Kansas Administrative Regulations

State Board of Pharmacy

Article 13.—Parenteral Products

68-13-3. Nonsterile preparations.

(a) This regulation shall apply to the following:

(1) Nonsterile preparations that are compounded in Kansas; and

(2) nonsterile preparations that are shipped or delivered into Kansas by a pharmacy and are to be administered to a patient in Kansas.

(b) "Pharmacy," as used in this regulation, shall mean a pharmacy, nonresident pharmacy, or outsourcing facility as defined by K.S.A. 2017 Supp. 65-1626, and amendments thereto.

(c) Any pharmacist may compound a nonsterile preparation that is commercially available only if it is different from a product approved by the FDA and there is sufficient documentation of a specific medical need for an individual patient.

(d) A pharmacist shall not compound a nonsterile preparation by any of the following methods:

(1) Using any component withdrawn from the market by the FDA for safety reasons;

(2) receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet the requirements of an official compendium;

(3) compounding finished drugs from bulk active ingredients that do not meet the requirements of a monograph listed in the official compendium; or

(4) compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs.

(e) For the convenience of any patient, any pharmacist may compound a nonsterile preparation before receiving an order based on routine, regularly observed prescribing patterns.

(f) Compounding for non-human animals shall meet the same requirements as those for human prescriptions, except that a pharmacist shall not compound bulk chemicals for food-producing animals.

(g) Each nonsterile preparation sold by a pharmacy to a practitioner for administration to a patient shall be packaged with a label that includes the following text: "For Office Use Only — Not for Resale."

(h) Any pharmacy may distribute nonsterile preparations without a prescription, including providing limited quantities to a practitioner in the course of professional practice to administer limited quantities to an individual patient, if the nonsterile preparations are not intended for resale.

(i) Each pharmacy selling any prescription nonsterile preparation to a practitioner for office use shall maintain an invoice documenting the following:

(1) The name and address of the practitioner;

(2) the drug compounded, including the lot number and expiration date of each component;

(3) the quantity sold; and

(4) the date of the transaction.

The invoice shall be maintained in the pharmacy and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(j) Within each pharmacy in which compounding occurs, one area shall be designated as the principal compounding area, where all nonsterile compounding shall take place.

(1) Each compounding area shall be well-lighted and well-ventilated, with clean and sanitary surroundings, and shall be free of food and beverages.

(2) Each compounding area shall provide the drugs, chemicals, and devices with necessary protection from deterioration due to light, heat, and evaporation and shall be arranged to protect all prescription drugs and devices from theft and any other unauthorized removal.

(3) All components used in compounding nonsterile preparations shall be stored in labeled containers in a clean, dry area and, if required, under proper refrigeration.

(4) Each compounding area shall include a sink that is equipped with hot and cold running water for hand and equipment washing.

(k) Each pharmacist compounding nonsterile preparations shall use purified water if the formulations indicate the inclusion of water.

(l) Each pharmacist-in-charge shall maintain a uniform formulation record for each nonsterile preparation, documenting the following:

(1) The ingredients, quantities, strength, and dosage form of the nonsterile preparation;

(2) the equipment used to compound the nonsterile preparation and the mixing instructions;

(3) the container used in dispensing;

(4) the storage requirements;

(5) the beyond-use date to be assigned;

(6) quality control procedures, which shall include identification of each person performing or either directly supervising or checking each step in the compounding process and which may include monitoring the following:

(A) Capsule weight variation;

(B) adequacy of mixing to ensure uniformity and homogeneity; and

(C) the clarity, completeness, or pH of solutions;

(7) the source of the formulation, including the name of the person, entity, or publication; and

(8) the name or initials of the person creating the formulation record and the date on which the formulation record was established at the pharmacy.

(m) Each pharmacist-in-charge shall maintain on the original order or on a separate, uniform record a compounding record for each nonsterile preparation, documenting the following:

(1) The name and strength of the nonsterile preparation;

(2) the identifier used to distinguish the nonsterile preparation's formulation record from other formulation records;

(3) the name of the manufacturer or repackager and, if applicable, the lot number and expiration date of each component;

(4) the total number of dosage units or total quantity compounded;

(5) the name of each person who compounded the nonsterile preparation;

(6) the name of the pharmacist, or the pharmacy student or intern working under the direct supervision and control of the pharmacist, who verified the accuracy of the nonsterile preparation;

(7) the date of compounding;

(8) the assigned internal identification number, if used;

(9) the prescription number, if assigned;

(10) the results of quality control procedures; and

(11) the assigned beyond-use date. In the absence of valid scientific stability information that is applicable to a specific drug or nonsterile preparation, the beyond-use date shall not be later than the expiration date of any component of the formulation and shall be established in accordance with the following criteria:

(A) For nonaqueous and solid formulations, either of the following:

(i) If a manufactured drug product is the source of the active ingredient, six months from the date of compounding or the time remaining until the manufactured drug product's expiration date, whichever is earlier; or

(ii) if a substance listed in an official compendium is the source of an active ingredient, six months from the date of compounding or the time remaining until the expiration date of any component of the formulation, whichever is earlier;

(B) for water-containing oral formulations, not more than 14 days when stored under refrigeration; and

(C) for water-containing non-oral formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier.

(n) The compounding record and the corresponding formulation record specified in subsections (m) and (l), respectively, shall be retained at the pharmacy for at least five years and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(o) If a patient requests a transfer of the patient's prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist. The transferring pharmacist shall also transfer the following written information with the prescription:

(1) Active ingredients;

(2) concentration;

(3) dosage form;

(4) route of delivery;

(5) delivery mechanism;

(6) dosing duration; and

(7) details about the compounding procedure.

(p) The pharmacist-in-charge shall ensure that all support personnel are trained and successfully demonstrate the following before performing delegated compounding:

(1) Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding as specified in the policy and procedure manual; and

(2) familiarity with the compounding techniques used at the pharmacy.

(Authorized by K.S.A. 65-1630 and K.S.A. 2017 Supp. 65-1637e; implementing K.S.A. 2017 Supp. 65-1626a, K.S.A. 65-1634, K.S.A. 65-1637c, and K.S.A. 2017 Supp. 65-1642; effective May 11, 2018.)