June 2013

Idaho State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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2013 Pharmacy Administrative Rule and Statute Changes

On April 4, 2013, four dockets of rule changes took effect, as detailed in the March 2013 *Newsletter*. On July 1, 2013, the following changes to an administrative rule and sections of Idaho Code will become effective. Copies of the pertinent docket of rules and bills are available on the Idaho State Board of Pharmacy's Web site. Engrossed versions of Idaho Code and the Board's administrative rules are expected to be available later this summer.

House Bill 239 gives the Board statutory authority to address compounding and the distribution of compounded drug product in rule, as well as extending to all pharmacies the sale of minimal quantities of prescription drugs to licensed practitioners for office use, without required wholesale licensure. Please see the Board's Web site for a draft version of such subsequent rules; the Board is currently accepting public comment on this draft.

House Bill 16 allows a pharmacist or practitioner to furnish another pharmacist or practitioner information legally obtained from the Board's Prescription Monitoring Program database.

House Bill 17 (HB 17) mainly expands the practice of pharmacy into Idaho, with considerably more regulation of such persons, practices, and practice sites; however, the bill also deletes outdated practices and contains several non-substantive changes. HB 17 merges the Out-of-State Mail Service Pharmacy Act into the Idaho Pharmacy Act, and defines central drug outlet, central pharmacist, mail service pharmacy, nonresident, pharmacist-in-charge (PIC), and centralized pharmacy services, which means the processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations. All persons and business entities engaging in the practice of pharmacy into Idaho, including but not limited to pharmaceutical care services, must be licensed and registered, except nonresident pharmacists practicing pharmacy into Idaho who are employed by and practicing for an Idaho registered nonresident mail service pharmacy. All nonresident mail service pharmacies and central drug outlets must also have a PIC or director who is licensed or registered by the Board.

Please note that nonresident pharmacist registration is a lower standard when compared to pharmacist licensure, as pharmacist registration does not require an applicant to reciprocate through the National Association of Boards of Pharmacy® or pass an Idaho-based Multistate Pharmacy Jurisprudence Examination®. However, the Board may take any action against a nonresident pharmacist registrant that it can take against a pharmacist licensee for violations of the laws of Idaho or the state in which the pharmacist resides. Additionally, the Board may take any action against a nonresident drug outlet that it may take against its agents and employees. A successful applicant for a nonresident central drug outlet, mail service pharmacy, or pharmacist registration or licensure must comply with the Board's laws and rules unless compliance would violate the laws or rules in the state in which the registrant is located, except a technician shall not exceed the practice limitations for technicians in Idaho and a pharmacist shall only substitute and generically select drug products in accordance with Idaho law and shall not exceed Idaho's pharmacy staffing ratio. Additionally, the Board may issue an order likewise suspending, revoking, restricting, or otherwise affecting the license or registration in Idaho, without further proceeding, as Drug Enforcement Administration or another state licensing board with authority over a licensee's or registrant's professional license or registration has issued. Also, if the Board conducts a nonresident inspection, the nonresident drug outlet shall pay the costs of such inspection. Lastly, HB 17 reestablishes the original out-of-state mail service pharmacy fees for all nonresident mail service pharmacies and central drug outlets: $500 for initial registration and $250 for renewal.

Docket 27-0101-1205 reiterates some of HB 17 for ease of reading the rules. Remote office location is defined and allowed with certain security requirements. While the category of "telepharmacy across state lines" is absorbed into the new nonresident rule and statute, the existing $250 registration fee for "telepharmacists across state lines" is expanded to all pharmacist registrants, but pharmacist licensure fees remain unchanged. New Rule 029 details which pharmacists practicing pharmacy in or into Idaho need to be registered or licensed. The registration category of "telepharmacist across state lines," who practice from nonresident institutional pharmacies, is expanded to all nonresident pharmacists who practice from within a pharmacy. Unless statutorily exempted (a nonresident pharmacist working for a mail service pharmacy) or a nonresident PIC or director, all other pharmacists practicing pharmacy in or into Idaho must be Idaho licensed, including those practicing from a central drug outlet that is not a pharmacy and remote office locations. Upon applying, nonresident central drug outlets and mail service pharmacies must submit an executive summary describing the centralized pharmacy services to be performed.

Docket 27-0101-1205 also addresses practice standards. For example, Rule 320 mandates that the independent practice of pharmacy is not to be construed to excuse compliance with the rules governing centralized pharmacy services. The independent practice of pharmacy rule's minimal standards are designed to recognize and regulate pharmacist activities outside of a drug outlet or institutional facility, such as at a health fair. Rule 610's expanded regulation pertains to centralized pharmacy services,

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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such as providing cognitive services for an institutional pharmacy, remote data entry, and central fill. A pharmacy may centralize pharmacy services to another Idaho registered business entity, to be performed at a pharmacy, central drug outlet, or remote office location, pursuant to a written contract, policies and procedures, certain training, appropriate communication, a common electronic file (or other secure technology), a continuous quality improvement program, audit trail documentation, and privacy considerations. For an institutional pharmacy, centralized pharmacy services are only allowed for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients or residents of the institutional facility.

2012-2013 Renewal Season

Pharmacists, technicians, and drug outlets are among the many registrants and licensees that are required to renew by June 30, and should have already have received a renewal form or a bright yellow postcard with online renewal instructions. By next year, the Board anticipates online renewal for the last few registrants and licensees that cannot currently do so. Online renewal is not required and paper forms are available at *http://bop.idaho.gov/renew/.* Late fees are imposed on July 1, and if not renewed by July 31, licenses and registrations will be required to be reinstated, which includes fingerprinting for pharmacists and technicians. Licensees and registrants may be subject to discipline if practicing without the proper license or registration. The online renewal process also allows for the reporting of changes to initial or prior renewal applications, if not already in compliance with Rule 017.06, which requires the Board to be notified within 10 days of such change. For questions or complications, please contact the Board at info@bop.idaho.gov or 208/334-2356.

Recent Board Discipline

B.O., PharmD: License and controlled substances (CS) registration revoked for diversion.

K.W., RPh: License and CS registration revoked for failure to follow an order of the Board.

J.E., PharmD: $1,000 fine and six additional continuing pharmacy education (CPE) hours for failing to follow the instructions of person writing, making, or ordering a prescription, failure to counsel, and failure to document counseling.

A.M., PharmD: $500 fine and six additional CPE hours for failing to follow the instructions of person writing, making, or ordering a prescription.

K.G., RPh: $500 fine and six additional CPE hours for failing to follow the instructions of person writing, making, or ordering a prescription.

J.N., PharmD: $500 fine and six additional CPE hours for failing to follow the instructions of person writing, making, or ordering a prescription.

J.A., RPh: $2,000 fine for delivering CS, filled prescriptions to a licensed or registered health care provider.

A.P., Pharmacy Technician: Registration revoked for failing to disclose a felony conviction on her initial application and subsequent renewal.

G.M., PA: CS registration revoked for diversion.

J.H., MD: CS registration revoked for diversion.

E.H., DDS: CS registration restricted for diversion.

T.S., PA: CS registration restricted due to mental illness, alcohol, or substance abuse, which affects the ability to perform any of the essential functions of his profession.

D.M., DVM: CS registration restricted for prescribing CS to herself and dispensing CS without a CS registration.

H.B., DDS: CS registration restricted for diversion.

E.N., MD: CS registration restricted, pursuant to State of Idaho Board of Medicine 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, 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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