



# Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## ***New Executive Director***

On September 24, 2007, Mark Johnston replaced Mick Markuson as the executive director of the Idaho Board of Pharmacy; Mick retired on June 30, 2007. Mark grew up in Hoosick Falls, NY, and attended Virginia Commonwealth University School of Pharmacy in Richmond, VA, graduating with a bachelor of science degree in pharmacy and a minor in psychology in 1990, where he also served as an elected class officer. He worked for American Stores Company's Osco and Savon stand-alone pharmacies in northern Nevada for 10 years post graduation, prior to moving to Eagle, ID, in 2000. For the past seven years, Mark has held the position of division pharmacy manager with Albertsons, overseeing pharmacies in Idaho, northern Nevada, and Jackson, WY. Mark is a past president of the Idaho State Pharmacy Association. Married to his wife Kristina for 10 years, Mark also has three daughters, including six-year old twins. Mark is an avid sports fan, and enjoys playing basketball, skiing, and fishing.

## ***Lisa Culley Returns as the Board's South Idaho Compliance Officer!***

In case you have not seen her in your pharmacy, Lisa Culley is back at her old job as the compliance officer for southern Idaho. Lisa left the job in July 2006 to pursue other opportunities but returned to her old position this September stating that she missed the people and being involved with pharmacy. Lisa was a pharmacy technician for nine years and then switched careers to sell real estate for two years before becoming a pharmacy compliance officer for the state of Idaho in 2000. Lisa and her husband Robert have two grown daughters, and they enjoy spending time with their family and traveling whenever possible.

Lisa brings a wealth of knowledge to the compliance officer position, and Board members and office staff, along with her fellow inspectors, are thrilled to have Lisa back inspecting for the Board of Pharmacy.

## ***Additional Work Location Form***

The Idaho Board of Pharmacy has changed the policy on the Pharmacy Technician Additional Work Location Form. Previously, a completed Additional Work Location Form has been required to be submitted to the Board of Pharmacy prior to working as a technician at every location in addition to the technician's original site of registration. The change: the Additional Work Location Form will only be required for each additional employer; the Additional Work Location Form will no longer be required for additional work locations within one company. As technician registrations will no longer be printed for each additional work location, a technician will be expected to post a copy of his or her registration at each work location and must also carry a wallet registration card.

## ***Next Scheduled Board of Pharmacy Meeting***

The next Idaho Board of Pharmacy meeting will be on January 4, 2008. Please check our Web site for updated information on meeting times and location. During legislation and rule review, the following topics are expected to be discussed: (1) pharmacotherapy; (2) central filling of prescriptions; (3) electronic medication administration record inducements; (4) technician registration, including minimum standards, technician/intern ratios, and clerk classifications; (5) limited service pharmacies; and (6) days supply. Public comment prior to, and during, this meeting is requested.

## ***Validity of Prescription Drug Orders***

54-1733 Validity of Prescription Drug Orders reads:

A prescription or drug order may be issued either:

- (a) By a practitioner acting in the usual course of his profession; or
- (b) By a physician, dentist, veterinarian, scientific investigator, or other person, other than a pharmacist, who is licensed in a jurisdiction other than the State of Idaho and is permitted by such license to dispense, conduct research with respect to or administer the prescribed legend drugs in the course of his professional practice or research in such jurisdiction, so long as the individual is acting within the jurisdiction, scope, and authority of his license when issuing the prescription order.

Thus, other states may authorize qualified pharmacists as mid-level practitioners, prescribing with Drug Enforcement Administration (DEA) numbers, but as listed in 54-1733 above, these prescriptions are not legal, at this time, in the state of Idaho.

## ***2007 Wholesale Drug Distribution Act***

Every wholesale distributor who engages in wholesale distribution of prescription drugs must be licensed by the Idaho Board of Pharmacy in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs. Every nonresident wholesale distributor shipping prescription drugs into this state must be licensed by the Idaho Board of Pharmacy in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs. Manufacturers distributing their own federal Food and Drug Administration approved drugs and devices are exempt from the wholesale distributor licensing requirement, but still must register as a drug outlet. Manufacturers and wholesalers shipping controlled substances (CS) directly into Idaho are required to obtain CS registration prior to shipping. Wholesalers and manufacturers directly shipping only over-the-counter drugs into the state of Idaho are still required to register as drug outlets, prior to shipping. The registration process for reverse distributors remains unchanged; they are required to obtain registration as drug outlets, including obtaining CS registration, if receiving CS.





◆ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit [www.ismp.org](http://www.ismp.org) and click on "Report Errors."

### **FDA Finds Consumers Still Buying Potentially Risky Medications via Internet**

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review [www.fda.gov](http://www.fda.gov) for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

### **Death in Canada Tied to Counterfeit Drugs Bought via Internet**

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

### **FDA Sets Standards for Dietary Supplements**

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments).

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at [www.cfsan.fda.gov/~dms/dscgmps7.html](http://www.cfsan.fda.gov/~dms/dscgmps7.html) and a fact sheet at [www.cfsan.fda.gov/~dms/dscgmps6.html](http://www.cfsan.fda.gov/~dms/dscgmps6.html).

More information is available on the FDA Unapproved Drugs Web site at [www.fda.gov/cder/drug/unapproved\\_drugs/default.htm](http://www.fda.gov/cder/drug/unapproved_drugs/default.htm).

## Electronic Prescriptions

Current DEA regulations **do not** allow e-prescribing of CS. According to 21 CFR 1306.05: Prescriptions for Schedule II CS “shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.” According to 21 CFR 1306.21 (a): “A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V . . . only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner’s agent to the pharmacy or pursuant to an oral prescription made by the individual practitioner and promptly reduced to writing by the pharmacist.”

## Tamper-Resistant Pad Requirement Postponed

Pharmacies won a six-month delay in the requirement to implement tamper-resistant pads by October 1, 2007, or risk loss of reimbursement from Medicaid. Congress unanimously passed an extension to March 31, 2008, and President George W. Bush signed it into law September 29.

State Medicaid directors and state boards of pharmacy are using the delay to educate prescribers and pharmacists about the requirement.

The Idaho Board of Pharmacy has established that noncopyable prescription blanks currently being required by the Board for CS prescriptions meet the necessary **one** characteristic to be considered tamper resistant by the Centers for Medicare and Medicaid Services. Beginning October 1, 2008, the tamper-resistant pads required for Medicaid patients must contain **all three** of the following characteristics to be considered tamper resistant:

one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form; or  
one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or

one or more industry-recognized feature designed to prevent the use of counterfeit prescription forms.

## Legislation Paves the Way for Idaho-based Narcotic Treatment Programs

Effective July 1, 2007, the addition of a new section to the Uniform Controlled Substance Act, Section 37-2727, Idaho Code allows for the operation of a narcotic treatment program in Idaho. Before operating as a narcotic treatment program the facility must apply for and

obtain a CS registration certificate from DEA and a registration from the Board of Pharmacy as a non-pharmacy drug outlet. A licensed nurse at that facility may, pursuant to a valid order of a physician, prepare and administer to a patient at that facility a CS whether or not a practitioner is present. Take-home doses of a CS may be delivered to a patient at the facility for off-site use provided that the patient is authorized to receive take-home doses of the CS, and take-home doses are prepared pursuant to a valid order of a physician **by a licensed pharmacist**. The pharmacist must deliver the take-home doses to the locked storage area of that facility in a suitable container appropriately labeled for subsequent delivery by the nurse to the patient entitled to receive take-home doses.

## Opioid Addiction Treatment Programs

Effective July 25, 2005, physicians must include their Drug Addiction Treatment Act of 2000 (DATA 2000) waiver identification number on prescriptions for opioid addiction treatment medications. The practitioner’s DEA registration number and the unique identification number (**DATA 2000 waiver ID number or “X” number**) **must be on the prescription 21 CFR 1306.05(a). The identification number is not in lieu of the DEA registration number, it is an addition.** If the prescription is telephoned to the pharmacy, the pharmacist must be sure both numbers are included on the prescription record, either by obtaining them from the physician’s office or from the pharmacy’s computer files.

## Special Notice

The *Idaho 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.

Page 4 – December 2007

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