October 2007

Kansas State Board of Pharmacy

Landon State Office Bldg
900 Jackson, Room 560
Topeka, KS 66612
www.kansas.gov/pharmacy/

Published to promote voluntary compliance of pharmacy and drug law.

Amended Regulations

The Kansas State Board of Pharmacy recently amended two regulations that place additional requirements on the pharmacist-in-charge (PIC). Whenever a PIC resigns his or her position as PIC he or she shall inventory all controlled substances (CS) in the pharmacy. The records must be kept for at least five years and should be made available to the Board or the inspectors upon request. Within 72 hours of beginning to function as a PIC he or she shall inventory all CS in the pharmacy. Likewise, these records must be maintained at least five years and shall be made available to the Board inspectors upon request. This regulation applies to all pharmacy settings. The regulation changes can be found at Kansas Administrative Regulations (KAR) 68-7-11 and KAR 68-7-12.

Amended Board of Healing Arts Statute

Senate Bill 62 amended the Kansas State Board of Healing Arts statute 65-2837a – Restrictions on prescribing, ordering, dispensing, administering, selling, supplying or giving certain amphetamine or sympathomimetic amine controlled substances.

Effective March 29, 2007, **the requirement that the prescription shall indicate in the licensee's or mid-level practitioner's own handwriting, has been removed.** The statute still requires the physician or mid-level practitioner that prescribes amphetamines or sympathomimetic amines designated in Schedule II, III, or IV under the uniform controlled substance act, to adequately document in the patient's medical record the purpose for which the drug is being given. The statute restricts the purpose to one or more of the following: (1) narcolepsy, (2) drug-induced brain dysfunction, (3) hyperkinesis, (4) differential diagnostic psychiatric evaluation of depression, (5) depression that was unresponsive to other forms of treatment, (6) clinical investigation after obtaining approval from the Board of Healing Arts, (7) treatment of obesity with CS as defined by rules and regulations adopted by the Board of Healing Arts, and (8) other disorders or diseases for which some drugs have been found to be safe and effective by competent scientific research, and which findings have been generally accepted by the scientific community. Subject to obtaining a determination from the Board of Healing Arts that the drug can be used for that particular condition.

Board of Healing Arts regulation, 100-23-1. Treatment of obesity, has not changed. A treating physician shall not dispense or prescribe more than a 30-day supply of CS to treat obesity for a patient at one time.

Schedule III and Schedule IV prescriptions for treating obesity are valid if they are handed to the patient and manually signed by the physician, faxed, or telephoned. Obesity prescriptions can not be prescribed for more than a 30-day supply and are subject to no refills.

Biennial Inventory

A biennial inventory is a complete and accurate record of all CS on hand on the date the inventory is taken.

CS shall be deemed to be "on hand" if they are in the possession of, or under the control of, the registrant, including substances returned by a customer, or ordered by a customer but not yet picked up/invoiced. In hospitals, this includes CS not only in the pharmacy, but also in operating rooms, emergency rooms, hospital ambulances, emergency kits, and other units.

After the initial biennial inventory, a new inventory is taken at least every two years thereafter. It may be taken on any date that is within two years of the previous inventory date. The minimum is every two years; more often is acceptable.

Records must be kept for five years.

If the substance is listed in Schedule II, an exact count is required. If the substance is listed in Schedule III, IV, or V, an estimated count is acceptable if the container holds 1,000 tablets/capsules or fewer. If it holds more than 1,000 units, then an exact count is required.

Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

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 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ 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* 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 "intrinsically unsafe practice." FDA also encourages consumers to review *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.*

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* and a fact sheet at *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.*

Notice Regarding the State Board Newsletter

The *Kansas State Board of Pharmacy Newsletter* serves as the official method of notification to licensees and registrants of the Board of Pharmacy. Information in *Newsletters* will suffice as proof of notification in Board hearings. Please read them carefully and keep for future reference. These *Newsletters* are also available on the Board Web site at *www.kansas.gov/pharmacy.*

Prescription Requirements

The changes in technology and the increased use of electronic systems by practitioners have raised questions by pharmacists about what signifies a legal prescription. Hard-copy prescriptions that are handed to the patient may be handwritten, typed, or computer generated, but the actual signature must be manually signed on the day issued by the prescriber, in the same manner as he or she would sign a check or legal document. A rubber stamped signature, computer-generated signature, e-signature, or signature of a nurse or other office personnel is not legal when given directly to the patient.

Verbal orders may be called in to the pharmacy by a prescriber, nurse, or other office personnel. The verbal order needs to be reduced to writing, and if someone other than the prescriber is calling, the pharmacy must document the name of the person calling.

Pursuant to 21 USC 1306.21 a pharmacist may fill a prescription for a CS Schedule III, IV, and V "electronically prepared" from a physician's laptop, hand-held device, notepad, etc that has been printed and faxed from the physician's office to the pharmacy fax machine. The fax may indicate an electronic or written signature of the practitioner, but the signature is not required. The distinction is that the transmission can not be electronically transmitted from the laptop, but it can be prepared on the laptop. The Board does not require a manual signature on a faxed prescription for anything other than a Schedule II. This means that a prescriber may send a fax prescription for Schedule III through V using a manual signature, stamped signature, a printed signature, an e-signature, or left without a signature.

Technician Biennial Renewal

Pharmacy technicians can renew their licenses online October 1, 2007. All technicians who have an odd-numbered registration are required to renew for the next two years. Renew online at *www.kansas.gov/pharmacy.*

Meeting Dates

The Board of Pharmacy meets four times during the year. The meetings are held on Tuesday and Wednesday of the week. The following dates are scheduled for 2007 and 2008:

December 11 & 12

March 4 & 5

June 10 & 11

Members of the public are welcome to attend the meetings and pharmacists can receive continuing education credit for attendance.

The *Kansas State Board of Pharmacy News* is published by the Kansas State 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.

Debra L. Billingsley, JD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

KANSAS STATE BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744