

## **Drug Shortage Alternatives**

This Guidance Document describes the Kansas Board of EMS' current approach to addressing drug shortages within the state of Kansas.

### **Applicable law**

- K.S.A. 65-6128 requires all ambulance services to be equipped in accordance with Board rules and regulations.
- K.A.R. 109-2-5(c) requires that "all medications, medical supplies, and equipment within the ambulance are maintained in good working order and according to applicable expiration dates."
- K.A.R. 109-2-8(n)(3) requires each ground ambulance to be equipped with "currently dated" medications.

### **The Board's Current Approach to the Applicable Law:**

#### **1) *Usage of a medication whose expiration date has been extended by the FDA***

Pharmaceutical manufacturers may apply to the FDA to have the expiration date extended for specific lots of their medications under specific circumstances. The Board considers medications within these FDA-approved extended expiration dates to be "currently dated" under the following conditions:

- a. The service's medical director acknowledges the usage of the medication beyond the original labeled expiration date, but within the new use date.
- b. The service provides the Executive Director of the Board documentation of the medical director's acknowledgement and a listing containing the name of the medication being potentially used, the lot number, and the total quantity on hand.
- c. The extended use date medication is stored in a manner consistent with its original labeling.

The Board strongly urges each service to QA/QI each run where an extended use date medication is used to assess that the medication is reaching the desired effect. If a service finds that an extended use date medication is not meeting that desired effect, it should be reported to the Board immediately.

#### **2) *Usage of expired medications***

The Board does not consider expired medications to be "currently dated" as required by Kansas law. EMS medications are typically not stored in "ideal" conditions which increases the potential for the medication to not achieve its intended therapeutic effect.

#### **3) *Usage of an alternative medication in protocol until the shortage has resolved***

A service medical director may substitute a medication in shortage with an alternative medication in the service's approved protocol without requiring the protocol to go through the formal statutory "protocol approval" process. The following conditions apply:

- a. The service's medical director must determine that the substituted medication does not disproportionately increase the risk to the patient.
- b. A copy of the updated protocol with the substituted medication must be promptly provided to the Executive Director of the Board and will be presented to the Medical Advisory Council (MAC) at their next scheduled meeting.
- c. The service must maintain documentation that all of the service's providers who may administer the substituted medication have been educated upon the mechanism of action, indications, contraindications, complications, routes of administration, side effects, interactions, dose, and any specific considerations for that medication.
- d. The MAC may, after reviewing the updated protocol, make a recommendation to the Board of a different alternative medication that may need to be considered by the service. Any recommendation from the MAC shall include reasoning as to why their recommendation may be a safer or more appropriate alternative.
- e. Once the shortage has resolved, the service shall promptly provide notice to the Executive Director of the Board.

This Guidance Document may be withdrawn by the Board at any time without notice.