November 2016

Utah Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 146741 • Salt Lake City, UT 84114-6741
www.dopl.utah.gov/licensing/pharmacy.html

Pharmacy Mailbag: Responses to Board Questions From the April 2016 Utah Pharmacy Association Convention

1. What information must be on the face of a prescription?

- From the July 28, 2015 Utah Board of Pharmacy meeting minutes (page 8):

  > The Board reviewed a concern regarding the information required on a hard copy of a prescription. The Board felt that putting a tag or sticker on the back of a prescription has not been a problem in [the] past. The Board may consider clarifying existing rule if a problem arises in the future . . . [A] motion for the [Utah Division of Occupational and Professional Licensing] inspectors to accept the back tag on a prescription [was made, seconded, and passed unanimously].

- However, Drug Enforcement Administration (DEA) does require the provider's DEA number to be on the face of the prescription: "The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number." (United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. Pharmacist's manual: an informational outline of the Controlled Substances Act. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf. Accessed October 5, 2016.)

- The following was also discussed at the May 24, 2011 Board meeting (page 4 of the minutes):

  > [A Board member] also reported [that] the DEA is going to become very stringent on Schedule II narcotics and if the DEA number is not on the prescription, the prescription will not be accepted. If the prescriber does not write the DEA number on the prescription, the pharmacist will need to. The DEA will no longer accept a second label, the DEA number has to be on the actual prescription.

2. Can a prescription continue to be filled or refilled once the prescriber is deceased?

- From the January 24, 2012 Board meeting minutes (pages 4-5):

  > [An email was received regarding] what happens to the prescription if it was written before the death of the prescribing practitioner. Board members agree that if the prescription was written by an appropriate practitioner with a valid license, the prescription is valid until the prescription expires. The provider makes a clinical judgment at the time the prescription is written and the prescription should remain valid for whatever length of time the practitioner determines.

3. What about partial Schedule II prescriptions?

- From the August 24, 2010 Board meeting minutes (pages 2-3):

  > [A Board member] had a question regarding splitting prescriptions. This issue was in regards to a patient who comes into the pharmacy, the insurance won't pay for the full prescription, the prescribing practitioner does not know if the insurance will pay for it, but the prescribing practitioner wants the prescription dispensed as written. It was reported that the DEA provided clarification that a controlled substance prescription [Schedule II] could not be split.

- Recent federal legislation (S 524 – Comprehensive Addiction and Recovery Act of 2016, Section 702) signed into law on July 22, 2016, broadened the time period for partially filling Schedule II controlled substances (CS) from 72 hours to "not later than 30 days after the date on which the prescription is written."

continued on page 4

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropr iate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.

(2) Know which medicines contain acetaminophen.

(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy*, or contact CompAssess@nabp.pharmacy.

continued from page 1

- This change has **not** been updated in Title 21 Code of Federal Regulations (CFR) Part 1306.13 on DEA's website at the time of this article's submission (*https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_13.htm;* accessed October 15, 2016). The Utah Attorney General's Office is currently reviewing the Utah laws and rules to determine if new legislation or rule writing needs to take place in Utah to implement and/or conform with the new federal statute. Stay tuned for more information on this subject.

4. Can we or can we not make changes to a Schedule II CS prescription?

- A law presentation at the Utah Pharmacy Association ("Did You Know? Utah Pharmacy Law Update 2008," St George, UT, April 19, 2008) described the items that could and could not be changed on a Schedule II prescription, which was extracted from DEA's website at the time.
- The 2010 DEA *Pharmacist's Manual* is silent on this issue.
- An April 27, 2010 document, which was posted on the Utah Division of Occupational and Professional Licensing website and mailed to all pharmacists, delineated the items that could and could not be changed.
- From the February 18, 2014 Board meeting minutes (page 5):

  > [The Bureau manager] advised the Board that there needs to be further research regarding the extent that pharmacists may modify prescriptions. This discussion was tabled for a future Board meeting. [The Bureau manager] stated he will obtain a copy of a letter addressing the issue that was mailed to pharmacists in 2010.

- From the January 20, 2015 Board meeting minutes (page 4):

  > [The Bureau manager] stated that he will reach out to the DEA again for clarification regarding changes that a pharmacy may make to controlled substance prescriptions [Schedule II]. **Until there is clarification, pharmacies should continue current practice.** (emphasis added)

- In a discussion with the Salt Lake City, UT DEA office on October 19, 2016, the agency confirmed that DEA has not further clarified this issue and the DEA website does not have any frequently asked questions relating to the changing of Schedule II CS prescriptions.
- At this point, pharmacists should follow their best judgment, original DEA guidance, and recent Division recommendations.

Compounding Task Force

The US Food and Drug Administration (FDA) announced that it issued a final rule, "Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness." The final rule amends the list of drugs appearing in Title 21 CFR Section 216.24 that cannot be compounded under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act because they have been withdrawn or removed from the market for safety or effectiveness reasons.

Below is a list of other draft guidance documents associated with the Drug Quality and Security Act and their particular release dates. They were recently introduced by FDA, closed for public comment on October 3, and should be reviewed by compounding facilities:

- Insanitary Conditions at Compounding Facilities Guidance for Industry (PDF – 95 KB) – August 3, 2016
- Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (PDF – 108 KB) – July 7, 2016
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (PDF – 348 KB) – July 7, 2016

CriticalPoint, LLC, created a link on its website for monthly sterile compounding pearls of knowledge under the Tools & Resources bar. The most recent (October) edition concerning master formulation records and compounding records can be found at *https://www.criticalpoint.info/sterile-compounding-pearls-of-knowledge-october-2016-edition.*

Compounding tip of the quarter: Division investigators and inspectors would like to encourage pharmacies to label components that do not have expiration dates assigned by the manufacturer or supplier with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt. This is in line and meets compliance with United States Pharmacopeia Chapter <795>.

The *Utah Board of Pharmacy News* is published by the Utah 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, the State of Utah, or the Board unless expressly so stated.

Utah Board of Pharmacy - State Newsletter Editor
doplbureau3@utah.gov
www.dopl.utah.gov/licensing/pharmacy.html
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager