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News



Arizona State Board of Pharmacy

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Arizona 51st Legislative Update

The Arizona State Board of Pharmacy had two bills, both sponsored by state Senator Nancy Barto representing Legislative District 15, making their way through the 51st Arizona Legislature at press time. By the publication date of the *Newsletter*, they may have completed the process in the legislature and may be awaiting the governor's signature. Assuming they are not vetoed, they both become law 90 days after the last day of the legislative session. A brief summary of each bill and amendments follows.

Senate Bill 1041

Currently, the Board is scheduled to terminate on July 1, 2014 (A.R.S. §41-3014.02). During the 2013 interim, the House of Representatives Health Committee and the Senate Health and Human Services Committee of Reference met and recommended the Board be continued for eight years. The bill:

- ◆ Continues the Board for eight years until July 1, 2022.
- ◆ Contains a purpose clause.
- ◆ Applies retroactively to July 1, 2014.

Senate Bill 1043

Allows naturopathic physicians to prescribe any drug that is reclassified from Drug Enforcement Administration (DEA) Schedule III to Schedule II after January 1, 2014.

- ◆ Requires applicants for an initial pharmacist, intern, or technician license to submit to the Board a full set of fingerprints for the purpose of obtaining a state and federal criminal records check.
- ◆ Allows the Arizona Department of Public Safety to exchange fingerprints with the Federal Bureau of Investigation regarding criminal records checks for pharmacists.
- ◆ Removes language requiring the Board to establish a list of drugs that must not be used by dispensing pharmacists as generic equivalents and establish a two-letter code in solid dosage forms.
- ◆ Makes technical and conforming changes.

Amendments in House Committee on Health

- ◆ Outlines requirements regarding the application for a permit to operate a pharmacy, drug manufacturing facility, or wholesale facility outside of the state that will dispense, sell, transfer, or distribute drugs into Arizona. Removes the

requirement for an Arizona-licensed pharmacist for nonresident pharmacies and manufacturers.

- ◆ Codifies current authority under the practice of pharmacy relating to collaborative agreements and immunizations. Establishes (once and finally) that pharmacists are health care professionals.

Compliance Officer Retires

Ed L. Hunter, compliance officer for the Board since 1998, has been helping Arizona pharmacists with pharmacy and other federal and state statutes, rules, and policies just as he did when he held the same position in the great state of Texas from 1982 until his permanent move to Arizona. Ed also served the citizens of Texas working within a unit of state government whose mission was to prevent welfare fraud there from 1976 to 1982. Some might describe such a career as government run amok, but all the rest of us government bureaucrats know it for what it truly is: a noble and necessary service to the public.

Dean Wright and Hal Wand, the only employees who have worked for the Board longer than Ed, remember his first week of work very well. They served everyone in the office waffles and bacon for breakfast in the early hours before Ed's first day of work, which resulted in power outages to various parts of the building on Camelback and 19th Avenue. Dean and Hal also rigged up a test on pharmacy law that had no correct answers just to see how Ed would react to stress on the job. Oh, the good old days! Good luck to Ed and his spouse, Cindi, in this new chapter in their lives.

Controlled Substances Inventory

May 1, 2014, is the 40th anniversary of the passage of the Controlled Substance Act of 1974 under then-President Richard Nixon. Unless you have arranged an alternate date with the Board and DEA, you must conduct the annual controlled substance inventory on this date.

Arizona Administrative Code R4-23-1003: Records and Order Forms

A. Records.

1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:


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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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



can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



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 an 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.

- a. Include an exact count of all Schedule II controlled substances;
 - b. Include an exact count of all Schedule III through Schedule V controlled substances or an estimated count if the stock container contains fewer than 1001 units;
 - c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
 - d. Be signed by:
 - i. The pharmacist-in-charge; or
 - ii. For other required inventories, the pharmacist who does the inventory;
 - e. Be kept separately from all other records; and
 - f. Be available in the pharmacy for inspection by the Board or its designee for not less than three years.
2. A loss of a controlled substance shall be reported:
- a. Within 10 days of discovery;
 - b. On a DEA form 106;
 - c. By the pharmacist-in-charge of a pharmacy or a manufacturer;
 - d. By the permittee or designated representative of a full-service wholesaler; and
 - e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.
3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain for not less than three years the manufacturing, repackaging, or relabeling date for each controlled substance.
4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than three years the following information:
- a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
 - b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
 - c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
 - d. The date of each transaction.
5. A full-service drug wholesale permittee or the designated representative shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or designated representative shall conduct this inventory:
- a. On May 1 of each year or as directed by the Board; and

- b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a designated representative.

6. A drug manufacturer permittee or the pharmacist-in-charge shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or pharmacist-in-charge shall conduct this inventory:

- a. On May 1 of each year or as directed by the Board; and
- b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a pharmacist-in-charge.

B. Order form. For purposes of A.R.S. §36-2524, "Order Form" means DEA Form 222c.

Disciplinary Actions and Updates Pharmacist

Hines, Jacinta (S014158) – Six-month probation; \$1,000 fine, eight additional hours of continuing education. Effective January 10, 2014.

Certified Pharmacy Technician

Espinoza, Ana (T006449) – Controlled Substance Accountability – Revoked. Effective January 8, 2014.

Disciplinary Actions and Updates – Other Health Boards

Arizona Board of Dental Examiners (DDSs, DMDs)

Hatch, Alexander (DDS) – Prescription prescribing privileges restored. May apply to DEA for new registration.

Arizona Board of Medicine (MDs)

Holper, Steven A. (MD – 24021) – License surrendered. Effective February 7, 2014.

Waqas, Ali (MD – 47449) – Shall not practice medicine within Arizona. He is prohibited from prescribing any form of treatment including prescription medication until respondent applies to the Board for permission to do so. Effective February 24, 2014.

Arizona Regulatory Board of Physician Assistants (PAs)

Harmston, Charles (PA – 1027) – License surrendered. Effective February 27, 2014.

Moffett, Erin L. (PA – 3787) – Shall not perform health care tasks within Arizona. Prohibited from prescribing any form of treatment including prescription medication until respondent applies to the Board for permission to do so. Effective January 29, 2014.

Arizona Osteopathic Board (DOs)

Fantauzzi, Mark R. (DO – 3209) – License surrendered. Effective January 28, 2014.