



ADMINISTRATIVE RULES OF MONTANA



37.106.2422 HOME INFUSION THERAPY AGENCY: PHYSICAL REQUIREMENTS FOR PHARMACIES

- (1) The pharmacy must have a designated area with entry restricted to designated personnel for preparing sterile products. This area must be:
 - (a) a separate room with a closed door, isolated from other areas with restricted entry or access, and designed to avoid unnecessary traffic and airflow disturbances from activity as required by United States Pharmacopoeia (USP) USP 31 General Chapter 797 Pharmaceutical Compounding - Sterile Preparations;
 - (b) used only for the preparation of sterile pharmaceuticals;
 - (c) 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; and
 - (d) one with cleanable work surfaces, walls, and floors.
- (2) If a home infusion therapy agency elects to use a Compounding Aseptic Isolator (CAI), the "separate room" requirement of (1)(a) is not required, provided that the home infusion therapy agency maintains documentation of meeting the standards for this exception of CAIs set forth in USP 31 General Chapter 797.
- (3) The pharmacy preparing the sterile products must have:
 - (a) appropriate environmental control devices capable of maintaining at least an ISO Class 5 in the workplace where critical activities are performed. The devices must be capable of maintaining this condition during normal activity. Examples of appropriate devices include vertical and horizontal laminar airflow hoods and zonal laminar flow of high efficiency particulate air filtered air. All airflow hoods used by the home infusion therapy agency must be certified as able to maintain an ISO Class 5 environment as required by USP 31 General Chapter 797 Pharmaceutical Compounding - Sterile Preparations;
 - (b) appropriate disposal containers for used needles, syringes, etc., and if applicable, for antineoplastic waste from the preparation of antineoplastic agents and infectious wastes from patients' homes;
 - (c) appropriate biohazard cabinetry when antineoplastic drug products are prepared;
 - (d) temperature controlled delivery containers, when necessary;
 - (e) infusion devices, when necessary;
 - (f) a sink with hot and cold running water which is convenient to compounding area for the purpose of hand scrubs prior to compounding; and

- (g) a refrigerator/freezer with a thermometer.
- (4) The pharmacy shall maintain supplies and provide attire adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- (5) The pharmacy shall maintain sufficient current reference materials relating to sterile products to meet the needs of the pharmacy personnel.
- (6) The pharmacy shall document a chain of possession for all controlled substances including return or disposal of unused controlled substances.
- (7) All pharmacies utilized by or part of a home infusion therapy agency must be able to deliver to the home infusion therapy agency patient any needed medications and therapies within 24 hours of the need being recognized. If a pharmacy is not able to ensure a 24-hour response time, a current contract with a pharmacy that is able to ensure a 24-hour response time is required, and must be kept at the home infusion therapy agency.
- (8) If the home infusion therapy agency utilizes a pharmacy located outside the state of Montana, documentation must be maintained at the home infusion therapy agency site that the pharmacy utilized has a current Montana pharmacy license per Board of Pharmacy requirements, and that it meets the requirements of this rule.

Authorizing statute(s): 50-5-103, MCA

Implementing statute(s): 50-5-103, 50-5-213, MCA

History: NEW, 1996 MAR p. 2587, Eff. 10/4/96; TRANS, from DHES, 2002 MAR p. 185; AMD, 2009 MAR p. 1668, Eff. 9/25/09.