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Arkansas State Board of Pharmacy

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License/Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacist and pharmacy permit renewals during November 2007. While these renewals are sent directly to the individual's mailing address of record, the Board has had a number of pharmacists who have called saying that they have not received any renewal notice. In most cases this has been due to a change of address of which the Arkansas State Board of Pharmacy has not been notified. This is a violation of pharmacist registration requirements and may result in disciplinary action. Furthermore, it should be noted that the permits that were not renewed expired on December 31, 2007. The Arkansas State Board of Pharmacy allows a renewal grace period until March 31 on permits; however, there is a $20 penalty on permit renewals if not renewed by February 1, a $40 penalty if not renewed before March 1, and if a permit is not renewed by April 1 then the license/permit is void. This means that in order to get a pharmacist license reactivated, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees. While pharmacists are responsible for keeping their licenses current, it is the responsibility of the pharmacist-in-charge of any pharmacy or other facility to be sure that all employees including pharmacists, pharmacy interns, and pharmacy technicians have current licenses in good standing with the Arkansas State Board of Pharmacy. Any pharmacist who works after April 1, without renewing his or her pharmacist license, will be called before the Board for disciplinary action. **Once again, the best way to renew your license will be through the Internet as this allows our staff to turn around your renewal much faster.** This is also the only way to use your credit card to renew any permit or license with the Arkansas State Board of Pharmacy. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of continuing education for a period of four years.

DEA Rule Change Regarding Issuance of Multiple Prescriptions

The following language became effective December 19, 2007, and has been added to Title 21 of the Code of Federal Regulations.

Sec. 1306.12 Refilling Prescriptions; Issuance of Multiple Prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Sec. 1306.14 Labeling of Substances and Filling of Prescriptions.

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Intern Regulation Overview

Regulations regarding intern training were changed in October 2007 and should be reviewed by anyone employing student pharmacists. These changes are dispersed throughout Regulation 2, which should be reviewed completely as the updated regulation has been posted in the Pharmacy Law Book of the Board's Web

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and can only be ascertained by examining t

NABP Testifies in Support of Proposed BTC Drug Class

NABP testi f ed at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health bene f ts of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer

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 and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. 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.*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drugs names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are dif f cult to pronounce and some have f ve syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Of f ce.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Of f ce of Surveillance and Epidemiology, formerly the Of f ce of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply ef f cacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site *www.med-errs.com* and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the f eld to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals

and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can signi f cantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see ***ISMP Medication Safety Alert!® Community/Ambulatory Edition***, Volume 4, issue 5, May 2005, **Reminyl®/ Amaryl® Your Reports at Work.**) may "smell" safer, and therefore "sweeter." Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with "illegible or incomprehensible" labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the f rst issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the f ndings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at *www.fda.gov/cder/dsn/default.htm* and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at *www.fda.gov/medwatch/safety.htm.*

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services' (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare bene f ciaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, *www.nabp.net.*

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency speci f cations for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised speci f cation.

More information is available on the FDA Web site at *www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.*

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety pro f le of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identi f er that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identi f cation technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Veri f ed Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

To order the *Survey*, visit *www.nabp.net* and download an order form; the cost is $20.

The CD-ROM is provided free of charge to all f nal-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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site at *www.arkansas.gov/asbp*. One important note when reviewing these regulations is that the term "Alternate Preceptor" has been removed from the regulation due to the fact that under these new guidelines the intern regulation committee determined that there was not a continuing need for the designation of alternate preceptors. The most signi f cant changes regarding preceptors and pharmacies are encompassed in Regulation **02-01-0004– Requirements for Internship Training:**

(g) **For the first 500 hours of pharmacy practice as a pharmacy intern**, for each pharmacy setting where an intern practices pharmacy, the intern shall complete and f le with the Board of Pharmacy of f ce, prior to any practice, a "Training Plan" that is signed by the **pharmacist in charge** for that particular work situation. **Prior to completion of the first 500 hours of practical experience, the pharmacy intern may only work under the direct supervision of a certified preceptor.** Hours of practical experience include only those hours worked under the direct supervision of **a** preceptor **when regularly scheduled classes are not in session (summer break, spring break, Christmas break and months not scheduled for rotations)** and may not exceed 40 hours per week. **The pharmacist in charge must approve and verify, by signing the affidavit of experience, that the intern has earned their hours of practical experience under the direct supervision of a certified preceptor.** Training plans shall expire on **May 31** of each year. At no time may a preceptor supervise more than one licensed intern. **Interns must file affidavits of experience prior to the expiration date of their training plan to get credit for these hours with the Board of Pharmacy.**

(h) **After the intern has completed 500 hours of intern training as specified in 02-01-0004 (g) and the hours have been approved by the Arkansas Board of Pharmacy, the intern may practice pharmacy in any Class A pharmacy under the supervision of a licensed pharmacist provided:**

1. **The intern notifies the Board of Pharmacy in writing of his or her employment as a pharmacy intern within five days of starting to work in any pharmacy, and**
2. **The intern notifies the Board of any change in his or her employment for any reason within five days of the change.**
3. **Notification is made in writing by letter, fax, email or through the Board website and must contain the name of the intern, the name and address of the pharmacy, and the date of hire or date of change in employment. It is the intern's responsibility to verify that the notification has been received and processed by the Arkansas Board of Pharmacy.**
4. **At no time may a supervising pharmacist or preceptor supervise more than one intern.**

Special Notice about the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an of f cial method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of noti f cation of the *Newsletter's* contents. Please contact the Board Of f ce (501/682-0190) if you have questions about any of the articles in this *Newsletter*.

Arkansas Pharmacy Support Group Help Line
870/636-0923

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