LARA
LICENSING AND REGULATORY AFFAIRS

BUREAU OF PROFESSIONAL LICENSING

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 Occupational Code and Administrative Rules for this profession can be found at the end of this guide.

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LICENSURE REQUIREMENTS CHECKLIST

APPLICATION AND FEES

- ☐ Online Application for a Manufacturer License - Complete all fields, answer all questions, and upload any supporting documentation.
- ☐ Online applications can be completed by visiting www.michigan.gov/miplus
- ☐ Application Fee + 2 year license fee: (Must be paid by Visa, Mastercard, American Express, or Discover credit or debit card)

  Manufacturer License: $127.50
  Controlled Substance License: $176.40

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.

An individual is not required to obtain a CBC if one has been obtained for the individuals within the 2 years preceding the date of application for a new pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker license. If fingerprints have been obtained within the two years preceding the date of the application, the individuals 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 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 FEIN certificate, certified copies of articles of incorporation or certificates of partnership and assumed name certificates, list of partners, owners, officers, and members of the board of directors.

☐ You must upload a list or catalog of all drug products or devices to be manufactured by the facility.

☐ 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. If you will be utilizing a facility manager, you must submit the Facility Manager Affidavit form with the application. Applicants who only manufacturer 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 must upload a floor plan of the area to be licensed. Do not send a copy of blueprints.

☐ You must upload photographs of the interior and exterior premises.

☐ If your facility is a manufacturer of biologicals, submit a copy of the FDA certification for the site to be licensed.

☐ 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.

- 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.
- 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.

ADDITIONAL REQUIREMENTS FOR THOSE APPLYING FOR RELICENSURE
(These are in addition to the requirements stated above that apply to All applicants)

- Online application can be completed by visiting www.michigan.gov/miplus and selecting **MiPLUS Login**. Once logged in select "**Modification**" next to your facility license number.
- 2 year Manufacturer Relicensure Application and Fee: $147.50 (Must be paid by Visa, Mastercard, American Express or Discover credit or debit card).

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**.
- Be sure to select "yes" to the question "Is this an existing Michigan licensed facility that is changing location?" and provide the current Michigan facility license number and proposed date of relocation.

ADDITIONAL REQUIREMENTS FOR LICENSE MODIFICATIONS
(CHANGING PHARMACIST-IN-CHARGE OR FACILITY MANAGER, 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** 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.**

- A manufacturer may change their organization name, DBA name, or Federal Employer Identification Number (FEIN) by visiting **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 – Must be completed by visiting **www.michigan.gov/miplus** no sooner than 90 days prior to the expiration date of current license.

- Renewal Application Fee (Must be paid by Visa, Mastercard, American Express or Discover 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 and clicking on the pharmacy link you can access the following helpful resources and forms:

  Resources:
  - Michigan Public Health Code
  - Administrative Rules for Pharmacy

FREQUENTLY ASKED QUESTIONS

1. **How can I contact the Board of Pharmacy, Licensing Division?**

   Email (Questions): BPLHelp@michigan.gov
   Email (Submit Documents): BPLData@michigan.gov
   Phone: (517) 241-0199
   Mailing Address: Bureau of Professional Licensing
   Board of Pharmacy
   PO Box 30670
   Lansing, MI 48909

2. How long are Manufacturer license types valid?

Manufacturer licenses are valid for 2 years.

3. How do I verify my Michigan Manufacturer license?

Certified license verification requests must be obtained from the Michigan Board of Pharmacy. You must submit your request via the MiPLUS system at www.michigan.gov/miplus. There is a $15.00 fee for certification processing for each address you list. Please note, if you submit both a USPS mailing adddress and an email address for the same recipient, you will be charged $30.00 since you have requested your certification to go to two different addresses. Normal processing time for verifications being sent by email is the same day, verifications being mailed are sent the next business day.

Licenses may also be verified online on the Bureau's License Verification website free of charge. You may need to confirm with the recipient if verifying a license on this website is acceptable or if a certified license verification is needed.

4. How will I know when I need to renew? Can I renew my license early?

You will be sent a renewal notification to both your mailing and email address on record approximately 90 days prior to the expiration date of your license. You will not be able to renew before that time. It is your responsibility as a licensed health professional to renew your license on time. **Failure to receive the renewal postcard, email notification, or to notify the Department of an address change does not exempt you from renewing your license on time.**

5. Is there a grace period for my renewal?

Yes, there is a 60-day grace period in which you may renew your license without having to go through the relicensure process. However, if you renew during the 60-day grace period, there is an additional $20.00 late fee for each license type when you renew your license(s).

6. What happens if my license expires?

If your license is not renewed within the 60-day grace period after your expiration date, your license will lapse. The expiration date will reflect the original expiration date – it will not include the grace period. For example: If your license expires January 31, you have until April 1 to pay your renewal fee. If you do not renew by April 1, the end of the 60-day grace period, your license is considered lapsed as of January 31.

7. How long will you keep my licensure application on file?

Your application and fee are valid for two years. If you fail to meet the licensure requirements within that time period, your application and fees are no longer valid.

8. If the facility is licensed in more than one state, Canada or in another country, do you need verification from all locations in which the facility holds or ever held a license in?

Yes, we need verification from any state of the United States, Canada or country in which the facility holds or has 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.

9. How long does it take to process my application for licensure? Once processed, how long before I receive my license?

Applications are reviewed in the order by date received. The average time to receive a new license is 4 to 6 weeks and could be sooner if all required documents are received with the application. Once all the required information is submitted and accepted your license will be issued. If all licensure requirements are not met upon application review, you will receive an email requesting any outstanding items needed to complete your application. Once you are approved for licensure, it takes approximately 7 to 10 business days to receive the license by mail, if requested. Immediately upon license issuance a PDF of the license will also be sent to the email address provided on the application.

10. Will the facility be subject to a pre-licensure inspection? Once assigned to an inspector, how long before an inspection is completed?

Once we are in receipt of the required documentation the application file will be forwarded to our Pharmacy and Drug Monitoring Section (PDMS) for inspection and/or review. Inspections are scheduled to be completed within 30 days once the application file has been assigned to an inspector.

11. How do I apply for a (Drug Enforcement Administration) DEA registration?

The State of Michigan and the DEA are two separate entities. The DEA is federally administered and regulated. If you have any questions concerning your DEA registration, you should visit their website at www.dea.gov or contact them directly at (800) 882-9539.

You must obtain a Michigan controlled substance license prior to a DEA registration, if applicable.

12. Do I need to notify the department that my facility is closing?

A manufacturer that is ceasing operations shall return the manufacturer license and the controlled substance license, if applicable, to the department, and provide the department with written notification of all the following not less than 15 days before closing:

a) The effective date of closing.
b) How controlled substances will be disposed.
c) How non-controlled substances will be disposed.
d) The location where records and prescription files will be stored.

A manufacturer shall comply with all applicable federal requirements for discontinuing a controlled substance business.

Records must be maintained for the same amount of time that is required if the manufacturer remains open.

13. How do I file a complaint against a health care professional?

Visit the Bureau of Professional Licensing's website at www.michigan.gov/bpl for information on how to File a Complaint Against a Health Care Licensee.