June 2010 News



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Disciplinary Actions

Kimberly Richardson, Pharmacy Technician, Registration No. 14-05545. Registration revoked for diversion of controlled substances from her employer.

Carol Toth-Bejan, Pharmacy Technician, Registration No. 14-05541. Registration revoked for diversion of controlled substances from her employer.

Diane Wasinger, RPh, Pharmacist, License No. 1-11386. Pharmacist license revoked based on revocation of license out of Missouri.

Changes to a Schedule II Prescription

The Kansas State Board of Pharmacy and Drug Enforcement Administration (DEA) have "Frequently Asked Questions" on their Web pages to assist medical care professionals. There was much confusion recently when DEA changed its position on an interpretation of the law related to what changes can be made to a Schedule II prescription. Specifically, the Kansas State Board of Pharmacy and DEA previously permitted certain changes to Schedule II prescriptions after consulting with the prescriber. The pharmacist was never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution as permitted by Kansas law), or the prescriber's signature. Recently, DEA advised the Kansas State Board of Pharmacy that it would no longer permit a pharmacist to make any changes to a Schedule II prescription. We put this information out to all pharmacies because DEA could fine the pharmacy for a practice that was previously permitted. After much discussion with DEA it has determined that a pharmacist must adhere to state regulations or policy regarding changes made to a Schedule II prescription after oral consultation with a prescriber.

Kansas Policy: Four (4) items on a Schedule II prescription **may not be changed.** They are the name of the patient, name of the drug (except for generic substitution), name of the prescriber, and the date of the prescription.

The Kansas Board has determined that it is in the best interest of the patient to allow a pharmacist to add the patient's

address, the prescriber's DEA number, and to select a dosage form if not indicated. These items must be on the front of the prescription. The following additions or changes may be made after oral consultation from the prescriber: add a date if not indicated on the prescription, change the drug strength, drug quantity, and the directions for use. The pharmacist should always document with his or her initials the time and date that the prescriber or the prescriber's agent was contacted and remind the prescriber to document the changes in the patient's chart. All Schedule II prescriptions shall be manually signed by the prescriber. Nothing else on the prescription is required to be in the prescriber's own handwriting. We apologize for any confusion this issue may have created. We appreciate the physicians' and pharmacists' patience as we worked with DEA to come to an agreeable solution.

Faxing a Schedule II Prescription

A prescription for a Schedule II narcotic substance for a patient enrolled in a program certified and/or paid for by Medicare under Title XVIII or a hospice program with the state may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy facsimile machine. The faxed prescription stands as the original prescription. The purpose of permitting an exception for hospice patients was to make every reasonable effort to ensure that the patient's pain is controlled. The prescription must be manually signed by the prescriber.

A faxed prescription for a Schedule II prescription may also serve as the original for patients in a long-term care facility, an assisted living facility, or for a patient receiving home infusion/IV pain management therapy. The fax must be signed by the prescriber.

Pharmacy Drug Disposal Programs

The Kansas State Board of Pharmacy has received requests that Kansas explore an initiative to safely dispose of unused patient medications that do not meet the requirements of the Unused Medication Donation Program. The Board recognizes

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NABP

Celebrating
30 Years of
Pharmacy
News

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National Pharmacy

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JCPP 'Future Vision' Sets Course for Advancement of Pharmacy Practice

The Joint Commission of Pharmacy Practitioners (JCPP) brings together the chief executive and chief elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice. Established in 1977, the JCPP meets quarterly and forms workgroups that focus on priority projects. The JCPP has facilitated strategic planning efforts that have shaped positive change in the practice of pharmacy for more than 30 years, and will continue to influence pharmacy practice through its vision articulated in "Future Vision of Pharmacy Practice."

Past Impact

Recommendations resulting from JCPP conferences and quarterly meetings have been aimed to ensure public health and safety by optimizing the medication use process. Working collaboratively through the JCPP, leaders in the profession "acknowledged that the focus of pharmacy must move beyond the important but narrow aspect of 'right drug to the right patient' and encompass the responsibility for assuring that appropriate outcomes are achieved when medications are part of a patient's individual treatment plan." This perception of the function and responsibility of pharmacy practice helped to facilitate changes such as the shift to a universal doctoral level of education, and practice and legal changes that have helped pharmacists to increase their scope of services.

Also as a result of JCPP collaborations, coalitions among pharmacy organizations and other stakeholders have been formed, and have helped to shape new state and national legislation and regulations. For example, JCPP coalitions helped influence changes that resulted in Medicare's prescription drug benefit requirement for medication therapy management services as of 2006.

Future Impact

Through the "Future Vision of Pharmacy Practice," adopted by JCPP member organization executive officers in 2004, the JCPP will continue to influence positive change in the practice well into the next decade. The JCPP "Future Vision of Pharmacy Practice," endorsed by each JCPP member organization's board of directors, envisions what pharmacy practice should look like in 2015, as summarized in the document's opening statement: "Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

In his incoming speech at the NABP 105th Annual Meeting in May 2009, President Gary A. Schnabel, RN, RPh, endorsed the future vision outlined in the JCPP "Future Vision of Pharmacy Practice," stating, "As boards of pharmacy, I feel that it is also imperative for us to embrace this future vision, and through our statutes and regulations define and advance that vision in the context of patient care and protection of the public health . . . If the boards of pharmacy can provide the regulatory environment that fosters the vision on behalf of the patient and the protection of the public health, then this collective vision of practitioners and regulators will serve as one of the pillars of a new foundation for the practice of pharmacy first proposed some 30 years ago and discussed ad nauseam every year since those words were first spoken and captured in the pharmacy journals."

The 2015 future vision is detailed in the document in three sections: the foundations of pharmacy practice, how pharmacists will practice, and how pharmacy practice will benefit society. The first section outlines the foundations of pharmacy education that prepares pharmacists

"to provide patient-centered and population-based care that optimizes medication therapy." The second section explains that the pharmacist's scope is to include managing medication therapy, accounting for patients' therapeutic outcomes, and promoting patient wellness. The section also emphasizes that as they work with other health care professionals, pharmacists will be the most trusted source of medications and supplies, and the primary resource for advice regarding medication use. Finally, the last section stresses that, by realizing the expanded scope of their practice, pharmacists will achieve public recognition as practitioners who are essential to providing effective health care.

In January 2008, the JCPP released the final version of "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice," which identifies three critical areas for initial focus as it works toward achieving the vision. JCPP anticipates more discussions to help align the action steps of the implementation plan and the policies of participating organizations. Thus, in keeping with the organization's mission, JCPP continues to implement its initiatives, including the "Future Vision of Pharmacy Practice," through the collaborative efforts it fosters.

The JCPP's "Future Vision of Pharmacy Practice" and "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice" can be downloaded from the National Alliance of State Pharmacy Associations' Web site at www.naspa.us/vision.html.

ISMP Stresses Need to Remove Non-Metric Measurements on Prescriptions and on Patient Labels to Prevent Error



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 a 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.

ISMP is calling upon prescribers, pharmacists, and other health care professionals, as well as pharmacy computer system and e-prescribing system vendors, to remove or prevent the use of "teaspoonful" and other non-metric measurements in prescription directions in order to better protect patients.

In the past, mix-ups involving confusion between measuring medications in milliliters or teaspoonfuls and other non-metric measurements have resulted in the serious injury of children and adults.

These mistakes continue to happen. ISMP has received more than 30 reports of milliliter-teaspoonful mix-ups, including cases where injuries required treatment or hospitalization. In one case, a child who recently had surgery was seen in an emergency department and later was admitted with respiratory distress following an unintentional overdose of acetaminophen and codeine liquid. The pharmacy-generated label on the child's medication bottle instructed the parents to give the child six

Compliance News

pliance News to a particular state or jurisdiction should not be assumed ing the law of such state or jurisdiction.)







teaspoonfuls of liquid every four hours. The original prescriber stated the prescription was for 6 mL. The child received five doses before arriving at the emergency department.

In a second case, a child received an overdose of the antifungal medication Diflucan® (fluconazole) suspension. The physician phoned a prescription for Diflucan 25 mg/day to a community pharmacy for a three-month-old child with thrush. The pharmacist dispensed Diflucan 10 mg/mL. The directions read "Give 2.5 teaspoons daily." The directions should have read "Give 2.5 mL daily." Prior to the error, the child had been ill for the previous three weeks with an upper respiratory infection, nausea, vomiting, and diarrhea. It is suspected that the child's subsequent hospitalization was related to this error.

ISMP Safe Practice Recommendations

The health care industry – including practitioners and computer vendors – needs to acknowledge the risk of confusion when using nonmetric measurements, especially with oral liquid medications. Steps, like the following ISMP recommendations, must be taken to prevent errors:

- Cease use of patient instructions that use "teaspoonful" and other non-metric measurements, including any listed in pharmacy computer systems. This should include mnemonics, speed codes, or any defaults used to generate prescriptions and labels.
- Express doses for oral liquids using only metric weight or volume (eg, mg or mL) – never household measures, which also measure volume inaccurately.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach, and ask patients or caregivers to demonstrate their understanding.

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy's (Model Act) labeling provisions state that the directions of use language should be simplified, and when applicable, to use numeric instead of alphabetic characters such as 5 mL instead of five mL. The Model Act also provides for the pharmacist to personally initiate counseling for all new prescriptions, which can decrease patient injuries due to improper dosing.

Clarification on HIPAA Regulations and Claims Submission

NABP received questions about a statement that appeared in the article, "Concerns with Patients' Use of More than One Pharmacy," published in the 2009 fourth quarter *National Pharmacy Compliance News* which read, "Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient."

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.501) establishes a foundation of federal protection for personal health information with which health care practitioners must comply. To avoid interfering with a patient's access to, or the efficient payment of quality health care, the privacy rule permits a covered entity, such as a pharmacy, to use and disclose protected health information, with certain limits and protections, for treatment, payment, and health care operations activities. The rule includes the determination of eligibility or coverage and utilization review activities as examples of common payment activities, therefore allowing a pharmacist to submit cash claims. Additional information may be found at www.hhs.gov/ocr/

privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo

Pharmacists should, however, verify with their state boards of pharmacy as to whether there are existing state laws that prohibit this practice.

State Newsletter Program Celebrates 30 Years of News on Pharmacy Regulation

This year, the NABP State Newsletter Program celebrates its 30th anniversary of partnering with the boards of pharmacy to provide pharmacists with vital information about their state's pharmacy laws and regulations.

The State Newsletter Program, which is part of the NABP Foundation, was developed to support the Association's educational programs and research and development projects. Published on a quarterly basis, the program serves the state boards of pharmacy by communicating board information to pharmacists, pharmacy technicians, pharmacies, and others throughout the pharmacy profession.

The goal of the State Newsletter Program was, to improve communications with practitioners regarding federal and state law, this allowing them to comply with the law on a voluntary basis, demonstrating that an informed and responsible professional is one of the most effective means of protecting the public health.

In addition to the news provided by the boards of pharmacy, a copy of the *National Pharmacy Compliance News* is included in each issue. Published quarterly by NABP, *National Pharmacy Compliance News* provides important news and alerts from the federal Food and Drug Administration, Drug Enforcement Administration, the Centers for Medicare and Medicaid Services, Consumer Product Safety Commission, and ISMP, as well as current national developments affecting pharmacy practice.

Using *National Pharmacy Compliance News*, merged with locally developed state news, a total of 16 states joined the program in its original summer 1979 publication, including 13 states that still participate today: Arizona, Arkansas, Delaware, Idaho, Kansas, Kentucky, Montana, Minnesota, North Carolina, Ohio, Oregon, South Carolina, and Washington.

Today, 31 states participate in the program. Of these, 18 state boards of pharmacy publish electronic newsletters rather than printed newsletters. The e-newsletter option was implemented in 2004, and has allowed boards with limited resources the opportunity to communicate important board information in a timely and cost-effective manner. State e-newsletters are posted on the NABP Web site rather than published by a printer; the board may also post the Newsletter to their Web site.

In 2006, the e-newsletter portion of the program was enhanced and NABP began offering the boards an e-mail alert service. The e-newsletter e-mail alert service, which consists of an e-mail notification that is sent through a state-specific e-mail database, is provided free of charge to participating state boards of pharmacy. Each alert notifies recipients that the e-newsletter is now available to download and provides a link to access the board's newsletter. The Arizona State Board of Pharmacy was the first state to utilize this free service, and now the number of participating boards has grown to 12 states.

All NABP Foundation State Newsletters, including a copy of the *National Pharmacy Compliance News*, are available on the NABP Web site at *www.nabp.net*. Please note, years prior to 2000 are only available in hard copy form, and therefore, cannot be downloaded online. For more information about the NABP State Newsletter Program, contact custserv@ nabp.net.

that pharmacists are in a position to ensure the safe and proper handling of medications from dispensing to disposal. However, DEA does not permit a pharmacy to acquire controlled substances from a non-registrant or a patient. Further, Kansas law has no provision that will permit a pharmacy to accept returns other than unit dose packaged medications from a nursing home returned for credit. The Office of National Drug Control Policy has issued guidelines for the proper disposal of unused, unneeded, or expired prescription drugs. The guidelines urge patients to:

- ◆ Take unused, unneeded, or expired prescription drugs out of their original containers.
- ♦ Mix the prescription drugs with undesirable substances, such as used coffee grounds or kitty litter, and put them in an impermeable, nondescript container, such as empty coffee cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children or pets.
- ♦ Throw these containers in the trash.
- ◆ Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so.

These guidelines are offered as a solution to consumers for the disposal of unused medications until such time when the Kansas State Board of Pharmacy can propose a safe and effective regulatory system for licensed pharmacies in Kansas.

What to Do When the Doctor Passes Away, Retires, or Relocates Practice

How do you handle refill requests when a prescriber passes away, retires, or relocates his or her practice? The Kansas State Board of Pharmacy and the Kansas State Board of Healing Arts have no specific regulations pertaining to the number of refills allowed under these circumstances. However, K.A.R. 68-2-20 does require the pharmacist to make reasonable efforts to determine that there is a legitimate medical purpose for the prescription. A legitimate medical purpose in regard to the dispensing of prescription drugs shall mean that the prescription was issued with a valid preexisting patient-prescriber relationship.

The following response to the issue was provided by the Office of Drugs, the National Center for Drugs, and the Biologics, Food and Drug Administration.

It is well established that a prescription by a practitioner given to a patient signifies generally that a physician/patient relationship exists. This relationship also connotes that during the life of that prescription; the patient is under the practitioner's professional care and includes the number of authorized refills. It is our opinion that once a physician/patient relationship is broken, the prescription loses its validity since the physician is no longer available to treat the patient and over see his or her use of the prescribed drug(s).

The Kansas State Board of Pharmacy recommends that if the pharmacist is aware of the situation, the pharmacist should counsel the patient to seek a new physician immediately. Since there is no longer a patient/care provider relationship, the refills become invalid. A refill of one time is acceptable to allow the patient time to find a new care provider. This would also occur if the provider moves out of the area and the patient is no longer seeing the prescriber.

New Pharmacy Regulations

The Board of Pharmacy voted to approve and adopt institutional drug room regulations. They can be found at K.A.R. 68-7-21 at www.kansas.gov/pharmacy under the link for Kansas Pharmacy and Related Laws. The regulation institutes requirements for the storage, record keeping, and control of drugs maintained by an institutional drug room. Each institutional drug room shall also be required to maintain incident reports and a policy and procedure manual.

The Board also voted to amend the regulation related to continuing education. Pharmacists may obtain continuing education that is Accreditation Council for Pharmacy Education (ACPE)-approved or up to eight hours of non-ACPE approved continuing education. If the continuing education is not ACPE-approved, the provider must request Board approval at least 120 days prior to the continuing education presentation.

Lastly, the Board amended 68-20-10a, authorizing an assisted living facility to fax a Schedule II prescription to the pharmacy. The Schedule II prescription fax will be treated as the original. The fax must be signed manually by the prescriber.

Special Notice About the Kansas State Board of Pharmacy Newsletter

The Kansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify licensees and registrants about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* can be used in hearings as proof of notification of the *Newsletter's* contents.

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