4729-16-04 **Drugs Compounded by a Prescriber.**

(A) A facility where a prescriber is compounding drugs shall be licensed as a terminal distributor of dangerous drugs. 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 personnel; and

(5) Assuring environmental control of the compounding areas.

(B) As used in this rule, a low-risk sterile compounded drug means all of the following:

(1) Does not involve any hazardous drugs as defined in rule 4729-16-01 of the Administrative Code.

(2) The drug is compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(3) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile product.

(4) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(5) Administration of the drug shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.

(C) A prescriber who prepares low-risk sterile compounded drugs as defined in paragraph (B) of this rule shall meet all of the following requirements:

(1) A policy and procedure manual shall be prepared, maintained, and reviewed regularly by the responsible person regarding the compounding, safe handling, personally furnishing, and administration of compounded drugs.

The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education. The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent. The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.

(2) Physical requirements

(a) The facility shall have a designated area with access limited to authorized personnel for preparing low risk sterile compounded drugs. This area shall be isolated from other areas; including areas used to prepare hazardous compounded products, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of low risk sterile compounded drugs and provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The facility shall have:

(i) (i) Appropriate primary engineering control devices capable of maintaining an ISO Class 5 environment in the work place where critical objects are exposed and critical activities are performed. These devices shall be capable of maintaining an ISO Class 5 environment during normal activity. Examples of such devices include laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

(ii) Infusion devices and equipment, if appropriate.

(iii) Appropriate temperature controlled transport containers.

(c) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(d) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.

(e) Low-risk sterile compounded drugs shall prepared within an ISO Class 5 environment except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(3) Patient training

(a) Whenever possible, a prescriber shall be involved in discussing with each patient receiving a low-risk sterile compounded product, or the caregiver of such individual, the following matters:

(i) Dosage form, dosage, route of administration, and duration of drug therapy;

(ii) Special directions and precautions for preparation and administration;

(iii) Stability or incompatibilities of the medication.

(4) Quality assurance

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities. At a minimum, there shall be written quality assurance programs developed that address:

(i) Adequate training and continuing competency monitoring, including an initial skills assessment and examination as well as annual assessments, of compounding personnel in all of the following areas:

(a) personal cleansing including proficiency of proper hand hygiene;

(b) proper attire;

(c) aseptic technique;

(d) proper clean room conduct; and

(e) clean room disinfecting procedures.

(ii) Continued verification of compounding accuracy including physical inspection of end products.

(iii) Continued verification of automated compounding devices.

(iv) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected.

(b) Instructors shall have the appropriate knowledge and experience

necessary to conduct the training.

(c) All clean rooms and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.

(5) Personal Protective Equipment (PPE)

(a) The following PPE is required for compounding sterile drug products:

(i) Sterile powder-free gloves;

(ii) Gowns, head, hair, and shoe covers.

(D) For non-sterile compounded drugs, the prescriber shall comply with the United States Pharmacopeia Chapter <795>.

(E) For low-risk with greater than 12 hour beyond use date, allergen extracts, medium and high-risk sterile compounded drugs as defined in United States Pharmacopeia Chapter <797>, the prescriber shall comply with United States Pharmacopeia Chapter <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

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

(G) A prescriber may designate an appropriately trained agent to assist the prescriber in the compounding of drugs.

(H) 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.

(I) Paragraph (H) of this rule does not apply if 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 do all of the following:

(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 dose;

(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 section (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.

(J) For all compounded drug products, the prescriber shall be responsible for:

(1) All compounding records pursuant to rule 4729-16-06 of the Administrative Code, including positive identification requirements pursuant to section (N) of rule 4729-5-01 of the Administrative Code;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(K) A compounded drug that is personally furnished by a prescriber must be labeled according to rule 4729-5-17 of the Administrative Code and must include the appropriate beyond use date, in accordance with United States Pharmacopeia Chapters <797> or <795> and complete list of ingredients. The statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(L) A prescriber shall not compound drugs in anticipation of prescriptions based on routine prescribing patterns.

(M) The prescriber shall comply with the drug database reporting requirements for Chapter 4729-37 of the Ohio Administrative Code.

(N) This rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741 of the Ohio 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.

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