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Arkansas State Board of Pharmacy

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Continuing Education Audit Results

The Arkansas State Board of Pharmacy recently finished signing and accepting orders related to the Pharmacists Continuing Education Audit performed in conjunction with pharmacists' licensure renewals. Through the audit process, Board staff performed continuing education (CE) audits on approximately 650 pharmacists licensed in Arkansas. Of these 650 pharmacists, 46 were unable to show proof that they had met the CE requirements as set out in Regulation 02-06-0003. As a result of these pharmacists failing to obtain the required CE and failing to show proof of required CE hours, the Board of Pharmacy entered into consent agreements that outlined how each pharmacist found in violation of this regulation was fined $100 per hour of deficient CE up to a $500 fine. Each pharmacist must also make up double the number of hours of deficient CE to be reported to the Board office. The CE made up as part of the consent agreement cannot be used as part of the biennial requirements for future license renewal. Fines for the 46 pharmacists ranged from $50 to $500 reflecting anywhere from one to 36 hours of CE to be made up. The total for the 46 agreements came to approximately 340 hours of additional CE to be reported, 215 hours of which must meet the live criteria and significant administrative fines. After discussing this information the Board directed staff to perform a CE audit each renewal period for pharmacists.

Asthma Inhaler Labeling

As a thought for pharmacists, when labeling medications that come in a container that is discarded before use, it is a good idea to label the actual bottle or tube of medication when dispensing the product to patients. In many ways this procedure will ensure that the correct directions for use are at hand for the patient even when the box has been discarded or misplaced. This labeling of the product directly for tubes of creams, eye drops, birth control, and inhalers will also help when traveling or when products are to be administered by another person. A better example of why this is a good practice is a story told to Board staff on behalf of a school nurse that was discussing the problem of having unlabeled inhalers such as albuterol in schools. Whenever an unlabeled inhaler is found it must be thrown away since there is no label to link it to the owner. If an inhaler was found in a school with a patient name on it, the school would be able to quickly get that medication back to the student. This way a rescue inhaler would indeed be available to that student if needed after having misplaced it or having dropped it in the hallway.

Medication Error Reduction CE

At a time when the profession of pharmacy is faced by more and more research, publicity, and scrutiny for medication errors boards of pharmacy are faced with issues such as the Food and Drug Administration (FDA) requirement to include the 1-800/FDA-1088 phone number on medication bottles or patient information leaflets to report medication-related adverse events and the Institute of Medicine report that charges regulatory boards to address the growing concern of medication errors in our profession. One very good tool for helping to understand and prevent future medication errors is to actively seek CE courses that help pharmacists understand the causes of medication errors so that they can be better identified in the workplace. One important note to point out in this area is that the Accreditation Council for Pharmacy Education (ACPE) has a newer CE topic designator of 05, which indicates that a program is related to patient safety. This topic designator is defined in the ACPE Accreditation Standards for Continuing Pharmacy Education as follows:

> 05 – Patient Safety: The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors (An unintended healthcare outcome caused by a defect in the delivery of care to a patient.) Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting. (definitions approved by the National Patient Safety Foundation® Board July 2003)

In an effort to better address and understand medication errors in Arkansas, the Arkansas State Board of Pharmacy has instructed staff to call a hearing to discuss any verified medication error that is reported to the Board when there is patient harm. This extends the previous instruction to staff where a hearing is called due to a medication error where there has been a lack of patient counseling. These hearings may be handled during a scheduled Board meeting or as part

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A Community Pharmacy Technician's Role in Medication Reduction Strategies

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 Food and Drug Administration (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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at *www.fda.gov/cder/guidance/6911fnl.pdf*) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- Drugs with potential safety concerns
- Drugs that lack evidence of effectiveness
- Fraudulent drugs
- Drugs with formulation changes made as a pretext to avoid enforcement
- Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs
Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: *www.fda.gov/cder/drug/unapproved_drugs/*.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at *www.rxpatrol.com/videos.asp* and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

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of the informal committee review process depending on the specifics of each case.

ACPE Topic Designators

01 – Disease state management/drug therapy
02 – AIDS therapy
03 – Law (related to pharmacy practice)
04 – General pharmacy
05 – Patient safety

Controlled Substance Inventory

Please remember whenever performing a controlled substance inventory that tramadol is in Schedule IV for Arkansas and that any solid dosage form of pseudoephedrine, ephedrine, or phenylpropanolamine is in Schedule V for Arkansas. All of these should already be on your current controlled substance inventory, but more importantly, do not forget to include these in your future controlled substance inventory counts.

Technician Duties

03-00-0005—Tasks, Responsibilities, and Duties of the Pharmacy Technician

(a) A pharmacy technician may assist the pharmacist in performing the following specific tasks in accordance with specific written policy and procedures established by the pharmacist-in-charge covering the areas described in this section. The supervising pharmacist is responsible for all tasks performed by the pharmacy technician. All tasks performed by the pharmacy technician must be supervised, checked, and approved by the supervising pharmacist. If the pharmacy technician performs any other task that is defined as the practice of pharmacy, it will be considered a violation.

As a reminder to pharmacists, Arkansas Pharmacy Regulations outline the tasks and responsibilities that can be performed by pharmacy technicians. An important note regarding these regulations is that the duties of a pharmacy technician must be described in the pharmacy's written policy and procedures as established by the pharmacist-in-charge. While pharmacies usually have policy and procedure manuals readily available, many of these manuals have not been reviewed or updated in quite some time. Each pharmacy utilizing pharmacy technicians must have set policies and procedures for what duties are allowed to be performed in that pharmacy by a pharmacy technician and should also cover how pharmacists will supervise the duties of the pharmacy technician. If the pharmacy technician will be performing order-entry duties, the policy should also address how the drug utilization review (DUR) and other cautions are handled to be overridden by the pharmacist. This is important to note as some pharmacy computer systems do not separate the input process from the verification and DUR. For more information on this issue, please review the following Arkansas Pharmacy Regulation in its entirety: **03-02-0005 – Tasks, Responsibilities, and Duties of the Pharmacy Technician.**

Special Notice about the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official 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 notification of the *Newsletter's* contents. Please contact the Board office (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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