DECEMBER 2021

KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Happy Holidays!

From the Kentucky Board of Pharmacy
Board Members and Staff

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between **January 1 through December 31** pursuant to 201 Kentucky Administrative Regulations (KAR) 2:015 Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education (CPE) provisions. At the March 30, 2021 Board meeting, the Board voted to defer the 2020 continuing education requirements until December 31, 2021, because of the coronavirus disease 2019 (COVID-19) pandemic. Pharmacists must complete three CEUs (30 contact hours) between January 1, 2020, and December 31, 2021.

2022 CAPTASA Conference

The 2022 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held at the Embassy Suites in Lexington, KY, on January 28-29, 2022.

Recognitions

The Board would like to recognize the following individuals for their service and dedication to the Board.

- **Matt Martin** has served a four-year term on the Advisory Council. His term expires December 31, 2021.
- **Lisa Bradley** has served a four-year term on the Pharmacist Recovery Network (PRN) Committee. Her term expires December 31, 2021.

- **Mary Ann Burch** has served a four-year term on the PRN Committee. Her term expires December 31, 2021.
- **Jody Forgy** has served a four-year term on the Board. His term expires December 31, 2021.
- **Jill Rhodes** has served as president of the Board for 2021. She has served a four-year term on the Board. Her term expires December 31, 2021.

President's Address

By Jill Rhodes

The year 2021 has been unprecedented for the pharmacy profession in many ways. The pharmacists and technicians of this commonwealth have displayed exceptional resolve while being called upon to protect public health and welfare during the pandemic. During this time, the Board has worked diligently on many initiatives that enhance patient access to pharmacist services and further identify the needs of our profession while increasing medication safety for consumers. Some of the highlights from the past year are included below. The Board:

- passed emergency regulations to allow pharmacists to prescribe and administer childhood immunizations, the COVID-19 vaccine, and the flu vaccine pursuant to specific guidelines;
- created new ad-hoc committees to focus on new approaches to improve medication safety, meet required CPE through contemporary professional development programs, and enhance the role of the pharmacy technician;
- entered into a memorandum of understanding addressing compounded human drug products between the Board and Food and Drug Administration (FDA);
- drafted new regulations, including creating a new medication repository regulation (in draft) and a new regulation to provide pharmacy technicians with the ability to administer immunizations;
- amended several regulations, including 201 KAR 2:360 allowing pharmacists to dispense naloxone to agencies and removing other barriers to harm reduction programs; and
- passed new and revised Board-approved protocols: colorectal cancer screening protocol and revision of diabetes testing, acute pharyngitis infection, acute influenza infection and chemoprophylaxis, and travel health therapies – with several more coming soon!

Serving with Board members, Executive Director Larry Hadley, Board counsel, staff, and the volunteer committee members for the commonwealth the past four years has been a privilege

and an honor. I look forward to the coming progress by the current and future volunteers and Board members and remain forever your pharmacy advocate.

Naloxone Emergency Response Cabinets

By Cody Sullivan, PharmD/MBA Candidate

Naloxone emergency response cabinets (eg, NaloxBox) are designed to increase public access to naloxone, an opioid overdose reversal medication. Like automated external defibrillators, naloxone emergency response cabinets are placed in public places where bystanders can administer lifesaving treatments until paramedics arrive. On average, more than 100 lives are lost due to opioid overdose in the United States every single day.[1] Studies have shown that increasing access to naloxone, especially in areas where overdoses may be common, reduces opioid-related morbidity and mortality.[2] By implementing naloxone emergency response cabinets in our communities, we can increase the public supply of naloxone to help combat the opioid epidemic. Installation of these cabinets in public spaces can also serve to raise awareness about this lifesaving medication and how to administer it and help fight stigma related to opioid use disorder. Each cabinet contains two doses of naloxone for intranasal administration along with directions for use, a barrier mask to facilitate rescue breathing, and information on local treatment resources. Although more research is needed to determine the impact of installing these cabinets, initial findings show that the average layperson can utilize the proper technique for administering naloxone 98% of the time.[3] Kentucky Revised Statutes §217.186 authorizes licensed health care providers and naloxone-certified pharmacists to prescribe and dispense naloxone to a person or agency. An agency can install naloxone emergency response cabinets to help increase the accessibility of naloxone for bystander use in areas where overdoses may occur. Agencies installing naloxone emergency response cabinets must have a process in place for monitoring the cabinet so that it can be refilled if the naloxone is used or have the naloxone product replaced before it reaches its expiration date.

While other states have utilized naloxone emergency cabinets for several years, they are just starting to be utilized in Kentucky communities. Pharmacists can play a key role in advocating for the use of naloxone emergency response cabinets and help facilitate their use in communities across the commonwealth to mitigate the opioid overdose crisis in Kentucky.

References

1. National Institute on Drug Abuse. Overdose death rates. January 29, 2021. Retrieved October 6, 2021, from *www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates*.
2. McClellan C, Lambdin BH, Ali MM, et al. Opioid-overdose laws association with opioid use and overdose mortality. *Addictive Behaviors*. 2018 Nov;86: 90-95, ISSN 0306-4603, *www.sciencedirect.com/science/article/pii/S0306460318301382*.
3. Capraro GA, Rebola CB. The NaloxBox Program in Rhode Island: A Model for Community-Access Naloxone. American *Journal of Public Health*. 2018 Dec;108(12):1649-1651. *doi.org/10.2105/AJPH.2018.304735*.

Pharmacists Now Able to Order and Administer COVID-19 Therapeutics

On September 14, 2021, current US Department of Health and Human Services secretary, Xavier Becerra, amended Section V of the Public Readiness and Emergency Preparedness Act Declaration.[1] The amendment authorized licensed pharmacists to both order **and** administer COVID-19 therapeutics subcutaneously, intramuscularly, or orally, so long as the therapeutic is authorized, approved, or licensed by FDA. Further, the amendment allows for registered interns and qualified technicians to administer COVID-19 therapeutics subcutaneously, intramuscularly, or orally. Prior to the amendment, pharmacists could administer COVID-19 therapeutics pursuant to a collaborative care agreement, but they could not independently prescribe COVID-19 therapeutics.

Criteria as Required by the Ninth Amendment

First, the COVID-19 therapeutic must be authorized, approved, or licensed by FDA. **Second,** when a licensed pharmacist orders a COVID-19 therapeutic, it must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing.**Third,** for licensed pharmacists, qualified technicians, and registered interns administering the therapeutic, it must be administered subcutaneously, intramuscularly, or orally in accordance with FDA. **Fourth,** for technicians, the supervising pharmacist must be readily and immediately available to assist the technician. **Fifth,** if the therapeutic is being administered through either intramuscular or subcutaneous injections, the pharmacist, intern, or technician must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education. Further, that training program must include guidance on a hands-on injection technique and guidance on the clinical evaluation of indications and contraindications of COVID-19 therapeutics. **Sixth,** the pharmacist, intern, and technician must maintain a current certificate in cardiopulmonary resuscitation. **Seventh,** the pharmacist must comply with its jurisdictions' requirements for record keeping and reporting. **Lastly,** the pharmacist, intern, and technician must comply with all applicable requirements that apply to the administration of COVID-19 therapeutics.

Critically, the implication of this amendment provides protection from liability for pharmacists, interns, and technicians who meet the criteria set forth above, based on the COVID-19 therapeutics that exist now and that will be approved by FDA **in the future.**[2]

References

1. *Federal Register*. Vol. 86, No. 175. *Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*. September 14, 2021. *https://www.federalregister.gov/documents/2021/09/14/2021-19790/ninth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical*.

2. American Society of Health-System Pharmacists. *Pharmacists Authorized to Order and Administer COVID-19 Therapeutics Under PREP Act Declaration*. September 9, 2021. *www.ashp.org/news/2021/09/09/pharmacists-authorized-to-order-and-administer-covid-19-therapeutics-under-prep-act-declaration?loginreturnUrl=SSOCheckOnly*.

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 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.

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Larry A. Hadley, RPh - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

State Office Building Annex, Suite 300 | 125 Holmes Street | Frankfort, KY 40601