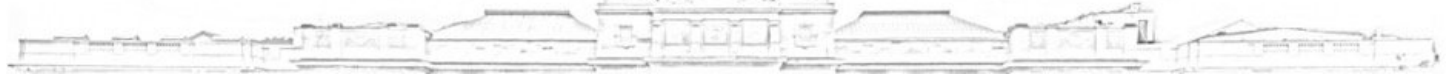




ADMINISTRATIVE RULES OF MONTANA



24.174.1202 MANUFACTURER AND REPACKAGER LICENSING

- (1) Every person seeking licensure as a manufacturer or repackager, for the purposes of wholesale distribution, as defined in 37-7-602, MCA, shall:
 - (a) be a legal entity registered and in good standing with the Montana Secretary of State;
 - (b) file an application on a form prescribed by the board;
 - (c) pay the appropriate licensing and annual renewal fees;
 - (d) meet the requirements of 37-7-604, MCA; and
 - (e) designate a person-in-charge of the facility.
 - (i) The person-in-charge must notify the board of any changes or termination of services.
 - (ii) Within 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.
- (2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.
- (3) The license shall be posted in a conspicuous place in the place of business for which it is issued.
- (4) No license may be issued to any applicant whose intended place of business is a personal residence.
- (5) Applicants located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.
- (6) A separate license is required for each separate location where drugs or devices are stored, repackaged, and/or directly distributed to Montana. For manufacturers, a license shall be issued to a facility meeting the requirements that is located in Montana.
- (7) Licensees shall operate in compliance with applicable federal, state, and local laws and regulations. Licensees who distribute controlled substances shall be licensed by the board, obtain an appropriate dangerous drug endorsement, register with the DEA, and shall comply with all applicable state, local, and DEA regulations.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-201, 37-7-604, 37-7-605, 37-7-610, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2022 MAR p. 1842, Eff. 9/24/22; AMD, 2025 MAR, Notice No. 2025-206, Eff. 12/6/25.