



Nevada State Board of Pharmacy

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Regulatory Update

For the betterment of the practice of pharmacy and ultimately for the benefit of the patient, the Nevada State Board of Pharmacy has been quite active on the regulatory front. Brief highlights follow:

1. You no longer are required to “cancel” a Schedule II prescription. Simply date and initial after verification as you do any prescription.
2. There is no longer an age limit on immunizations by pharmacists and the reporting requirements have been simplified.
3. The Exam for the Certification of Pharmacy Technicians (ExCPT) is now recognized as pharmacy technician certification along with the old standard, the Pharmacy Technician Certification Examination (PTCE).

4. There are new regulations governing the duties of consulting pharmacists in the surgical center setting.

Finally, the Board office continually receives calls regarding the changing of the date on a Schedule II prescription, and many of you have misinterpreted the rule. The date change rule simply allows the pharmacist, upon speaking with the practitioner who wrote the prescription, to **correct** a mistake written in the date. **It does not circumvent the 14-day rule.** You may **not** change the date of a Schedule II prescription that has not been properly tendered within 14 days (in other words, a patient may not bring you a Schedule II prescription that he or she has been carrying around for months and ask you to call the prescriber and get the date changed; however, the rule does allow you to correct the date on a properly tendered Schedule II prescription where the prescriber simply wrote the wrong year.

Prescriber’s Name

Reminder: It is unacceptable to substitute a practitioner’s name on the prescription label. We often find a prescription written by a physician assistant-certified or advanced practice nurse labeled with their collaborating physician’s name, presumably to get the prescription through the insurance company. The actual prescriber is legally the name required on the label.

Counterfeit Drugs

The Nevada Supreme Court ruled in favor of the Nevada State Board of Pharmacy by affirming the Board’s actions of revoking the pharmaceutical wholesaler license of Dutchess Business Services, Inc, and its successor, Legend Pharmaceuticals, Inc. The Board charges against the wholesalers related to purchase and resale of undocumented and/or counterfeit Zoladex®, Lupron®, and Serostim® from three Florida wholesalers and one South

Continued on page 4



FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through www.fda.gov/healthprofessionals.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at www.fda.gov/consumer/default.htm.

Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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: 200 Lakeside Dr;

Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- ◆ Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- ◆ If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- ◆ If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- ◆ Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).

	LORAZEPAM 0.5MG TABLET
Sig:	1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days
Dispense:	90 Tablet(s)
Special Instructions:	Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills:	5
Signature:	_____

- ◆ Ask prescribers to include the indication for use whenever they write or call in a prescription.
- ◆ Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- ◆ Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- ◆ Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at www.ismp.org/Tools.



- ◆ Let them know you will dispense measuring devices every time they order a liquid medication.
- ◆ Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The "Advertising Prescription Drugs and Medical Devices" Web site provides a "one-stop shop" portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at www.fda.gov/oc/promotion/.

The direct-to-consumer Web site, "Be Smart about Prescription Drug Advertising: A Guide for Consumers" is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient's understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at www.ethicad.org.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at www.fda.gov/cder/ethicad/index.htm.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than

200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, "Issuance of Initial Pharmacist Licensure," asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at www.nabp.net and download an order form; the *Survey* costs \$20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Carolina wholesaler. The Board found that the wholesalers violated the statute by holding and selling counterfeit drugs and failed to maintain adequate pedigrees, even though they claimed no knowledge of the drugs being counterfeit. This affirmation of the actions of the Board of Pharmacy is a huge victory in the continuous battle against bad wholesalers and counterfeit drugs not only in Nevada, but nationally as well.

Reminder

Albuterol inhalers containing chlorofluorocarbon (CFC) will be illegal to market, distribute, or produce after December 31, 2008. Recent surveys show that roughly 33% of albuterol inhaler patients are still using CFC product. Pharmacies are prohibited from dispensing or returning any inventory after the December date. The rule only applies to single ingredient albuterol inhalers, not others such as Combivent®.

New General Counsel

The Board of Pharmacy is pleased to introduce our new general counsel, Ms Carolyn Cramer. Carolyn comes to the Board from the Reno City Attorney's Office, with vast experience in government law, including at the Nevada Attorney General's Office and the Nevada Public Service Commission. A graduate of the University of Puget Sound (Tacoma, WA), Carolyn is an amateur meteorologist, an avid bicycle rider, and the daughter of a commercial fisherman. The members and staff of the Board wish her a long and rewarding "ride" down the challenging path of the world of pharmacy law.

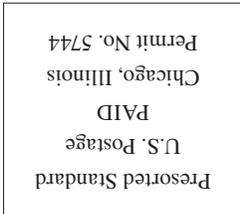
Final Thoughts

More than 40% of patients with chronic illnesses are functionally illiterate and cannot understand simple

instructions on a vial of pills. Almost 25% of all adult Americans read at or below a fifth-grade level and three out of four patients throw out the written medication information usually provided with a prescription. So how important does counseling become in that light? If the patient cannot read or understand what they read, their only opportunity to ensure any understanding at all is through your efforts. Try not to get "lost" behind the counter.

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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