



ADMINISTRATIVE RULES OF MONTANA



37.106.2420 HOME INFUSION THERAPY AGENCY: POLICY AND PROCEDURE MANUAL

- (1) The home infusion therapy agency shall develop a policy and procedure manual for the organization and operation of the home infusion therapy agency. A copy of the manual must be kept current at all times, and be readily available at all times, and to all who request it.
- (2) The manual must include an organizational chart delineating the lines of authority, responsibility, and accountability for the administration and patient care services of the agency.
- (3) The manual must specifically detail the storage, stability, handling, compounding, labeling, dispensing, and delivery of all sterile pharmaceuticals and address requirements relating to:
 - (a) security measures, which ensure that the premises where sterile pharmaceuticals are present are secured, and which prevent access to patient records by unauthorized personnel;
 - (b) sanitation, including the methodology of cleaning biological safety cabinets and laminar flow hoods, and of inspecting filters for deterioration and microbial contamination;
 - (c) the annual certification of safety cabinets and laminar floor hoods;
 - (d) the orientation of personnel;
 - (e) the duties and qualifications of staff;
 - (f) record keeping requirements;
 - (g) medication profiles;
 - (h) the administration of parenteral therapy to include infusion devices, drug delivery systems, and monitoring;
 - (i) the pharmacy patient evaluation and documentation;
 - (j) prescription processing;
 - (k) clinical services;
 - (l) drug and product selection;
 - (m) 24-hour emergency access to a pharmacist;
 - (n) the handling of antineoplastic agents, a description of which must include protective apparel to be worn by compounding personnel;
 - (o) drug destruction, returns, and proper waste management;

- (p) equipment management, including tracking, cleaning, and testing of infusion pumps;
- (q) end product testing;
- (r) a quality assessment program;
- (s) a risk management program including incident reports,
adverse drug reactions, product contamination, and drug recalls;
- (t) education and training of the patient or the patient's caregiver;
- (u) emergency drug and supply procurement;
- (v) guidelines for handling investigational drug administration;
- (w) reference materials; and
- (x) an emergency preparedness plan.

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.