



Idaho State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

3380 Americana Terr, Suite 320, Boise, ID 83706

Introducing the Pharmacist Recovery Network

The Idaho State Board of Pharmacy subsidizes the Pharmacist Recovery Network (PRN). The PRN is coordinated by John Southworth and Southworth Associates. The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence. This includes, but is not limited to, intervention, consultation, monitoring, advocacy, education, and support. The scope of the PRN is not limited to cases of chemical dependence but can also provide all of the above mentioned services to pharmacy professionals with cognitive disorders, and to those with a combination of a cognitive disorder and chemical dependency (dual diagnosis). Please do not hesitate to contact the PRN for assistance. All phone calls and correspondence are kept strictly **confidential**.

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2008 Statute and Rule Changes

Rule 464. Filling Controlled Substance Prescription and Positive Identification: Persons receiving controlled substances shall be positively identified by the staff at the pharmacy at the time any controlled substance is dispensed directly to an individual at the pharmacy, except when:

- 1) The prescription is to be paid for, in whole or in part, by an insurer,
- 2) The pharmacy is part of the health care facility where the patient is being treated, or
- 3) An individual whose identity is personally and positively known to a staff member of the pharmacy who is present and who identifies the individual at the time of delivery of the prescribed controlled substance may be so identified by the staff member; in such instances, the pharmacy shall maintain a record of:
 - i) The name of the person receiving the prescribed controlled substance (if other than the patient);
 - ii) A notation indicating that the patient or other person receiving the prescribed controlled substance was known to the pharmacy staff; and
 - iii) The name of the pharmacy staff person making the identification.

Positive identification shall consist of either a valid, current state or military driver's license or identification card, or a valid, current passport, each of which must contain a photo of the individual and the individual's signature. For each

controlled substance prescription dispensed directly to an individual at the pharmacy, the pharmacy shall:

- 1) Make and maintain a photocopy of the identification presented, or
- 2) Maintain a record of the name of the person receiving the prescribed controlled substance, which record shall contain notation of the type of positive identification presented by such person (the state, military branch or other issuing government entity) and the specific identification number.

Statute 54-1705 (24): "other than a pharmacist" was struck from the definition of practitioner, which now reads:

"Practitioner" shall mean a physician, dentist, veterinarian, scientific investigator or other person licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

Rule 497: Information From Controlled Substances Prescription Data Base: This rule establishes conditional access to the online Prescription Monitoring Program 24 hours a day, seven days a week, for licensed practitioners and pharmacists, who have registered with the Board. To obtain a user account, login name, and password, please contact Teresa at 208/334-2356.

Statute 37-2726: Filing Prescriptions – Database: Any person who knowingly misrepresents to the board that he is a person entitled to receive information from the controlled substances prescriptions database under the conditions therein provided, and who receives information from the controlled substances prescriptions database resulting from that misrepresentation, or any person in possession, whether lawfully or unlawfully, of information from the controlled substances prescriptions database which identifies an individual patient and who knowingly discloses such information to a person not authorized to receive or use such information under any state or federal law, rule or regulation shall be guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six (6) months, or by a fine not to exceed \$2,000, or both.

Rule 270. Technician-checking – Technician: The Board, through its Executive Director, may authorize institutional pharmacies located within acute care hospitals to participate in a Technician-Checking-Technician Pilot Program. The purpose of the Technician-Checking-Technician Pilot Program is to allow pharmacy technicians to review the work of other pharmacy technicians in connection with the filling of floor and ward stock and Unit Dose distribution systems for hospital patients whose orders have previously been reviewed and approved by a licensed pharmacist. During the pilot project phase of the Technician-

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A Community Pharmacy Technician's Role in Medication Reduction Strategies



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (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 Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.



Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at www.fda.gov/cder/guidance/6911fnl.pdf) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

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| Extended release combination drug products containing guaifenesin (competed with approved products) |
| Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness) |
| Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs) |
| Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information) |
| Carbinoxamine drug products (associated with 21 infant deaths) |
| Colchicine injectables (50 reports of adverse events, including 23 deaths) |

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: www.fda.gov/cder/drug/unapproved_drugs/.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at www.rxpatrol.com/videos.asp and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

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Checking-Technician Pilot Program, designation to participate in the program shall be at the discretion of the Board and the Executive Director.

Saint Alphonsus in Boise, under the direction of Larry Munkelt, is currently instituting the first technician-checking-technician pilot program.

Rule 469. Prescription Reporting: All pharmacies which hold a DEA retail pharmacy registration will report weekly, certain data, as required by the Board, on all Schedule II, III and IV controlled substance prescriptions filled. The data may be reported in the form of diskette, direct computer link, magnetic tape or other method as approved by the Board.

Rules 265 to 269. Remote Dispensing Pilot Program: The temporary status was extended for another year. The sole existing pilot program exists in Council, ID, at the Adams County Health Clinic in conjunction with Park-Vu Pharmacy in Weiser, ID.

Rules 321 to 332. These temporary rules, as required to be promulgated by the 2007 Idaho Wholesale Drug Distribution Act, were made permanent, establishing licensure (as opposed to the historic registration) of wholesale distributors and pedigrees for the distribution of prescription drugs that leave the normal distribution channel.

Statute 54-1751 to 54-1759. Idaho Wholesale Drug Distribution Act: The \$100,000 security bond, irrevocable letter of credit, or deposit in a trust account or financial institution requirement for licensure as a wholesale distributor has been struck, as has the fund in which to deposit such bonds. Changes also clarify which court proceedings the wholesale distributor's designated representative would have to provide information about, prior to licensure.

The Idaho Society of Health-Systems Pharmacists Annual Meeting

The Idaho Society of Health-Systems Pharmacists (ISHP) Annual Meeting will be held September 26-28, 2008, at the Sun Valley Lodge/Inn. Fourteen hours of Accreditation Council for Pharmacy Education - approved continuing pharmacy education will be available. Sessions include Board of Pharmacy Executive Director Mark Johnston's Idaho Pharmacy Law on Sunday, September 28. To register visit ISHP's new Web site at <http://ishp.shuttlepod.org>.

Disciplinary Actions from July 30, 2008 Meeting

B.G., RPh, violation of statute 54-1726 and rule 184 for unprofessional and inappropriate conduct: two years conditional probation, \$250 fine, \$600 costs.

R.A., RPh, violation of statute 37-2720 for record-keeping violations: \$2,000 fine, order disallowing position as pharmacist-in-charge for five years, controlled substance registration having been suspended since April 29, 2008 reinstated.

Physician Assistants

Physician assistants (PAs) are able to write prescriptions in Idaho. The PA's name should be the name printed on the prescription label. The PAs name should be written as "John Smith, PA-C" (add appropriate designation as applicable). The prescription should not state Dr Smith if John Smith is a PA. Labeling a prescription with a different clinician (eg, the attending physician) on the prescription other than the one who actually wrote it can lead to medication errors, significant delays in therapy, patient confusion, and is also against pharmacy laws. The public's perception, as well as that of professionals, of the PA is sometimes misguided by old habits. The National Association of Physician Assistants hopes that the continued education of individual pharmacists through a collaboration with the board of pharmacy in each state can help to achieve an understanding of the importance of this policy.

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.

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