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Missouri Board of Pharmacy

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Changes Made to Change of Owner Requirements

Changes to regulations governing the change of ownership of pharmacies and drug distributors have been finalized by the Missouri Board of Pharmacy and are contained within 4 CSR 220-2.020 and 4 CSR 220-5.020. These changes were made in order to ensure regulations would reflect statutory intent. The biggest change came with the elimination of the 30-day grace period from the date of ownership change. Instead, applications should reach the Board prior to the change in ownership taking place. An area on the application is provided to record the effective date of when the change occurs. The Board will then issue a temporary license for continued operation of the pharmacy while outstanding issues such as the required inspection can be completed.

Compounding Issues

4 CSR 220-2.400(9) prohibits the compounding of drugs that are **essentially copies** of commercially available products. There must be sufficient documentation within the prescription record of a specific medical need for a compounded variation of a commercial product. Essential copies may include different dosage forms (suspension vs solution; tablet vs capsule). Sufficient documentation is considered a prescription from the prescriber indicating the medical need or a notation indicating verbal authorization was obtained. The notation should include the name of the person giving such authorization, the date, and the specific medical need given. The notation can be on the hard copy prescription or stored electronically in the pharmacy as long as it is readily retrievable. A specific medical need is considered the **medical** reason why the commercially available product cannot be used. Economic or convenience reasons do not suffice. 4 CSR 220-2.400(12) allows a pharmacy to advertise concerning the provision of compounding services; however, specific claims about compounded drugs are not considered to be legal. As an example, a pharmacist cannot claim that a compounded product is "slow release" without analytical data specific for each product to support such claims. A pharmacy cannot rely on data obtained from other sources but must produce data for their specific product. Kits are now available that contain the ingredients needed to compound certain products. The use of these kits is considered compounding and compliance with compounding regulations is required. These kits are not considered to be "commercially available" in reference to CSR 220-2.400(9) above. The mixing of ingredients of a Food and Drug Administration-approved drug product (BenzaClin[®], Sulfacet-R[®], Benzamycin[®], etc) is not considered compounding and compounding regulations would not apply in these instances.

Combat Methamphetamine Epidemic Act of 2005

Congress recently passed, and President George W. Bush signed into law, the new Patriot Act, which also contains the federal initiative to thwart the manufacturing and distribution of methamphetamine. There are portions of this law still to be proposed as regulations in the near future, but the federal law will require changes in how pharmacies dispense ephedrine, pseudoephedrine, and phenylpropanolamine products. Highlights are as follows: All forms of these products are covered under the federal law. There are no exceptions. While the federal act does not make any products a controlled substance (CS), it designates all nonprescription drug products as a "scheduled listed chemical product." Retail pharmacies will be limited to dispensing no more than 3.6 grams/day to a consumer or 9 grams over a 30-day period. Non-liquid forms such as gelscaps must be sold in unit dose packages. Additional information required in the log book will include the date and time of each transaction, the use of photo identification for proof of identity, and the purchaser must sign the log book. A notice must be available with the log book that will notify purchasers that any false statements in the log book may result in criminal penalties. Training of personnel that assist in any transactions of these products will be required. Pharmacies will have to certify online with the United States attorney general that such training has taken place. A self-certification process for pharmacies will be required as well. Regulations governing this process and the fact that it will be completed over the Internet will be proposed by the US Attorney General's office. The same office will be promulgating rules concerning the maintenance of confidentiality of the log book information. Release of information by a pharmacist to state, federal, or local law enforcement agencies in good faith will be immune from civil liability. Pharmacies will be required to take steps not to employ persons who present a risk of theft or diversion. The effective date for most of the provisions of the Act will be September 30, 2006. The limit on single transaction sales and the requirement for dosage units in blister packs became effective on April 8, 2006.

Reminder for Pharmacists Renewing Licenses

It will once again be time for pharmacists to renew their licenses this fall. Renewal notices will be mailed out during the first part of August 2006. Licenses expire on October 31, 2006, and it is illegal for a person to practice any type of pharmacy on an expired license. It is important that you make sure the Board office has your current address since any renewal returned to this office as undeliverable will not be sent out a second time. You may update your address electronically on the Board of Pharmacy's Web site located at <http://pr.mo.gov/pharmacists.asp>. It is important that pharmacists be aware of the 30 hours of continuing education (CE) that are required for renewal of license and that

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



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, then publishes its recommendations. 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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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the hours must be obtained between the dates of September 1, 2004 to August 1, 2006. Insufficient credit hours or hours that do not adhere to regulatory requirements will result in a delinquency fee of \$500 along with other possible remedial/disciplinary actions that the Board may take.

Licensing Actions

Pharmacists

Kurtis E. Wages, #042997, Battlefield, MO. January 28, 2006. Probation until October 18, 2008. Violation of original terms of discipline. Regarding working at pharmacies without performing a Class II and Class III CS inventory as required.

Richard J. Drury, #028299, St Louis, MO. January 20, 2006. Revoked and cannot reapply for licensure for seven years. Found guilty of four counts of mail fraud in US District Court, Eastern District of Missouri. Section 338.065.1, RSMo Supp. 2004.

Jeffrey L. Smith, #040099, Ozark, MO. March 1, 2006. Probation for three years. Altered the quantity prescribed and/or refill status of prescriptions without physician authorization; charged family members for a 30-day supply of prescribed medication when in accordance with physician orders it should have been a 90-day supply; failed to pay for and/or obtain co-pay amounts on drugs dispensed to himself and family members. Section 338.055.2(4), (5), (6), (13), (15), (16), and (17), RSMo Supp. 2002.

Bryan T. Simpson, #2002007014, Joplin, MO. January 23, 2006. Suspension for one year, followed by probation for five years. Impaired pharmacist, disciplinary action in another state, routinely misappropriated CS from employer. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

Jonathan M. Poynter, #2003010532, Kansas City, MO. January 23, 2006. Three years suspension retroactive to March 8, 2005, followed by probation for five years. Misappropriated CS from employers for personal use. Section 338.055.2(1), (5), (13), (15), and (17), RSMo Supp. 2004.

Kevin S. Earnest, #042289, Columbia, MO. January 23, 2006. One-year suspension followed by five years probation. Impaired pharmacist, admitted diversion of drugs for personal use from employer. Dispensing errors that resulted in misbranded drugs. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Jerrod S. Brown, #2002004556, St Louis, MO. January 23, 2006. Six-month suspension followed by five years probation. Violation of original terms of discipline. Criminal prosecution of driving while intoxicated. Section 338.055.2(1) and (13).

Kevin C. Barlow, #2001020422, Olathe, KS. January 23, 2006. One year probation. While serving as pharmacist-in-charge, practiced with an expired license (October 31, 2004-May 19, 2005). Section 338.055.2(5), (6), (10), (12), (13), and (15), RSMo Supp. 2002.

Matthew J. Carr, #2004000195, St Louis, MO. January 30, 2006. One-month suspension followed by five years probation. Violation of original terms of discipline. Failed to complete CE hours as required for renewal of his license. Section 338.055.2(6) and (13).

Pharmacies

Rogers Pharmacy, #005685, St Joseph, MO. December 29, 2005. Two years probation. Failed to maintain adequate security to deter theft of drugs by personnel; stock bottles overfilled and misbranded; received drugs from unlicensed distributor; failed to timely report theft or loss of CS; did not maintain complete and accurate records. Sections 338.285 and 338.055.2(5), (6), (13), and (15).

Drug Distributors

Healthcare Supplies & Equipment, #901208, Camdenton, MO. March 18, 2006. Two weeks suspension followed by five years probation. Violation of original terms of discipline. Failed to maintain records of employee training; failed to establish and maintain a policy and procedures manual; incomplete or inaccurate distribution records. Section 338.055.3, RSMo 2000.

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