



ADMINISTRATIVE RULES OF MONTANA



24.174.2002 DEVICE NON-PHARMACY FACILITY REQUIREMENTS

- (1) In-state device facilities shall be inspected by the board and the board reserves the right to inspect out-of-state device facilities for cause.
- (2) Out-of-state device facilities must comply with the following:
 - (a) be a legal entity registered and in good standing with the Montana Secretary of State with a registered agent in Montana for services of process;
 - (b) maintain, in readily retrievable form, records of products dispensed to Montana patients pursuant to a prescription drug order;
 - (c) supply, upon request, all information needed by the board to carry out the board's responsibilities; and
 - (d) upon application, provide verification of licensure in the state in which the facility is located and provide the home-state inspection report.
- (3) A device facility must establish and implement policies and procedures for compliance with the following and be available upon inspection:
 - (a) maintaining records pertaining to the acquisition and supply of, and complaints related to, devices, DME, and/or medical gases;
 - (b) facility security;
 - (c) product storage and security;
 - (d) copy of prescription and records of dispensing pursuant to ARM 24.174.833;
 - (e) labeling of a dispensed product pursuant to ARM 24.174.832 that includes on the device, container, or in the educational information the name, address, and telephone number of the facility;
 - (f) providing directions and/or educational information to the patient regarding the dispensed product;
 - (g) procedures for ensuring patient safety for the appropriate patient care, treatment, and service response requirements for devices dispensed to a patient. The device facility must address how it will perform the following functions for a device provided to a patient:
 - (i) provide all supplies necessary to operate the equipment, and provide information on appropriate storage;
 - (ii) deliver, unpack, and assemble equipment and perform safety and operational checks for a device;

- (iii) adapt, fit, or adjust medical equipment to meet patient need; and
- (iv) maintain, inspect, and test medical equipment;
- (h) provide emergency maintenance, replacement, or backup of medical equipment when needed; and
- (i) for ventilators, life-sustaining infusions, or oxygen, the device facility must provide a backup system, means to provide a duplicate, or a power supply that provides a minimum of three times the licensee's response time to a patient.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-102, 37-7-201, MCA

History: NEW, 2025 MAR, Notice No. 2025-206, Eff. 12/6/25.