



Idaho State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

3380 Americana Terr, Suite 320, Boise, ID 83706

Rule 458: Time for Filling Prescription

The following rule change is currently effective as a temporary rule, due to the federal code change concerning multiple Schedule II prescriptions:

No person shall fill a prescription for a controlled substance listed in Schedule II unless the prescription is tendered to him on or before the thirtieth day following the date of issue drug order shall be filled more than ninety (90) days after the date the order was written.

Changes Pharmacists May Make to Schedule II Prescriptions

On November 19, 2007, Drug Enforcement Administration (DEA) stated in a preamble to the Final Rule on *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* that “the essential elements of the schedule II prescription written by a practitioner i.e. the name of the controlled substance, strength, dosage form and quantity prescribed may not be modified orally.” However, those instructions are in direct opposition to current DEA and Idaho State Board of Pharmacy policy regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber. Current Board of Pharmacy policy allows a pharmacist to **change or add** the dosage form, issue date, drug strength, drug quantity, and directions for use only after consultation with and agreement of the prescribing practitioner.

Until such time as DEA resolves this matter through future rulemaking, pharmacists are instructed to adhere to existing Board of Pharmacy policy, as outlined above.

Update on CFC Albuterol Inhalers

After December 31, 2008, Food and Drug Administration (FDA) will no longer allow prescriptions for albuterol to contain the propellant chlorofluorocarbon (CFC), and all such canisters of albuterol or like medications must use hydrofluoroalkane (HFA). Pharmacies with existing inventories of albuterol products containing the CFC propellant are no longer allowed to dispense prescriptions that contain the CFC propellant after December 31, 2008.

Board of Pharmacy Attends DEQ Pharmaceutical Waste Disposal Workshop

In September 2008, the Department of Environmental Quality hosted a Pharmaceutical Waste and Disposal Workshop that drew nearly 50 participants including representatives of the Idaho State Board of Pharmacy, Drug-Free Idaho, Boise State University, and various local governments and nonprofit groups throughout the state. The workshop was held to allow experts to present information on pharmaceutical waste disposal and for participants to contribute ideas and suggestions. Input from the workshop was the first step in learning about the issues and concerns related to developing a pharmaceutical waste and disposal program in Idaho. Follow-up meetings are planned to begin exploring potential legislative or regulatory

changes needed, funding options, and public education and outreach efforts. Currently, controlled substance prescriptions and medications can only be collected by DEA or members of local law enforcement. In order to run a successful take-back program that includes controlled substances, law enforcement must maintain immediate custody during the take-back program and also be responsible for its disposal. Prescriptions “shall not be accepted for return by any pharmacist or pharmacy.” Please see IDAPA rule 27.01.01.156.05. for more details.

Online 24/7 Access to Prescription Monitoring Program Data

The Board of Pharmacy has implemented a 24/7 online program where authorized practitioners and pharmacists may check controlled substance prescriptions filled for specified individuals. Controlled substance prescriptions (Schedules II, III, IV) are maintained in the program database, which is updated on a weekly basis. This system has proven to be useful in identifying prescription fraud or those individuals who may be “doctor shopping.” Practitioners and pharmacists must register to access the Web site. Applications may be obtained by contracting the Board of Pharmacy at 208/334-2356 or by e-mailing Teresa Anderson at teresa.anderson@bop.idaho.gov.

October 2008 Tamper-Resistant Pad Requirements

By October 1, 2008, all written, non-electronic prescriptions for Medicaid outpatient drugs must be executed on tamper-resistant pads containing all three of the characteristics listed below in order to be reimbursable by the federal government. Computer-generated prescriptions must be printed on paper that meets these requirements.

- ◆ One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form
- ◆ One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the provider
- ◆ One or more industry-recognized features designed to prevent the use of counterfeit prescription forms

The tamper-resistant requirement does not apply when a prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax. Centers for Medicare and Medicaid Services also allows emergency fills with a noncompliant written prescription as long as the prescriber provides verbal, faxed, electronic, or compliant prescription within 72 hours.

Prescription Drug Disposal by Hospice Employees

Hospice agencies are licensed by the state to provide care within the health and safety standards established by Idaho statute and rule.

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**[®]*

***Community/Ambulatory Edition** by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medi-*

cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (www.fda.gov/cder/drug/MedErrors/meeting_names.pdf) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc[®], has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to www.med-errs.com and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at www.fda.gov/psn or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair[®] HFA Inhalation Aerosol, Proventil[®] HFA Inhalation Aerosol, and Ventolin[®] HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex[®] HFA Inhalation Aerosol. More information is available on the FDA Web site at www.fda.gov/cder/mdi/albuterol.htm.

Currently all Schedule II through IV controlled substances no longer needed by the hospice patient should be disposed of in the patient's home following the guidelines given below. All destruction of controlled substance prescriptions should be witnessed by a family member or another caregiver. Currently there is no provision in Idaho that allows a hospice nurse or care provider to remove unwanted controlled substances from a patient's home for off-site disposal, storage, and/or reuse. Pharmaceuticals that are prescribed to patients and disposed of in the patient's home by hospice or home health care workers or family members are considered household waste, rather than hazardous waste and may be disposed of through the sewer or trash following federal guidelines for proper disposal. These guidelines include removing the pharmacy label and adding kitty litter or coffee grounds to the medication before adding it to the garbage in a nondescript container or by adding water to the medication and reducing it to a sludge-like preparation before disposing of the contents.

Authorization to "Refill" Received Via Fax

Rule 447.03 requires that "additional quantities of controlled substances . . . only be authorized . . . through the issuance of a new prescription." Statute 54-1732 (3)(b) mandates the same for all legend drugs. "Refill" authorization received via fax, can be signed by the prescribing practitioner or their agent. This authorization may then be utilized to generate a prescription hard copy; however, the authorization, most likely, cannot stand on its own as a hard copy, because it does not conform to all requirements of a prescription, as per rule 159.01. If the authorization does conform to rule 159.01, it may be used as the prescription hard copy, realizing it must be signed by the practitioner and not the practitioner's agent. Authorization to refill may be telephoned to the pharmacy by the practitioner's agent as an oral prescription. A pharmacy technician may receive verbal refill information from a practitioner or the practitioner's agent, regarding the amount authorized, but not changes to the original prescription, ie, strength, quantity, directions, or practitioner name. Any change to the original prescription must be taken by a pharmacist.

Discipline from the October 29, 2008 Board of Pharmacy Meeting

SO, Pharmacy, violation of rule 154.04.a.: All (remodel) plans submitted must receive Board approval before a pharmacy permit is issued: \$1,000 fine.

AB, Wholesaler, violation of statute 54-1755 (1): with respect to the requirement for providing a pedigree for each drug that leaves the normal distribution channel: \$2,000 fine.

TP, Pharmacy, violation of rule 180.08: Hours of Operation: \$1,000 fine, submittal of written plan of correction, and copy of employee's future schedules.

TR, RPh, violation of 180.08: Hours of Operation: \$250 fine.

MB, Pharmacy Technician, violation of rule 251.05.c.: preparing a prescription in a negligent or improper manner: \$100 fine.

JG, RPh, violation of rule 184.04: failing to strictly follow the instructions of the person writing or making or ordering a prescription order and rule 184.10: performing a duty of a pharmacist in an incompetent, unskilled, or negligent manner: \$500 fine.

DD, DMD, diversion: controlled substance registration suspended.

SS, RPh, diversion: enroll in Southworth Associates Program Pharmacist Recovery Network.

Future Board Meetings

- ◆ December 17, 2008, 8 AM
Spring Hill Suites, Boise
- ◆ February 5, 2009, 1 PM and February 6, 2009, 8 AM
Spring Hill Suites, Boise
- ◆ April 8, 2009, Time to be announced
Pocatello, ID

Pending Rule Changes

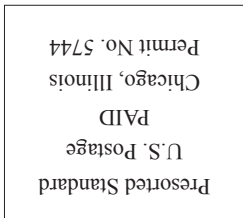
The Board of Pharmacy has submitted changes to 35 rules for the 2009 legislative session. This pending language can be viewed at our Web site: <http://bop.accessidaho.org>, under the Policies & Law link.

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. We encourage 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 Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary 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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