September 2013

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Pharmacy Provision of Prescription Blanks

The Idaho State Board of Pharmacy has reviewed and considered the provision of pre-printed, hard copy prescription drug order blanks containing compounding formulas, by a pharmacy to a prescriber, and has concluded it is legal. However, considering the best interest and safety of the public, the Board has concluded that the provision of hard copy prescription blanks containing pharmacy-specific information, such as pharmacy name or address, is prohibited. In reaching this conclusion, the Board considered the following law:

> **504. UNLAWFUL ADVERTISING.**
>
> **01. Unlawful Advertising or Inducements.** A licensee or registrant may not promote or induce, directly or indirectly, the provision of professional services or products through the dissemination of a public communication that contains a false, misleading, or deceptive statement or claim.

The Board's decision is based upon the determination that the inclusion of pharmacy-specific information on such a prescription blank creates too great of a risk of being "misleading" or "deceptive," as the patient would likely be led to believe that his or her prescription drug order may only be dispensed by that specific pharmacy.

The Board also cautions pharmacies that engage in such provision of blanks containing controlled substances (CS), that blanks for CS are required to be on non-copyable paper as per Section 37-2725, Idaho Code, and that they may be deemed by Drug Enforcement Administration (DEA) to have been illegally prepared for the prescriber's signature by someone other than the prescriber's agent.

2014 Proposed Rules

The Board has held four negotiated rulemaking sessions in 2013, mostly focused on compounding rules in the wake of the New England Compounding Center tragedy and post-2013 changes to non-resident drug outlet law. Other rulemaking topics include secured delivery rooms and limiting Board-approved continuing pharmacy education (CPE) programs. The Board is very thankful for the immense amount of public input that has helped form these proposed rules, which are posted on the Board's Web site. Upon printing of the proposed rules in the October Idaho Administrative Bulletin on October 2, 2013, a 21-day comment period will commence. On the 21st day, October 23, 2013, the Board will meet at the Idaho State Capitol to hear final verbal comments at an open public meeting. Written comments may be submitted to the Board at any time during the 21-day comment period. The Board will consider all comments on October 24, 2013, post the resulting pending rules on its Web site, print the pending rules in the January Idaho Administrative Bulletin, and request approval by the 2014 Idaho Legislature.

Restrictions on Prescribing for Self and Family

Rule 110.04: **"A prescription drug order for a controlled substance is invalid if written for the prescriber's own use."** Rule 110.05: **"A prescription drug order written for a family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession."** While the restriction on self prescribing CS is easily understood, Rule 110.05 refers to the prescriber's particular licensing board for restrictions on prescribing to one's family members. The Idaho Board of Medicine prohibits its licensees from prescribing, selling, administering, distributing, or giving any drug legally classified as a CS or recognized as an addictive or dangerous drug to him or herself or to a spouse, child, or stepchild. The Idaho Board of Nursing prohibits its licensees from prescribing, dispensing, or selling any drug classified as a CS to a family member or to him or herself, and family member is defined as the licensee's spouse, child (biological, adopted, or foster), parent, sibling, grandparent, grandchild, or the same relations by marriage. Idaho licensed dentists and optometrists are not restricted from prescribing to their family members. Ascertaining the validity of a prescription drug order written by a prescriber in a jurisdiction other than Idaho becomes even more challenging. Pharmacists have a corresponding responsibility to ensure that prescriptions are only dispensed pursuant to valid prescription drug orders.

Counseling Documentation

Section 54-2739, Idaho Code, requires counseling on new medications and an offer to counsel on all refilled or renewed prescriptions. Rule 105 requires documentation of these statutory requirements of "counseling and offers to counsel." As Rule 105 specifically lists "offer to counsel," then it specifically requires documentation of offers to counsel on refilled or renewed prescriptions. The offer to counsel can be made by a pharmacist (or pharmacist intern) or a technician. Additionally, Rule 105 does not detail exactly what form of documentation you may choose to utilize; this is a business decision, as you gauge what might hold up in a contested case hearing.

Fraud by Computer

Section 18-2202(1), Idaho Code, details fraud by computer and attaches felony penalties upon conviction. Recently, prosecutors in Idaho were successful in obtaining such a felony conviction against a pharmacist for petit theft of prescription drugs because the pharmacist attempted to conceal the diversion by altering the drug's "on hand quantities" in the pharmacy's computer system. The Board supports the Pharmacy Recovery Network, as administered by Southworth Associates, and warns of such potential criminal prosecution.

Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit ***www.MyCPEmonitor.net*** to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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The Board Welcomes a New Member and Two New Employees

The Honorable C.L. "Butch" Otter, governor of Idaho, has appointed Kristina Jonas to serve on the Board. Ms Jonas currently works in retail pharmacy, has been a pharmacy district manager for a large chain pharmacy where she received the pharmacy district manager of the year award, and is a past president of the Idaho State Pharmacy Association (ISPA). Ms Jonas has served on the Medical Care Advisory Committee for the Idaho Department of Health and Welfare and Idaho State University (ISU) College of Pharmacy's Dean's Advisory Council, as well as being honored as a Woman in Pharmacy by ISU.

Replacing longtime employee Jan Atkinson, former chief compliance officer, is Berkeley Fraser, deputy executive director. Mr Fraser served on the Board for the past seven years, is a former ISPA board member, and for the last 11 years has held the position of pharmacy coordinator for a large chain pharmacy, overseeing 19 pharmacies in two states. The Board welcomes Mr Fraser's 23 years of diverse pharmacy experience into this new role.

Replacing longtime employee Mike Brown, former inspector in eastern Idaho, is Jaime Sommer. Ms Sommer earned a bachelor of science degree in biochemistry from ISU, is a certified pharmacy technician, and has worked for the past eight years in institutional pharmacy. Ms Sommer will attend the National Association of Boards of Pharmacy® sterile compounding inspector training this fall.

Continuing Education

The Idaho Society of Health-System Pharmacists will hold its fall meeting at the Sun Valley Resort on September 27 through September 29, 2013. All continuing education is Accreditation Council for Pharmacy Education accredited and will focus on medication safety issues in pharmacy, including one hour of law CPE at 11:30 AM on Sunday, September 29, 2013, presented by Mark Johnston, the Board's executive director.

New Technician Certification Testing Site

Pursuant to Board negotiations, the Pharmacy Technician Certification Board (PTCB) announces a new Pearson VUE testing site on campus at ISU in Pocatello, ID. This is the first testing location in eastern Idaho. The address is 1001 S 8th Ave, Graveley Hall, So. Side Room 351, Campus Box 8027, Pocatello, ID 83209.

For information concerning PTCB, please visit *www.ptcb.org/.*

Fingerprinting and Background Checks

The Board began fingerprint-based background checks on July 1, 2010. Employers should consider conducting their check before hiring employees. Public information related to legal background is available at no cost at *https://www.idcourts.us/repository/start.do.*

Recent Board Discipline

R.P., DO: CS registration revoked pursuant to Board of Medicine order.

K.N., PA: CS registration restricted pursuant to Board of Medicine order.

L.L., MD: CS registration revoked pursuant to DEA registration lapse.

J.A., PA: CS registration revoked pursuant to Board of Medicine order.

L.H., PharmD: License and CS registration revoked for diversion.

J.M., Pharmacy Technician: Registration revoked for diversion.

C.M., Pharmacy Technician: Registration revoked for felony burglary convictions.

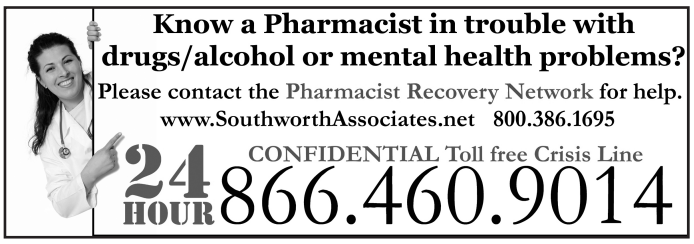
L.M., RPh: License and registration restricted for five more years for not following an order of the Board, for Pharmacy Recovery Network noncompliance.

L.W., RPh: Fined $5,000 and completion of three additional CPE hours for illegally accepting the return of prescription drugs for a period of five years.

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

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.



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