March 2018

News

Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Pharmacy Technician Registration Renewal Due by March 31, 2018

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.

Paper renewal applications must be received in the Board office by close of business on Friday, March 30, 2018 (not postmarked). All online registrations must be completed before 12:01 AM (EDT) on April 1, 2018. Your registration will be valid until March 31, 2019.

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.

Larry Hadley

At its October 20, 2017 meeting, the Board named Larry Hadley, RPh, as the executive director to replace Steve Hart, RPh, who had previously announced his retirement effective December 31, 2017. Larry's appointment became effective January 1, 2018.

John Romines

Dr John Romines, PharmD, began working as a pharmacy and drug inspector for the Board on November 16, 2017. He is a 2007 graduate of the Lloyd L. Gregory School of Pharmacy at Palm Beach Atlantic University. Prior to employment with the Board, he worked in retail pharmacy. Dr Romines is a resident of Somerset, KY, and will be inspecting the southern part of the state.

Jill Rhodes

Dr Jill Rhodes, PharmD, has been appointed by Governor Matt Bevin to the Board for a four-year term expiring January 1, 2022. Dr Rhodes is employed at the University of Louisville Hospital Pharmacy and St Matthews Community Pharmacy, both in Louisville, KY. Dr Rhodes resides in Crestwood, KY.

Joe Davis Forgy

Joe Davis "Jody" Forgy has been appointed by Governor Bevin to the Board for a four-year term expiring January 1, 2022. Mr Forgy is a retired pharmacy operator. He will represent citizens at-large. Mr Forgy resides in Morgantown, KY.

Peter P. Cohron

Peter P. Cohron, JD, RPh, has been appointed by Governor Bevin to the Board for a four-year term expiring January 1, 2022. Mr Cohron is employed at T&T Drug Store in Henderson, KY, and also resides in Henderson.

2018 Board Officers

The Board has elected Cathy Hanna as president and Craig Martin as vice president for 2018. Dr Hanna is serving her second term as president and is in her eighth year as a Board member. This is Dr Martin's first term as vice president. He completed an unexpired term of a previous Board member and is in his second full year as a Board member.

Hazardous Drug Task Force Committee

The Board has appointed a Hazardous Drug Task Force Committee directed with promulgating a Kentucky-specific hazardous drug regulation instead of adopting United States Pharmacopeia General Chapter <800>. Members include:

- Matt Martin, Task Force Chair, Professional Compounding Centers of America;
- John Carver, Baptist Health La Grange Kresge Infusion Pharmacy;
- Paul Daniels, Board Pharmacy and Drug Inspector;
- Jennifer Grove, Owner, Bluegrass Drug Center;
- Chris Harlow, Owner, St Matthews Community Pharmacy, and President, Kentucky Pharmacists Association;
- Barb Jolly, Professor, Sullivan University College of Pharmacy;

Continued on page 4

National Pharmacy Compliance News

March 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

Continued from page 1

- Trenika Mitchell, Professor, University of Kentucky College of Pharmacy; and
- Alyson Roby, Owner, Medica Pharmacy and Wellness Center.

The meetings are open to the public, and all are invited to attend. Please watch for information about the committee, including meeting times and locations, agendas, and minutes, through emails and the Board website.

Board-Authorized Protocols: 201 KAR 2:380

By Katie Busroe, RPh, Pharmacy Inspections and Investigations Coordinator

On December 13, 2017, 201 Kentucky Administrative Regulation (KAR) 2:380 became effective, allowing Kentucky pharmacists and prescribers to enter into Board-authorized protocols for 13 specific conditions:

1. Acute influenza infection, pursuant to recommendations by the Centers for Disease Control and Prevention (CDC);
2. Acute streptococcal pharyngitis infection;
3. Acute, uncomplicated urinary tract infection;
4. Acute mucocutaneous fungal infection;
5. Allergic rhinitis;
6. Anaphylaxis;
7. Human immunodeficiency virus infection prevention through pre-exposure prophylaxis, pursuant to recommendations by CDC;
8. Nutritional supplementation with vitamins and minerals;
9. Opioid use disorder, pursuant to recommendations by the American Society of Addiction Medicine;
10. Tobacco use disorder;
11. Travelers health, pursuant to recommendations by CDC;
12. Tuberculosis prevention and control through skin testing, and referral as necessary, pursuant to recommendations by CDC; and
13. Self-care conditions appropriately treated with over-the-counter medications and products.

At this time, four protocols have been authorized by the Board: Tobacco Use Disorder; Opioid Use Disorder (Naltrexone Therapy); Tuberculin Skin Testing; and Self-Care Conditions – Diabetes Testing Supplies. Protocols must be authorized by the Board. Making any changes to the authorized protocols invalidates them until they are presented to the Board and authorized with the new language. As protocols are authorized, they will be posted on the Board's website for use by any pharmacist. The Board would like to thank all the associations, pharmacists, and physicians who collaborated on this regulation.

Pharmacy Renewal Deadline June 30, 2018

Pharmacy permits expire on June 30, 2018. Pharmacy permits may be renewed online. At the completion of online renewal, you will be prompted to print your pharmacy permit. Pharmacy permits will not be mailed from the Board office unless a paper renewal application is submitted. Renewal applications 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, relocation within the current premises of the existing permit, or 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, 2018. All paper renewal applications must be in the Board office by the close of the day on Friday, June 29, 2018 (not postmarked).

Kentucky Board of Pharmacy 2017 Statistics

Resident pharmacies:	**1,346**
Charitable:	7
Hospital:	117
Hospital-ambulatory:	37
Infusion:	31
Mail order:	11
Nuclear:	6
Nursing home:	24
Retail independent:	573
Retail chain:	540
Out-of-state:	724
Pharmacists:	**9,855**
Technicians:	**15,693**
Interns:	**2,613**
Cases: Some cases have multiple parts. For example, a permit, a pharmacist, and a technician named in one case, resulting in a large number of total cases.	**570**
Total number of cases:	822
Self-reported continuing education (CE) cases:	54
Board audit discovered CE cases:	138
Medication errors/drug utilization review cases:	25
Confidentiality cases:	15
Technician registration issue:	12
Failure to renew technician:	77
Technician diversion:	28
Pharmacist impairment:	2
Forgery of prescriptions:	6

Board Inspectors

Contact information and counties of responsibility for Board inspectors may be found on the home page of the Board website at *www.pharmacy.ky.gov* by clicking on Inspector Regions.

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.

Page 5 – March 2018

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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