March 2013

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

2013 Pharmacy Administrative Rule Changes

At *sine die* of the 2013 Idaho legislative session, at least four dockets of rule changes will take effect. Additional rule and statute changes may also take effect, but such potential changes had not progressed through the legislative process as of press time. You are encouraged to visit the Idaho State Board of Pharmacy's Web site for updated information. In addition to several housekeeping changes, said four dockets include, but are not limited to, the following changes:

Various rules, including **Rule 052:** Eliminate the terminology, "Continuing Pharmacy Education Unit (CPEU)" and replaced it with "Continuing Pharmacy Education (CPE) hour."

Rule 011.09: Clarification that the practice of pharmacy does not include the practice of medicine, but that pharmacists can order lab tests.

Rule 012.07: Recognition of Food and Drug Administration's "Green Book" for allowable, veterinarian generic drug selection.

Rule 019: Change the license and registration posting requirement to an immediately retrievable requirement.

Rules 036 and 041: Expansion of student pharmacist and technician-in-training rules, with the addition of the Board's power to cancel such registrations if the registrant fails to maintain the requirements of registration.

Rule 130: Allowance for pharmacists to substitute, upon a drug shortage, so long as directions are modified to equate to an equivalent amount of drug dispensed as is prescribed.

Rule 131: Expansion of the "brand only" designation to allow for similar verbiage on prescription drug orders.

Rules 140 and 142: Addition of pharmacist initials to general and parenteral admixture labeling requirements.

Rule 200: Addition of "positive ID" exceptions for certain delivered prescriptions.

Rule 206: Allowance to conduct annual controlled substances (CS) inventory within seven days of the prior year's inventory.

Rule 260: Expansion of the drug product storage requirements to over-the-counter drugs.

Rule 262: Reintroduction of written protocol mandate for pharmacies accepting the restricted return of drugs or devices.

Rules 290, 291, and 292: Several changes to automated dispensing and storage (ADS) rules addressing password delegation, nurse stocking, refrigeration, prescriber access, wasted drugs, drug re-stocking, and self-service ADS system use in a hospital's emergency room.

Rule 503: Allowance of delivery to a "correctional facility."

Rule 600: Clarification that a pharmacy must have a pharmacist-in-charge or director upon opening.

Rule 602: Addition of grandfathering clause to separate phone line and door security requirement.

Rule 605: Clarification that non-institutional pharmacist breaks are only allowed without closing the pharmacy if another technician or student pharmacist is on duty in the pharmacy.

Rule 606: Requirement of seven days public notice for a pharmacy's change of hours of operation.

Rule 622: Addition of a public notice requirement: change of director, within 10 days of the change.

Rule 637: Certain changes to registered nurse dispensing in hospital emergency rooms.

Rule 730: Addition of mail order pharmacy toll-free phone hours of operation requirement.

Notice of Intent to Promulgate Rules-Negotiated Rulemaking

When: April 4, 2013, 8 AM MST

Where: Idaho State University (ISU), Pond Student Union, Pocatello, ID

Descriptive Summary: The public meeting will address at least the following two topics: compounding and prescription delivery law.

Method of Participation: Anyone may submit written or verbal comments regarding this negotiated rulemaking. All written comments may be directed to Mark Johnston at mark.johnston@bop.idaho.gov on or before March 19, 2013. Written and verbal comments will be heard before the Board in the open, public meeting.

Upcoming Continuing Education

When:	March 10, 2013, 8:30 AM
Where:	ISU, 1303 E Central Dr, Meridian, ID
Who:	Part of ISU's Annual Conference: Debra Wynn, 208/282-2586, ce@pharmacy.isu.edu
What:	1 hour of Accreditation Council for Pharmacy Education (ACPE)-accredited, live, jurisprudence (law) CPE
When:	March 17, 2013, 8:30 AM
Where:	ISU, Pond Student Union, Pocatello, ID

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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IDAHO STATE BOARD OF PHARMACY

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Who:	Part of ISU's Annual Conference: Debra Wynn, 208/282-2586, ce@pharmacy.isu.edu
What:	1 hour of ACPE-accredited, live, jurisprudence (law) CPE
When:	April 4, 2013, 7 PM
Where:	Eastern Idaho Regional Medical Center (EIRMC), Conference Rooms A and B, Idaho Falls, ID
Who:	No RSVP required
What:	1 hour of Board-approved, live, jurisprudence (law) CPE
When:	April 5, 2013, 7 AM
Where:	EIRMC, Cancer Center, Idaho Falls, ID
Who:	No RSVP required
What:	1 hour of Board-approved, live, jurisprudence (law) CPE
When:	April 7, 2013, 1 PM
Where:	St Luke's Regional Medical Center, Boise, ID
Who:	Part of Idaho Society of Health-System Pharmacists' Spring Conference, *http://ishp.shuttlepod.org,* 208/342-2581
What:	1 hour of ACPE-accredited, live, jurisprudence (law) CPE
When:	April 14, 2013, TBA
Where:	Red Lion Templin's Hotel, 414 E First Ave, Post Falls, ID
Who:	Part of ISU's Annual Conference: Debra Wynn, 208/282-2586, ce@pharmacy.isu.edu
What:	1 hour of ACPE-accredited, live, jurisprudence (law) CPE
When:	April 23, 2013, 7:30 PM
Where:	St Luke's Magic Valley Medical Center, Twin Falls, ID
Who:	Magic Valley Pharmacy Association: Troy Jackman, 208/731-3950
What:	1 hour of Board-approved, live, jurisprudence (law) CPE
When:	April 24, 2013, 7:30 PM
Where:	St Joseph's Regional Medical Center, Lewiston, ID
Who:	No RSVP required
What:	1 hour of Board-approved, live, jurisprudence (law) CPE

Recent Board Discipline

N.E.C.C., Mail Service Pharmacy: License revoked pursuant to Massachusetts Board of Registration in Pharmacy action.

T.F., DDS: CS registration revoked for failing to provide effective controls and procedures to guard against theft and diversion of CS.

J.M., DMD: CS registration revoked for failing to properly and securely store CS.

B.B., PA: CS registration revoked for illegally obtaining a CS.

J.J., DMD: CS registration restricted for inventory and record keeping violations and furnishing CS for oneself.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy intern/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, Inc, 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 the Foundation or the Board unless expressly so stated.

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