



ADMINISTRATIVE RULES OF MONTANA

37.106.2401 HOME INFUSION THERAPY AGENCY: DEFINITIONS

In addition to the definitions in 50-5-101, MCA, the following definitions apply to this subchapter:

- (1) "Antineoplastic" means a pharmaceutical that has the capability of killing malignant cells.
- (2) "Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents.
- (3) "Critical area" means an area where sterilized products or containers are exposed to the environment during aseptic preparation.
- (4) "Enteral" means a preparation compounded in an ISO Class 5 environment, dispensed by a pharmacist, and administered by way of the intestine.
- (5) "Home infusion therapy (HIT) services" means the preparation, administration, or furnishing of parenteral medications, or parenteral or enteral nutritional services to an individual in that individual's residence. The services include an educational component for the patient, the patient's caregiver, or the patient's family member.
- (6) "ISO Class 5" means a classification of air cleanliness as defined in United States Pharmacopoeia (USP) USP 31 General Chapter 797 Pharmaceutical Compounding - Sterile Preparations.
- (7) "Licensed health care professional" means a physician (M.D. or D.O.), a physician assistant-certified, a nurse practitioner, or a registered nurse practicing within the scope of their license.
- (8) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin with infusion administration time determined by the recommendation of the pharmaceutical manufacturer.
- (9) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph."
- (10) "Pharmacist-in-charge or their designee" means a licensed pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of such pharmacy.
- (11) "Pharmacy" means an established location, either physical or electronic, registered by the Board of Pharmacy where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.
- (12) "Prescribing practitioner" means a licensed health care professional authorized by state statute or federal law to prescribe pharmaceuticals and/or treatments.

- (13) "Sterile pharmaceutical or product" means an aseptic dosage form free from living micro-organisms.

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.