



Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Board of Pharmacy
PO Box 30670
Lansing MI 48909
(517) 373-8068
www.michigan.gov/bpl

MANUFACTURER/WHOLESALER LICENSE APPLICATION PACKET

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MANUFACTURER/WHOLESALER LICENSURE INSTRUCTIONS

Please read application instructions carefully and answer all questions completely.
Failure to do so may cause a delay in your application process.

PROCEDURE FOR OBTAINING A MANUFACTURER/WHOLESALER LICENSE

Authority: PA 368 of 1978, as amended.
This form is for information only.

NOTE: An Application accompanied by the appropriate fee is valid for two years. If an applicant fails to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid.

Manufacturers or wholesale distributors of any prescription drug or prescription device that are doing business in the State of Michigan, whether or not located in the State of Michigan, shall be licensed by the Board of Pharmacy and pay a fee of \$85.85. If controlled substances are also to be manufactured or distributed, an additional fee of \$85.85 is required under provisions of the Michigan Public Health Code.

A manufacturer or wholesale distributor that distributes prescription drugs in Michigan from a location outside of this state must obtain a license to do business in Michigan. If the license is for a corporation, the license should be obtained in the name of the parent or subsidiary corporation under which the business will be conducted in Michigan. Information about obtaining a license to do business in Michigan can be obtained by contacting the Corporation Division of the Bureau of Corporations, Securities & Commercial Licensing at (517) 241-6470 or www.michigan.gov/corporations.

A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in this state from one or more locations in this state shall obtain a separate license for each location in this state from which prescription drugs are manufactured or distributed. A separate application with all supporting documents must be filed for each location.

PROCEDURES FOR OBTAINING A NEW MANUFACTURER/WHOLESALER LICENSE

1. The application must be completed in its entirety and returned to the Board office with the appropriate fee(s).
2. The individuals listed below for a manufacturer/wholesaler license are required to undergo a Criminal Background Check (CBC) and provide evidence of fingerprint processing from an authorized agency.
 - a. An individual, if the person applying is an individual.
 - b. All partners and any individual who will manage the day-to-day operations, if the person applying is a partnership.
 - c. Any individual who will manage the day-to-day operations, if the person applying is a privately held corporation. This subdivision only applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application..

An individual is not required to obtain a Criminal Background Check if one has been obtained for the individual(s) within the 2 years preceding the date of application for a new pharmacy, manufacturer, or wholesale distributor license. If fingerprints have been obtained within the two years preceding the date of the application, the individual(s) must submit proof of the previous criminal history check with the application for a manufacturer/wholesaler license.

3. Arrange for a verification and/or certification to be sent directly to the Michigan Board of Pharmacy from any state or province where the manufacturer/wholesaler facility is currently or has ever held a permanent license or registration. Copies of licenses are not acceptable.

MANUFACTURER/WHOLESALER LICENSURE INSTRUCTIONS CONTINUED

4. With the application, submit photographs of the interior and exterior premises and a floor plan of the area to be licensed. DO NOT SEND A COPY OF BLUEPRINTS. Applicants who handle controlled substances may submit a copy of their DEA registration in lieu of photographs and floor plan.
5. If you are an outsourcing facility, submit a copy of the FDA outsourcing registration.
6. Effective September 30, 2014, the Michigan Board of Pharmacy requires manufacturer/wholesaler applicants to designate a pharmacist in charge (PIC) to be responsible for compliance with the Michigan pharmacy laws and rules. The PIC may be licensed in or outside of Michigan. Please indicate the name and license number of the PIC in the space indicated on the application. Effective March 30, 2015 a wholesale distributor has the option of designating a PIC or a facility manager (FM) who is responsible for the wholesaler's compliance with Michigan Pharmacy laws & rules.
7. Effective March 30, 2015, a PIC or FM is not required for a manufacturer or wholesaler with respect to a device salable on prescription only, but is required with respect to any drug salable on prescription only.
8. Applicants from businesses that are partnerships, corporations, or operating under an assumed name must file the application for a manufacturer/wholesaler license along with copies of:
 - a. Partnership Certificates
 - b. Articles of Incorporation and/or Assumed Name Certificates
9. Provide a list or catalog of all drug products and/or devices salable upon prescription that are manufactured or distributed in Michigan.
10. Complete the Compliance Checklist in its entirety.
11. Complete the information on the application regarding the opening date, name of person to contact and telephone number.

Upon receipt of the required documentation, your application will be reviewed for compliance with the laws and rules of the Michigan Board of Pharmacy. If a satisfactory inspection and/or review is received, a permanent identification number will be assigned and the license(s) will be issued.

PROCEDURE FOR TRANSFER OF A MANUFACTURER/WHOLESALER LICENSE

The following changes constitute a transfer:

1. Change of ownership
2. Sale or transfer of stock from original stockholder to new stockholder.
3. Sale or transfer of membership interested to a new member.

If you are applying for a transfer of a manufacturer/wholesaler license, you must follow the instructions as outlined in Procedures for obtaining a new manufacturer/wholesaler license.

Upon receipt of the complete application, fee(s), and required documentation, an inspection or review will be requested. If a satisfactory inspection or review is received, a new permanent identification number and new license(s) will be issued.

PROCEDURE FOR MISCELLANEOUS CHANGE

The following changes constitute miscellaneous changes. Complete the application in its entirety and return it to the Board of Pharmacy.

1. Partner, stockholder or member change.
 - a. Stockholder change-submit minutes of stockholder meeting reflecting the change
 - b. Corporation or partnership change-submit amended Articles of Incorporation reflecting the change.
 - c. Membership change –submit copies of Board meeting minutes approving the change.
2. Change in name of business entity where no change in ownership occurs.
 - a. Submit a letter indicating the effective date of the name change.
 - b. Submit a copy of the amended Articles of Incorporation or other appropriate documentation approving the change.
 - c. If you want the license(s) re-issued under the new name, submit \$10.10 for each license held. Re-issuance of the license(s) is not required.

MANUFACTURER/WHOLESALER LICENSURE INSTRUCTIONS CONTINUED

PROCEDURE FOR CHANGE IN LOCATION

A fee is required for an existing manufacturer/wholesaler moving to a new location.

1. Follow the instructions as outlined under Procedures for Obtaining a New manufacturer/wholesaler license on page 3 of these instructions. The fingerprinting/criminal background check is not required when applying for a change in location.
2. Complete the information on the application regarding the proposed date of the change of location, person to contact and telephone number.

Upon receipt of the completed application, fee(s), and required documentation, an inspection or review will be requested. If a satisfactory inspection or review is received, the same permanent identification number will be retained and new license (s) will be issued to reflect the new address.

PROCEDURE FOR RELICENSURE

1. The application for manufacturer/wholesaler license should be completed in its entirety and returned to the board office with the appropriate fee(s).
2. If the Michigan manufacturer/wholesaler license has been lapsed for more than 3 years, the applicant is required to complete the fingerprinting process as described in instruction #2 under Procedures for Obtaining a New Manufacturer/Wholesaler License.
3. Follow the other instructions as outlined under Procedures for Obtaining a New Manufacturer/Wholesaler License.

QUARTERLY REPORTING-SCHEDULE 2

The Michigan Public Health Code requires that wholesalers and manufacturers report, on a quarterly basis, all Schedule 2 controlled substances that are sold to licensed practitioners and retail pharmacies. To facilitate compliance with the reporting requirements, you may submit your written reports in whatever format you currently utilize, PROVIDED all the following information for Schedule 2 controlled substances is included:

1. Name, address, and ZIP code of purchaser
2. Purchaser's DEA number (7 Digits prefixed by 2 alpha characters)
3. Drugs listed by name (generic, trade or brand name) and NDC number
4. Date of sale (the date the order is filled by the supplier)
5. Quantity of each drug purchased by dosage unit
6. Name of the supplier
7. Address of the supplier
8. DEA number of the supplier

NOTE: The ARCOS format lacks flexibility and cannot be utilized for these reports.



Bureau of Professional Licensing
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 Telephone: (517) 335-0918
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BPLHelp@michigan.gov

APPLICATION FOR MANUFACTURER/WHOLESALER LICENSE	
I am applying for the following:	
<input type="checkbox"/> New Manufacturer/Wholesaler Fee: \$85.85 71-5306-01	
<input type="checkbox"/> New Manufacturer/Wholesale and Controlled Substance Fee: \$85.85 71-5306-01 \$85.85 71-5306-3757 Total Fee \$171.70	
<input type="checkbox"/> Transfer Manufacturer/Wholesaler Fee: \$85.85 71-5306-01	
<input type="checkbox"/> Transfer Manufacturer/Wholesaler and Controlled Substance Fee: \$85.85 71-5306-01 \$85.85 71-5306-3757 Total Fee: \$171.70	
<input type="checkbox"/> Change of Location Manufacturer/Wholesaler Reissue Fee: \$85.85 71-5306-01	
<input type="checkbox"/> Change of Location Manufacturer/Wholesaler and Controlled Substance Fee: \$85.85 71-5306-01 and 71-5306-3757 Total Fee: \$171.70	
<input type="checkbox"/> Relicensure Manufacturer/Wholesaler Fee: \$105.85 71-5306-01	
<input type="checkbox"/> Relicensure Manufacturer/Wholesaler and Controlled Substance Fee: \$105.85 71-5306-06 and \$85.85 71-5306-3757 Total Fee: \$191.70	
<input type="checkbox"/> Miscellaneous Change-Partner or Stockholder-No Fee	
<input type="checkbox"/> Miscellaneous Name Change-\$10.00 for each new license issued (re-issuance of license (s) not required) 71-5306-33	
TYPE OF OPERATION	
<input type="checkbox"/> DME Provider for devices salable on prescription	<input type="checkbox"/> Repackager
<input type="checkbox"/> DME Provider for drugs salable on prescription	<input type="checkbox"/> Distribution
<input type="checkbox"/> Full Service Wholesaler	<input type="checkbox"/> Buying Group
<input type="checkbox"/> Import/Export	<input type="checkbox"/> Manufacturer for devices salable on prescription
<input type="checkbox"/> Other _____	<input type="checkbox"/> Manufacturer for drugs salable on prescription
Your check or money order drawn on a U.S. financial institution and made payable to the STATE OF MICHIGAN must accompany this application. DO NOT SEND CASH. Fees are deposited upon receipt and can only be refunded under refund rules promulgated by the Department.	
Proposed Opening Date:	
Proposed Date of Transfer:	

Proposed Date of Location Change:
Proposed Date of Name Change:

Name of Company Under Which You Conduct Business:		
Street Address:	Ste/Bldg#:	
City:	State:	Zip Code:

NEW APPLICATION INFORMATION OR NEW OWNERSHIP AND LOCATION INFORMATION

Name of Company (Under Which You Conduct Business):					
Facility Street Address:			Ste/Bldg. #:		
City:		State:		Zip Code:	
Name of Corporation (if Different than Name above):					
Mailing Address (if Different than Name above):			Ste/Bldg. #:		
City:		State:		Zip Code:	
Type of Ownership:	<input type="checkbox"/> Individual	<input type="checkbox"/> Privately Held Corporation LLC	<input type="checkbox"/> Publically Held Corporation	<input type="checkbox"/> Partnership	Federal ID Number:
Current MI Pharmacy Permanent I.D./License Number:			Phone Number:		
Name of Current Contact Person:					
Address: (Street, City, State, and Zip Code):					

FORMER OWNERSHIP AND LOCATION INFORMATION (if applicable)

Name of Company (Under Which You Conduct Business):					
Facility Street Address:			Ste/Bldg. #:		
City:		State:		Zip Code:	
Name of Corporation (if Different than Name above):					
Mailing Address (if Different than Name above):			Ste/Bldg. #:		
City:		State:		Zip Code:	
Type of Ownership:	<input type="checkbox"/> Individual	<input type="checkbox"/> Privately Held Corporation <input type="checkbox"/> LLC	<input type="checkbox"/> Publically Held Corporation	<input type="checkbox"/> Partnership	Federal ID Number:
Current MI Pharmacy Permanent I.D./License Number:			Phone Number:		
Name of Current Contact Person:					
Address: (Street, City, State, and Zip Code):					

List the name and date of birth of the individual owner; or, if a partnership, all partners and any individual who will manage the day-to-day operations; or, if applying as a privately held corporation, any individual who will manage the day-to-day operations
(Note: This only applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application.). Attach a separate sheet, if necessary.

NAME AND ADDRESS	TITLE	% OF STOCK OWNED

The individual named below is hereby designated by the applicant to be the Pharmacist in Charge (PIC) or Facility Manager for this manufacturer or wholesaler distributor. The PIC is responsible for compliance with federal and state laws and Board of Pharmacy rules regulating the manufacturing and distribution of prescription drugs.

Name of PIC or Facility Manager:
State Where PIC Pharmacist License is Held:
PIC License Number:

License(s) in Other State(s)

Does this facility hold or has it ever held a permanent license or registration in any other state? If yes, list each state, the license or registration number, and the date issued.		
State	Permanent License/Registration Number	Date of Issue

Check the appropriate answer to each of the following questions. Attach a detailed explanation for any Yes answer you check.

1. Has any director, employee, officer, owner, partner, member or stockholder ever been convicted of a misdemeanor, or felony?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Has any director, employee, officer, owner, partner, member or stockholder ever had a financial interest in a pharmacy, manufacturer, or wholesale distributor which: a) was denied a license or federal registration? b) had its license or federal registration limited, surrendered, revoked or otherwise disciplined? c) was subject to any other criminal, civil, or administrative penalty?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Has the applicant or any owner, director, employee, partner, member or stockholder ever had a license or federal registration a) denied, limited, reprimanded, suspended, revoked or otherwise disciplined? b) subject to any other criminal, civil, or administrative penalty?	<input type="checkbox"/> Yes <input type="checkbox"/> No

CERTIFICATION

I understand that Michigan State Law requires this agency to secure a criminal conviction history as part of the pre-licensure screening process. I authorize this agency to use the information provided in this application to obtain a criminal conviction history file search from the Central Records Division of the Michigan Department of State Police, law enforcement, or judicial record-keeping organization.

I further consent to the release of information to this agency regarding any disciplinary investigations conducted by a similar licensure, registration, or specialty certification board of this or any other state, of the United States military, of the federal government, or of another country.

I certify under penalty of perjury that the statements in this application are true and correct. I have not withheld information that might affect the decision to be made on this application. In signing this application, I am aware that a false statement or dishonest answer may be grounds for denial of my application or revocation of my license and that such misrepresentation is punishable by law.

Signature of Applicant _____ Date _____

Print Name _____ Title _____

FACILITY MANAGER

I certify under penalty of perjury that I am involved in the daily operation of the facility, that I have the necessary education or experience required by statute and rules and that I have knowledge of all current regulatory requirements for this Wholesale Distributor.

Name of Facility Manager _____

Signature of Facility Manager _____ Date _____

The Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

Michigan Department of Licensing and Regulatory Affairs

Board of Pharmacy

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COMPLIANCE CHECKLIST FOR MANUFACTURERS/WHOLESALERS

Authority: Public Act 368 of 1978, as amended.

If this form is not completed, a license will not be issued.

Name of Manufacturer/Wholesaler:	
Street Address:	Ste/Bldg.#:
City:	State:
Zip Code:	County:
Name of Contact Person	Phone Number:
Name of PIC or Facility Manager:	Phone Number:

If you handle controlled substances, complete the following as applicable and submit a copy of your DEA registration.

DEA Registration #:	Registration Expiration Date:
Application Date (If recently applied):	

Check the answer to each of the following questions:

MANUFACTURING PRACTICE	
Do you maintain the building, operate the equipment, and administer the controls, records and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions 21 C.F.R. 211.1 TO 211.208?	
WHOLESALING PRACTICE	
1. Does the facility meet the following standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records:	
a. Is this facility of suitable size to facilitate cleaning, maintenance and proper operations?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Does the facility have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Does the facility have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated or that are in immediate or sealed secondary containers that have been opened?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Is this facility maintained in a clean and orderly condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Is this facility free from infestation by insects, rodents, birds, or vermin of any kind?	<input type="checkbox"/> Yes <input type="checkbox"/> No

The Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

Name of Manufacturer/Wholesaler:	
2. Does this facility meet the following security and general provisions:	
a. Is access from the outside kept to a minimum and well-controlled?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Is the outside perimeter of the facility well-lit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Is entry into areas where prescription drugs are held limited to authorized personnel?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Is the facility equipped with an alarm system to detect any entry after hours?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Is the facility equipped with a security system to provide protection against theft and diversion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Are computers, electronic records and other documents kept under security to prevent tampering with the records?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Will all prescription drugs be stored at appropriate temperatures and conditions in accordance with label requirements or in accordance with requirements in the current edition of the official compendium?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Do you maintain and enforce written policies and procedures which include all of the following?	
a. Making sure the oldest approved stock of a prescription drug product is distributed first?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Handling recalls and withdrawals of prescription drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Making sure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other emergency situations?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Ensuring that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Do you maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs which include all of the following:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of location from which the drugs were shipped?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. The identity and quantity of the drugs received and distributed or disposed of?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. The dates of receipt and distribution or other disposition of the drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Are inventories and records maintained and available for inspection for a period of two years after disposition of the drugs?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
7. Do you maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling that includes a description of their duties and a summary of their qualifications?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
8. Do all employees have sufficient education, training, and experience to perform their assigned functions in a manner that assures that the drug product quality, safety and security is maintained at all times?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

CERTIFICATION

I certify under penalty of perjury that I have been authorized by the applicant to complete this compliance checklist, and that the answers and statements given are complete, true and correct.

Signature _____ Date _____

Print Name _____

Title _____ Telephone Number _____

Please print out the Application (pages 6-10), Compliance Check List for Manufacturer/Wholesaler Form (pages 11-12). Sign and date your application and submit the application along with your check or money order made payable to the "State of Michigan" to:

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Complete the Compliance Check List for Manufacturer/Wholesalers Form and send it to our office.

TOP THINGS APPLICANTS SHOULD KNOW

1. NOTE: If you have ever been licensed in another state and you have a current disciplinary sanction on that license (even if the license is inactive), you are not eligible for licensure in Michigan according to the Public Health Code, PA 368, as amended, Section 333.16174 (2). Sanctions include probation, limitation, suspension, revocation, or fine. Upon resolution of the sanction and verification that the license is active with no disciplinary action in effect, you can proceed with the filing of an application for a Michigan license or registration.
2. Read the entire application before submitting it and DO NOT send the checklist to the Board of Pharmacy office.
3. Applications and mail are processed as quickly as possible in date-received order.
4. Please allow time to process your application before you call or email our office to check on the status. Applications may take up to 2 weeks to reach our office. Applications with fees are first processed through our central mailroom then through our payment processing office.
5. Mail, including mail sent overnight, is first received by our central mailroom prior to reaching the Board.
6. Supporting documentation will not be accepted if faxed into our office.
7. REFUND POLICY: If you wish to withdraw your application, you must notify the Board of Pharmacy in writing to request a partial refund.

FREQUENTLY ASKED QUESTIONS

Q. How long will it take to process my application?

Applications and mail are processed as quickly as possible in date-received order. Applications with fees are first processed through our central mailroom then through our payment processing office.

Q. What do I do if I forgot to include my payment with my application?

Please submit the fee along with a copy of your application and a letter indicating that you failed to submit the required payment with your previous application. Mail to: Licensing and Regulatory Affairs, Bureau of Professional Licensing, Board of Pharmacy, PO Box 30670, Lansing, MI 48909.

Q. How do I check on the status of my application?

Within approximately three weeks of mailing your application to our office, you should receive an Application Confirmation letter containing your customer number. You may use your customer number to check the status of your application at www.michigan.gov/appstatus.

Q. If I have been convicted of a felony or misdemeanor will it stop me from being licensed?

We ask that you submit your application, fee and information regarding the occurrence. The Board will review your file and make a decision at that time. Please keep in mind that we do take into consideration the type of conviction, the age that you were when the incident occurred and the time that has elapsed since the conviction.

Q. How long is my license valid?

The initial license is good for a partial licensure cycle and will expire on the upcoming June 30 renewal date. Each subsequent license will cover a full two-year cycle.

Q. How do I renew my license?

You will be mailed a renewal notice approximately six to eight weeks prior to the expiration date of your license. The notice will include instructions on how to renew your license online.

WEBSITES:

Michigan Department of Licensing and Regulatory

www.michigan.gov/lara

Affairs

Bureau of Professional Licensing

www.michigan.gov/bpl

Licensing Division

www.michigan.gov/healthlicense

Michigan Board of Pharmacy Rules

www.michigan.gov/healthlicense

Michigan Public Health Code

www.michigan.gov/healthlicense

Application Status

www.michigan.gov/appstatus

Verify a Health Professional License

www.michigan.gov/verifylicense

Renewal Website

www.michigan.gov/elicense