March 2014

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

What Changes May a Pharmacist Make to a Prescription Written for a Schedule II Controlled Substance?

During the past few years, Drug Enforcement Administration (DEA) had provided guidance on what a pharmacist should do when he or she is provided with a prescription that has missing information. K.A.R. 68-20-18 states, "to be effective, a prescription for a controlled substance shall be issued for a legitimate medical purpose by a practitioner or mid-level practitoner acting in the usual course of professional practice. The responsibility for proper prescribing and dispensing of controlled substances shall rest with the prescriber, but a corresponding responsibility shall rest with the pharmacist who fills the prescription." The regulation further states that all controlled substance (CS) prescriptions shall be dated and signed on the day issued and bear the following information: (1) the full name, address, and registration number of the practitioner or mid-level practitioner; (2) the name and address of the patient; and (3) the drug name, strength, dosage form, quantity prescribed, and directions for use.

In a policy letter dated October 15, 2008, DEA instructed pharmacists to adhere to state regulations or policy regarding those changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

The Kansas State Board of Pharmacy previously issued a policy that stated it was in the best interest of the patient to permit a pharmacist to add the date if it is not indicated and to change the drug strength, quantity, and directions for use after consultation with the prescriber. The pharmacist may also add the patient's address, the prescriber's DEA number, and select a dosage form if one is not indicated. The pharmacist must document with his or her initials the time and date that the prescriber or prescriber's agent was contacted. Remind the prescriber to document the changes in the patient's chart. The Board and DEA expect a pharmacist to use his or her professional judgment and knowledge of state laws and policies when determining whether it is appropriate to make changes to a prescription.

HIPDB

The Health Insurance Portability and Accountability Act of 1996 established the Healthcare Integrity and Protection Data Bank (HIPDB), a national health care fraud and abuse data collection program. All state health licensing agencies are required to report disciplinary actions imposed on their licensees. These actions include any loss of a license – or the right to apply for, or renew a license – whether by operation of law, voluntary surrender, or nonrenewal (excluding those due to non-payment of licensure renewal fees, retirement, or change to inactive status). After HIPDB receives a report from the Kansas Board it will send a copy of the report to the licensee. The licensee is then given an opportunity to respond to the report. The subject of the report should review the report for accuracy, including such information as current address and place of employment.

Help Is Available

Do you know a pharmacist who may be depressed, drinking alcohol in more than moderate amounts, abusing drugs, has a physical or mental impairment, or is not practicing pharmacy in a manner that is in the public's interest? If you do, please give the Kansas Pharmacists Association's Kansas Pharmacists Recovery Network (KsPRN) an opportunity to help. All calls are kept strictly confidential. For information, call KsPRN at 785/217-7091.

2014 Board Meeting Dates

Following are the meeting dates and locations of the Board meetings for 2014:

- April 24 and 25, 2014, Topeka, KS – Kansas State Board of Healing Arts, Board Room
- July 24 and 25, 2014, Topeka – Kansas State Board of Healing Arts, Board Room
- October 16 and 17, 2014, Wichita, KS – Via Christi Hospital, Conference Room A

Fee Reduction Regulations

The Board has scheduled a public hearing on April 24, 2014, at 9 AM at the regularly scheduled Board meeting related to fees. The Board has proposed amending K.A.R. 68-11-1 and K.A.R. 11-2, which would reduce all license, registration, and permit fees by 20%. This change will permit the Board to reduce the balance of its fee fund. These funds are used for the daily operations of the Board office and for staff salaries. Interested parties who wish to make comments can appear in person at the Board meeting or may submit written comments via e-mail to pharmacy@pharmacy.ks.gov.

K-TRACS Regulations

The Board has scheduled a public hearing to amend two Kansas Tracking and Reporting of Controlled Substances (K-TRACS) regulations at the regularly scheduled Board meeting

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 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.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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on April 24, 2014, at 9 AM. The amendment is to K.A.R. 68-21-1, which changes the definition of patient identification number to include a patient's unexpired temporary or permanent driver's license number or state-issued identification card number. If the patient does not have one of those numbers, the dispenser shall use the patient's insurance identification number. If the patient does not have an insurance identification number, the dispenser shall use the patient's first, middle, and last initials followed by the patient's eight-digit birth date.

The regulations also amend the definition of zero report to mean an electronic data submission reflecting no dispensing activity for a given period.

K.A.R. 68-21-2 has been amended to require each zero report to cover not more than a seven-day period in which no drugs were dispensed, and to be filed on the day following the end of the period covered by the zero report.

Both of these regulations can be reviewed in their entirety on the Board web page at *www.pharmacy.ks.gov;* under Highlights of Changes, click State Law Changes. Any person may appear at the Board meeting to make comments regarding the adoption of these regulations. Any person may also make written comments by sending them electronically to pharmacy@pharmacy.ks.gov.

K-TRACS Prescription Drug Monitoring Update

The goal of K-TRACS is to improve the monitoring of CS and to reduce the incidence of patients who utilize multiple pharmacies and multiple prescribers to obtain CS in Kansas. If you or your staff have not signed up to request data, visit the Board web page at *https://Kansas.pmpaware.net/login* (online registration link). If you have used K-TRACS previously, just click on "I forgot my password" and enter your e-mail address. Follow the instructions e-mailed back to you to reset your password. Go back to *https://Kansas.pmpaware.net/login* and log in. If you have any difficulty with this process, contact the help desk at 855/544-4767. The hours of operation are 24/7.

Pharmacists Renewal and Continuing Education

Renewal notices are going to be sent out late April reminding even-numbered pharmacist licenses, pharmacies, distributors, and other businesses that renewals will be open online May 15, 2014. The Board's web page is found at *www.pharmacy.ks.gov.* All licenses and permits expire on June 30, 2014, but there is a 30-day grace period that will not result in a late fee. Any renewals received after July 31, will result in a late fee. Pharmacists-in-charge need to be checking the licensure status of pharmacists to ensure that no unlicensed person is performing pharmacy functions.

No continuing education (CE) records are to be provided to the Board at this time. The renewal asks whether you are current for the biennial year, and that has been interpreted to mean that you must have 30 hours of CE by June 30, 2014. The Board will not accept CE hours that are obtained during or after July. A random CE audit will be performed in September 2014. Be sure to check your CPE Monitor® activity records at *www.MyCPEmonitor.net* by logging in with your e-Profile ID for Accreditation Council for Pharmacy Education-accredited CE completed in 2013 and 2014 before completing your renewal to make sure that you are current on your CE. The Board holds licensees accountable if they do not have the correct number of hours.

Patient Counseling

The Board has been receiving more complaints and comments about the lack of counseling in pharmacies. If a patient asks why his or her medication looks different, it would behoove the pharmacist to check the drug again and not make an assumption that it was a change of the manufacturer. This is a great opportunity to catch any errors before the patient leaves the pharmacy. K.A.R. 68-2-20 requires a pharmacist to personally offer to counsel each patient or the patient's agent with each new prescription dispensed, once yearly on maintenance medications, and, if the pharmacist deems appropriate, with prescription refills. Every Schedule II prescription is a new prescription and the law applies that the pharmacist shall make the offer to counsel. Some pharmacies have computerized signature logs that ask, "Do you have questions for the pharmacists?" and some pharmacists have the intern, pharmacy technician, or sales clerk make the inquiry. This does not meet the requirements of the regulation. The law clearly states that it is the pharmacist's responsibility to personally talk to the patient. This cannot be delegated.

The patient should not be expected to understand the importance of counseling. Not only does counseling increase compliance but it can reduce errors and prevent misuse of the drug by the patient. The patient needs to be verbally advised about what the medication is supposed to do. He or she needs to know exactly how long to take the medication and what to do if he or she forgets to take his or her medicine. He or she needs to know what the side effects are and what to do if they occur. Counseling shows the patient that you care and it provides an opportunity to prevent problems. The Board has seen an increase in medication errors that would have been prevented if the pharmacist had taken the time to counsel the patient and to look once more at the medication that is being dispensed.

Useful Contact Information

Kansas State Board of Pharmacy.....785/296-4056
1-888/792-6273

K-TRACS.....785/296-6547

Kansas State Board of Healing Arts.....785/296-7413
1-888/886-7205

Kansas Dental Board.....785/296-6400

Kansas State Board of Nursing.....785/296-4929

Kansas Board of Examiners in Optometry.....785/832-9986

DEA (Kansas City).....913/825-4200

Food and Drug Administration, Center for Drug Evaluation and Research.....1-855/543-3784

Kansas Pharmacists Association.....785/228-2327

Kansas Council of Health-System Pharmacists.....785/271-0208

KsPRN.....785/217-7091

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