March 2017

Kentucky Board of Pharmacy News

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Pharmacy Technician Registration Renewal Due by March 31, 2017

The registration renewal process is available online at *www.pharmacy.ky.gov*. At the completion of the application process and payment of the $25 registration fee, you will print your certificate of registration. If you are unable to complete the process online, you may print a registration renewal application form from the Kentucky Board of Pharmacy website.

Registrations must be received in the Board office by close of business on Friday, March 31, 2017 (not postmarked). All online registrations must be completed before 12:01 AM (EDT) on April 1, 2017. Your registration will be valid until March 31, 2018.

As a reminder, a pharmacy technician must renew his or her pharmacy technician registration and **must not apply as a new pharmacy technician,** whether he or she has changed pharmacies or is attempting to renew his or her pharmacy technician registration late.

Pharmacists-in-charge (PICs), please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2017 deadline.

New Pharmacy and Drug Inspector

Rhonda Hamilton, PharmD, began working as a pharmacy and drug inspector for the Board on February 1, 2017. She is a 2012 graduate of McWhorter School of Pharmacy at Samford University. Prior to employment with the Board, she worked in retail pharmacy. Rhonda is a resident of Owensboro, KY, and will be inspecting the western part of the state.

Compliance Corner

The Board office and inspectors still receive frequent calls concerning the controlled substance (CS) prescriptive authority of advanced practice registered nurses (APRNs) and midwives.

A reference guide may be downloaded from the Kentucky Coalition of Nurse Practitioners and Nurse Midwives website at *www.kcnpnm.org*.

The guide contains many frequently asked questions concerning collaborative care agreements for both CS and non-CS.

APRNs and midwives in jurisdictions outside of Kentucky may have more privileges; however, Kentucky law is more stringent and therefore applies to all prescriptions written by an APRN or midwife. As a reminder, physician assistants in Kentucky are **not** allowed to prescribe any CS; therefore, CS prescriptions written by physician assistants from other jurisdictions are not valid in Kentucky.

Scheduled Drug Laws for APRNs at a Glance*

Drug Schedule	KASPER Query	Maximum Prescription	Refills	Method of Prescription	Prescription Expiration
II	Required before prescribing and at least every three months during treatment	72 hours** (see psychiatric mental health exception below)	No	Written only	60 days after date of issue
II (combination hydrocodone products in liquid and solid form)	Required before prescribing and at least every three months during treatment	30 days	No	Written only	60 days after date of issue
III	Required before prescribing and at least every three months during treatment	30 days	No	Written, oral, or fax	Six months after date of issue
IV (Ativan®, Klonopin®, Valium®, Xanax®, and Soma®)	Required before prescribing and at least every three months during treatment	30 days	No	Written, oral, or fax	Six months after date of issue
IV (other)	Required before prescribing and at least every three months during treatment	Original prescription	Maximum six-month supply	Written, oral, or fax	Six months after date of issue
V	No requirement to check a KASPER report	Original prescription	Maximum six-month supply	Written, oral, or fax	Six months after date of issue

Prescribing prerequisites for APRNs:

1. Licensed to practice as APRN for at least one year
2. Collaborative Agreement for Prescriptive Authority for Controlled Substances (CAPA-CS)
3. Drug Enforcement Administration (DEA) registration and certificate/number
4. Notify Kentucky Board of Nursing of CAPA-CS and physician name; submit copy of DEA certificate
5. Kentucky All Schedule Prescription Electronic Reporting (KASPER)

* Your CAPA-CS may place additional restrictions on your prescribing authority.

** APRNs nationally certified in psychiatric mental health nursing may prescribe a 30-day supply of psychostimulants.

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.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

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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Pharmacy Renewal Deadline June 30, 2017

Pharmacy permits expire June 30, 2017. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about May 1, 2017. If you want to send in a paper renewal, this form may be printed from the Board's website at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your pharmacy has an address change, a relocation within the current premises of the existing permit, or an ownership change, you must complete a new pharmacy application. A pharmacy application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is June 30, 2017. All paper renewal applications must be in the Board office by the close of the day on Friday, June 30, 2017 (not postmarked).

Kentucky Board of Pharmacy 2016 Statistics

Resident pharmacies:	**1,360**
Independent:	582
Chain:	551
Out-of-state:	730
Pharmacists:	**9,478**
Technicians:	**15,475**
Interns:	**2,734**
Cases: Some cases have multiple parts. For example, a permit, a pharmacist, and a technician named in one case, resulting in a total of 720 individuals or facilities named in a case. Specific case statistics follow.	**519**
Self-reported continuing education (CE) cases:	41 pharmacists
Board audit discovered CE cases:	236 pharmacists
Medication errors/drug utilization review:	28 cases involving 27 permit holders and 36 pharmacists
Confidentiality:	6 cases involving 6 permit holders, 7 pharmacists, 5 technicians, and 1 intern
Unprofessional conduct by failing to dispense:	15 (14 dismissed)
Technician registration issue:	24
Failure to renew technician registration and continued to work:	79
Technician diversion:	19
Pharmacist impairment:	7
Pharmacist forgery of non-controlled prescriptions:	2
Violations of agreed orders:	6 cases involving 4 pharmacists and 2 technicians
Mental competency:	3
Disciplined in another state:	18
Failure to name a PIC:	1
Failure to notify the Board of closure:	6
Failure to notify the Board of a move:	1
Failure to notify the Board of an ownership change:	2
Failure to report to KASPER:	1
Failure to renew a permit:	1
Failure to obtain an out-of-state permit to ship into Kentucky:	4
Miscellaneous:	19
Number of individuals or facilities named in a case that was dismissed:	177

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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

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