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Alabama State Board of Pharmacy

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Alabama Board of Pharmacy 2008 Meeting Dates

January 15-16	May 13-14	September 16-17
February 12-13	June 17-18	October 21-22
March 11-12	July 15-16	November 18-19
April 15-16	August 19-20	December 16-17

Technician Registrations are Delinquent December 31, 2007

The Alabama State Board of Pharmacy is making every effort to notify **all** pharmacists and technicians of the requirement for current working technicians to register with the Board for 2008-2009. A goal of 100% registration by December 31, 2007, is in the works! Take advantage of the initiatives in place at the Board to remind everyone of this important process.

1. On September 21, 2007, the Board sent postcard renewal notices to each technician's Board-noted address. If you did not receive a renewal notice, most likely the Board does not have your current address. Go to the Board Web site, www.albop.com, and visit the section on forms and applications to submit your new address, then **renew online**.
2. Current registered technicians, pharmacists, and pharmacies will receive home phone message reminders periodically throughout the renewal time frame of October 1 through December 31, 2007.
3. Technician registrations can be completed two ways:
 - a. electronic transmittal **online** at www.albop.com (**fast, efficient, no notary required**), or
 - b. request a paper copy of the renewal application addressed to your home or to an e-mail address. A **notary signature** is required on all paper applications. Allow three (3) weeks for this selection process. Late fees apply to renewals received after the deadline.
4. If you do not have your continuing education (CE) requirements completed by the time you would like to register ... **do not wait!** Register and make sure you complete the three (3) hours of CE (one live hour) by December 31, 2007. The Board Web site lists live CE events throughout the state.

Beware of Filling Internet Prescriptions

The Board is aware that multiple Web site recruiters are making phone calls and sending faxes regarding electronic prescriptions, prescription faxes, and prescribing system schemes to increase prescription volumes and, of course, portraying some nice eye-catching fees of \$20 per script. Be alert of the "fulfillment" center pitch. Many of these prescriptions are generated from an online questionnaire allegedly reviewed by a physician who then authorizes the prescription. The Web recruiter may say this is legal in Alabama and send check and safety procedures for your review describing the patient-physician relationship. The newest design described is a webcam doctor-patient interview, which also does not meet the re-

quirement of a relationship. The physicians as well as the patients may or may not be located in the same state. Often, physicians will issue multiple prescriptions a day to patients around the country for controlled substances or lifestyle drugs. These organized schemes affect public health and safety, and for that reason, the Board encourages all pharmacists to be aware of Rule 680-X-2-.33 Internet Pharmacies.

680-X-2-.33 Internet Pharmacies

A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or **reasonably should have known** under the circumstances, that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

Author: James S. Ward, JD.

Statutory Authority: Code of Alabama 1975, §34-23-92

Caution

Are you ordering large pint quantities of iodine for a tattoo shop or someone who says they are doing wound cleaning? Iodine is used to make methamphetamine!

HHS Office of Inspector General

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95452 (as amended) is to protect the integrity of the United States Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report, both to the Secretary and to Congress any program and management problems and recommendations to correct them. The OIG's duties are carried out through a nationwide network of audits, investigations, inspections, and other mission-related functions performed by OIG components. The OIG, under this congressional mandate, established a program to exclude individuals and entities affected by these various legal authorities, contained in sections 1128 and 1156 of the Social Security Act, and maintains a list of all currently excluded parties called the List of Excluded Individuals/Entities (LEIE). The following is the effect of an exclusion (not being able to participate):

- ◆ No payment will be made by any federal health care program for any items for services furnished, ordered, or prescribed by an excluded individual or entity.
- ◆ No program payment will be made for anything that an excluded person furnishes, orders, or prescribes. This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider where the excluded

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FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at www.fda.gov/cder/guidance/7654fnl.htm. FDA is accepting electronic comments on the guidance at www.fda.gov/dockets/ecomments.

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards

of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at www.fda.gov/cder/drug/podcast/default.htm.

Prevent Tragedies Caused by Syringe Tip Caps



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.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefepodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe

person provides services, and anyone else. The exclusion applies regardless of who submits the claims and applies to administrative and management services furnished by the excluded person.

Accordingly, the OIG maintains the LEIE, a database that provides information to the public, health care providers, patients, and others relating to parties excluded from participation in Medicare, Medicaid, and all federal health care programs. The LEIE is available in two formats:

- ◆ Online Searchable Database – The Online Searchable Database enables users to enter the name of an individual or business and determine whether exclusion is currently in effect. If a match is made on an individual, the database can verify with an individual's Social Security number that the match is unique.
- ◆ Employer Identification Numbers (also known as Tax Identification Numbers) are being included for recently excluded entities.
- ◆ Downloadable Database – The Downloadable Database File enables users to download the LEIE file to a personal computer and establish an independent database or combine the file with existing data.
- ◆ Visit www.oig.hhs.gov for more information.

What does this mean to pharmacists hiring a new employee, buying a store, or collaborating with individuals or entities? It is **important** to review the LEIE search at <http://exclusions.oig.hhs.gov> prior to employing any new hire or entering into contracts with individuals or companies. If an individual's name/company name appears on the LEIE Web site, the Web site has contact information on measures to take for removal. Access to the OIG database is available on the Board Web site.

680-X-2-.19 Parenteral Therapy

- (1) Purpose: Whereas the Alabama State Board of Pharmacy is charged with the duty and responsibility to control the compounding and distribution of prescription drug products in the State of Alabama, and is further charged to protect the citizens from inferior drug products and inappropriate compounding procedures. This rule shall provide guidelines and regulations for the compounding and distribution of parenteral products in Alabama, and to assure the citizens of Alabama of sterile parenteral products that are dispensed or prepared by qualified pharmacists using acceptable pharmaceutical techniques and equipment.
- (2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of parenterals shall be registered with the Alabama State Board of Pharmacy . . . and receive a permit in accordance with the Code of Alabama 1975, §34-23-30. Such pharmacies shall be certified, futher, by the Alabama State Board of Pharmacy as a **parenteral pharmacy**.

- (3) Registration and Certification, Pharmacists: All pharmacists engaged in compounding and dispensing of parenteral solutions, including cytotoxic agents, shall register . . . with the Board of Pharmacy in accordance with Code of Alabama 1975, §34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for parenteral pharmacists which has been approved by the Board, will not be registered as **parenteral pharmacists** with the Board until they have completed said certifying course. Programs submitted for certification shall be a minimum of five (5) contact hours, including didactic and hands on experience. All programs certified by the Board shall require a written exam as a part of the training.

- (a) It shall be the responsibility of the **supervising pharmacist** to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

Review the rule in its entirety at www.albop.com. **Pharmacists should carry their pocket license cards indicating parenteral certification, and pharmacies should have the facility parenteral certification posted accordingly. Employers check the Board verification site to ensure all working pharmacists needing parenteral certification have the appropriate parenteral credentials.**

Special Notice about the Newsletter

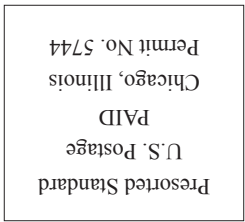
The *Alabama State Board of Pharmacy Newsletter* has been designated as the official method of notification to pharmacists, pharmacy technicians, and interns licensed by the Alabama State Board of Pharmacy. These *Newsletters* will be used in hearings as proof of notification and are available for review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

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

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

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