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New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Reminders

- Did you complete your annual controlled substance (CS) inventory?
- If you are registered as a hospital pharmacy, you may fill discharge prescriptions and prescriptions as an employee benefit only. You may not fill prescriptions for the general public unless the pharmacy is also registered as a retail pharmacy.
- A pharmacist, pharmacist intern, or pharmacy technician may sell pseudoephedrine-containing products. A non-registered clerk may not sell these products.
- Also, non-registered clerks may not make the offer to counsel on refilled medications.
- The New Mexico Board of Pharmacy lets certified law enforcement officers within New Mexico become designated agents of the Board. These designated agents may review your logs for pseudoephedrine sales. They will carry identification issued by the Board.
- Please complete your Pharmacist Workforce Survey. Information is in a separate article within this *Newsletter*.

Significant Adverse Drug Events

1. A 72-year-old patient was prescribed morphine sulfate ER 15 mg, but was dispensed morphine sulfate ER 30 mg. Patient reported that the medication made him sick. Pharmacist recommends following policy and checking the drug strength on the stock bottle against the pharmacy label.
2. Patient was prescribed warfarin 2 mg, but was dispensed warfarin 4 mg. Patient did not require additional medical care. Pharmacist recommends checking the National Drug Code (NDC) number on the label against the bottle.
3. An 86-year-old patient was prescribed ipratropium nebulizer solution, but was dispensed ipratropium and albuterol nebulizer solution. Patient reported that she became shaky and her heart pounded. Pharmacist indicated that the pharmacy was busy, did not have enough help, and that the pharmacist had worked a long shift.
4. An 82-year-old patient was prescribed warfarin 1 mg, but was dispensed warfarin 10 mg. Prescriber verified that the patient was fine. Pharmacist recommends making a list of dangerous drugs: drugs with a small therapeutic index or similar. Then, keep the list by the computer to draw attention to these medications.
5. A 50-year-old patient of a Methadone clinic was dispensed his medication. Patient immediately complained that the dose was too strong. Patient reported numbness of tongue and sleepiness. Patient was monitored at a hospital. An audit showed that approximately 300 mg of Methadone was missing. Pharmacist said that on investigation, it was found that this was possibly a problem with the Methasoft software program. Due to a glitch in the software, Methasoft can prime the pump more than once when preparing a patient's dose. Pharmacist recommends instructing nurses to only use the mouse when clicking on the "dose patient" key and not to use the "enter" key.
6. Patient was prescribed Cipro® 250 mg, but was dispensed Cipro 500 mg. Patient complained of vision disturbance. Pharmacist recommends double checking orders.
7. A 78-year-old patient was prescribed doxycycline 20 mg, but was dispensed doxycycline 100 mg. Patient reported stomach upset and indigestion. Pharmacist recommends following policy and scanning the NDC number rather than typing the NDC number by hand.
8. Patient was prescribed oxycodone 30 mg IR, but was dispensed OxyContin® 30 mg CR. Patient reported shortness of breath, difficulty breathing, and extreme sedation. Pharmacist recommends stricter dose attention.

Disclaimer: The suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. The New Mexico Board of Pharmacy may not necessarily agree with these suggestions.

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

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.

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Pharmacists & Technicians:
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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.

Board Meeting Dates

The June 2014 Board meeting has been moved forward one day. The meeting will be held Wednesday and Thursday, June 18 and 19, 2014. The meeting date was changed to allow Board members the opportunity to attend the 2014 New Mexico Pharmacy Wholesalers' Invitational Golf Tournament. Please update your calendars.

The following is the current 2014 Board meeting schedule:

- ♦ Wednesday, June 18 and Thursday, June 19
- ♦ Monday, August 25 and Tuesday, August 26 – meeting to be held in Ruidoso, NM
- ♦ Thursday, October 16 and Friday, October 17

Remember to check the Board website for the agenda.

Pharmacist Workforce Survey

The Board is required to survey pharmacists relating to the workforce in New Mexico.

The Board needs each licensed New Mexico pharmacist practicing in New Mexico to complete this survey by August 1, 2014. This will bring the data up to date from 2012 to August 2014. The survey is available on the Board website at *www.rld.state.nm.us/Pharmacy.aspx*.

Beginning in January 2015, all pharmacists will complete the survey as part of their renewal process. Instructions will be provided on the mailed renewal form. The survey will be available with online renewals and on the Board website for mail-in renewals.

Health Care Work Force Data Collection, Analysis and Policy Act 24-14

The Health Care Work Force Data Collection, Analysis and Policy Act was signed into law by the governor in February 2012. This act requires health professional licensing boards to conduct electronic surveys of their health professionals. Professional licenses shall not be issued or renewed until the survey is completed. A portion of the act is listed below.

> **24-14c-5. Health Care Work Force Data Collection by Boards . . .**
>
> B. A board shall not approve a subsequent application for a license or renewal of a license until the applicant provides the information pursuant to Subsection C of this section.
>
> C. A board shall adopt rules regarding the manner, form and content of reporting data; the consistency of data entry fields used; and the information that an applicant, pursuant to Subsection A of this section, shall provide to a board. . .

The Board adopted rule changes on October 18, 2013. A portion of the rule is listed below.

> **16.19.4.15 Issuance or Renewal of Pharmacist License**
>
> A. The Board shall not approve the application for a pharmacist license or renewal of a pharmacist license until the applicant provides the data required by the Health Care Work Force Data Collection, Analysis and Policy Act.

Disciplinary Actions

Renee Dimas, PT – License PT-5649. Respondent was reported as not in compliance with her child support order. Respondent voluntarily surrendered her pharmacy technician registration. Must pay $100 fine. Upon presentation of a statement of compliance with the child support order, respondent's registration shall be reinstated after receipt of a renewal application and applicable fees.

Flourish Integrative Pharmacy – Unlicensed in New Mexico. On June 21, 2012, a resident of New Mexico had a prescription filled by respondent, Flourish Integrative Pharmacy. At this time, respondent was not registered with the Board as a nonresident pharmacy. The prescription was for hydroxyprogesterone caproate. The prescription was incorrectly filled with testosterone. Respondent agrees to discontinue conducting business in New Mexico for at least two years. After this two-year period, respondent may register with New Mexico. Respondent must register prior to shipping drugs into New Mexico. Respondent shall pay a fine and investigative costs of $1,400.

David Lansford, RPh – License #RP-4668. Respondent plead no contest to the Board allegation that a prescription for methimazole was incorrectly filled with metolazone at the pharmacy where he works. Respondent is the pharmacist-in-charge at this pharmacy. Respondent must pay a $500 fine and $600 investigative costs. Respondent must upgrade workflow at the pharmacy in order to identify the pharmacist that performs the drug utilization review and to document the pharmacist who performs product verification. Respondent is placed on probation for a one-year period.

Michael Lopez, PT – License PT-9141. Respondent voluntarily surrendered his pharmacy technician registration because of a New Mexico Controlled Substances Act violation. Respondent must pay a fine of $100.

New England Compounding Center Pharmacy – License PH-2575. Respondent was registered as a nonresident pharmacy in New Mexico. Respondent distributed non-patient-specific compounded sterile product into New Mexico. Respondent filed for bankruptcy. Prior to filing for bankruptcy, respondent ceased doing business within New Mexico. Respondent surrendered its pharmacy registration. Respondent agrees to never renew pharmacy license.

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Armin Quedzuweit, RPh – License #RP-7774. On September 14, 2013, respondent was ordered by the Board's Impaired Health Care Provider Examining Committee (Examining Committee). The order from the Examining Committee was to contact the New Mexico Monitored Treatment Program (MTP) by September 30, 2013, to be evaluated within 15 days for possible substance abuse. Respondent was ordered to give written consent to MTP to provide the results of the evaluation to the Board by September 30, 2013. Respondent was also ordered to continue with his 12-step program. On December 20, 2013, MTP notified the Board that respondent had canceled an appointment set for October 4, 2013, and failed to reschedule. This is a violation of the Examining Committee order. Failing to comply with the Examining Committee order resulted in the Board immediately and summarily suspending respondent's registration to practice as a pharmacist in New Mexico until further order of the Board.

Mark Shortencarier, RPh – License #RP-5166. Respondent plead no contest to allegation that a prescription for doxycycline was incorrectly filled with doxepin and dispensed to a customer. Respondent must pay $1,000 fine and $250 investigative costs. Respondent must complete a continuing education course in the subject area of preventing medication errors. Respondent is on probation for one year.

Joshua R. Smith – Pharmacist Applicant. Respondent had previous Board action. In a Stipulation of Licensure agreement signed by the Board on February 12, 2014, respondent's application for a pharmacist license shall be granted. Respondent agrees to complete his contract with MTP. Respondent is on probation for five years. Respondent must notify employers of this agreement for a three-year period.

Gretchen Steininger, DVM – License #CS00214671. Respondent voluntarily surrendered her CS registration. Respondent must pay investigative costs of $100.

Andrew Wood, RPh – License #RP00007743. Respondent plead no contest to improperly supervising a pharmacy technician. Respondent allowed technician to perform outside the technician's scope of practice. Respondent did this by letting technician provide patient consultations, take or review medical histories, order or receive laboratory results, and make drug therapy recommendations. Respondent's pharmacist registration was suspended for 30 days. Respondent must pay investigative costs of $400. Respondent must take and pass the Multistate Pharmacy Jurisprudence Examination®. After completing the suspension period, respondent shall be placed on probation for a period of six months.

Regulation Change – Compounded Sterile Preparations

During the April 24-25, 2014 Board meeting, changes were approved regarding the regulation concerning compounded sterile preparations. The previously-approved regulations were found in 16.19.6 NMAC – Pharmacies. The portion of this regulation concerning compounded sterile preparations was repealed and moved to a new regulation. The new regulation is **16.19.36 NMAC – Compounded Sterile Preparations.**

Also during the April Board meeting, a public hearing was held to review the proposed new rule **16.19.36 NMAC – Compounded Sterile Preparations.** The new rule was developed and submitted by the Sterile Preparations Committee (SPC), which serves as an advisory group to the Board. The primary goal of the SPC was to establish standards pursuant to those of United States Pharmacopeia to ensure that New Mexico citizens receive properly compounded, contaminant-free sterile preparations. SPC members present at the hearing fielded questions about the proposed rule from the public as well as from Board members and Board staff. The Board unanimously passed the new rule with directions to the SPC members to expand and clarify **16.19.36.13 NMAC Requirements for Training** and **16.19.36.15 NMAC Quality Assurance of Compounded Sterile Preparations** at a subsequent Board meeting. Please visit the Board website to review the current Compounded Sterile Preparations regulation.

The *New Mexico Board of Pharmacy News* is published by the New Mexico Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote 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 NABPF or the Board unless expressly so stated.

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