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Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

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2007 Board Meeting Schedule

October 24-25 ..... Las Vegas
December 5-6..... Reno

Of Historical Interest

1901 – The Nevada State Board of Pharmacy was created by the legislature.

The original Board consisted of five members: Hodgkinson from Reno; Cole from Virginia City; Tabor from Elko; Brown from Winnemucca; and Steinmetz from Carson City. The Board met twice a year on the first Mondays of May and November. One of the Board's charges was to certify competence in the practice of pharmacy by a "thorough and searching" examination of candidates to include "at least a grammar school preliminary education and not less than four years experience in pharmacy work compounding prescriptions." Board fees were $5 to examine and $10 on issuance of a license, which was to be recorded in the county of residence of the pharmacist.

The pharmacy act also provided for failing "to use due care and reasonable caution" or being "grossly negligent in compounding drugs or in the filling of prescriptions," constituting a misdemeanor punishable by a fine of up to $500 and by imprisonment for 50 to 180 days for each offense.

1906 – Frederick Hopkins theorized that food contains trace substances essential to life that later became known as vitamins. This is also the year that Congress enacted the first Federal Food and Drug Act to prevent adulterated or misbranded food and drugs.

1931 – There were 60,000 pharmacies in the United States each with average annual sales of $26,500.

1956 – There were approximately 180 pharmacists registered in Nevada (including out-of-state pharmacists) with Reno/Sparks home to 32 pharmacies, 15 in the Las Vegas area, and 33 pharmacies spread throughout the remainder of the state. The first testing on birth control pills began in Puerto Rico.

2007 – The Board currently licenses over 500 pharmacies, over 2,000 pharmacists, and over 2,300 pharmaceutical technicians in state.

The Board's Role

The role of the Board of Pharmacy is often confusing to both the public and to practitioners as well. Some guidelines:

The Board is a government body responsible for protecting the public.

The Board is not a membership organization of pharmacists and pharmaceutical technicians responsible for protecting the profession.

The Board is responsible for enforcing the statutes and regulations that govern the practice of pharmacy (which may be accessed via our Web site: *http://bop.nv.gov*).

The Board cannot independently change statutes adopted by the legislature; however, it is empowered to adopt regulations to clarify statutes and establish legal standards of practice. Regulatory adoption and changes are a public process including workshops, public hearings, review by the Legislative Council Bureau, and approval by the Legislative Committee on Regulations.

The Board does regulate the scope of pharmacy practice; however, it does **not** regulate conditions of employment such as hiring and firing and discipline imposed by an employer.

Special Request

In an effort to streamline and more efficiently communicate with all of you, we are asking all pharmacists and

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

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.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

- and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit *www.ismp.org* and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- inadequate labeling for safe use;
- inappropriate packaging and, therefore, uncertain product integrity;
- possible previous withdrawal from the US market for safety or efficacy reasons;
- drug-specific risks requiring initial screening and/or periodic patient monitoring;
- potential harm or abuse, such as with the use of controlled substances; and
- potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments.*

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html*.

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

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technicians to provide us with, and keep updated, a valid e-mail address. You can provide this via our Web site (***http://bop.nv.gov***) by clicking on the icon on our home page. This will allow Board staff a much more effective avenue to communicate such information as relicensure, bulletins, regulatory changes, and the like.

Board staff is also requesting that each of you ask for Internet access at your place of employment. This will allow you to access our Web site when necessary, so that you can easily verify a license, look up a law, link to everything from Drug Enforcement Administration to Food and Drug Administration, keep current on regulatory changes, view frequently asked questions, and such. Another huge advantage to Internet access in your pharmacy is to allow you the ability to access the Controlled Substance Abuse Prevention Task Force should you be presented with a questionable prescription. Our physicians, especially in the emergency rooms around the state, constantly utilize this feature in their efforts to curtail drug diversion, and love it.

Your Initials

Pharmacists and pharmaceutical technicians engaged in filling prescriptions are required to put their handwritten initials on original prescriptions to document who filled the prescriptions. Many registrants believe computer-generated initials printed on a sticker satisfy the legal requirement for initials to identify who filled the prescription, but they are mistaken. Nevada Revised Statutes 639.236 clearly states that each prescription on file must be personally signed or initialed by the registered pharmacist or practitioner that filled it. Therefore, a computer-generated sticker with the pharmacist's and technician's initials attached to the original prescription does not satisfy Nevada's statutory requirement.

It is the standard of practice in Nevada to hand initial the original prescription at the time a particular function is performed by the registrant. That is to say, when a pharmaceutical technician fills the product portion of a prescription, he or she is required to initial the product label and if applicable, the original prescription, during that process. When the pharmacist checks the prescription for accuracy prior to dispensing the final product he or she also initials the product label and the original prescription for new prescriptions at the time of verification.

Nevada pharmacy regulations do not address the situation of multiple pharmacists being involved in the filling process. This makes it vitally important for the final pharmacist in the filling process to ensure the accuracy of the complete prescription before signing his or her initials.

We've Moved!!

As of August 15, 2007, the Board office in Reno has relocated to a more central location. Our new address is 431 W Plumb Ln, Reno, NV 89509. Our phone and fax numbers remain the same. All pharmacists received this notice with their renewal forms, and postcards were mailed to all other licensees in September.

The *Nevada State Board of Pharmacy News* is published by the Nevada State 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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