

August 2006



# Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## Pharmacists and Pharmacies Can Start the Biennial Renewal Process Online October 1, 2006

Mark your calendar to renew **early!** There is **no** late renewal grace period. Your license to practice is null and void after December 31 of the renewal year. **Save time, renew online at [www.albop.com](http://www.albop.com).**

## Annual Law Seminar Registration

Register online at [www.albop.com](http://www.albop.com) for the upcoming Annual Law Seminar held by the Alabama State Board of Pharmacy.

## Information to Know When Preparing for Renewal

Pharmacy continuing education (CE) must be Accreditation Council for Pharmacy Education (ACPE) approved **or** approved by the Alabama Board of Pharmacy. Physician, nursing, or other health care CE programs are not **automatically** approved for pharmacy CE. An ACPE or Alabama Board of Pharmacy approval number will be assigned to **every** pharmacy-approved CE. Pharmacy CE documentation should be retained for **two (2)** years representing the biennial license or registration renewal.

## Prescriptive Authority of Health Professionals in Alabama

Prescriptive Authority	Regulatory Board	Non-Controlled Rx Drugs	CS II	CS III-V	Refill(s); Other Information	DEA Number
Doctor of Medicine (MD) Rule 540-X-(3,4) Web site	AL Board of Medical Examiners 334/242-4116 <a href="http://www.albme.org">www.albme.org</a>	Yes	Yes	Yes	CS II-no refills, C III-V — No more than five (5) times in a six (6)-month period. MDs have unlimited, independent prescribing authority in every state.	Apply and obtain own DEA No.
Doctor of Osteopathy (DO) Rule 540-X-(3,4) Web site	AL Board of Medical Examiners 334/242-4116 <a href="http://www.albme.org">www.albme.org</a>	Yes	Yes	Yes	CS II-no refills, C III-V — No more than five (5) times in a six (6)-month period. DOs have unlimited, independent prescribing authority in every state.	Apply and obtain own DEA No.
Physician Assistant, Surgical Assistant (PA,SA) Rule 540-X-7-.28 Web site	AL Board of Medical Examiners 334/242-4116 <a href="http://www.albme.org">www.albme.org</a>	Yes	No	No	<b>CS II-V — no independent prescribing authority.</b> PA/SA shall identify his or her supervising physician when calling in a prescription for drugs authorized to prescribe.	No
Physician assistants who have prescriptive authority in another state will have those privileges honored in Alabama.						
Adv RN Practitioner (CPNP,CRNP,CNM) Rule 540-X-8-(11,25) Web site	AL Board of Nursing 334/242-4060 <a href="http://www.abn.state.al.us">www.abn.state.al.us</a>	Yes	No	No	<b>CS II-V — no independent prescribing authority.</b> Prescriptive authority is granted on collaborative practice with approved protocol standards.	No
Advanced (certified) registered nurses who have prescriptive authority in another state will have those privileges honored in Alabama.						
Optometrist 630-X-5-.08 Web site	AL Board of Optometry 205/481-9993 <a href="http://www.al-optometry.org">www.al-optometry.org</a>	Yes	No	Yes	<b>CS III-V — prescribing authority.</b> Optometrists may purchase, possess, administer, & prescribe for examination, treatment, and diseases of the eye.	Apply and obtain own DEA No.
Doctor of Podiatry (PDM) Rule 730-X-1-.07 Web site	AL Board of Podiatry 334/269-9990 <a href="http://www.alabamapodiatryboard.org">www.alabamapodiatryboard.org</a>	Yes	Yes	Yes	Same as MD, except limited to scope of practice (treatment if feet, toes, heels).	Apply and obtain own DEA No.
Doctor of Veterinary (DVM) Rule 930-X-1-.11 Web site	AL Board of Veterinary Medicine 205/353-3544 <a href="http://www.asbvme.us">www.asbvme.us</a>	Yes	Yes	Yes	Same as MD, except limited to scope of practice (treatment of animals).	Apply and obtain own DEA No.
Doctor of Dentistry (DDS,DMS) Rule 270-X-2 Web site	AL Board of Dental Examiners 205/985-7267 <a href="http://www.dentalboard.org">www.dentalboard.org</a>	Yes	Yes	Yes	Same as MD, except limited to scope of practice (treatment of teeth, gums, mouth).	Apply and obtain own DEA No.
Doctor of Naturopathy and Homeopathy are not licensed in Alabama. Doctors of Chiropractic have no prescriptive authority in any state.						

Joyce C. Altman, RPh, Director of Compliance and Education, Alabama State Board of Pharmacy



## 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<sup>®</sup> tablets, who recently released Zanaflex Capsules<sup>™</sup> (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<sup>®</sup> (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL<sup>®</sup> (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](http://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](mailto: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](http://www.ismp.org)), FDA ([www.fda.gov](http://www.fda.gov)), and USP ([www.usp.org](http://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](http://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.dea diversion.usdoj.gov/meth/cma2005.htm](http://www.dea diversion.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](http://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.

## Continuing Education Requirements

**Pharmacists** shall obtain no less than fifteen (15) hours of approved CE, three (3) hours of which shall be of “live” exposure. Hours in excess of the minimum annual requirement may be carried forward to the succeeding calendar year; however, no more than twelve (12) hours shall be carried over and no less than three (3) “live” hours shall be obtained in each calendar year.

**Consultant pharmacists** shall obtain annually no less than six (6) “live” consultant-approved hours in not less than two (2) “live” hour increments. No “live” consultant hours can be carried over from each calendar year.

**Preceptor pharmacists** must attend a preceptor-approved training seminar at least once every three (3) years.

**Parenteral pharmacists** shall have attended a one-time, five (5)-hour approved parenteral certification course, including didactic and hands-on experience, requiring a written examination as part of the training.

**Nuclear pharmacists** shall attend no less than a one (1) hour, nuclear-approved CE course each year.

**Registered pharmacy technicians** shall obtain not less than three (3) hours of approved CE, one (1) hour of which shall be of “live” exposure. No hours in excess of the minimum requirement may be carried forward to the succeeding calendar year.

## Well Wishes to Louise Foster Jones

Executive Director Louise Foster Jones will be leaving the State Board of Pharmacy to serve as the executive director of the Alabama Pharmacy Association. The Board wishes to thank Louise for her contributions, exemplary service, and numerous accomplishments. She will continue her advocacy for pharmacy and successes in health care by leading this professional organization in Alabama.

## Special Notice About This Newsletter

The *Alabama State Board of Pharmacy News* has been designated as the official method of notification to pharmacists and pharmacy technicians licensed by the Alabama State Board of Pharmacy. These *Newsletters* will be used in hearings as proof of notification. *Newsletters* are available for review on the Board’s Web site [www.albop.com](http://www.albop.com).

## The USA Patriot Act

On March 9, 2006, President George W. Bush signed legislation enacting the USA PATRIOT Act, Title VII of which is the Combat Methamphetamine Act of 2005. This federal law also addresses the sale and control of **all non-prescription** medicines containing pseudoephedrine (PSE), ephedrine (EPH), and phenylpropanolamine (PPA) and where it is more restrictive **preempts** state law. This includes gels, liquids, and pediatric medicines. The following are the dates for the implementation of this act.

**April 8, 2006 – Purchase Limits:** limits the **base** product quantity one (1) person can purchase to nine (9) grams in a thirty (30)-day calendar month and 3.6 grams in a single calendar day. Mail order **base** product is limited to 7.5 grams in thirty (30) days. Non-liquid dosage forms (including gels) must be in blister packaging or unit dose packaging.

**September 30, 2006 – ID Requirements:** Purchaser must present an identification (ID) card that provides a photograph and is issued by a state or federal government, or a document that, with respect to ID, is considered acceptable as noted in the Code of Federal Regulations.

**Recordkeeping Requirements:** The purchaser signs a written or electronic logbook and enters his or her name, address, and the date and time of the sale. The seller, (1) determines that the name entered in the logbook corresponds to the name provided on such ID and that the date and time entered are correct, (2) shall enter in the logbook the name of the product and the quantity sold, and (3) maintains each entry in the logbook for not fewer than two (2) years after the date on which the entry is made.

**Retailer Liability Protection:** A retailer who releases logbook information in good faith to federal, state, or local law enforcement authorities is immune from civil liability.

**Product Placement:** Affected products must be stored behind a counter or in a locked cabinet.

**Training Requirements:** Individuals who deal directly with purchasers must undergo training provided by their employer. Training certification is specific to location, not employee, and training re-certification will be required on a periodic basis to cover new employees. Drug Enforcement Administration (DEA) is to provide a uniform, comprehensive, training program for employees via an Internet site.

**Other Provisions:** A regulated seller should take reasonable measures to guard against employing persons who may present a risk with respect to the theft and diversion of EPH, PSE, and PPA, including asking employee applicants whether or not they have been convicted of any crime involving or related to such substances, or a controlled substance. **Penalties:** Civil penalty of up to \$25,000; and if committed knowingly, then imprisonment of up to one (1) year in addition to a fine to be determined by existing federal criminal laws.

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Page 4 – August 2006

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