September 2008

Kentucky Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Drug Manufacturer and Wholesaler Renewal Deadline September 30, 2008

Drug manufacturer and wholesaler permits expire on September 30, 2008. Drug manufacturers and wholesalers may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharamcy Web site at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesaler application that provides only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2008.

Board Meeting and Retreat 2008

The Friday, November 14, 2008 Board meeting will be held at the Marriott Downtown Louisville beginning at 9 AM.

The Board will be hosting a Board Retreat on Saturday and Sunday, November 15 and November 16, 2008, at the Marriott Downtown Louisville. The agenda will be set at the September 10, 2008 Board meeting. If you have a suggested item for the agenda, please forward it to the Board office, or if you have questions, please contact the Board office. All pharmacists and individuals are invited to attend.

Pharmacy Technician Registration

House Bill 328 (sponsored by Representative Susan Westrom) was passed during the 2008 Legislative Session and signed by Governor Steve Beshear (KRS 315.135, KRS 315.136, KRS 315.137, and KRS 315.138). This law requires the registration of all pharmacy technicians with a $25 fee by April 1, 2009. At this time the Board is working on the application process. As this process is developed information will be provided to pharmacies and pharmacists via e-mail, the Board's Web site, and professional organizations. If you have any questions, please contact the Board office. To view the above laws please visit the Board's Web site at *www.pharmacy.ky.gov*.

USP 797 Revisions

The Board of Pharmacy, at its May 14, 2008 meeting, accepted the recommendations of the United States Pharmacopeia (USP) 797 Advisory Committee. The committee's recommendations were that Board inspectors educate pharmacists on the following topics contained in USP Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

- Certified ISO Class 5 Compounding Area(s) (PECs)(USP 797; 201 KAR 2:076)
- Certified ISO Class 7/8 Buffer/Ante Area(s) (USP 797; 201 KAR 2:076)
- Buffer and Ante Areas Appropriately Maintained (USP 797; 201 KAR 2:076)
- Hazardous Drugs Stored Separately in Ante-Area (USP 797; 201 KAR 2:076)
- Pressure Differential Monitored and Documented (USP 797; 201 KAR 2:076)
- Hand and Hygiene and Garbing Practices Observed (USP 797; 201 KAR 2:076)
- Personnel Training and Competency Documented (USP 797; 201 KAR 2:076)
- Daily Cleaning and Disinfection Practices Observed (USP 797; 201 KAR 2:076)
- Monthly Cleaning and Disinfecting Documented (USP 797; 201 KAR 2:076)

If you have any questions, please contact the Board office or a Board inspector.

Wholesale Distributor/Pedigree Legislation

Senate Bill 112 (sponsored by Senator Julie Denton) was passed during the 2008 Legislative Session and signed by Governor Beshear (KRS 315.400, KRS 315.402, KRS 315.406, KRS 315.408, KRS 315.410, and KRS 315.412). These laws allow new definitions, including changing from wholesaler to wholesale distributor; licensure of wholesale distributor (not permitting); prescription drug pedigrees; and electronic track-and-trace system. A committee is in the process of reviewing and amending current regulations on wholesaler requirements (201 KAR 2:105). Please contact the Board office to request any information.

201 KAR 2:220. Collaborative Care Agreement

This regulation became law on August 1, 2008. This amended regulation states the procedure for a pharmacist to utilize a collaborative care agreement to achieve optimal patient care in an efficient process. To view this regulation visit the Board's Web site at *www.pharmacy.ky.gov*. If you have any questions, please contact the Board office.

Alcoholism

Submitted by Brian Fingerson, RPh, Chair of the Pharmacist Recovery Network Committee

This is one definition of alcoholism (or you may substitute drug addiction) that may help us to understand a bit better why the alcoholic acts the way he or she does. **Alcoholism (or addiction) is a disease, the very nature of which renders the victim incapable of recognizing the severity of the symptoms, the progression of the disease, and of accepting any ordinary offers of help.** This definition comes from Father Vernon Johnson, the founder of the Johnson Institute. It is most

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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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important in that it says the disease itself renders the victim **incapable** of recognizing the severity of the symptoms. This may well be why it is a waste of time to say to the alcoholic or addict "Don't you see how bad your drinking is?" or "Don't you see how much worse you're drinking is?" Of course they do not see this. The disease has rendered them incapable of seeing these facts. It is contrary to the nature of the disease for them to see this.

So, what do you as a concerned loved one or colleague do when you see this happening? You may make the **extraordinary** offer to help and call the Kentucky Pharmacists Recovery Network (KYPRN) at 502/749-8385 and speak with Brian Fingerson or contact him via e-mail at kyprn@insightbb.com about how to obtain help for the person for whom you care. We are most fortunate here in Kentucky that health care professionals have options for help.

Changes to Controlled Substance Prescriptions

Submitted by Dave Sallengs, RPh, Branch Manager for the Office of Drug Enforcement and Professional Practices Branch

KRS 217.216, 218A.180(4), and 902 KAR 55:105 require the following items on a written prescription for a controlled substance:

- Date of issue
- Quantity check-off boxes marked
- Patient's name
- Directions for use
- Patient's address
- Refill instructions (Schedule III-V)
- Drug name
- Practitioner's name printed
- Drug strength
- Practitioner's telephone number
- Dosage form
- Practitioner's Drug Enforcement Administration (DEA) number
- Quantity (numeric)
- Practitioner's signature

These laws are administered and enforced by the Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services. It is the interpretation of this office that a pharmacist may take the following action with respect for a written prescription for a controlled substance.

1. **After consulting with the prescribing practitioner,** a pharmacist may add or modify the following items:
   - Date of issue – May be added, but not changed
   - Drug strength
   - Quantity – May be modified **only** in conjunction with a change of strength, **and** the total quantity dispensed must not exceed the total dosage authorized
   - Quantity check-off box marked
   - Directions for use
   - Refill instructions (Schedule III-V)
   - Practitioner's name, printed (not signature)

   All consultation must be documented.
2. The following items may be **added or modified without consulting the practitioner** if the information can be obtained from other, reliable sources:
   - Patient's address
   - Dosage form
   - Practitioner's address, printed
   - Practitioner's telephone number
   - Practitioner's DEA number

A pharmacist may **never** change or add the patient's name, the name of the controlled substance (except generic substitution permitted by state law), or the signature of the practitioner.

Both state and federal law still require professional judgment by the pharmacist on every prescription filled. Caution is advised whenever a change or addition is made to any prescription.

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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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