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Arkansas State Board of Pharmacy

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Record Keeping For Schedule V OTC Sales

Arkansas State Board of Pharmacy staff has visited various pharmacies in Arkansas and examined the logs for the sale of newly scheduled over-the-counter ephedrine combination and pseudoephedrine containing products. We have seen various log books that gather an array of information, but not all of these log books are compliant with the Arkansas Department of Health's (ADH) record keeping requirements for these transactions. As a review for our pharmacists the following is required for each transaction of these Schedule V products:

- Date of transaction
- Purchaser's signature (signature must be legible or name of person must be printed along with the signature)
- Address
- Quantity of product (name of product, number of packages, size of packages)
- Pharmacist or technician signature

Example:
04/15/2005
John Doe (signature), John Doe (printed if sig. is illegible)
123 Any Road
Sudafed 12hr, 1x12
Jane Small, P.D.

The initial inspection of these logs was handled non-punitively on an educational basis to help pharmacies comply with this law. Board staff will inspect these logs as part of the pharmacy inspection process; in the future pharmacies will be cited for failure to comply with these requirements.

DEA Statement on Schedule II Prescriptions

The following excerpt from the *Federal Register* addresses Drug Enforcement Administration (DEA) policy regarding the practice of physicians writing multiple Schedule II prescriptions at one time with "Do not fill until" written on the prescription.

Federal Register: Nov 16, 2004; 69: 67170-67172.

Drug Enforcement Administration – Interim Policy Statement

Refills of Schedule II prescriptions – The August 2004 Frequently Asked Questions stated:

'Schedule II prescriptions may not be refilled; *however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.*' (Italics added.)

The first part of this sentence is correct, as the CSA [Controlled Substances Act] expressly states:

'No prescription for a controlled substance in [S]chedule II may be refilled." 21 U.S.C. 829(a). However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a [S]chedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a). Indeed, as the factors quoted above from the Rosen case [the physician wrote more than one prescription on occasions in order to spread them out] indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes.

It is worth noting here that DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01-1306.27.

This document was accessed on March 29, 2005, at http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-25469.htm.

The National Association of Boards of Pharmacy® (NABP®) has written DEA requesting that DEA reconsider its position on this issue. NABP appealed to DEA on behalf of several state boards that had expressed concerns related to reversal of the existing policy. The letter from NABP stated:

If the practice of issuing multiple prescriptions under controlled and monitored circumstances, as was the accepted practice, is not acceptable then NABP respectfully requests that the DEA provide an alternative solution to allow for the treatment of patients that rely on this practice to manage legitimate medical needs.

The Arkansas State Board of Pharmacy will keep you updated with any changes in DEA's current policy as outlined in the *Federal Register* document excerpted above.

Conscience Clause

The Arkansas State Board of Pharmacy receives several calls each year regarding the conscience clause for pharmacists. While there is a law in Arkansas that addresses a pharmacist's right to refuse filling certain prescriptions, it is actually a public health law that has been in place since 1973.

20-16-304. Public policy – Availability of Procedures, Supplies, and Information – Exceptions.

It shall be the policy and authority of this state that:

(1) All medically acceptable contraceptive procedures, supplies, and information shall be available through legally recognized channels to each and every person desirous of the procedures, supplies, and information regardless of sex, race, age, income, number of children, marital status, citizenship, or motive;

(2) Medical procedures for permanent sterilization, when performed by a physician on a requesting and consenting person

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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eighteen (18) years of age or older, or less than eighteen (18) years of age if legally married, be consistent with public policy;

(3) Dissemination of medically acceptable contraceptive information in this state and in state and county health and welfare departments, in medical facilities, at institutions of higher learning, and at other agencies and instrumentalities of this state be consistent with public policy;

(4) Nothing in this subchapter shall prohibit a physician, pharmacist, or any other authorized paramedical personnel from refusing to furnish any contraceptive procedures, supplies, or information; and

(5) No private institution or physician, nor any agent or employee of such institution or physician, nor any employee of a public institution acting under directions of a physician, shall be prohibited from refusing to provide contraceptive procedures, supplies, and information when the refusal is based upon religious or conscientious objection. No such institution, employee, agent, or physician shall be held liable for the refusal.

History. Acts 1973, No.235, §4.

Biennial CE Requirements for Pharmacists

Since 2005 is the second year of the pharmacist license biennium, pharmacists must have completed their continuing education (CE) in 2004-2005 when renewing their pharmacist license at the end of the year. The CE requirements for pharmacist licensure in Arkansas are found in the following regulation:

02-06-0003 – Implementation of Pharmacy Continuing Education

(c) Beginning with the 2002-2003 biennium – for licensure in the 2004-2005 biennium, and in all future two year periods, the requirements for [CE] will be as follows:

(1) 30 hours of [CE] each biennium, as approved by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

(2) A minimum of twelve (12) [CE] hours of the thirty (30) required hours, must be live contact hours, as defined by the Committee. The live hours must be concerning drug therapy or patient care.

(d) The Arkansas State Board of Pharmacy will accept [CE] credits, approved by State Boards of Pharmacy in other states, toward licensure as a pharmacist in Arkansas provided that there is a reciprocal arrangement and that the requirements of this section are met.

(e) Pharmacists are required to retain certificates of participation in [CE] for a period of four years and to certify completion of the required [CE] on a form furnished by the Board of Pharmacy with the license renewal forms. The pharmacist must present certificates of participation to any representative of the Board of Pharmacy if requested to do so.

Surrender of Unwanted Controlled Substances

ADH regulations require that controlled substances, submitted for destruction by pharmacies, hospitals, long-term care facilities, or related facilities occur **at least quarterly**. In addition, discontinued or unwanted controlled substances must be submitted each time there is a **change in the licensed person responsible (pharmacist-in-charge)** for the controlled substances at the facility. There is no change in the requirement that the discontinued or unwanted controlled substances must be identified in such a manner as to determine the exact location in the facility where the controlled substances were last recorded in the accountability record, to determine what person or persons had access to, or administered, such controlled substances during the time they were in the controlled substance inventory in the facility.

All controlled substances submitted for destruction, which are no longer usable because of deterioration, or expired date, or are unwanted, shall be delivered in person, by registered mail or by other means of shipment (with a return receipt), to: Arkansas Department of Health, Division of Pharmacy Services and Drug Control, 4815 W Markham, Slot 25, Little Rock, AR 72205, and be accompanied by all completed copies of Report of Drugs Surrendered (Form PhA: DC-1) furnished by the Department of Health. Drug surrender forms can be obtained by calling the ADH at 501/661-2325.

Arkansas Pharmacy Support Group Confidential Help Line

870/636-0923

If you think you have a problem, you are probably right. Without help, alcohol and drug problems always get worse – **never better**!

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