# Kansas Administrative Regulations

## State Board of Pharmacy

### Article 7.—Miscellaneous Provisions

**68-7-15. Packaging of drugs or devices in advance of immediate need.**

All drugs or devices, whether in a unit-dose container or multiple-dose container, packaged in advance of immediate need shall meet the requirements of this regulation.

(a) Packaging shall be done by a pharmacist or under the pharmacist's direct supervision. The pharmacist shall verify and document verification of the packaged drugs or devices before the packaged drugs or devices are released from a facility registered with the board.

(b) Packaging shall be limited to the drugs or devices dispensed from or supplied by the facility registered with the board or in accordance with a shared services agreement.

(c) All containers used for packaging shall preserve the stability and integrity of the drug or device. The storage conditions of each packaged drug or device shall be maintained according to the manufacturer's recommendations to preserve the stability and integrity of the drug. The beyond-use date assigned to each packaged drug or device shall be the manufacturer's expiration date, the maximum allowable beyond-use date for the type of packaging material used, or not more than 12 months from the date of packaging, whichever is earlier.

(d) An electronic or a written record shall be established for lot numbers for recall purposes and shall be kept readily retrievable in the facility registered with the board.

(e) If an area apart or separated from the prescription drug area is used for packaging, the area shall be enclosed and locked when a pharmacist is not in attendance in that area.

(f) In lieu of separately dispensing a drug and an ingestible event marker approved by the food and drug administration to monitor whether a patient is taking the drug as prescribed, any pharmacist may use an ingestible event medication adherence package pursuant to a valid prescription order or after obtaining the consent of the practitioner, caregiver, or patient.

(g) For purposes of this regulation, "ingestible event medication adherence package" shall mean an ingestible unit-dose package designed to ensure medication adherence that contains drugs from a manufacturer's original container and an ingestible event marker, as defined by 21 C.F.R. 880.6305, effective February 1, 2022 and hereby adopted by reference.

(h) In addition to meeting the requirements of this regulation, all packaging of sterile preparations shall meet the requirements of K.A.R. 68-13-4.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2022 Supp. 65-1626a and K.S.A. 65-1634; effective May 1, 1978; amended Dec. 15, 2017; amended Nov. 29, 2019; amended June 2, 2023.)