

## MICHIGAN MANUFACTURER LICENSING GUIDE

### OVERVIEW:

The manufacturer license type allows a licensee to manufacture prescription drugs or devices.

*NOTE: The content contained below is a general overview of licensing requirements. Links to access the Public Health Code and Administrative Rules for this profession can be found at the end of this guide.*

### LICENSURE REQUIREMENTS CHECKLIST

(Listed below are the minimum requirements needed to obtain a manufacturer license.)

#### APPLICATION AND FEES

- Online Application For a Manufacturer License - Complete all fields, answer all questions, and upload any supporting documentation. Online application can be completed by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus).
- Application Fee + 2-year License Fee (Must be paid by Visa, Mastercard, Discover, or American Express credit or debit card.):
  - Manufacturer License – \$127.50
  - Controlled Substance License – \$176.40
  - Manufacturer Relicensure – \$147.50

#### THE FOLLOWING REQUIREMENTS APPLY TO ALL APPLICANTS

- Criminal Background Check – Once the online application is completed and submitted you will be emailed an Application Confirmation letter containing instructions to complete the Criminal Background Check.
 

The individuals listed below for a manufacturer license are required to undergo a Criminal Background Check (CBC):

  - An individual, if the person applying is an individual.
  - All partners and any individual who will manage the day-to-day operations, if the person applying is a partnership.
  - An 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, wholesale distributors or wholesale distributor-brokers on the date the corporation submits its license application.

## MICHIGAN MANUFACTURER LICENSING GUIDE

An individual is not required to obtain a CBC 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 license. Relicensure applications lapsed 3 years or less are also not required to obtain a CBC.

- Criminal/Disciplinary History Questions – Criminal conviction and/or disciplinary documentation will be required if you answer “yes” to either question.
- Verification of Licensure – If your manufacturer holds a current manufacturer license or ever held a pharmacy profession license, verification of licensure must be sent directly to our office by the licensing agency of any state of the United States or country in which you hold or ever held a license. The verification must show that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application. Verification can be emailed to [bpldata@michigan.gov](mailto:bpldata@michigan.gov) or mailed to the Bureau of Professional Licensing, PO Box 30670, Lansing, MI 48909.
- If your manufacturer is a partnership, corporation, or is operating under an assumed name, you must submit business documentation showing the business ownership structure, including partnership certificates, corporate articles, assumed name certificate, list of partners, stockholders, officers, and members of the board of directors.
- You must upload a floor plan of the area to be licensed, along with a description of the type of activities carried out in each building. Do not send a copy of blueprints.
- You must upload photographs of the interior and exterior premises.
- A licensed manufacturer of drugs must have a pharmacist in charge (PIC) licensed in or outside of Michigan or a facility manager. If the proposed manufacturer location is also licensed as a pharmacy, a PIC is required. You must provide the license number of the PIC or the pharmacist application number of the PIC if the PIC is applying for Michigan licensure. Applicants who only manufacture devices salable on prescription only and do not manufacture or distribute any drugs salable on prescription only are not required to have a PIC or facility manager.
- You may apply for a controlled substance license by completing the controlled substance license fields on the application. Be sure that the controlled substance license address matches the manufacturer address. If you do not apply for a controlled substance license on your initial application, you must wait for the manufacturer license to be issued before applying for a controlled substance license.
- You must upload a list or catalog of all drug products and/or devices salable upon prescription that are manufactured or distributed in Michigan.
- If you are an outsourcing facility, you must submit the pharmacy license application.
- A virtual manufacturer falls under the wholesale distributor license type.
- A pharmacy that is applying for licensure as a manufacturer must show a clear delineation between the pharmacy and manufacturer stock, records, policies, and procedures at the time of inspection.
- If your facility is a manufacturer of biologicals, submit a copy of the FDA certification for the site to be licensed.

## MICHIGAN MANUFACTURER LICENSING GUIDE

- All non-resident applicants must provide an inspection from the U.S. Food and Drug Administration (FDA) or manufacturer's resident state board of pharmacy, that is dated not more than 2 years before application or current NABP drug distributor accreditation.

### ADDITIONAL REQUIREMENTS FOR THOSE APPLYING FOR RELICENSURE

- Online application can be completed by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus), and then select **MiPLUS Login**, and then **"Modification"** next to your license number.

### ADDITIONAL REQUIREMENTS FOR THOSE APPLYING FOR RELOCATION

- A manufacturer with a current Michigan manufacturer license that is moving the facility to a new address must complete the Online Application For a Manufacturer License - Complete all fields, answer all questions, and upload any supporting documentation. Online application can be completed by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus).
- Be sure to select "yes" to the question "Is this an existing Michigan licensed facility that is changing location?" and provide the manufacturer license number.

### REQUIREMENTS FOR CHANGING PHARMACIST-IN-CHARGE, CHANGING FACILITY OWNERSHIP, OR CHANGING COMPANY INFORMATION

- A manufacturer of drugs salable on prescription only must notify the department of a change in pharmacist-in-charge within 30 days of the change. This can be done by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus) and submitting a modification to the manufacturer license. Choose the Manufacturer PIC Change option.
- A manufacturer of drugs or devices that has changed ownership must notify the department within 30 days of the change. In order to notify the department, the **new owner** must submit a Pharmacy Facility Change of Ownership application by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus).
- A manufacturer may change their organization name, DBA name, or Federal Employer Identification Number (FEIN) by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus) and submitting a modification to the manufacturer license. Choose the Company Information Change option.

## RENEWAL REQUIREMENTS CHECKLIST

- Online Application For a Manufacturer Renewal – Can be completed by visiting [www.michigan.gov/miplus](http://www.michigan.gov/miplus)
- Renewal Application Fee (Must be paid by Visa, Mastercard, Discover, or American Express credit or debit card.):  
Manufacturer Renewal Fee: \$51.00  
Controlled Substance Renewal Fee: \$165.40
- Renewal Cycle: 2 years
- Your controlled substance license will renew along with the manufacturer license unless you uncheck the “renew cs” box on the renewal application.
- Disciplinary Question – Documentation will be required if you answer “yes” to having sanctions imposed against you by a similar licensure, registration, certification, or disciplinary board of another state or country you have not previously reported to the department.

## HELPFUL RESOURCES AND FORMS

- By visiting [www.michigan.gov/healthlicense](http://www.michigan.gov/healthlicense) and clicking on the pharmacy link you can access the following helpful resources and forms:  
  
Resources:
  - [Michigan Public Health Code](#)
  - [Administrative Rules for Pharmacy](#)