



Nevada State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Faces

Governor Jim Gibbons has announced the appointment of two new Nevada State Board of Pharmacy members effective November 1, 2009. Board staff is excited to welcome Beth Foster and Kirk Wentworth, both exceptional pharmacists as well as exceptional individuals. Beth, the chief of pharmacy service for the Veterans Affairs Sierra Nevada Health Care System, graduated from the University of Montana School of Pharmacy in 1984. Married to Lorin Foster, also a pharmacist in the Reno area, Beth has spent most of her stellar career in hospital pharmacy and is a welcome asset to the Board. Incidentally, Beth was the 2009 recipient of the Bowl of Hygeia for the state of Nevada.

Kirk graduated with a bachelor of science in biological sciences from the University of California, Irvine in 1973, and from the University of Arizona College of Pharmacy in 1978. He is the owner of MedCare Pharmacy in Carson City, NV, where he has been for the past 23 years. Active over the years in pharmacy associations, Kirk is also an avid skier, snowboarder, and cyclist. His wife Pat is a high school teacher.

Sadly, the appointment of two new Board members means the ending of terms for two members as well. Leo Basch served the public on the Board since 2005, acting as treasurer for the Board during most of his tenure. David Chan gallantly served out the remainder

of our past president's term. Both Leo and David served admirably over their tenures and will be sorely missed. Board staff wishes them well!

Tid Bits

- ◆ The Board of Pharmacy is **not** the Prescription Controlled Substance Abuse Prevention Task Force. For task force issues and requests for fax broadcasts, please contact their office via phone at 775/687-5694 or via fax at 775/687-5161.
- ◆ Pharmacy technicians need one hour of law continuing education (CE) each renewal period (as do pharmacists), and that law CE can only be satisfied by attending a program presented by the Nevada State Board of Pharmacy or by attending a Nevada State Board of Pharmacy meeting. Generic law CE programs, even though often accredited by Accreditation Council for Pharmacy Education, do not satisfy this requirement.
- ◆ A faxed prescription, even though often generated by a computer, must be signed by the prescriber. A faxed prescription is not an electronic prescription, and must be treated as such. An electronic signature on file is unacceptable.
- ◆ A prescription written by a practitioner licensed in Guam is OK to fill (Guam is a US territory).
- ◆ An intern pharmacist is not included in the pharmacist to technician ratio. A pharmacist may supervise up to three technicians regardless of whether he or she is supervising an intern pharmacist.
- ◆ The pharmacy refrigerator must maintain proper temperature, which can only be ensured through daily monitoring of the refrigerator thermometer. This is especially critical as we work through immunization season. A refrigerator log, which is required if you stock vaccines, is a good idea for any pharmacy refrigerator.



FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at www.ismp.org/safetyalerts/20091015-Tamiflu.asp.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers “are going overboard to avoid violations” of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the “minimum necessary” rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the “minimum amount of information necessary” on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol[®] Arthritis and Tylenol[®] PM products. Pharmacists should be wary of the following Tylenol products:

- ◆ Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- ◆ Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm. Pharmacists should verify pedigrees they receive with any wholesale drug

purchases. News regarding the alert can be found at www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- ◆ Lehigh Valley Technologies Inc in Allentown, PA
- ◆ Cerovene Inc in Valley Cottage, NY
- ◆ Dava International Inc in Fort Lee, NJ
- ◆ Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for \$195 by visiting the publications section of the NABP Web site at www.nabp.net, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Pharmaceutical Technician Certification (PTCB or ExCPT)

At the beginning of 2009, the Nevada State Board of Pharmacy recognized the Exam for the Certification of Pharmacy Technicians (ExCPT) as an acceptable certification for pharmacy technicians. In addition to the Pharmacy Technician Certification Board (PTCB) examination, these certifications promote standards of practice for pharmacy technicians. These certification recognitions also aim to promote safe and effective patient care by encouraging the use of highly qualified pharmacy technicians.

Both the PTCB and the ExCPT certifications allow for certified pharmacy technician recognition. Both examinations require 20 continuing education units biannually. Candidates may take these exams online, so traveling what may sometimes be a long distance to Sacramento or to Las Vegas, is no longer necessary.

Currently, there is a nationwide movement through various pharmaceutical organizations to require mandatory certification for all pharmacy technicians.

The Joint Commission of Pharmacy Practitioners (JCPP) Future Vision of Pharmacy Practice 2015 statement states that “Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.” To help make this vision a reality, pharmacists will need the support of well-qualified, competent pharmacy technicians to ensure they can fulfill their professional role.

The National Association of Boards of Pharmacy® (NABP®) Task Force on Standardized Pharmacy Technician Education and Training recommended, and the NABP Executive Committee approved, that NABP amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to include a proposal that all boards of pharmacy require pharmacy technicians to be certified

by 2015, in accordance with the JCPP Future Vision of Pharmacy Practice.

Training materials and study guides are available at the ExCPT and the PTCB Web sites. Pharmacy technicians seeking certification may schedule their examinations locally and receive an immediate pass or fail response. Currently, Nevada has 1,629 certified pharmacy technicians through PTCB and about 420 certified pharmacy technicians through ExCPT.

In light of the above positions taken by the JCPP and the NABP task force, the Nevada Pharmaceutical Technician Advisory Committee has recommended that the Board wait on the revisions of the *Model Act* before moving forward with a recommendation for mandatory certification of all pharmacy technicians.



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