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# Arkansas State Board of Pharmacy

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101 E Capitol, Suite 218, Little Rock, AR 72201
Tel: 501/682-0190 Fax: 501/682-0195

## Disciplinary Actions from June Board Meeting

During the June 2006 Arkansas State Board of Pharmacy meeting, a disciplinary hearing was held regarding a failure to comply with the requirement of a pharmacist-in-charge (PIC) to work half the hours a pharmacy is open up to a maximum of 32 hours per week being required for pharmacies open 64 hours per week or more. The following action was taken as a result of this hearing.

**PD License #8155** – Charged with violation of Regulation 04-00-0002(a)(1), failure to work a minimum of fifty (50) percent of the hours said pharmacy was open each week. The Board ordered the pharmacist to pay a monetary penalty of one thousand dollars ($1,000), imposed a two (2)-year probation on the pharmacist, and also required the pharmacist to retake the Arkansas Pharmacy Law test within sixty (60) days of the order.

## Regulation Changes from the June Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulation at the June 2006 Board Meeting.

**Regulation 4: Pharmacy**

Amend section 04-04-0001—**OUT OF STATE PHARMACY REGULATION** to clarify the requirements of an out-of-state pharmacy licensed in Arkansas to have an Arkansas licensed pharmacist on staff and to also clarify notification requirements for changes in the status of the Arkansas licensed pharmacist. The new regulation states in part that:

(b) A pharmacist currently licensed in Arkansas, shall be named in the application and shall serve as the pharmacy's [PIC] for the Arkansas permit and as the contact person for communications by the Board. Said Arkansas Pharmacist shall be an employee of the out-of-state pharmacy who shall be present at the pharmacy's physical location at least fifty (50) percent of the number of hours per week the pharmacy is open up to a maximum of twenty (20) hours per week. The [PIC] for the Arkansas Permit need not be the same person as the [PIC] of the pharmacy pursuant to the law in the state in which the pharmacy is located.

(1) That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.

(2) If at anytime the pharmacist so designated as the [PIC] for the Arkansas permit shall leave that capacity or not be able to serve in that capacity, the pharmacy shall notify the Board within ten (10) calendar days and designate another Arkansas licensed pharmacist to perform this function by written notice to the Board within thirty (30) calendar days.

This regulation change also clarifies the definitions of changes in ownership for out-of-state pharmacies licensed by the Arkansas State Board of Pharmacy. The updated regulation may be viewed in its entirety in the Pharmacy Lawbook section of the Board's Web site at www.arkansas.gov/asbp.

## Office Stock for Prescribers

The Board of Pharmacy has had several questions and has come across some interesting prescriptions lately while on routine inspections. The issue at hand is pharmacists trying to determine exactly how to keep track of their inventory and properly make a record of prescription medications that are sold to prescribers for office use and administration. In many instances the Board has seen pharmacies record these sales in their prescription software with the patient named as the prescriber or with the name being "office stock" with the requesting prescriber listed as it would be on a normal prescription. While many pharmacists might see this as an easy way to keep track of what they have sold to other health professionals, it is not a proper way to sell legend drugs for office stock. The problem in this specific situation is that a prescription is written and filled for a specific person, as ordered by a prescriber, and should not be transferred to or used by anyone else by law. Recording these sales as prescriptions is a misrepresentation of what is actually happening. The correct way to sell office stock medications to a prescriber would be to sell the medications on a pharmacy invoice, which would be kept along with wholesaler invoices to track the inventory. This would be true for Schedule III through V controlled substances (CS) as well as non-scheduled legend drugs; however, Schedule II CS may only be transferred to another Drug Enforcement Administration (DEA) registrant via a DEA Form 222.

## Suggested Procedures When Buying or Selling a Pharmacy

**Board of Pharmacy Procedures**

A. 1) A retail pharmacy application must be completed and sent to the Board along with the appropriate fee ($150). Item number 6 on the application should be marked "YES" to indicate that this application is for a change of ownership. This application should be submitted to the Board in advance of the sale of the pharmacy as early as possible to allow time to correct any discrepancies with the application.

2) A [CS] inventory must be completed on the date of the sale and:

a. If the [PIC] **does not change** as part of the sale of the pharmacy then the continuing [PIC] may sign the [CS] inventory alone and **it is not necessary** to send a copy of the inventory to the Board or

*Continued on page 4*

## Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

## Preventing Errors Linked to Name Confusion

*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.*

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

## Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

## Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

## Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

## Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

*Continued from page 1*

b. If the [PIC] **changes** then the [CS] inventory must be completed and signed by both the incoming and the outgoing [PIC] and a copy of the inventory **must be** mailed to the Board of Pharmacy. If the incoming [PIC] has not previously taken the [PIC] examination, this requirement must be completed before the new permit will be issued for the change of ownership.

3) Notify the Board that the sale has been completed by phone, fax, mail, or e-mail. Upon a pharmacy's change of ownership, the new owner(s) can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership; after the said fourteen (14)-day period, the permit issued to the prior owner shall be void and shall be surrendered to the Executive Director of the Board of Pharmacy.

- Lease agreements for pharmacies cannot include language that would give the leasor the ability to enter the premises without a licensed pharmacist being present and the lease agreement cannot allow seizure of property such as prescription drugs for default of the lease.

B. Required Forms:
Retail Pharmacy Application available at:
www.arkansas.gov/asbp/forms-instructions.html
or contact the Board Office

C. Fees – $150 payable to the Board of Pharmacy

**Suggested DEA procedures and information regarding National Council for Prescription Drug Programs numbers can be found on the Board Web site.**

### *Combat Meth Act of 2005*

The Arkansas State Board of Pharmacy has received a number of calls and inquiries regarding the new federal act that has changed the way that all over-the-counter products containing ephedrine, pseudoephedrine, and phenylpropanolamine must be handled by retailers in the United States. Pharmacies have expressed a great deal of concern and confusion trying to better understand exactly how this will impact pharmacy sales of these products. The following is a summary of changes that a pharmacy should take note of that helps to clarify what changes should be made. The summary interprets the two laws to incorporate the stricter parts of each to show how they work together in Arkansas.

**Overview of Methamphetamine Precursor Rule Changes and Continuations for Arkansas Mandated by the Combat Methamphetamine Act of 2005:**

- All dosage forms of products containing pseudoephedrine, ephedrine, or phenylpropanolamine must be kept behind a counter or in a locked cabinet (effective September 30, 2006), solids are pharmacy only sales. (This will move liquids and liquid-filled gelcaps behind the counter starting September 30, 2006.)
- 3.6 grams is the maximum amount of pseudoephedrine, ephedrine, or phenylpropanolamine that can be sold per day, no matter what dosage form it is in. *This is a reduction from the previous 9 grams-per-day limit for Arkansas.
- Maximum of three packages for any combination of dosage forms. (Maximum of 3 grams in any single package per Arkansas Law)
- 9 grams per 30 days is the maximum that can be sold for any dosage form. (5 grams for ephedrine)
- No sales of the solid forms to customers under the age of 18. (Liquids and liquid-filled gelcaps can still be sold to customers under the age of 18.)
- Solids are still Schedule V and will continue to be logged under Arkansas law, all other products will require logging starting September 30, 2006.

A comparison chart outlining these regulatory changes can be viewed on the Board Web site.

**Arkansas Pharmacy Support Group 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!**



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

John Kirtley, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

ARKANSAS STATE BOARD OF PHARMACY

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

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