# Ohio Administrative Code

## Rule 4729-16-13 Immediate Use Non-Hazardous Sterile Drugs Compounded by a Prescriber.

Effective: April 1, 2017

(A) A facility where a prescriber is compounding dangerous drugs for immediate use shall be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.541 of the Revised Code. The responsible person on the license shall be an Ohio licensed prescriber as defined in section 4729.01 of the Revised Code and is responsible for all of the following:

(1) Developing and implementing appropriate procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;

(4) Ensuring competency of compounding personnel; and

(5) Ensuring that compounded drug products maintain their quality and sterility until administered.

(B) Immediate use sterile compounded drug products are exempt from the requirements in rule 4729-16-04 of the Administrative Code when all of the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous drug products 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 of the following:

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

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

(3) If not immediately administered, the finished drug product is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug products, and direct contact of outside surfaces.

(4) Notwithstanding paragraph (B)(1) of rule 4729-9-01 of the Administrative Code, the beyond-use date for an immediate use compounded drug product is no later than six 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 discarded.

(6) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded drug product shall bear a label listing the exact beyond-use date.

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

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

(C) Preparations that are medium-risk level and high-risk level compounded drug products as defined in United States Pharmacopeia Chapter <797>, USP 39 - NF 34, or any official supplement thereto (5/1/2016) shall not be prepared as immediate use. Preparations that cannot meet any of the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729-16-04 of the Administrative Code.

(D) Sterile compounded drug products for immediate use shall be prepared in a designated clean

medication area that is not adjacent to areas where potentially contaminated items are placed. Cleaning and disinfecting of areas within the designated area including counters, easily cleanable work surfaces and floors shall occur each business day. If compounding is done less frequently than each business day (e.g., once a week or once a month), cleaning shall occur before and after each compounding session. Cleaning and disinfection agents must be selected and used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(E) A prescriber may designate an appropriately trained agent to assist the prescriber in the preparation of the sterile drug products.

(F) For all compounded drugs prepared pursuant to this rule, the prescriber shall:

(1) Inspect and approve the compounding process.

(2) Perform the final check of the finished product.

(G) Paragraph (F) of this rule does not apply if either:

(1) A compounded product is being administered to a patient in the facility by a licensed health professional in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two licensed personnel approved by the responsible person to prepare or administer compounded drugs complies with the requirements in paragraph (H) of this rule.

(2) A compounded drug product is being prepared and administered to a patient in the facility by a registered nurse in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, the same registered nurse complies with paragraph (H) of this rule.

(H) The following are required prior to the administration of a compounded drug product in accordance with paragraphs (G)(1) and (G)(2) of this rule:

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

(2) Confirm with the patient his/her 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) Sign using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code to indicate verification was completed;

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

(6) For hazardous compounded drugs, the prescriber shall comply with rule 4729-16-11 of the Administrative Code.

(I) This rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729-16-11 of the Administrative Code.

(J) Immediate-use compounded drug products shall be prepared in accordance with this rule except in an emergency situation, 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.

(K) A prescriber shall not compound drugs for anticipated needs or engage in compounding practices where multiple non-patient specific doses are produced in a single activity.