ADMINISTRATIVE RULE OF MONTANA
HEALTHCARE FACILITIES
37.106 Subchapter 24
Home Infusion Therapy

RULE

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.

37.106.2404 HOME INFUSION THERAPY AGENCY: RESPONSIBILITY FOR SERVICES

(1) Where a home infusion therapy agency directly provides either the home infusion therapy services or skilled nursing services and arranges for the provision of the other services, the parties must enter into a written contract defining the nature and scope of the services to be provided by each party. The contract must:

(a) describe the services to be provided by each party; and

(b) specify the responsibilities of each party in the provision, coordination, supervision, and evaluation of the care or services provided. This must include each party's role in:

(i) the patient admission process;

(ii) the patient assessment process;

(iii) the patient education process;

(iv) the development, review, and revision of the patient plan of care;

(v) the development, review, and revision of the patient medical record;

(vi) the provision of clinical services;

(vii) the timely reporting of adverse reactions to treatment, medical symptoms, or abnormal lab values;

(viii) the timely reporting of the patient failing to comply with the home infusion regiment;

(ix) the patient care conferences; and

(x) discharge planning.

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.

37.106.2405 HOME INFUSION THERAPY AGENCY: ADMINISTRATOR AND PERSONNEL

(1) Each home infusion therapy agency must employ an administrator who shall:

(a) organize and direct the home infusion therapy agency's ongoing functions;

(b) be responsible for ongoing oversight of the home infusion therapy agency's quality assessment system, including the establishment of policies and procedures which address the safe control, accountability, distribution, and administration of infusion products;

(c) employ qualified personnel and ensure adequate staff

education and evaluation; and

(d) be familiar with and assure compliance with the rules

of this subchapter.

(2) For a pharmacy which is licensed as a home infusion therapy agency, the pharmacist-in-charge may serve as the administrator.

(3) All services provided by the home infusion therapy agency and its employees must be provided in accordance with state laws, regulations, and home infusion therapy agency policies and procedures.

(4) The home infusion therapy agency must maintain, at all times, a pharmacist-in-charge (or designee) and a Montana licensed nurse that are both accessible and physically able to respond 24 hours a day, seven days per week.

(5) The home infusion therapy agency shall document in the employee record:

(a) all professional employee orientation;

(b) competency assessments;

(c) specialized training required within the respective professions; and

(d) a current license.

(6) The pharmacist-in-charge may be assisted by supportive personnel. Supportive personnel must work under the immediate supervision of a licensed pharmacist and have specialized training in the field of home infusion therapy. The duties and responsibilities of these personnel must be consistent with their training and experience.

(7) The licensed health care professional providing skilled nursing services shall:

(a) provide those services in accordance with the plan of care;

(b) dictate or write clinical notes at the time of service. Clinical notes must be signed, recorded, and incorporated into the patient's medical record within three working days of providing the service;

(c) assist in coordinating all services provided; and

(d) notify the pharmacist, the prescribing practitioner, and the home infusion therapy agency's personnel responsible for the care of the patient, of any significant changes in the patient's condition.

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

Implementing statute(s): 50-5-103 and 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.

37.106.2406 HOME INFUSION THERAPY: CLINICAL SERVICES

(REPEALED)

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; REP, 2009 MAR p. 1668, Eff. 9/25/09.

37.106.2407 HOME INFUSION THERAPY AGENCY: QUALITY ASSESSMENT

(1) Each home infusion therapy agency shall prepare and maintain on file an annual report of improvements made as a result of a quality assessment program.

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.

37.106.2411 HOME INFUSION THERAPY AGENCY: EDUCATION SERVICES

(1) Each home infusion therapy agency, and any contracted party providing services to the patient, together, shall:

(a) provide the patient or the patient's caregiver with education and counseling on proper storage, scheduling, and risks associated with specific drugs and infusion therapy in general, the proper disposal of unused or outdated medications, and document the counseling sessions in the patient's medical record;

(b) provide to the patient and/or patient caregiver written educational material which must include at a minimum:

(i) drug information sheets for prescribed therapy;

(ii) compounding, admix technique, adding medications to solutions, and withdrawing medications from vials;

(iii) function, operation, and troubleshooting durable medical equipment when prescribed; and

(iv) supplies and training for safe and proper handling and disposal of antineoplastic, infectious, and hazardous waste.

(c) reassess on an ongoing basis, the patient's competency or the patient's caregiver's competency, in managing home infusion therapy in the home environment and document the reassessment process in the patient's medical.

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.

37.106.2412 HOME INFUSION THERAPY AGENCY: MEDICAL RECORD

(1) Each home infusion therapy agency shall establish and maintain for each patient accepted for care, a medical record which must be accessible to home infusion therapy personnel and which must include the following information:

(a) admission data, including the:

(i) name;

(ii) current address;

(iii) date of birth;

(iv) sex;

(v) date of admission;

(vi) name and contact information of the patient's caregiver or family member; and

(vii) name and contact information of the pharmacist-in-charge and the prescribing practitioner.

(b) admission diagnosis and pertinent health information relevant to the plan of care;

(c) any allergies and known adverse reactions to drugs and food. This information must be given such prominence in the record so as to make it obvious to any persons who provide food or medication to the patient;

(d) laboratory reports;

(e) documentation that a list of patient rights and responsibilities have been made available to each patient or the patient's caregiver;

(f) the plan of care;

(g) clinical assessments and services documentation;

(h) the prescribing practitioner's order for home infusion therapy;

(i) a monthly clinical therapy summary for any patient receiving services 30 days or longer; and

(j) a discharge summary of therapy at the end of treatment.

(2) The responsibilities of the patient and the home infusion therapy agency, including any contracted parties, in the areas of delivery of care and monitoring of the patient, must be clearly documented in the patient's medical record.

(3) The home infusion therapy agency, and any contracted party providing services to the patient, together, shall develop a plan of care within three working days of the initiation of therapy, which must include:

(a) a diagnosis;

(b) the types of services and equipment required;

(c) the access device and route of administration;

(d) the estimated length of service;

(e) a statement of treatment goals;

(f) the regimen and prescription ordered;

(g) the concurrent legend and over the counter drugs;

(h) an assessment of mental status;

(i) permitted activities;

(j) the prognosis, discharge, transfer or referral plan; and

(k) instructions to patient and family.

(4) All records of dispensed sterile pharmaceuticals must be a part of the patient's medical record.

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.

37.106.2415 HOME INFUSION THERAPY AGENCY: ADMINISTRATION OF MEDICATION AND TREATMENT

(1) All medications and treatments administered by the home infusion therapy agency's personnel or contracted parties must be administered by a Montana licensed health care professionals.

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.

37.106.2416 HOME INFUSION THERAPY AGENCY: PARENTERAL OR ENTERAL SOLUTIONS

(1) In addition to the minimum requirements for a pharmacist and a pharmacy established by Title 37, chapter 7, MCA, and ARM Title 24, chapter 174, any parenteral or enteral solution provided by the home infusion therapy agency or obtained through contract with a third party pharmacy and provided to patients of the home infusion therapy agency must be dispensed by a licensed pharmacist in a Montana licensed pharmacy, whom and which are in compliance with the requirements of ARM 37.106.2404, 37.106.2407, 37.106.2422, 37.106.2423, and 37.106.2430 through 37.106.2433.

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.

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.

37.106.2421 HOME INFUSION THERAPY AGENCY: INCORPORATION BY REFERENCE

(1) The department adopts and incorporates by reference United States Pharmacopoeia (USP) 31 General Chapter 797 Pharmaceutical Compounding - Sterile Preparations, June 1, 2008, which sets practice standards to help ensure that compounded sterile preparations are of high quality. A copy of USP 31 General Chapter 797 Pharmaceutical Compounding - Sterile Preparations may be obtained from USP Headquarters, 12601 Twinbrook Parkway, Rockville, MD 20852-1790, telephone (800) 227-8772 or http://www.usp.org/products/797Guidebook.

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

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

History: NEW, 2009 MAR p. 1668, Eff. 9/25/09.

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.

37.106.2423 HOME INFUSION THERAPY: DISPENSING OF STERILE PHARMACEUTICALS

(1) The pharmacy shall maintain a record of each sterile pharmaceutical dispensed for at least two years after the last dispensing activity. This record must include, but not be limited to:

(a) the products and quantity dispensed;

(b) the date dispensed;

(c) the prescription identifying number;

(d) the directions for use;

(e) the identification of the dispensing pharmacist and preparing pharmacy technician, if appropriate;

(f) the manufacturer lot number and expiration date, stability date (or recall policy if the lot number is not recorded);

(g) the compounding or special instructions, if applicable; and

(h) the next scheduled delivery date.

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.

37.106.2426 HOME INFUSION THERAPY: PHARMACY PERSONNEL

(REPEALED)

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; REP, 2009 MAR p. 1668, Eff. 9/25/09.

37.106.2430 HOME INFUSION THERAPY AGENCY: LABELING

(1) Parenteral pharmaceuticals dispensed to patients must have a permanent label with the following information:

(a) the name and contact information of the pharmacy including a phone number which provides access to a pharmacist 24 hours per day, seven days per week;

(b) the date the product was prepared;

(c) the prescription identifying number;

(d) the patient's full name;

(e) the name of the prescribing practitioner;

(f) the directions for use including infusion rate and infusion device, if applicable;

(g) the name of each component, its strength, and amount;

(h) the expiration date of the product based on published data;

(i) the appropriate ancillary instructions such as storage instructions or cautionary statements including antineoplastic warning when applicable; and

(j) the identity of the pharmacist compounding and dispensing the product.

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.

37.106.2431 HOME INFUSION THERAPY AGENCY: ANTINEOPLASTIC DRUGS

(1) The following requirements must be met by those pharmacies that prepare antineoplastic drugs to ensure the protection of the personnel involved:

(a) All antineoplastic drugs must be compounded in a vertical flow, Class II, biological safety cabinet.

(b) Protective apparel must be worn by personnel compounding antineoplastic drugs according to the home infusion agency's policies and procedures. This must include gloves, gowns with tight cuffs, and appropriate equipment as necessary.

(c) Appropriate safety and containment techniques for compounding antineoplastic drugs must be used in conjunction with the aseptic techniques required for preparing sterile pharmaceuticals.

(d) Written procedures for handling both major and minor spills of antineoplastic agents must be included in the policy and procedure manual.

(e) Prepared doses of antineoplastic drugs must 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.

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.

37.106.2432 HOME INFUSION THERAPY AGENCY: DISPOSAL OF ANTINEOPLASTIC, INFECTIOUS, AND HAZARDOUS WASTES

(1) Disposal of antineoplastic, infectious, and hazardous waste is governed by the Infectious Waste Management Act, Title 75, chapter 10, part 10, MCA.

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.

37.106.2433 HOME INFUSION THERAPY AGENCY: DELIVERY OF MEDICATIONS

(1) The home infusion therapy agency shall ensure that medications are delivered according to the prescribed start of therapy so that the prescription for sterile pharmaceuticals can be implemented as ordered. Once therapy has been initiated, the home infusion therapy agency shall continue to provide sterile pharmaceuticals in a timely fashion so as not to interrupt ongoing therapy.

(2) If the start of therapy is to be delayed for more than two hours from the prescribed start time, the home infusion agency shall notify both the patient and the prescribing practitioner.

(3) Patients must be notified in advance of delivery of the products. Patients must be provided with a receipt for all sterile products and supplies delivered to them.

(4) The pharmacy shall document a chain of possession for all controlled substances.

(5) The home infusion therapy agency shall ensure the environmental control of all products shipped. All compounded, sterile pharmaceuticals must be shipped or delivered to a patient in appropriate, temperature-controlled delivery containers as defined by the United States Pharmacopeia/National Formulary and stored appropriately in the patient's therapy setting.

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.