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Kansas Board of Pharmacy

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KBOP Memo on Pharmacy Emergencies, Public Health Issues, Shortages, etc.

Revisions from 4/28/23 in Green
Revisions from 10/3/23 in Purple

BOARD OPERATIONS

The Board office is open to the public by appointment only. Drops-offs can be made at the agency during office hours. The Board asks that consumers, licensees, and registrants use email as the primary method of communication with staff. Contact information can be found here. Voicemail messages will be retrieved by office staff daily and calls returned within five business days.

REMOTE WORK

At their meeting on September 28, 2023, the Board decided to discontinue emergency remote work allowances on November 1, 2023. On this date, pharmacy employees shall return to pre-pandemic, in-pharmacy practice and direct supervision requirements in compliance with all Kansas laws.

AMOXICILLIN SHORTAGE

The FDA recently added amoxicillin to its list of drugs that are experiencing shortages. Amoxicillin, specifically the "amoxicillin oral powder for suspension" was added to the FDA drug shortages list on October 28, 2022. As a result, this drug may be compounded under section 503A of the FDCA provided that all conditions of 503A are met, including a patient-specific prescription. Additionally, Kansas laws and regulations require compliance with USP standards (see Article 13 of the Board's regulations). Due to amoxicillin being added to the FDA drug shortages list, the FDA does not consider the drug product to be commercially available.

In addition to pharmacy compounding, amoxicillin that is in shortage may also be produced by registered outsourcing facilities.

FDA Announcement

Final Guidance Document: Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food Drug and Cosmetic Act.

BEST PRACTICE RECOMMENDATIONS

To minimize contact and spread of COVID-19, the Board recommends pharmacies encourage customers to utilize drive-through or delivery where they are available. The Board also recommends requesting customers space themselves out when waiting in line and that the pharmacy consider the use of some sort of counter extension or plastic barrier to establish a larger gap between the customer and the cashier, where possible.

Pharmacists should use their professional judgment to ensure policies and procedures are in place to protect Kansas patients. The Board has received consumer complaints related to pharmacy personnel observing appropriate health and safety protocols and prevention measures. Pharmacies are required to comply with all state and local orders. As a reminder,

the Board may discipline any pharmacist, intern, or technician upon a finding of unprofessional conduct, which includes conduct likely to harm the public.

COVID-19 THERAPEUTICS

The U.S. Department of Health and Human Services has expanded the PREP Act to include authority for pharmacists to order and administer COVID-19 therapeutics, and authority for pharmacy interns and technicians to administer COVID-19 therapeutics under the direct supervision of the ordering pharmacist. Such authority supersedes the authority of the Pharmacy Act of the State of Kansas or any other Kansas law.

According to HHS, amendments independently authorize State-licensed pharmacists to order and administer COVID-19 therapeutics authorized, approved, or licensed by the FDA. In addition, HHS has granted authority for interns and technicians to administer these therapeutics under the direct supervision of the ordering pharmacist. COVID-19 therapeutics must be ordered for subcutaneous, intramuscular, or oral administration in accordance with the FDA approval, authorization, clearance, or licensing. All pharmacy personnel are required to be properly licensed/registered in Kansas to perform these functions. The authority is subject to the following requirements:

- Participating pharmacists, interns, and technicians must:
    - Complete a practical training program approved by the ACPE which must include:
        - hands-on injection technique;
        - clinical evaluation of indications and contraindications of COVID-19 therapeutics;
        - the recognition and treatment of emergency reactions to COVID-19 therapeutics; and
        - any additional training required in the FDA approval, authorization, clearance, or licensing.
    - Have a current CPR certificate.
    - Comply with Kansas recordkeeping and reporting requirements, including informing the patient's primary-care provider and reporting adverse events.
    - Comply with applicable requirements or conditions of use that apply to the administration of COVID-19 therapeutics.
- The ordering and supervising pharmacist must be readily and immediately available to the pharmacy technician administering the immunization.

Review the HHS guidance for additional requirements:

- https://public-inspection.federalregister.gov/2021-19790.pdf
- https://files.constantcontact.com/99d8fc57be/b5c216c5-6a46-4d36-afef-2d5aba0123d7.pdf

The Board is aware that KDHE has distributed Molnupiravir to many hospital pharmacies. The Board has reviewed its statutes and regulations and has authorized hospitals to provide an **emergency supply** of the medication to patients presenting to the Emergency Department and receiving a first dose in-person. The remaining supply may be sent home with the patient in the manufacturer's original packaging according to the specific requirements of K.A.R. 68-7-11(d), K.A.R. 68-7-14, and K.A.R. 68-7-15. Please call your inspector with any questions.

The Board has also authorized hospitals to provide an **emergency supply** of Paxlovid for the full five-day treatment course to patients presenting to the Emergency Department. The emergency supply must be prepackaged and labeled by the pharmacist, as required under the Pharmacy Practice Act. This waiver will be readdressed at the end of the year.

On July 6, 2022, the FDA revised the Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir and ritonavir), to authorize Kansas-licensed pharmacists to **prescribe** Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid. **This authorization is only valid until expiration of the PREP Act declaration (October 31, 2024)**

unless earlier terminated. APhA has provided helpful resources at the following site: APhA Press Release.

The FDA also provided the following information:

"Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid:

- *Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.*
- *A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.*

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation with a physician, APRN, or PA licensed or authorized under state law to prescribe drugs, if any of the following apply:

- *Sufficient information is not available to assess renal and hepatic function.*
- *Sufficient information is not available to assess for a potential drug interaction.*
- *Modification of other medications is needed due to a potential drug interaction.*
- *Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.*

Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19, including hospitalization or death. Patients in the authorized population who report a positive home test result from a rapid antigen diagnostic test, or a positive PCR test, to their provider are eligible for Paxlovid under the EUA. Confirmation of a positive home rapid antigen diagnostic test with additional direct SARS-CoV-2 viral testing, such as a PCR, is not required. Antibody tests are not considered to be direct SARS-CoV-2 viral tests."

CONTRAST MEDIA SHORTAGE

Due to the national shortage of contrast media, the Board is authorizing pharmacies to extend the beyond use date (BUD) of single-use syringes provided the repackaging is completed in accordance with all USP requirements for sterile products to 4 days (96 hours). This is consistent with guidance for medium-risk preparations stored at room temperature. This authorization is temporary pending resolution of the national shortage. See USP <797>.