

Michigan Department of Licensing and Regulatory Affairs

Board of Pharmacy

P.O. Box 30670

Lansing, Michigan 48909

(517) 335-0918

www.michigan.gov/healthlicense

PROCEDURE FOR OBTAINING A MANUFACTURER/WHOLESALE LICENSE

Authority: P.A. 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to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid. Please allow 6-8 weeks processing time.

Enclosed is an application for a manufacturer/wholesaler license, Compliance Checklist, Public Health Code (PA 368 of 1978, as amended) and the Administrative Rules for the Michigan Board of Pharmacy.

Manufacturers or wholesale distributors of any prescription drug 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 \$85.00. If controlled substances are also to be manufactured or distributed, an additional fee of \$85.00 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 Commercial Services 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/WHOLESALE LICENSE

1. The application must be completed in its entirety and returned to the Board office with the appropriate fee(s).
2. 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.
3. If you are a manufacturer or distributor of biologicals, submit a copy of the FDA registration for the site to be licensed.
4. 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:
 - 1) Partnership Certificates
 - 2) Articles of Incorporation and/or Assumed Name Certificates
5. Provide a list or catalog of all drug products manufactured or distributed in Michigan.
6. Complete the Compliance Check List in its entirety.
7. Complete the information on the application regarding the opening date, name of person to contact and telephone number.

Upon receipt of #1-7 above, your application will be reviewed for compliance under Administrative Rule 23(a-f) 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 of stock from original owner to new owner.

If you are applying for a transfer of a manufacturer/wholesaler license, you must follow steps 1 through 7 as outlined in Procedures for Obtaining a New Manufacturer/Wholesaler License.

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, 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 office.

1. Partner or stockholder change.
 - a. Stockholder change - submit minutes of stockholder meeting reflecting the change in corporate ownership.
 - b. Corporation or partnership change - submit amended Articles of Incorporation reflecting the change.
2. Change in name of corporation 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.
 - c. If you want the license(s) re-issued under the new name, submit \$10.00 for each license held. Re-issuance of the license(s) is not required.

PROCEDURE FOR CHANGE IN LOCATION

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

1. Follow steps 1 through 7 as outlined under Procedures for Obtaining a New Manufacturer/Wholesaler License on page 1 of these instructions.
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 should be completed in its entirety and returned to the Board office with the appropriate fee(s).

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; and
8. DEA number of the supplier.

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

GENERAL INFORMATION

1. **NAME AND/OR ADDRESS CHANGES:** If your name and/or address changes please notify the Board of Pharmacy in writing. To change a name or address, you can download the [Data Change/Duplicate License Request Form](#) from our website www.michigan.gov/healthlicense and fax it to (517) 373-2179 or mail the form to Bureau of Health Professions, PO Box 30670, Lansing, MI 48909. Telephone calls are NOT accepted for these changes.
2. **REFUND POLICY:** If you wish to withdraw your application, you may be eligible for a partial refund. You must
3. **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.

ORIGINAL LICENSES ARE VALID FOR ONE YEAR OR LESS; SUBSEQUENT RENEWALS ARE FOR A TWO-YEAR PERIOD.

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APPLICATION FOR MANUFACTURER/WHOLESALER LICENSE

Authority: Public Act 368 of 1978, as amended
If this form is not completed, a license will not be issued

A controlled substance license is required for every person who prescribes, manufactures, distributes, or dispenses any controlled substance in Michigan as described in Article 7 of Public Act 368 of 1978, as amended. Information on obtaining a Federal controlled substance license may be obtained by contacting the Regional Branch, Drug Enforcement Administration, 431 Howard Street, Detroit, MI 48226 (Telephone (313) 234 - 4300).



Board Use Only

License Number:

Controlled Substance License Number:

Date of Licensure:

Type or Print Only

I AM APPLYING FOR THE FOLLOWING LICENSE(S) FOR:

Name of Company (Under Which You Conduct Business)

Address of Facility (Street, City, State and ZIP Code)

(If you manufacture, repackage, re-label, or distribute controlled substances in Michigan, you must also apply for a controlled substance license).

New

- Manufacturer/Wholesaler Fee: \$85.00 71-5306-01
Controlled Substance License Fee: \$85.00 71-5306-3757

Proposed Opening Date:

Transfer

- Manufacturer/Wholesaler Fee: \$85.00 71-5306-01
Controlled Substance License Fee: \$ 85.00 71-5306-3757

Proposed Date of Transfer:

Change of Location

- Manufacturer/Wholesaler Reissue Fee: \$65.00 71-5306-01
Controlled Substance License Fee: \$20.00 71-5306-33

Proposed Date of Location Change:

Relicensure

- Manufacturer/Wholesaler Fee: \$105.00 71-5306-06
Controlled Substance License Fee: \$85.00 71-5306-3757

Miscellaneous

- Partner or Shareholder Change: No fee required.
Name Change Fee: \$10.00 for each new license issued (re-issuance of license(s) not required). 71-5306-33

Proposed Date of Name Change:

Type of Operation:
Manufacturer
Repackager
Full Service Wholesaler
Buying Group
Import/Export
Distribution Center
Other

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.

Name

NEW APPLICATION INFORMATION OR NEW OWNERSHIP AND LOCATION INFORMATION

Name of Company (Under Which You Conduct Business)	
Address of Facility (Street, City, State and ZIP Code)	
Mailing Address if Different from Location Above (Number and Street Name, City, State, and ZIP Code)	
Name of Corporation (if Different Than Name Above)	
Check Type of Ownership: <input type="checkbox"/> Individual <input type="checkbox"/> Corporation <input type="checkbox"/> Partnership	Federal I.D. Number
Current Michigan Pharmacy Permanent I.D./License Number	Telephone number
Name of Current Contact Person	Address (Number and Street, City, State, and ZIP Code)

FORMER OWNERSHIP AND LOCATION INFORMATION (if applicable)

Name of Company (Under Which You Conduct Business)	
Address of Facility (Street, City, State and ZIP Code)	
Mailing Address if Different from Location Above (Number and Street Name, City, State, and ZIP Code)	
Name of Corporation (if Different Than Name Above)	
Check Type of Ownership: <input type="checkbox"/> Individual <input type="checkbox"/> Corporation <input type="checkbox"/> Partnership	Federal I.D. Number
Current Michigan Pharmacy Permanent I.D./License Number for this Facility	Telephone number
Name of Current Contact Person	Address (Number and Street, City, State, and ZIP Code)

If PARTNERSHIP OR CORPORATION, include names, addresses, telephone numbers of all partners or shareholders, including the percentage of stock owned by each. Use a separate sheet, if necessary.

Name and Address	Telephone	Amount of Stock Owned	Social Security Number

The individual named below is hereby designated by the applicant to be the license to be licensee for the within named manufacturer or wholesaler distributor or responsible for compliance with federal and state laws and Board of Pharmacy rules regulating the manufacturing and distribution of prescription drugs.

Name

Address

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

CERTIFICATION

I understand that it is the policy of this agency to secure a criminal conviction history as part of their 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 or other 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.

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

Name

d. Are all facilities equipped with an alarm system to detect any entry after hours?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Are all facilities equipped with a security system to provide protection against theft and diversion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Are computers and electronic records 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:	
a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the 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 that I have been authorized by the applicant to complete this compliance check list, and that the answers and statements given are complete, true and correct.

Signature of Contact Person	Date
Title	Telephone Number