October 2013

News



# Nevada State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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### Legislative Update

In an effort to keep you all abreast of legislative activities that affect the practice of pharmacy, please note the following.

#### **Bills That Passed**

- ♦ AB 39: National Precursor Log Exchange
  - Requires a "real-time" stop-sale electronic system for methamphetamine precursors, replacing the old "logbook."
- ♦ AB 155: Reporting of child abuse
  - Requires all health care professionals to report child abuse if in their professional opinion such activity is occurring.
  - You will be required to respond on your renewal application that you are aware of this new requirement.
- ♦ AB 170: Advanced Practice Registered Nurses (APRNs)
  - Advanced Practice Nurses, now known as APRNs, who will be "licensed" rather than "registered," are allowed to practice and prescribe without a collaborating physician.
- ♦ SB 220: Unlicensed practice of pharmacy
  - ♦ Increases criminal penalties and authorizes cite and fine ability
- ◆ SB 327: Telemedicine, Electronic refill log
  - ♦ Allows a telephonic or video "examination" (rather than just "physical") to prescribe; allows prescription refill records to be kept electronically; allows a pharmacist, in his or her professional judgment, to dispense up to a 90-day supply of any dangerous drug with valid periodic refills (maintenance drugs only and no controlled substances) without authorization by the prescriber.
- ♦ SB 410: Sale of hypodermic devices
  - Allows the sale of hypodermic devices, not requiring a prescription by federal law, for any purpose.
- ♦ AB 362: Establishes the HIV/AIDS Drug Donation Program
- ◆ SB 453: EpiPen<sup>®</sup> in schools
  - Allows schools to possess auto injectable epinephrine not pursuant to a prescription for a specific patient (student).
- ♦ SB 374: Provides for medical marijuana dispensaries to be regulated by the Health Division of the Department of Health and Human Services (HHS)

♦ AB 95: Allows the patient to request the "substituted for brand name" language to be left off the prescription label

#### **Bills That Failed**

- ♦ SB 75: Would have allowed patients who become addicted to prescription drugs to bring a cause of action against the prescribing practitioners and the drug companies
- ♦ SB 126: "Therapeutic equivalence" language once again failed

#### Medical Marijuana

SB 453, which was signed into law in June 2013, provides for the establishment of medical marijuana dispensaries to be regulated by the Health Division of HHS. It should be noted that the use, possession, growing, and selling of marijuana is still against federal law. For your patients who inquire, the contact information is **Nevada State Health Division**, Attn: Medical Marijuana Division, 4150 Technology Way, Suite 104, Carson City, NV 89706 and 775/684-7594.

#### Board Subpoena Power

Are you aware that the Nevada State Board of Pharmacy has subpoena power? Apparently, many of you are not, as is evidenced by three recent cases in which two pharmacy technicians and an intern pharmacist were subpoenaed by the Board to appear at hearing and did not show. The subpoenas were simply "blown off," resulting in the Board having to take action against the registrations and licenses of those subpoenaed. Excuses ranged from "my supervisor said I did not have to go" to "my child was sick that day," neither of which were communicated to Board staff for consideration prior to the hearing. No one can excuse you from a Board-issued subpoena other than the Board itself, so when subpoenaed, either show or give the Board a call to avoid being the subject of your own hearing!

# Immunization Update – What Is New for the 2013-2014 Influenza Season?

By Christina M. Madison, PharmD, BCACP; Rhea Conlu and Kseniya Kozlova, PharmD Candidates, Class of 2014 Roseman University of Health Sciences College of Pharmacy, Henderson, NV

Patients receiving an annual influenza vaccination is an essential component to our communities' overall health and wellness. As one of the most trusted health care providers, pharmacists play a key role in making sure our communities are appropriately immunized. Universal vaccination for all individuals age six months and above remains the standard of care recommended by the Centers for Disease Control and Prevention (CDC). CDC recommends immunizing as soon as the vaccine is available to prevent illness. Determining which vaccine product to use should be based on age indication and vaccine availability (see the following chart). There are a few important changes to this year's seasonal influenza vaccination that all pharmacists need to know. The influenza vaccine is manufactured to protect against the three main Continued on page 4

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# **National Pharmacy**

(Applicability of the contents of articles in the National Pharmacy Compand can only be ascertained by examini

# Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at <a href="https://www.fda.gov/Safety/Recalls/ucm357909">www.fda.gov/Safety/Recalls/ucm357909</a>.

## Barcoding Technology for Community Pharmacy

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES 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 an 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006<sup>2</sup> study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.<sup>3</sup> Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at <a href="https://www.ismp.org/AHRQ/Default.asp?link=sa">www.ismp.org/AHRQ/Default.asp?link=sa</a>.

<sup>1</sup>Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." Joint Comm J Qual Pt Safety. 2007;33(5):293-301.

Ukens C. "New study sheds light on medication errors." Drug Topics. 2002;146(21):33.

<sup>2</sup>Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." J Amer Pham Assoc. 2006; 46(2):154-160.

<sup>3</sup>American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

#### ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With ISMP Medication Safety Alert! publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.

# Compliance News

liance News to a particular state or jurisdiction should not be assumed ng the law of such state or jurisdiction.)





# FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/Consumer Updates/ucm363010.htm.

### Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at <a href="https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm">www.fda.gov/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm</a>.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp .net/programs/accreditation/vawd.

### Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

## Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



#### **Pharmacists & Technicians:**

Don't Miss Out on Valuable CPE Credit. Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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strains of the virus that research has indicated will be the most likely to cause illness. Due to an increase in influenza B virus strain circulation, a fourth antigen has been added to a majority of vaccine formulations for this year, forming a quadrivalent vaccine (A/California/7/2009 (H1N1), A(H3N2)-like virus A/Victoria/361/2011, B/Massachusetts/2/2012-like virus, and B/Brisbane/60/2008-like virus). In addition to the product change, there is also a change in the terms used to describe this vaccine, which is outlined below.

## Nomenclature Changes for the 2013-2014 Influenza Season

- IIV refers to the inactivated influenza vaccine, both egg-based and cell culture-based
  - ♦ IIV replaces the TIV abbreviation
- ◆ Trivalent and quadrivalent vaccines are distinguished numerically (eg, IIV3 or IIV4)
- ◆ Cell culture-based vaccines (egg-free) are preceded by cc (eg, ccIIV3)
- ◆ RIV refers to the recombinant hemagglutinin influenza vaccine (egg-free)
  - $\Diamond$  Available as a trivalent formulation for the 2013-2014 influenza season
- ◆ LAIV4 refers to the live, attenuated influenza vaccine, available as a quadrivalent formulation

Influenza Vaccine Products for the 2013-2014 Influenza Season			
Trade Name (Vaccine Abbreviation)	How Supplied	Age Group	
Afluria (IIV3)	Single and multi-dose	≥9 years	
Fluarix (IIV3)	Single-dose	≥3 years	
Fluarix (IIV4)	Siligie-dose		
FluLaval (IIV3)	Multi-dose	≥3 years	
FluMist (LAIV4)	Nasal spray	2-49 years	
Fluvirin (IIV3)	Single and multi-dose	≥4 years	
Flucelvax (ccIIV3) *egg free	Single-dose	≥ 18 years	
Flublok (RIV3)	Single-dose	18-49 years	
Fluzone (IIV3)	Single and multi-dose	6-35 months	
	Single and multi-dose	≥3 years	
Eluzana (IIV/4)	Single-dose	6-35 months	
Fluzone (IIV4)		≥3 years	

Fluzone High-Dose (IIV3)	Single-dose	≥65 years
Fluzone Intradermal (IIV3)	Single-dose	18-64 years

Adapted from Immunization Action Coalition Influenza Vaccine Products for the 2013-2014 Influenza Season Chart

For the most up-to-date vaccine information and continuing pharmacy education offerings please visit:

- ♦ Nevada State WebIZ: www.webiz.nv.gov
- ♦ Immunize Nevada: www.immunizenevada.org/
- ♦ Southern Nevada Immunization and Health Coalition: http://snihc.org/

Every patient encounter is a potential missed opportunity to vaccinate. Annual flu vaccination is a perfect time to verify if a patient needs other recommended vaccines.

#### Reference

1. Centers for Disease Control and Prevention. Interim Recommendations: Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2013 [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2013 Jul 1 [updated 2013 Jul 1; cited 2013 Jul 25]. Available from: www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm.

#### **Immunization CE Requirements**

The Board office often gets inquiries regarding the continuing education (CE) requirements for an immunization pharmacist. Please review NAC 639.2974, which mandates the following of immunizing pharmacists:

- 1. Must maintain certification in basic cardiac life support from the American Heart Association.
- On or before October 31, of each year, complete at least two hours
  of CE that address life cycle diseases, drugs, and administration of immunizations, or a course provided by CDC regarding
  epidemiology and prevention of diseases that are prevented by
  immunization.

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