December 2016

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *https://pharmacy.ks.gov*

Guidelines on Receiving Faxed Schedule III-V Controlled Substance Prescriptions

At a recent gathering of pharmacists, there was an inquiry regarding the receipt by facsimile of an electronically sent prescription for a controlled substance (CS). The following information is provided for purposes of clarification. There are no changes to the current statutes and regulations regarding this issue.

Regarding transmission of prescription drug orders, K.S.A. 65-1637b(c)(1) indicates that for non-CS, new written or electronically prepared and transmitted prescription orders shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the first and last names of the transmitting agent shall be included in the order. Section (c)(2) of the same statute provides that if the prescription is for a **CS** and is handwritten or printed from an electronic prescription application, the prescription shall be **manually** signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy. Also, K.A.R. 68-20-18 notes that all written prescriptions for CS must be dated and manually signed on the date issued.

Therefore, if the pharmacy receives a faxed prescription for a CS that is only digitally or electronically signed, the prescription is not valid. To validate the prescription, the pharmacist has two options:

(1) Call the physician's office to confirm the faxed prescription received and document on the fax the date, time, and person confirming the fax. After documentation, the original fax can serve as the hard copy of the prescription.

(2) After calling the physician's office and confirming the fax, the pharmacist can rewrite the prescription with proper documentation, treating the transaction in the same manner as a phoned-in prescription.

In the case of a Schedule II prescription, receipt by facsimile is not a valid prescription. The pharmacist can prepare the prescription based on the prescriber's fax, but may only dispense the Schedule II prescription when the customer presents the manually signed hard copy.

Who Is Responsible for an Expired Pharmacy Technician?

The Kansas State Board of Pharmacy just completed renewals for the pharmacy technician group expiring October 31, 2016. Effective November 1, those technicians who did not timely renew their registrations have expired status and are not authorized to work as pharmacy technicians in Kansas. The Board holds the pharmacist-in-charge (PIC) responsible for ensuring all individuals working in the pharmacy have current, active registration/licensure status. If you are the PIC, have you checked the expiration dates on the wall lately? If not, now is the time! Make sure your pharmacy technicians all have a current registration. Failure to do so may result in disciplinary action against the PIC's pharmacist license and potentially against the pharmacy.

Any pharmacy technician who failed to renew and wants to continue providing pharmacy technician services in Kansas will be required to submit a completed pharmacy technician application, fingerprint card, and $67 application fee.

K-TRACS Reminder for Zero Reporting

In a recent audit of Kansas Tracking and Reporting of Controlled Substances (K-TRACS) reporting for resident and nonresident pharmacies registered in Kansas, it was noted that several pharmacies were marked as delinquent for failing to file a zero report. As a reminder, K.A.R. 68-21-2 states a zero report shall be filed with the Board. The regulation requires each zero report cover no more than a seven-day period, in which no CS or drugs of concern were dispensed. If you are having difficulty submitting the zero report, please contact the K-TRACS Clearinghouse Help Desk at 855/544-4767.

FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

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 appropriate 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 Item Writer Volunteer Interest Form available at 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.

Guidelines for Facilities Moving to a New Location

With implementation of its new licensing software, the Board staff has updated its processes for facilities moving from one location to another (with no ownership change). These updates specifically apply to pharmacies, durable medical equipment providers, manufacturers, distributors, nonprescription distributors, and institutional drug rooms. When a facility is moving from its currently registered location to a new location, it is actually closing one facility and opening a brand new facility. That is why the Board requests the appropriate original application form be completed in total, which is located on the Board website at *www.pharmacy.ks.gov/resources-consumer-info/forms*. By selecting the change in address option (without any ownership change), the Board staff is alerted to the facility move and a series of important review steps are triggered. However, the registered facility number will be retained. This allows the facility inspection, operation, and disciplinary history to remain intact.

The application also asks for the "effective date of change," which should reflect the planned opening date for the new facility, ie, the date the new location will begin operating or dispensing. In order to be considered a "change," the old facility location must cease dispensing or operating prior to the effective date. Generally, the application should not reflect an effective date that is more than 60 days in the future.

One of the processing steps involves a Board inspector conducting a pre-opening inspection and checking that the old and new facilities will not be operating simultaneously. This inspection **must** be conducted prior to the planned opening date or the facility registration may not be approved by the Board. In order to ensure that a pre-opening inspection is timely conducted in association with the planned opening date for the new location, the application must be filed with the Board early enough to allow proper review of the application and sufficient time for scheduling and conducting the inspection prior to the planned opening date.

Failure to timely submit an application for a facility change of address could result in a delay in issuing the facility registration, which means the facility cannot open, operate, or dispense until that time. Issue dates for new registrations cannot be backdated or issued retroactively. In extreme cases, failure to submit an application prior to the opening/effective date or a facility opening/operating the new location without obtaining approval by the Board may result in disciplinary action, including, but not limited to, fines or denial of a facility registration.

If the facility needs verification for the new facility location for notification purposes, the Board is unable to issue an official license verification until the effective date of the new registration. However, the Board is able to provide written documentation of approval once the new facility has passed its pre-opening inspection and all other application review steps. The Board does not currently generate reports resulting from the pre-opening inspection and, therefore, cannot provide a copy of any such report.

Staff Additions

This past September, the Board was pleased to have Ashley Riley join the full-time staff as a senior administrative specialist in the licensing division, after serving for the past two years as a part-time administrative assistant. Ashley is from Topeka, KS, and has a degree in business administration from Washburn University. Her main duties include licensing facilities and the registration of pharmacy technicians and interns for Kansas. Ashley has learned so much about the Board and enjoys her work!

Upcoming Events

January 6, 2017
Board of Pharmacy Quarterly Meeting
Curtis State Office Building, 5th Floor Board Room
1000 SW Jackson, Topeka

February 17, 2017
Prescription Monitoring Program Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

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