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Kentucky Board of Pharmacy News

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COVID-19 Testing by Pharmacists

On April 24, 2020, the secretary of the governor's executive cabinet granted Kentucky pharmacists the authority to order and administer coronavirus disease 2019 (COVID-19) tests during the governor's declared state of emergency. The secretary's order stipulates pharmacists must:

1. use COVID-19 tests, including serology tests, that have been authorized by United States Food and Drug Administration (FDA);
2. have a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver if required by the COVID-19 test being used;
3. be appropriately educated and trained on the COVID-19 test being used;
4. have appropriate policies and procedures in place; and
5. prioritize patients being tested based on the Kentucky Department for Public Health (KDPH) guidance.

FDA-Authorized Tests and CLIA Waivers

Some COVID-19 tests are fraudulent and not authorized by FDA. There have been examples of so-called COVID-19 clinics offering fraudulent tests in Kentucky. FDA has authorized some COVID-19 tests under the Emergency Use Authorization (EUA). An EUA allows the COVID-19 tests to be used without going through the normal FDA approval process in order to respond to a public health emergency. There are two types of COVID-19 tests:

1. High complexity tests that are not allowed to be completed in a community pharmacy setting. These are the tests where pharmacists may collect the nasopharyngeal swab specimen for send out testing.
2. Point-of-care (POC) testing for use in a patient care setting, including a pharmacy. The pharmacy must be a CLIA-waived pharmacy in order to perform POC testing.

At the time of this article, no serology tests have been authorized by FDA. Please refer to FDA's website for questions on COVID-19 testing and a list of EUA COVID-19 tests at *www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.*

Training and Other Considerations

In order to perform COVID-19 testing, pharmacists must have sufficient access to resources, including, but not limited to:

1. training of pharmacy staff to appropriately collect samples for send out testing and conducting POC testing;
2. appropriate personal protective equipment (PPE); and
3. appropriate areas for sample collection for send out testing and POC testing.

Policies and Procedures

Policies and procedures must include, but not be limited to:

1. collecting samples;
2. storing samples;
3. shipping samples;
4. processing samples, including interpreting results (if POC testing is being conducted);
5. infection control, including use of PPE and disinfection of areas used for sample collection and testing;
6. notifying KDPH of persons under investigation (PUI);
7. notifying KDPH of positive tests;
8. notifying patients of test results; and
9. caring for patients without a primary care provider.

Prioritize Patient Testing per KDPH

When testing patients for COVID-19, pharmacists must refer to the testing priorities, if any, set forth by KDPH. Please visit *KyCovid19.ky.gov* for the latest KDPH testing

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National Pharmacy Compliance News

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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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

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prioritization. Pharmacists must notify KDPH of PUI and persons testing positive. If a patient who tests positive does not have a primary care provider, the pharmacist must have a care plan for that patient.

COVID-19 information is fluid and constantly changing. Please refer to the Kentucky Board of Pharmacy's website and visit *KyCovid19.ky.gov* for the latest information.

Suspensions of Regulations During COVID-19 Declared State of Emergency

Pursuant to Executive Order 2020-243, the Board has suspended the following parts of regulations for the duration of the state of emergency due to COVID-19.

201 KAR 2:205 Pharmacist-in-charge. The Board is exercising enforcement discretion regarding the following parts of 201 Kentucky Administrative Regulations (KAR) 2:205 due to the difficulty that may be encountered in staffing pharmacies during the COVID-19 pandemic, including naming a pharmacist-in-charge (PIC):

- Section 2(3)(d)1: the requirement that the PIC provide notification in writing to the Board within 14 calendar days of any change in the employment of the PIC. If a pharmacy cannot name a PIC within 14 calendar days, please contact the Board office or the inspector for guidance. Board staff will work with each pharmacy permit holder and pharmacy staff on an individual basis to determine an appropriate solution.
- Section 2(3)(d)2: the requirement that the PIC provide notification in writing to the Board within 14 calendar days of any change in employment of staff pharmacists. Pharmacies will not have to provide notice of change in staff pharmacists during the state of emergency.
- Section2(3)(d)3: the requirement that the PIC provide notification in writing to the Board within 14 calendar days of any change in schedule of hours for the pharmacy. Pharmacies do not have to notify the Board of a temporary change of hours during the state of emergency.

The rest of 201 KAR 2:205 is in effect. The requirement in Kentucky Revised Statute 315.020(1) for a pharmacy to name a PIC is in effect.

Please contact the Board office or the inspector for guidance should this become an issue. Board staff will work with each pharmacy permit holder and pharmacy staff on an individual basis to determine an appropriate solution.

201 KAR 2:280 Prescription Dispensing for Formulary Compliance. The Board is suspending the following parts of 201 KAR 2:280 due to the shortage of critical medications during the COVID-19 pandemic:

- Section 1(1)(a): the prescriber does not have to indicate "formulary compliance approval" on the prescription. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA "Orange Book."
- Section 1(1)(b): the pharmacist does not have to receive a formulary change as a consequence of the patient's third-party plan. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA "Orange Book."
- Section 1(1)(c): the drug does not have to be designated as "preferred" by the third-party formulary; however, the drug must be in the same therapeutic class. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA "Orange Book."
- Section 1(2): the 24-hour notification window for the pharmacist to notify the prescriber of the therapeutically equivalent substitution is extended to two business days or the next day the prescriber can be reached.
- Section 2: the drug dispensed does not have to be the preferred formulary therapeutic alternative, however, it must be on the FDA Drug Shortage List. The pharmacist may make adjustments in the quantity and directions of the alternative drug dispensed to provide for an equivalent dose of the drug that is on the FDA Drug Shortage List.

The following parts of 201 KAR 2:280 are **not** suspended:

- Section 1(2)(a): the pharmacist must notify the prescriber in an original writing or by facsimile that the pharmacist substituted a drug because of the FDA Drug Shortage List.
- Section 1(2)(b): the pharmacist must notify the prescriber in an original writing or by facsimile which therapeutically equivalent product was dispensed.

Please note that the drug must be on the FDA Drug Shortage List, not any other group or association's drug shortage list. This does not apply to biological products.

201 KAR 2:370 Pharmacy Services in Long-Term Care Facility. In an effort to limit the number of people entering long-term care facilities (LTCFs), the Board is suspending the following parts of 201 KAR 2:370:

- Section 2(4)(d)2: the requirement that a pharmacist,

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pharmacist intern, or certified pharmacy technician review the emergency medication kit (EMK) for outdated, damaged, or adulterated drugs and stock adequacy of **non-controlled drugs** on a monthly basis. This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.

- Section 2(5)(f): the requirement that pharmacy personnel inspect the stock of the LTCF drug stock for outdated drugs and stock adequacy on a monthly basis. This may be performed by an RN or LPN at the LTCF.
- Section 2(5)(g)(3): the requirement that LTCF drug stock be replenished by a pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the immediate supervision of a pharmacist on site, if there is no pharmacy on site. This may be performed by an RN or LPN at the LTCF.
- Section 4(5)(a), (b), and (c): the requirement that the stocking of an automated dispensing system (ADS) be done by a pharmacist, pharmacist intern, or certified pharmacy technician under the supervision of a pharmacist on site. This may be performed by an RN or LPN at the LTCF.
- Section 4(6): the requirement that if the pharmacy utilizes a tamper-resistant barcoding technology, microchip, or other equivalent tamper-resistant ADS, a pharmacist-verified drug may then be loaded by a PIC-trained pharmacist, pharmacist intern, or certified pharmacy technician. The loading of the pharmacist-verified drug into the ADS may be performed by an RN or LPN at the LTCF.

The rest of 201 KAR 2:370 is not suspended, including, but **not** limited to:

- Section 2(4)(d)1: the requirement that a pharmacist or any lawful person as stated in 902 KAR 55:070 review the EMK for outdated, damaged, or adulterated drugs and stock adequacy of **controlled substances (CS)** on a monthly basis. 902 KAR 55:070 Section 2(4)(d) requires the pharmacy provider to document completion of a physical inventory of the CS in an EMK no less than one time per month. This must be done by the pharmacy provider.
- Section 2(2)(a): the requirement that a prescription drug order from a licensed practitioner is obtained prior to the administration of a CS from the EMK.
- Section 2(2)(b): the requirement that a prescription drug order or medical order from a licensed practitioner is obtained prior to the administration of a non-CS from the EMK.
- Section 2(5)(e): the requirement that a pharmacist must review the prescription drug or medical order before the release of medication from LTCF drug stock.

Information regarding the governor's declared state of emergency due to COVID-19 is fluid and continually changing. Please refer to the Board's website and visit *KyCovid19.ky.gov* for the latest information.

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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