MONTANA BOARD OF PHARMACY
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WHOLESALE DRUG DISTRIBUTOR APPLICATION INSTRUCTIONS

ILLEGIBLE AND INCOMPLETE APPLICATIONS WILL BE RETURNED. Please allow 30 days for processing from the date that the Board has a complete routine application.

A BUSINESS CANNOT OPERATE IN MONTANA IN ANY MANNER WITHOUT AN ACTIVE MONTANA LICENSE

Mont. Admin. Rule (ARM) 24.174.1201 WHOLESALE DRUG DISTRIBUTOR LICENSING
(1) Every person engaged in manufacturing, wholesale distribution, which includes reverse wholesale distribution, or selling of drugs, medicines, chemicals, poisons for medicinal purposes, medical gases, or legend devices other than to the consuming public or patient, in the state of Montana, shall be licensed annually by the board.

NOTICE OF WHOLESALE DRUG DISTRIBUTOR LICENSURE CHANGES

- The Board of Pharmacy will be implementing future licensure changes for all Wholesale Drug Distributor (WDD) licensees as required by the Food and Drug Administration and the Drug Quality and Security Act of 2013 (which includes the Drug Supply Chain Security Act).
- 2017 Montana law, Senate Bill (SB) 68, authorizes the Board to change its existing WDD license type, which includes all prescription drug supply chain entities, so that separate license types will be issued for wholesale distributors, third-party logistics providers (3PLs), manufacturers, and repackagers.
- All supply chain entities must continue to be licensed in Montana as WDD until rules are in place to implement the new license types.
- To assist in a future one-time automatic transition to a new license type, applicants are required to self-identify what would be your new primary license type based on your business and scope of work. If you have additional business services that warrant an additional license type(s), you will need to submit a separate application(s) once such applications are available.
- The application question is to self-identify one of the following license types that applies to the business:
    - Wholesale Distributor
    - Third-party Logistics Provider (3PL)
    - Manufacturer (including Medical Gas)
    - Repackager
- For additional information on the Board's new license type definitions and requirements, please see 2017 SB 68 language at: http://leg.mt.gov/bills/2017/billpdf/SB0068.pdf.

LICENSE REQUIREMENTS:

Wholesale Drug Distributor

- Businesses with more than one location must submit an application for each location.
- Include a schematic (floor plan) of office, wholesale area and storage areas.
- Include a description of the security system and security measures in place.
- Legal entity registered and in good standing with the Montana Secretary of State by applying for a certificate of authority and identifying a registered agent. Information available at http://www.sos.mt.gov (domestic is located in-state; foreign is located out-of-state).

Medical Gas Distributor

- Every person engaged in the manufacture, or distribution of medical gases other than to the consuming public or a patient, in the state of Montana, shall register annually.
- Register with the Board as a Wholesale Drug Distributor.
- File an application to register as a Medical Gas Distributor.
- Provide proof of registration with the Food and Drug Administration (FDA).

Medical Gas Supplier

- Every person engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of Montana that is not a licensed pharmacy shall register annually with the Board.
- Register with the Board as a Wholesale Drug Distributor.
- File an application to register as a Medical Gas Supplier.

FEES

$240.00 (Non-Refundable) - Application Fee
$100.00 (Non-Refundable) - Montana Dangerous Drug Act Distribution Fee
$100.00 (Non-Refundable) - Montana Dangerous Drug Act Manufacture Fee
$75.00 (Non-Refundable) - Medical Gas Distributor
$75.00 (Non-Refundable) - Medical Gas Supplier

Make check or money order payable to the Montana Board of Pharmacy

DOCUMENTS

The following documents must be submitted to the Board office in order to complete your license application. Please make 8-1/2"x11" copies of the following and submit with your application.

- Schematic (floor plan).
- Description of security measures in place.
- Proof of registration with Montana Secretary of State by submitting a certificate of authority that identifies the registered agent.
- Medical Gas Distributor - copy of proof of registration with the Food & Drug Administration (FDA).

ADDITIONAL FORMS TO BE SUBMITTED FOR AN APPLICATION TO BE COMPLETE

- **National Practitioner Data Bank (NPDB) Self-Query.** This form can be obtained by calling NPDB at 800-767-6732 or online at: www.npdb-hipdb.hrsa.gov. Order an Organization Self-Query for the facility location applying for licensure in Montana. This form must be mailed directly to the address indicated in the instructions. The results will come to you; upon receipt please forward them to the Board office.
- If out-of-state, verification of licensure in good standing in the state in which the business is located.

APPLICATION PROCEDURES

- When the application file is complete, it will be processed and considered by Board staff for permanent licensure. The applicant may be notified if additional information is required or if required to appear before the Board for an interview.
- If the application is considered a non-routine application, there may be a delay in processing of the application. You may be requested to provide additional information, or make a personal appearance before the Board during a regularly scheduled Board meeting and/or the application may require Board consideration. Non-routine applications may take up to 120 days to process.
- Keep the Board office informed at all times of any address changes, changes in license status and complaints or proposed disciplinary action by another Board. This is essential for timely processing of applications and subsequent licensure.

PROCESSING PROCEDURES

- Once a routine application is complete, the application takes up to 30 days to process from the time it is received in the Board office.
- The applicant will be notified in writing of any deficient or missing items from the application file.
- Once a routine application is processed and approved a permanent license will be issued.

ADDITIONAL RULE INFORMATION

- The wholesale drug distributor license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.
- No license may be issued to any wholesale distributor whose intended place of business is a personal residence.
- A separate license is required for each separate location where drugs are stored. If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.
- Wholesale drug distributor shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale drug distributors who deal in controlled substances shall register with the Board and with the DEA, and shall comply with all applicable state, local, and DEA regulations
- Whenever a Wholesale Drug Distributor facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The Wholesale Drug Distributor facility shall submit a new license application for the new location at least 30 days before such change occurs.
- When a Wholesale Drug Distributor changes ownership, the original license becomes void and must be surrendered to the Board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership. A change in ownership shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.
- The Board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

ADDITIONAL MEDICAL GAS DISTRIBUTOR/SUPPLIER RULE INFORMATION

- Wholesale Drug Distributor license with the Medical Gas Distributor/Supplier endorsement shall be posted in a conspicuous place in the place of business for which it is issued.
- A Medical Gas Distributor shall establish and implement written procedures for maintaining records pertaining to medical gas production, processing labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.
- A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and supply of, and complaints related to medical gases.
- Records shall be retained for at least two years after distribution or one year after the expiration date of the medical gas, whichever is longer.
- Records shall be retained for at least three years after supply to a patient or one year after the expiration date of the medical gas, whichever is longer.
- Records shall be readily available for review by the Board, its inspector or the FDA.

Go to www.pharmacy.mt.gov and click on Regulations for details on statutes and rules.

For additional information on the processing of this application or other concerns please contact the Board of Pharmacy at 406-841-2300 or email dlibsdpha@mt.gov.