

## SUMMARY OF LAWS & RULES

### FLUID THERAPY

[Chapter 4729-19 of the Ohio Administrative Code]

Rule 4729-19-01 Definitions. [OAC: 07/01/93]  
(Amplifies 3719.01, 3719.28, 4729.02, 4729.26, 4729.66)

(A) As used in Chapters 4729-1 to 4729-19 of the Administrative Code:

- (1) "Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment according to "National Sanitation Foundation (NSF) Standard 49".
- (2) "Class 100 environment" means an atmospheric environment which contains less than one hundred particles of 0.5 microns in diameter per cubic foot of air according to "Federal Standard 209D."
- (3) "Compounding facility" means a site licensed as a terminal distributor of dangerous drugs where the compounding of sterile product prescriptions occurs.
- (4) "Cytotoxic" means a drug that has been shown to be carcinogenic or mutagenic to humans through active or passive exposure.
- (5) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.
- (6) "Sterile product" means a dosage form free of living micro-organisms (aseptic).

(B) Compounded sterile product prescriptions include, but are not limited to, the following preparations:

- (1) Total parenteral nutrition (TPN) solutions;
- (2) Parenteral analgesic drugs;
- (3) Parenteral antibiotics;
- (4) Anti-neoplastic agents;
- (5) Electrolytes;
- (6) Vitamins;
- (7) Irrigating fluids;
- (8) Ophthalmic preparations.

(C) Sterile product prescriptions shall not include commercially manufactured products that do not require compounding prior to dispensing.

Rule 4729-19-02 Prescriptions for sterile products. [OAC: 11/25/94]  
(Amplifies 3719.06, 3719.07, 3719.28, 4729.26, 4729.37, 4729.66)

Sterile product prescriptions must meet the requirements of rule 4729-5-30 of the Administrative Code except that a sterile product prescription prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to

a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained as in paragraphs (D) and (K) of rule 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the practitioner's office or the institutional facility where it was issued.

Rule 4729-19-03 Labeling. [OAC: 07/01/93]  
(Amplifies 3719.08, 3719.28, 4729.02, 4729.26, 4729.66)

No sterile product prescription may be dispensed to an outpatient unless the container in which such prescription is dispensed is labeled pursuant to rule 4729-5-16 of the Administrative Code nor to an inpatient unless the container in which such prescription is dispensed is labeled pursuant to rule 4729-17-10 of the Administrative Code. In addition, the label shall include the beyond-use date of the final preparation.

Rule 4729-19-04 Minimum standards for compounding parenteral or sterile product prescriptions.  
[OAC: 07/01/93]  
(Amplifies 4729.55, 4729.66)

- (A) A compounding facility shall meet the minimum standards for institutional facility and health care facility pharmacies pursuant to rule 4729-17-08 of the Administrative Code.
- (B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile product prescriptions.
  - (1) 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.
  - (2) The policy and procedure manual shall include policies and procedures for cytotoxic waste, if applicable.
  - (3) The policy and procedure manual shall be current and available for inspection by a board of pharmacy designated agent.
- (C) Physical requirements
  - (1) The facility shall have a designated area with access limited to authorized personnel for preparing parenteral and sterile products. This area shall be isolated from other areas 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 these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
  - (2) The facility compounding parenteral and sterile product prescriptions shall have:
    - (a) Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
    - (b) Appropriate disposal containers for used needles, syringes, etc. and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents;

- (c) Appropriate environmental control including approved biohazard cabinetry when cytotoxic drug products are prepared;
  - (d) Infusion devices and equipment, if appropriate;
  - (e) Appropriate temperature-controlled transport containers.
- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
  - (4) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.
  - (5) The compounding of sterile products shall be done within a class 100 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.

(D) Delivery service

The responsible person shall assure the environmental control of all products shipped to the patient.

(E) Disposal of cytotoxic and/or hazardous waste

The responsible person shall assure that there is a system for the disposal of cytotoxic and/or hazardous waste in a manner so as not to endanger the public health.

(F) Cytotoxic drugs

The following requirements are necessary for those facilities that prepare cytotoxic drugs to ensure the protection of the personnel involved:

- (1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet. Other products should not be compounded in this cabinet.
- (2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include at least gloves and gowns with tight cuffs.
- (3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- (4) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
- (5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed and shall be included in the policy and procedure manual.
- (6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(G) Patient training

Whenever possible, a pharmacist shall be involved in discussing with each patient receiving an outpatient parenteral or sterile product prescription, or the caregiver of such individual, the following matters:

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

- (2) Special directions and precautions for preparation and administration;
- (3) Proper storage; and
- (4) Stability or incompatibilities of the medication.

(H) Quality assurance

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities.

- (1) All clean rooms and laminar flow hoods shall be certified for operational efficiency at least every six months. Appropriate records shall be maintained.
- (2) There shall be written procedures developed requiring appropriate sampling if microbial contamination is suspected.
- (3) If bulk compounding of parenteral or sterile products is performed using non-sterile chemicals, extensive end-product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- (4) There shall be written justification for the chosen beyond-use dates of compounded products.

(11/01/96)