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Kansas State Board of Pharmacy News

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Announcements

- Updated Kansas statutes and regulations concerning the practice of pharmacy are now available in searchable, electronic format in the "Legal" section of the Kansas State Board of Pharmacy website at *http://www.pharmacy.ks.gov/statutes-regs/statutes-regs.*
- Coming soon to the Board website: an index of Board *Newsletters* containing the subject matter, issue number, date, and location of previous articles that licensees might want to reference or review.
- Drug Enforcement Administration (DEA) makes the following website available for pharmacies to verify DEA registrations: *https:///www.deadiversion.usdoj.gov/webforms/validateLogin.jsp.* Searches require a login using the pharmacy's DEA number and federal employer identification number.

Epinephrine Auto-Injector Generic Exchanges

Epinephrine auto-injectors have recently come under fire for the high price tag attached to them. They come in two strengths, 0.3 mg and 0.15 mg, and they come in multisource products, EpiPen® (epinephrine injection, USP), Auvi-Q®, and Adrenaclick®, as well as authorized generics for EpiPen and Adrenaclick. Unfortunately, Auvi-Q was recalled in 2015 due to the risk of inaccurate dose delivery, but was returned to the market in February 2017.

There has been much discussion about the EpiPen, its cost, and generic alternatives. Mylan, the drug company producing EpiPen, has recently introduced an authorized generic of the product. Per Food and Drug Administration (FDA):

> The term "authorized generic" drug is most commonly used to describe an approved, brand name drug that is marketed as a generic product without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. It may be marketed by the brand name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand name product, the authorized generic may be sold at a lower cost than the brand name drug.

Mylan's authorized generic is given a rating of "BX" in FDA's *Approved Drug Products With Therapeutic Equivalence Equations* (commonly known as the "Orange Book"), which indicates there is not sufficient data to determine therapeutic equivalence. An article from the June-July 2013 issue of the *NABP Newsletter* states that a "code beginning with a 'B' indicates that the product in question is not considered therapeutically equivalent to other pharmaceutically equivalent products." However, this only reflects that other epinephrine auto-injectors such as the Auvi-Q and Adrenaclick are not therapeutically equivalent to the EpiPen. Per Mylan, its generic auto-injector is made at the same facility by the identical manufacturing process and to the identical specifications as the EpiPen, only lacking the EpiPen labeling.

Is one epinephrine auto-injector any better than the rest? Well, that depends on the patient. Both EpiPen and Auvi-Q require removing **one** safety cap, while Adrenaclick has **two** safety caps. EpiPen is supposed to be held in the thigh for three seconds, five seconds for Auvi-Q, and 10 seconds for Adrenaclick. For patients who rarely use their epinephrine auto-injectors, this may not be a deal breaker. Pharmacist counseling is the key part of this equation in ensuring that patients understand and are able to operate their device effectively.

What does all of this mean for Kansas pharmacies? Pharmacists may exercise brand exchange unless FDA has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication, per K.S.A. 65-1637(a)(2)(D). Therefore, if a generic drug does not have an "Orange Book" "A" rating, it has not been deemed therapeutically equivalent by FDA. When in doubt, always verify with the prescriber when exchanging a generic epinephrine auto-injector for the brand name product or encourage the prescriber to write for "epinephrine auto-injector" to provide a choice on selection for the patient.

Facility Inspection Reports on Hold

The Board office is currently undergoing a data migration and reformatting of the inspection database. As a result, inspection reports cannot currently be printed. The Board

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National Pharmacy

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

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

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3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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anticipates this issue will be resolved in spring 2017. In the interim, Board inspectors will provide compliant pharmacies with a copy of an inspection short form, which documents the date, location, pharmacy name, and license number of the inspection and some brief comments. Please contact the Board office if you need assistance with a license verification or another registration transaction that requires a copy of your most recent inspection report.

Pharmacist Continuing Education

In 2016, the Board amended the continuing pharmacy education (CPE) requirements for pharmacists to renew a license (K.A.R. 68-1-1b). Kansas pharmacists with licenses expiring June 30, 2017, are required to have completed 30 hours of CPE between July 1, 2015, and the date of their renewal (no later than June 30, 2017). There is no grace period for renewal or for completion of CPE.

Each CPE program must be approved by the Board. The Board has automatically approved all Accreditation Council for Pharmacy Education courses that are documented in the National Association of Boards of Pharmacy® (NABP®) CPE Monitor® section of a pharmacist's NABP e-Profile. The Board will also accept CPE courses approved by other state boards of pharmacy as long as sufficient proof of approval is provided to the Board along with the certificate of completion. A list of other Board-approved courses can be found on the Board's website at *http://pharmacy.ks.gov/licensing-registration/ce,* along with the process for having a new CPE course approved prior to completion.

New This Year: Pharmacists may not be able to renew until the Board has received proof of completion of the required 30 hours of CPE. Hours reported to CPE Monitor do not need to be submitted to the Board. However, any other courses must be submitted to the Board prior to renewal. No credit shall be given for any certificate of completion received by the Board after June 30, 2017. Submissions can be made by mail or fax, or by email to pharmacy@ks.gov.

Complaints and Referrals

The adage "if you see something, say something" has become rather commonplace. While the circumstances for its use vary, it should be applied in the pharmacy setting as well. Staff inspectors cannot be everywhere to monitor compliance with Kansas laws and regulations, so the Board relies on licensees and consumers to submit complaints when something is unusual, concerning, or wrong in the practice of pharmacy. Whether it is about a facility or another practitioner, an ethical obligation of the profession involves protecting the public by notifying the Board about potentially harmful or dangerous circumstances in the pharmacy. Kansas licensees are the first line of defense for public safety! This is especially true when an incident involves an impaired provider, a theft/diversion, or an unlicensed individual in the pharmacy.

Complaints should be submitted to the Board using the C-100 Complaint Form, available on the Board's website at *http://pharmacy.ks.gov/resources-consumer-info/complaint-process,* and should include detailed information that might be important or relevant. Once the Board has received a complaint, the following takes place:

- Notification to the sender that the complaint has been received,
- Review by the executive secretary and assignment to an appropriate investigator,
- Assigned investigator conducts a thorough investigation and compiles a report, and
- The Board's investigative member and attorney review the report and determine if any violations of Kansas law have occurred and what, if any, action should be taken.

The Board has the legal authority to revoke, suspend, or restrict the individuals that it regulates. Monetary fines are also a part of the Board's authority. However, a licensee is always given an opportunity to request a hearing before the Board to dispute the allegations.

Sometimes, complaints are outside of the Board's jurisdiction, and the Board refers the complaint to another state agency. More often, the Board assigns the complaint to a staff inspector for investigation. An investigation may take anywhere from a few weeks to a few years, depending on the complexity and severity of the issues as well as the caseload of the inspectors. Most investigations are completed within nine months.

Complaints and investigations are not open to the public. However, if formal disciplinary action is taken against an individual or facility, the order is made available on the Board's website and is reported to NABP and the National Practitioner Data Bank. Such actions and the original complaints are subject to disclosure under the Kansas Open Records Act, K.S.A. 45-215 et seq, once the investigation and case have been concluded. Complaints can be filed anonymously, but these do not carry as much weight because it is more difficult to conduct an investigation, determine facts, obtain documents, and corroborate or clarify information with the person filing the complaint.

Upcoming Events

April 6, 2017
Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka, KS

May 5, 2017
Prescription Monitoring Program Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

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