time to ensure you are choosing the correct prescriber and entering the patient's **full** name into the system. The Board has had pharmacies enter an initial for the patient's name, which does not provide meaningful purpose for the PMP.

## Board Policy on Lavatory Storage

Compliance officers are noticing the use of lavatory facilities as overflow storage for pharmacy products. In some cases the storage in the lavatory is impacting the use of facilities by pharmacy staff. This issue was brought before the Board at the August 3, 2016 meeting by compliance staff. After a discussion by the Board, it was determined that all products injected, inhaled, ingested, or handed to a patient or any item that will ultimately be in contact with a patient cannot be stored in the lavatory. Exceptions to this list are products such as walkers, canes, and crutches.

The Board feels that storing such items in the lavatory violates IDAPA 27.01.01.601.01, which states: "A pharmacy must be well-lit, ventilated, temperature controlled, and have sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and **sanitary condition** appropriate for the safe preparation and compounding of prescriptions. (3-21-12)." (emphasis added)

In addition, if storage of items in the lavatory prevents the use or ease of use by pharmacy staff, that is a violation of IDAPA 27.01.01.601.03.b, which states: "Include a lavatory facility in the pharmacy restricted to pharmacy staff. (3-21-12)."

The storage of personal items as well as storage of records in lavatories was not restricted by the Board.

## Fingerprinting for Technician Applications

The Board is authorized to receive and review fingerprint-based background checks by Idaho Code 54-1753 (Idaho Wholesale Drug Distribution Act) and 54-1718 (Idaho Pharmacy Act). Because of the reduced return time for fingerprint results, and to be more in line with Idaho Code, fingerprints will now be required for applicants under the age of 18 (with permission needed from a guardian) and for those technicians upgrading from a technician-in-training registration to a certified technician registration. Please contact Berk Fraser (berk.fraser@bop.idaho.gov or 208/334-2356) with any questions.

## Recent Board Discipline

For a more detailed report on cases, view the draft minutes of the June 2, 2016 Board meeting at *http://bop.idaho.gov/board_meeting*.

- **J.K., PharmD:** $500 fine for violation of Board rules regarding outdated products on the stock shelves in the pharmacy.
- **J.Y., Technician-in-Training:** $50 fine and two hours of CE on patient safety for a medication error (selected wrong patient).

## 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.





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