

MONTANA BOARD OF PHARMACY
(301 S PARK, 4TH FLOOR, HELENA, MT 59601 - Delivery)
P. O. Box 200513
Helena, Montana 59620-0513
PHONE (406) 841-2300 FAX (406) 841-2344
E-MAIL: dlibsdpaha@mt.gov WEBSITE: pharmacy.mt.gov

APPLICATION FOR: WHOLESALE DRUG DISTRIBUTOR

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**

LICENSE REQUIREMENTS:

ARM 24.174.1201-1213 Wholesale Drug Distributor Licensing:

- Every person engaged in manufacturing, wholesale distribution, which includes reverse wholesale distribution, or selling of drugs, medicine, chemicals, poisons for medicinal purposes, medical gases, or legend device other than to the consuming public or patient, in the state of Montana, shall be licensed annually by the Board.
- File an application on a form prescribed by the Board and pay the appropriate licensing and registration fees.
- 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 distributors located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board before a license is issued.
- 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 is available at <http://www.sos.mt.gov> (domestic is located in-state; foreign is located out-of-sate).
- 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.
- Manufacturers, distributors, and suppliers of medical gases shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers, distributors, and suppliers of medical gases shall register with the Board to obtain the appropriate endorsement on their Wholesale Drug Distributor license.
- If out-of-state, proof of corresponding licensure in good standing in the state in which the applicant resides.
- A schematic (floor plan) of office, wholesale area and storage areas.
- A description of the security system and security measures in place.

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/Manufacturer**
- **\$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 to complete your license application. Please make 8 ½" x 11" copies of the following and submit with your application:

- Schematic (floor plan).
- Description of security system and security measures in place.
- Proof of registration with Montana Secretary of State by submitting a certificate of authority that identifies the registered agent.

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.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 the 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 Rules and Statutes for Wholesale Drug Distributor:

- Meet the requirements of 37-7-604 MCA.
- The wholesale drug distributor license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.
- Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
- Any changes in information contained from ARM 24.174.1202 in items (a) through (e) shall be submitted to the Board within 30 days of the change.
- 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.

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 new question 33 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> or Mont. Code Ann. 37-7 Part 6 at: http://leg.mt.gov/bills/mca/title_0370/chapter_0070/part_0060/sections_index.html

PLEASE BE SURE TO REVIEW THE MONTANA LAWS AND RULES AT WWW.PHARMACY.MT.GOV

For information on the processing of this application or other questions, please contact the Montana Board of Pharmacy via email at dlibsdp@mt.gov, contact Licensing Unit C at (406) 444-5773, or go to www.pharmacy.mt.gov.

8. PLEASE CHECK THE TYPE OF OWNERSHIP OR OPERATION

Sole Proprietor Partnership Corporation Other _____

9. NAME UNDER WHICH THIS BUSINESS IS REGISTERED WITH THE SECRETARY OF STATE TO DO BUSINESS IN THE STATE OF MONTANA

10. DATE OF REGISTRATION WITH MONTANA SECRETARY OF STATE _____

11. NAME OF AGENT OF RECORD IN MONTANA FOR SERVICE OF PROCESS _____

12. IS THIS BUSINESS REGISTERED AS A VAWDS PHARMACY WITH THE NABP?

Yes No

IF YES, THE NAME UNDER WHICH THE VAWDS REGISTRATION IS LISTED

13. DESCRIBE THE SCOPE AND TYPE OF SERVICES TO BE PROVIDED BY THIS BUSINESS

14. CHECK THE TYPES OF DRUGS DISTRIBUTED.

Controlled Substances Non-Controlled Prescription Drugs Legend Devices Reverse
 (If your business intends to distribute/manufacture controlled substances, it will be necessary for you to complete the application for Registration under The Montana Dangerous Drug Act)

15. Verification of licensure in good standing in the state which the business is located:

State	License #	Issue Date	Expiration Date	License Type	Requested State Verification
					<input type="checkbox"/> Yes <input type="checkbox"/> No

16. Please list all state(s) where this business has an active license (include a separate sheet, if need):

17. Does this facility have policies and procedures in place to meet the requirements of 37-7-604 MCA? Yes No

18. Has the person in charge of this business who is listed on this application ever been denied the privilege of taking an examination required for any professional or occupational license? If yes, please attached a detailed explanation and provide supporting documentation from the source. Yes No

- 19. Has the person in charge of the business who is listed on this application ever withdrawn or been suspended, placed on probation, expelled or required to resign from any postsecondary education program? If yes, please attach a detailed explanation and provide supporting documentation from the source. Yes No
- 20. Has the person in charge of the business who is listed on this application ever requested temporary or permanent leave of absence, been placed on probation, restricted, suspended, revoked, allowed to resign, or otherwise (i.e., residency, internship, apprenticeship, etc.)? If yes, please attached a detailed explanation and provide supporting documentation from the source. Yes No
- 21. Has a licensing agency initiated or completed disciplinary action against this business or the person in charge of this business who is listed on this application? If yes, please provide agency documentation including the complaint, initiating documents, orders, final orders, stipulations and consent and/or settlement agreements directly from the source. Yes No
- 22. Has the business or the person in charge of the business who is listed on this application ever voluntarily surrendered, cancelled, forfeited, failed to renew a professional or occupational license in anticipation of or during an investigation or disciplinary proceeding or action? If yes, please attached a detailed explanation and provide supporting documentation from the source. Yes No
- 23. Is there a pending complaint or investigation against the business or person in charge of this business who is listed on this application with a professional or occupational licensing agency? If yes, please attach a detailed explanation and provide supporting documentation from the source. Yes No
- 24. Has this business or the person in charge of this business who is listed on this application ever been the subject of any sanction or action, denial, suspension, revocation, restriction or termination regarding hospital, facility or staff privileges; health maintenance organization participation, third party provider or Medicare/Medicaid participation; or any other privileges? If yes, please attach a detailed explanation and provide supporting documentation from the source. Yes No
- 25. Has this business or the person in charge of this business who is listed on this application ever been censured, expelled, denied membership or asked to resign from a professional organization related to the profession of occupation? If yes, please attach a detailed explanation and provide documentation from the source. Yes No
- 26. Has this business or the person in charge of this business who is listed on this application ever been subject of any sanction or action, denial, suspension, revocation, restriction, restriction or termination regarding your ability to prescribe, dispense or administer drugs including controlled substances? If yes, please attached a detailed explanation and provide documentation from the source. Yes No
- 27. Does this business or the person in charge of this business who is listed on this application have any initiated or completed action against you by any state, federal, tribal, or foreign licensing jurisdiction? (For example, Drug Enforcement Administration; Alcohol, Tobacco and Firearms; Homeland Security; Indian Health Service, etc.) If yes, please attached a detailed explanation and provide documentation from the source. Yes No
- 28. Have any civil legal proceedings been filed against this business or the person in charge of this business who is listed on this application by a patient/client, former patient/client, or employer/employee? If yes, please attach a detailed explanation and documentation from the source including initiating document(s) and documentation of final disposition. Yes No
- 29. Has this business or the person in charge of this business who is listed on this application ever been convicted of a misdemeanor or felony crime or do you have a pending criminal charge? "Convicted" for the purposes of this question includes a conviction under appeal, guilty plea, no contest plea, and/or forfeiture of bond. "A Yes No

pending criminal charge" for purposes of this question includes a deferred imposition of sentence and/or deferred prosecution. If you answer yes, you must submit a detailed explanation of the events AND the charging documents and final judgements or orders of dismissal. You must report but may omit documentation for: (1) misdemeanor traffic violations older than 10 years ago and that resulted in fines of less than \$200; and (2) convictions prior to your 18th birthday unless you were tried as an adult.

- 30. Has the person in charge of this business who is listed on this application ever been diagnosed with chemical dependency or another addiction or have you participated in a chemical dependency or other addiction treatment program? If yes, please attach a detailed explanation and recommendations and monitoring from the source. Yes No
- 31. Has the person in charge of this business who is listed on this application ever been diagnosed with a physical condition or mental health disorder involving potential health risk to the public? If yes, please provide a detailed explanation Yes No
- 32. Has the person in charge of this business who is listed on this application ever been court-martialed or discharged other than honorably from any branch of the armed service? If yes, attach a detailed explanation and documentation from the source. Yes No
- 33. Please self-identify one of the following license types that applies to your business; this information is needed to implement 2017 Montana Law SB 68 and future wholesale distributor license changes required by FDA. See page three of this application for additional information.
 - Wholesale Distributor
 - Third-party Logistics Provider (3PL)
 - Manufacturer (including Medical Gas)
 - Repackager

I authorize the release of information concerning education, training, record, character, license history and competence to practice, by anyone who might possess such information, to the Montana Board of Pharmacy. I hereby declare that the information included in this application to be true and complete to the best of my knowledge. In signing this application, I am aware that a false statement or evasive answer to any question may lead to denial of my application or subsequent revocation of licensure on ethical grounds.

I have read and will abide by the current licensure statutes and rules of the State of Montana governing the profession. I will abide by the current laws and rules that govern my practice.

Signature of Applicant

Date

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APPLICATION FOR: MONTANA DANGEROUS DRUG ACT REGISTRATION

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**LICENSE REQUIREMENTS FOR MONTANA DANGEROUS DRUG ACT
50-32-301 MCA**

ARM 24.174.1401 Dangerous Drug Act

- Complete a Wholesale Drug Distributor application or Montana License Number if already licensed as a Wholesale Drug Distributor and adding distribution/manufacturing to license
- Complete the Dangerous Drug Act application if distributing/manufacturing controlled substances

FEE: \$100–(Non-Refundable)–Distribute/Manufacture under the Montana Dangerous Drug Act

APPLICATION PROCEDURES:

- ◆ When the application file is complete, it will be processed. The applicant may be notified if additional information is required.
- ◆ Keep the Board office informed at all times of any address changes, changes in license status and complaints or proposed disciplinary action. 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.

For information with regard to the processing of this application or other concerns please contact the Board of Pharmacy staff at pharmacy.mt.gov or email at dlibsdpdpha@mt.gov

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APPLICATION FOR: MONTANA DANGEROUS DRUG ACT REGISTRATION

Distribute Manufacture

Name of Business: _____ Contact: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Fax Number: _____

DEA Registration Number: _____ Federal Tax I.D. Number: _____

Signature _____ Date _____
(Signature of applicant or authorized individual)

Title _____
(If applicant is a corporation, institution or other entity)

NOTE:
The application for DEA Number may be obtained at www.dea.gov
DEA will be notified when a Montana Pharmacy license has been issued

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**APPLICATION FOR: MEDICAL GASES REGISTRATION TO MANUFACTURE,
DISTRIBUTE, OR SUPPLY**

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**LICENSE REQUIREMENTS FOR REGISTRATION TO MANUFACTURE, DISTRIBUTE OR SUPPLY
MEDICAL GASES:**

- ◆ Complete a Wholesale Drug Distributor application
- ◆ Complete the Application for Medical Gas Distributor/Manufacturer/Supplier
- ◆ If already licensed as a Wholesale Drug Distributor adding Medical Gas Distributor/Manufacturer/Supplier to license only complete the application for Registration for Medical Gas Distributor/Manufacturer/Supplier

ARM 24.174.1204 Medical Gas Distributor/Manufacturer:

- 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 with the Board
- File an application to register as a Wholesale Drug Distributor with medical gas distributor endorsement and pay appropriate fees
- Provide proof of registration with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all FDA requirements

Additional Rules and Statutes for Medical Gas Distributor/Manufacturer:

- The wholesale drug distributor license with the medical gas distributor endorsement shall be posted in a conspicuous place in the wholesaler's 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
- 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 readily available for review by the Board, its inspector, or the FDA

ARM 24.174.1205 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 with Medical Gas Supplier endorsement and pay appropriate fees

Additional Rules and Statutes for Medical Gas Supplier:

- The Wholesale Drug Distributor license with the medical gas supplier endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.
- A medical gas supplier shall not:
 - Supply prescription medications, except medical gases, without appropriate licensure as a pharmacy
 - Manufacture or distribute medical gases without appropriate licensure as a medical gas distributor; or
 - Instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner
- A medical gas supplier shall supply medical gas only pursuant to prescription order by an authorized prescriber
- A medical gas supplier must label each medical gas container with the name, address, and telephone number of the supplier
- 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 three years after supply to a patient or one year after expiration date of the medical gas, whichever is longer
- Records shall be readily available for review by the board of its inspector

**FEE: \$75–(Non-Refundable)–Medical Gas Distributor/Manufacturer
\$75–(Non-Refundable)–Medical Gas Supplier**

APPLICATION PROCEDURES:

- ◆ When the application file is complete, it will be processed. The applicant may be notified if additional information is required.
- ◆ Keep the Board office informed at all times of any address changes, changes in license status and complaints or proposed disciplinary action. This is essential for timely processing of applications and subsequent licensure.

PROCESSING PROCEDURES:

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APPLICATION FOR: MEDICAL GAS REGISTRATION

Medical Gas Distributor/Manufacturer Medical Gas Supplier

Name: _____ Contact: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Fax Number: _____

Email Address _____

FDA Registration Number: _____ Federal Tax I.D. Number: _____

Signature _____ Date _____
(Signature of applicant or authorized individual)

Title _____
(if applicant is a corporation, institution or other entity)

VERIFICATION OF LICENSURE

THIS IS NOT AN ENDORSEMENT CERTIFICATION

IF APPLYING FROM OUT OF STATE, PLEASE COMPLETE THIS SECTION OF THE FORM AND MAIL TO THE STATE BOARD IN WHICH THE BUSINESS IS LOCATED AS A WHOLESALE DRUG DISTRIBUTOR. SOME BOARDS REQUIRE A FEE FOR THIS SERVICE.

STATE BOARD:

This is your authority to release any information in your files, favorable or otherwise, **DIRECTLY** to the **BOARD OF PHARMACY, P. O. BOX 200513, 301 SOUTH PARK AVENUE, HELENA, MT 59620-0513.** Your early response is appreciated.

(Signature) Name: _____
(Please print)

Address: _____

My License Number is: _____

DO NOT DETACH -- THIS SECTION TO BE COMPLETED BY AN OFFICIAL OF THE STATE BOARD AND RETURNED DIRECTLY TO THE MONTANA STATE BOARD OF _____

State of: _____

Full Name of Licensee: _____

License No. _____ Issue Date: _____

License is current? _____ If NO, explain _____

Has license been suspended, revoked, placed on probation or otherwise disciplined? _____

If YES, explain and attach documentation _____

Has licensee ever been requested to appear before your Board? _____

If YES, explain _____

Derogatory information, if any _____

Comments, if any _____

Signed: _____

BOARD SEAL

Title: _____

State Board: _____ Date: _____