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Louisiana Board of Pharmacy

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5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537
www.labp.com

Emergency Preparedness and Disaster Response (06-07-248)

As we enter a new hurricane season, the Lousiana Board of Pharmacy believes it worthwhile to review some of the lessons learned in the aftermath of Hurricanes Katrina and Rita in the summer and fall of 2005.

Preparations

- Help your patients prepare for the hurricane season by providing them with copies of their patient profiles, and encourage them to keep that profile with their critical documents during an evacuation. **Communicate before they evacuate!**
- Help your pharmacy prepare for the next emergency by reviewing your data security and environmental control policies and procedures. We know that you backup your electronic prescription data on an appropriate schedule; are any of those backup copies stored off site? If you need to close the pharmacy for evacuation, try to prepare multiple copies of your data, preferably on different media. This could be useful if you have an opportunity to re-open your pharmacy using different computer equipment.
- If your prescription drug inventory includes items labeled for storage at "controlled room temperature" (most non-refrigerated oral solid dosage forms), what measures do you have to ensure the continuity of those temperatures in the absence of electricity from your local electrical power generation or distribution company? Have you considered the use of supplemental electrical generators to ensure appropriate temperatures for the storage of prescription drugs? If you do use such devices, please adhere to the safety precautions affixed to those devices.

Responses

- If the emergency situation was serious enough to prompt the Office of the Governor to issue a proclamation declaring a State of Emergency for some or all of the state, and if your pharmacy is operating within the area under the declaration of emergency, please remember two standing rules already approved by the Board:
  1. Using sound professional judgment, a pharmacist may dispense a one-time emergency prescription for any medication, for up to a 30-day supply, **if**
     a. in the pharmacist's professional opinion, the medication is essential to life or the continuation of previously prescribed therapy, **and**
     b. the pharmacist prepares a written record marked "Emergency Prescription," and then files and maintains that record as required by law.
  2. If you are assisting a shelter or other relief effort, that organization may accept offers of assistance from pharmacists from other states, even if not licensed in Louisiana. They must present and retain on their person a copy of a valid license in another state.

  Remember, these rules are already in place; they are triggered by the governor's declaration of a State of Emergency.
- If you need to change the location of your pharmacy, please contact the Board office for assistance with that process. We may be able to streamline certain requirements for you.

Changes in Pharmacy Technician Regulation (06-07-249)

The Board published a proposal to amend the technician regulation in the June 2005 *Louisiana Register* and conducted a public hearing on July 27, 2005, to receive oral and written testimony concerning that proposal. Following its review of the testimony, the Board voted to make no changes to the original proposal and then filed its report to the Joint Health and Welfare Oversight Committee of the Louisiana Legislature on August 25, 2005. Since Hurricanes Katrina and Rita totally consumed the legislative comment period, the Board re-filed the Oversight Committee report on January 30, 2006. The Legislative Oversight Committee convened a legislative hearing on February 14, 2006, to review the proposal and receive additional testimony. During the hearing, the Oversight Committee was required to interrupt its hearing due to its responsibilities during the existing special legislative session. At the Oversight Committee chairman's request, the Board interrupted its rulemaking process until the Oversight Committee could re-convene. The chairman of the Legislative Oversight Committee recently informed the Board that no further hearing would be conducted, and the Board was free to continue the rulemaking process. The Board published the Final Rule in the June 2006 *Louisiana Register*, amending certain provisions in §907 of the Board's rules.

Some highlights of the new rule for pharmacy technicians:

- A supervising pharmacist may allow a technician to accept an original verbal prescription. When a technician accepts an original verbal prescription, the order must be reduced to written form immediately. Before releasing that prescription for processing, both the receiving technician and the supervising pharmacist shall initial the hard copy of the prescription.
- A supervising pharmacist may allow a technician to give or receive verbal transfers of prescriptions. However, please remember that with respect to the transfer of prescriptions for controlled substances (CS), federal rules require such transfers to be accomplished between two licensed pharmacists.
- The new rule also provides some flexibility in the pharmacist-to-technician ratio. When there are no pharmacy technician candidates present, then one pharmacist on duty may supervise as many as three pharmacy technicians on duty.

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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.

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- The new rule makes **no** changes relative to scope of practice or ratio for pharmacy technician candidates.
- Finally, the new rule also clarifies the restriction on the "interpretation" of a prescription. A supervising pharmacist may allow technicians and technician candidates to translate abbreviations and other phrases into patient-oriented language as they enter prescriptions into a dispensing software system. However, the "interpretation" of a prescription, which includes the analysis of a new prescription order, its integration into the patient's existing medication regimen, as well as drug utilization review procedures, is a professional activity restricted to pharmacists and pharmacy interns under the supervision of a pharmacist.

The Board is currently compiling a *Louisiana Pharmacy Law Book* update that will include the new laws passed during the just completed legislative session. When that compilation is complete, we will forward updates to all subscribers. Until then, the new language for §907 can be found on the Board's Web site: www.labp.com → Laws & Regulations → Title 46 → Chapter 9.

Disciplinary Actions (06-07-250)

Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information. During its May 18, 2006 administrative hearing, the Board took final action in the following matters:

Thomas James Lemoine (Pharmacist License No. 14604), Voluntary Consent Agreement: License reinstated, suspended for five (5) years with execution thereof stayed, and then placed on probation for five (5) years, beginning on November 12, 2005, subject to certain terms as enumerated in the agreement. Respondent assessed investigative and administrative costs. *Charges:* (1) unlawful possession of Schedule III CS, and (2) unlawful possession of Schedule IV CS.

Health Mart Pharmacy of Breaux Bridge (Pharmacy Permit No. 5052), Voluntary Consent Agreement: Permit revoked. Permit holders assessed $25,000 plus investigative and administrative costs. *Charges*: (1) dispensation of prescriptions based solely on electronic questionnaires, and (2) failure to verify authenticity and legitimacy of prescriptions.

Dickie Ewell Hebert (Pharmacist License No. 9195), Voluntary Consent Agreement: License suspended for five (5) years, beginning March 13, 2006, with execution of all but first month stayed, and license placed on probation for remainder of suspensive period, ending March 13, 2011, subject to certain terms as enumerated in the agreement. Respondent also assessed $7,500 plus administrative costs. *Charges:* (1) dispensation of prescriptions based solely on electronic questionnaires, and (2) failure to verify authenticity and legitimacy of prescriptions.

Jeanine Rodgers Kidd (Technician Certificate No. 4023), Voluntary Consent Agreement: Certificate suspended for five (5) years, beginning September 8, 2005, with acceptance of any future application for reinstatement conditioned upon certain terms as enumerated in the agreement. Respondent assessed investigative and administrative costs. *Charges:* (1) unlawful acquisition of controlled substance by fraud, forgery, or deception, and (2) unlawful possession of Schedule IV CS.

The Board also issued Letters of Warning to three pharmacy permit holders and four pharmacists, as well as Letters of Reprimand to two pharmacy permit holders and one pharmacist. With respect to the reinstatement of lapsed credentials, the Board granted requests from two pharmacists. With respect to impaired practitioners, the Board accepted the voluntary surrender of license from three pharmacists and one technician candidate, and then granted petitions for reinstatement from two pharmacists.

Calendar Notes (06-07-251)

The next Board meeting and administrative hearings will be held August 15-18, 2006, at the Board office. **Please note this represents a change from previous announcements**. The office will be closed July 4, 2006, for Independence Day.

Special Note (06-07-252)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

The *Louisiana Board of Pharmacy News* is published by the Louisiana 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.

Malcolm J. Broussard, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

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

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