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Ohio Administrative Code

Rule 4729:7-3-04 Immediate-Use, Sterile Non-Hazardous Drugs Compounded by a Prescriber.

Effective: April 2, 2021

(A) The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring that compounded drug preparations maintain quality and sterility until administered;

(6) Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code;

(7) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(8) Ensuring aseptic technique for the preparation of all sterile compounded drugs.

(B) Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

(1) The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(2) Personnel shall adhere to appropriate aseptic technique, including all the following:

(a) Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure; and

(b) Compounding personnel shall don gloves prior to engaging in compounding activities.

(3) If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces.

(4) The beyond-use date for an immediate-use compounded drug preparation is as follows:

(a) Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug.

(b) For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug.

(5) If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code.

(6) Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

(a) Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name;

(b) The name and quantity of each ingredient;

(c) The beyond-use date and time prepared; and

(d) The name or initials of the person who prepared the compounded drug preparation.

(7) Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber.

(8) For an immediate-use compounded drug preparation administered via injection, a new sterile needle shall be used to administer the compounded drug preparations to the patient.

(C) Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins.

(D) Preparations that are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797> shall not be prepared as immediate-use.

(E) Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code.

(F) Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(1) Except as provided in paragraph (G)(2) of this rule, compounding for anticipated needs or

engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.

(2) A prescriber may compound preparations of buffered lidocaine containing antimicrobial preservatives for anticipated needs where multiple non-patient specific doses are produced in a single activity.

(H) Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code.

(1) Except as provided for in paragraph (I)(2) of this rule, this rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling hazardous drug preparations, a prescriber who is a veterinarian shall comply with rule 4729:7-3-05 of the Administrative Code.

(2) A veterinarian engaged in the compounding of immediate-use sterile drug preparations shall comply with the following:

(a) Unless administered immediately, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner, if applicable, and the name or identification of the animal;

(ii) The name and quantity of each ingredient;

(iii) The date and time prepared; and

(iv) The name or initials of the person who prepared the compounded drug preparation.

(J) For hazardous compounded drugs, the prescriber shall comply with rule 4729:7-3-05 of the Administrative Code.

(K) A prescriber may designate an appropriately trained agent to prepare compounded drug preparations.

(L) For all compounded drugs prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered.

(M) The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

(1) A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule; or

(2) A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule.

(N) All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

(1) Verify patient identification using at least two identifiers (e.g., last name, medical record number, DOB, etc.).

(2) Confirm with the patient the patient's planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed.

(5) A licensed prescriber is on-site and immediately available.