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Alabama State Board of Pharmacy News

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Rule Changes Effective March 5, 2012

680-X-2-.11 PHARMACY KEYS OR OTHER CONTROLLED ACCESS DEVICE OR METHOD (Formerly 'Partitioning/Separate Entrance')

Allows the owner of the pharmacy to:

designate one (1) unregistered person to have a key or other controlled access device or method to the pharmacy and still be considered in their possession . . . The permit holder (owner) must execute a signed agreement with the individual in possession of a key or other controlled access device or method to the pharmacy and must submit a copy to the Board of Pharmacy for approval prior to issuing a key or other controlled access device or method to any person that does not hold an active pharmacist license in the State of Alabama.

680-X-2-.14 THE ROLE OF TECHNICIANS IN PHARMACIES IN ALABAMA

680-X-2-.18 INSTITUTIONAL PHARMACIES

Both rules deleted the specific names of two national certification boards in which the Alabama State Board of Pharmacy recognized a technician's certification. This was changed to read "certified by any credentialing organization approved by the Board."

Questions the Board of Pharmacy Receives About Hospice Prescriptions

1. Can we dispense prescriptions for controlled substances from Hospice Order Sheets that lack some of the elements of a prescription?

   No. See Drug Enforcement Administration (DEA) *Pharmacist's Manual,* Section IX.

2. Can we dispense multiple controlled substance prescriptions written on the same piece of paper and comply with DEA record keeping requirements?

   Maybe. See DEA *Pharmacist's Manual,* Section VI; DEA offers two options only for filing hard copy prescriptions. No exceptions are provided to allow cutting up prescriptions for filing purposes.

3. In order to take advantage of the exceptions for Schedule II prescriptions written for hospice patients, must the prescriber write "hospice" or "terminally ill" on every prescription?

   A. Regarding accepting a fax of a Schedule II prescription as the <u>original</u>, the DEA *Pharmacist's Manual* in Section IX indicates the **practitioner <u>will</u> note on the prescription that it is for a hospice patient.**

   B. In order to claim the exception for partial filling a Schedule II prescription in units as small as a single dose for up to 60 days the DEA *Pharmacist's Manual* in Section X states that **if there is a question of whether a patient has a terminal illness, the pharmacist must contact the prescriber and the practitioner and pharmacist have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.**

4. Can I accept a fax from a hospice or must it come from the prescriber?

   There can be no intermediary – you cannot accept a fax of a fax. Some hospice agencies have physicians that practice at the agency. If the agency has blanks with prescriber names and DEA numbers printed on the blank, make certain the registration for the prescriber matches the address on the blank. Each location where the prescriber practices and dispenses and/or administers from a maintained supply of controlled substances must be registered separately with DEA.

5. In an emergency situation, how much of a Schedule II drug can I dispense on an oral order? How long do I have to get a hard copy?

   In Section X of the DEA *Pharmacist's Manual,* the "emergency" is defined to mean that the immediate administration is necessary for proper treatment and that no alternative (including use of a non-Schedule II drug) is available. In a bona fide emergency a practitioner may telephone a Schedule II prescription to a pharmacist and the practitioner must furnish a written, signed prescription to the pharmacist within **seven days. The quantity is limited to the amount needed to treat the patient during the emergency period. On the face of the written prescription the words "Authorization for Emergency Dispensing" must be**

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

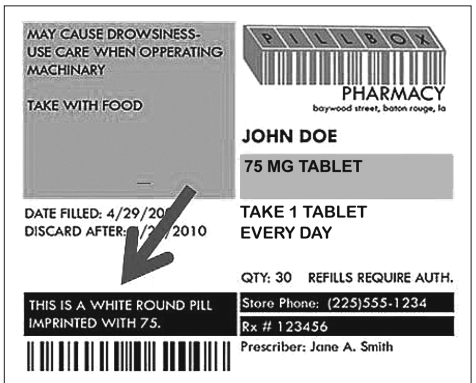
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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written. The pharmacist must, by regulation, notify the DEA Diversion Field Office if the prescriber fails to provide the hard copy within seven days. However, due to the stricter limit of a 72-hour supply found in Title 20 of the Code of Alabama, the lesser of the amount needed to treat the patient during the emergency or a 72-hour supply can be dispensed.

Calls to the Board Office

When calling the Board office, please have your license/registration number available. This will expedite inquiries.

ACPE-Accredited Continuing Education

Pharmacists and/or technicians can visit the Board of Pharmacy's Web site listed below to find all available continuing education programs.

1. Visit *www.albop.com.*
2. Select "Continuing Education."
3. Scroll down until you see the heading "External links for Continuing Education."
4. Select *www.acpe-accredit.org/pdfwebtool/plan/searchplan.aspx.*

CPE Monitor Service

With the electronic transmission of continuing pharmacy education (CPE) data now live, the CPE Monitor™ service is fully operational. Nearly 50 Accreditation Council for Pharmacy Education (ACPE)-accredited CPE providers have already transitioned their systems to transmit data and are now requiring licensees to submit their National Association of Boards of Pharmacy® (NABP®) e-Profile ID and date of birth (MMDD) in order to obtain CPE credit. All ACPE-accredited providers will have until the end of 2012 to implement their systems to CPE monitor.

As additional ACPE-accredited providers transition their systems, pharmacists and pharmacy technicians will be able to begin viewing their CPE contact hours online through their NABP e-Profile. The streamlined CPE Monitor process will eventually eliminate the need for hard-copy statements of CPE credit for activities taken from ACPE-accredited providers.

Pharmacists and technicians, visit *www.MyCPEmonitor.net* to create your NABP e-Profile and obtain your e-Profile ID. Failure to set up an e-Profile or inaccuracies in an e-Profile may result in unrecorded or mis-recorded CPE, with possible adverse consequences for licensees/registrants when renewing their licenses/registrations.

Pharmacists 2013/2014 Renewals

All pharmacists are required to renew their pharmacist licenses and controlled substances permits this calendar year. Pharmacists will have to provide information in regard to their continuing education (CE) completed in calendar years 2011 and 2012. Pharmacists shall complete 15 hours of CE every year as a condition of licensure renewal. CE may be completed by either attendance or by a distance-based program, video, or publication; however, a pharmacist must complete at least three hours of live CE through attendance at a course(s). A pharmacist may carry over and receive credit for 12 hours of CE in the succeeding calendar year. Mailings will begin in August with due dates based on mailing dates of the notices.

Reminder

Please notify the Board, in writing, of any change of address or employment.

Do You Know A Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help-line at 205/981-2273. All calls are confidential.

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