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Kansas Board of Pharmacy

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KBOP Memo on Pharmacy Emergencies, Shortages, Pandemic Response, etc.

Revisions from 12/9/2022 in Purple
Revisions from April 28, 2023 in Green

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.

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.

PANDEMIC 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. The CDC has also issued recommendations for face coverings and mitigation measures.

REMOTE WORK

The Board has made the decision to temporarily allow remote work by pharmacy employees. This allowance only applies to pharmacies physically located in Kansas and persons licensed or registered with the Board. This allowance will remain in effect **through December 31, 2023**. The Board suggests the pharmacy maintain documentation regarding the employee's high-risk status. The Board expects nonresident pharmacies to allow remote work only in accordance with guidance issued by the governing body in the resident state. The Board guidelines for remote work are as follows:

Pharmacies:

- Remote workers must have secure, electronic access to the pharmacy prescription processing software.
- ***Special Reminder from the Board:*** Any technology used by pharmacy personnel must meet HIPAA compliance standards. The Board also expects HIPAA safeguards to be in place at the location of remote work so that non-employee persons present at the location are not able to see or have access to patient information.
- The Board will not offer guidance as to whether a pharmacy's established processes meet federally-required security and privacy standards.
- The pharmacy must maintain a document (for 5 years) at the pharmacy that includes:
    - A list of all employees working remotely which shall include:
        - Name and license/registration/permit number of the employee
        - Address where the employee will be located when performing the remote activities
        - Phone number where the employee can be reached when performing the remote activities
    - The date range that the pharmacy conducted remote work activities
- All remote activities must be able to meet Kansas requirements for recordkeeping and documentation including, but not limited to, tracking the specific personnel who performed various steps in the dispensing process.
- All physical dispensing activities (tablet counting, packaging, labeling, compounding, etc.) and final product review must occur on-site at the pharmacy.
- Nothing in this guidance is intended to allow a pharmacy to be open without a pharmacist physically present at the pharmacy. See K.S.A. 65-1637c.

Pharmacists:

- The pharmacist must be licensed in Kansas.
- Any supervision of technicians, including those working remotely, must be conducted by a pharmacist physically located at the pharmacy. A pharmacist working remotely may not supervise a technician.
- The 4:1 technician to pharmacist ratio is still in effect and includes any technician working remotely. See updated K.A.R. 68-5-16, effective February 7, 2020.

Technicians:

- Only grandfathered technicians and technicians that have passed an approved national certification exam may work remotely. This includes technicians with 14- prefixes to their registration number. Technicians with 24- prefixes to their registration number are not allowed to work remotely.
- Technicians may only work remotely during the pharmacy's regular business hours.
- Technicians may perform the following tasks when working remotely:
    - Data Entry
    - Order Entry (hospital pharmacies)

    - Refill queue processing
    - Sending refill requests to prescribers by automated methods
    - Insurance Processing or Billing
    - Contacting patients for clarification of personal data and insurance processing information (i.e., date of birth, insurance information, etc.)
        - *Please note: Patients may be unwilling to provide personal information to a person calling from a phone number unrelated to the pharmacy. Please do not be forceful with patients in these situations and have the technician contact the pharmacy to call the patient directly.*
- While working remotely, technicians may not:
    - Directly contact prescribers or prescriber offices for clarifications or refills
    - Directly contact patients for issues related to medication therapy.
    - *Please note: This list is not exhaustive and the supervising pharmacist should rely on the aforementioned list of approved activities to direct technicians.*
- Any technician working remotely must maintain direct communication capabilities with the supervising pharmacist (located at the pharmacy) at all times. A video component is not required.
- Electronic supervision services are separate from remote supervision allowance provides by the Board. Electronic supervision is already allowed for hospital pharmacies for the supervision of one technician per pharmacy. The pharmacist may still supervise up to the 4:1 technician ratio. See K.A.R. 68-22-1 through K.A.R. 68-22-5.

For interns:

- Except as provided below, interns may work remotely to perform technician functions and are expected to follow the guidelines for technicians. Any hours spent working remotely to perform technician duties shall not count towards the intern hours required by the Board.
- Interns may complete non-patient intern hours remotely through journal clubs, drug updates, presentations, etc. at the direction and discretion of the school and preceptor.
- Interns completing APPE rotations and paid interns with at least a P4 status may work remotely to fulfil non-dispensing functions at the discretion and direction of their preceptor.
- Pharmacists should exercise appropriate discretion but are not limited by a specific ratio in supervising interns providing immunizations at vaccine clinics.

IMMUNIZATIONS

The U.S. Department of Health and Human Services has expanded the PREP Act to include authority for pharmacists, pharmacy interns, and pharmacy technicians to provide immunizations. Such authority supersedes the authority of the State of Kansas related to immunizations (KSA 65-1635a).

According to HHS, amendments independently authorize State-licensed pharmacists to order and administer FDA-approved immunizations to children ages 3-18 years, and order and administer COVID-19 immunizations pursuant to FDA authorization. In addition, HHS has granted authority for interns and technicians to administer these immunizations under the direct supervision of the pharmacist who has ordered the immunization. HHS has now expanded this authority in an eighth amendment to allow interns and technicians to administer seasonal influenza vaccines to persons 19 years of age and older under the direct supervision of the pharmacist who has ordered the immunization. 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 an ACPE immunization certification course;
    - Have a current CPR certificate. No expiration date waiver is allowed.

    - Complete a 2-hour, ACPE-approved continuing education course in immunizations within the current state license period. Note: This is not required by Kansas law, but is required to be eligible under the PREP Act and will count toward Kansas CE requirements.
- Comply with Kansas immunization recordkeeping and reporting requirements, including informing the patient's primary-care provider, submitting to Kansas WebIZ, reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine. See K.S.A. 65-1635a.
- Inform any pediatric patient and the patient's adult caregivers of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.
- The ordering and supervising pharmacist must be readily and immediately available to the pharmacy technician administering the immunization.

The federal guidance **does not** require a physician protocol and independently authorizes pharmacists to order immunizations. Pharmacists may continue using a physician protocol but cannot update the protocol to cover any immunization not authorized by KSA 65-1635a. The Board statewide immunization protocol has been updated to include FDA-approved COVID-19 vaccines and is available at https://pharmacy.ks.gov/resources-consumer-info-2/collaborative-practice.

Review the HHS guidance for additional requirements. Links to HHS guidance:

- https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html
- https://www.hhs.gov/about/news/2020/09/09/trump-administration-takes-action-to-expand-access-to-covid-19-vaccines.html
- https://www.hhs.gov/about/news/2020/10/21/trump-administration-takes-action-further-expand-access-vaccines-covid-19-tests.html
- https://www.federalregister.gov/documents/2021/08/04/2021-16681/eighth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for

The Kansas Department of Health and Environment has published the State COVID-19 Vaccination Plan, which can be access here: https://www.coronavirus.kdheks.gov/284/COVID-19-Vaccine. Information includes COVID-19 vaccination provider recruitment and enrollment; ordering, distribution, and inventory; and storage and handling; and documentation and reporting. Make sure to check for any updates!

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 not aware of any current training courses that would meet the ACPE requirement. However, certain pharmacy associations or organizations may provide training courses and the Board will make this information available.

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>.