

July 2008



Nevada State Board of Pharmacy

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2008 Board Meeting Schedule

July 16-17..... Las Vegas
September 3-4..... Reno
October 15-16..... Las Vegas
December 3-4 Reno

Around the Profession

Congratulations are in order for two of Nevada’s many outstanding pharmacists who have been recently recognized for their professional and community activities:

- ◆ Paul J. Oesterman, PharmD, has been named the 2008 recipient of the Bowl of Hygeia for Nevada. Paul, a graduate of the University of the Pacific, is currently the early pharmacy practice experience coordinator/assistant professor at the University of Southern Nevada in Las Vegas and has amassed an impressive list of both professional accomplishments and unselfish dedication to his community.
- ◆ Keith W. Macdonald, RPh, past executive secretary of the Nevada State Board of Pharmacy and currently a pharmacist at Wal-Mart in Carson City, has been recognized as the 2008 “Community Pharmacist of the Year – Western US” by Wal-Mart Stores, Inc. Incidentally, Keith, with an equally impressive resume, was the recipient of the Bowl of Hygeia for Nevada in 1975.

The state of Nevada is truly honored by the positive recognition that these two gentlemen bring to our profession.

Inspector’s Corner

Apparently, pharmacies around the country are being randomly visited by Food and Drug Administration (FDA)

checking that drug recalls have indeed been removed from active stock. Although FDA does not require the keeping of a log or file on drug recalls, it might be prudent to do so in the event that a patient were to make the claim that a recalled product was dispensed after the recall date.

Be on the lookout for OxyContin® mix-ups. The Institute for Safe Medication Practices is reporting numerous instances of OxyContin **immediate release** being mixed-up with OxyContin **controlled release**. The possibility of ill consequences is apparent. Some recommendations: clarify the release rate if not indicated on the prescription; avoid using the abbreviations “IR” and “CR” since they may look the same; incorporate a high-dose alert for controlled-release products dosed more often than every eight hours; store the immediate and controlled-release products in separate locations; and most importantly, counsel the patient.

Reminder: FDA does **not** consider chlorofluorocarbon (CFC)- and hydrofluoroalkane (HFA)-containing albuterol inhalers as therapeutically equivalent; therefore, a new prescription is required if a CFC inhaler is to be changed to an HFA inhaler. We are hearing that some pharmacies are making this substitution without contacting the practitioner. Please refer to the January 2007 Board of Pharmacy *Newsletter* for full details.

Continuing Education Audit

The Board of Pharmacy, by regulation, is in the process of auditing continuing education (CE). The audit is a computerized random process, even though it may seem to some that you are audited time after time. One important point to consider is that when you sign (or electronically submit) your renewal application, you are legally certifying that you have **completed** your CE. Your signature is **not a promise** to complete it, and should not be executed prior to actually completing the CE.

Another realization is that the longer you wait to renew your license, the less likely you will be renewed on time to continue working. For example, if you renew on October 31, it takes time for that renewal application to get to our office and it takes time for staff to process that application, which would

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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.

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.

make it highly unlikely that you would be legally licensed by November 1 to continue practicing.

The Nevada Immunization Learning Exchange

As pharmacists increase their role within the medical community by providing immunizations, it is important that they recognize the reasoning behind reporting. The goal is that each patient has an up-to-date medical record, that medical providers have access to an updated medical record, and that the proper government entity has access to this data.

NAC 639.2976 lists current requirements of reporting for pharmacists administering immunizations. The regulation states that pharmacists must report to the physician of protocol, the primary care physician, the county health department, and the statewide immunization registry. When this requirement was adopted, the legislature had not yet created the department to establish and run the immunization registry. This has resulted in confusion over this portion of the regulation, mainly that which refers to reporting to the immunization registry.

There is a now a solution. The Nevada State Immunization Program is currently revisiting its regulations and would like pharmacists to have access to the immunization registry, Nevada WebIZ, as well. The Nevada Immunization Learning Exchange (NILE) is a program that provides free training for health care professionals. Up until recently, the NILE program was mainly offered to physicians, physician assistants, nurse practitioners, and medical assistants. These groups were the only ones with access to the state of Nevada immunization registry.

The NILE program is free. Sessions are either given as one three-hour program, or broken down into three one-hour programs. During this program, the pharmacist or other health care professional will become more familiar with WebIZ. This

program will also provide the participant with information on current immunization recommendations, immunization techniques, vaccine updates, vaccine handling, and vaccine storage.

For more information about the NILE program, contact Heidi Hurst.

- ◆ Phone number775/770-6713
- ◆ E-mail addressHeidi.Hurst@chw.edu

Nevada Now Reciprocates with All States

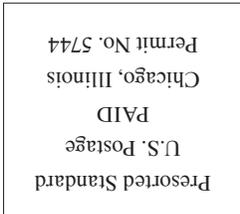
Starting July 1, 2008, Nevada will allow reciprocation of pharmacists licensed in all states, including California and Florida. Due to previous regulatory restrictions, Nevada was unable to accept reciprocation with California and Florida.

Pharmacists reciprocating from California will need to have been issued a license by taking and passing the North American Pharmacist Licensure Examination™ (NAPLEX®). Therefore, we can only accept California pharmacists who were licensed after January 1, 2004. There are no restrictions for pharmacists reciprocating from Florida. We hope this change in regulation will encourage more pharmacists to seek employment in Nevada.

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