

MICHIGAN PHARMACY LICENSING GUIDE

OVERVIEW:

The pharmacy license type allows a licensee to dispense prescription drugs or prepare prescription drugs for delivery or distribution.

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 pharmacy license.)

APPLICATION AND FEES

- Online Application For a Pharmacy License - Complete all fields, answer all questions, and upload any supporting documentation. Online application can be completed by visiting www.michigan.gov/miplus.
- Application Fee + 2-year License Fee (Must be paid by Visa, Mastercard, Discover, or American Express credit or debit card.):
 - Pharmacy License – \$178.50
 - Controlled Substance License – \$176.40
 - Pharmacy Relicensure – \$198.50

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 pharmacy 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, or wholesale distributors 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 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 pharmacy license. Relicensure applications lapsed 3 years or less are also not required to obtain a CBC.

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- 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 pharmacy holds a current pharmacy 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 pharmacy 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.
- A licensed pharmacy must have a pharmacist in charge (PIC) licensed in Michigan. You must provide the license number of the PIC or the pharmacist application number of the PIC if the PIC has not yet obtained Michigan licensure. If your pharmacy will be distributing or dispensing controlled substances in Michigan, the PIC and the pharmacy must have a controlled substance license.
- If your pharmacy has an NABP E-Profile Identification Number, you may enter it on the application.
- If your pharmacy is not located in Michigan and you will not be shipping sterile compounded products into Michigan, you must submit an inspection report from your resident state board of pharmacy or from the National Association of Boards of Pharmacy Verified Pharmacy Program (VPP) performed within the last 2 years.
- 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 pharmacy address. If you do not apply for a controlled substance license on your initial application, you must wait for the pharmacy license to be issued before applying for a controlled substance license.

ADDITIONAL REQUIREMENTS FOR STERILE COMPOUNDING PHARMACIES

- Sterile compounding pharmacy applicants must upload a copy of a current accreditation certificate (if applicable) AND an inspection report completed within the last 18 months showing compliance with USP standards in a manner approved by the Michigan Board of Pharmacy. Approved entities include:
 - Gates Healthcare Associates, Inc.
 - Joint Commission Home Care Accreditation Program
 - Joint Commission Medication Compounding Certification Program
 - National Association of Boards of Pharmacy Verified Pharmacy Program (VPP)
 - National Association of Boards of Pharmacy – Multistate Pharmacy Inspection Blueprint Program
 - Pharmacy Compounding Accreditation Board (PCAB)
 - The Compliance Team, Inc.
- If the application is for an outsourcing facility, you must upload verification that the facility is in compliance with requirements of the FDA applicable to compounding services for sterile pharmaceuticals. Documentation may include the FDA-483 form and the plan of corrections. In addition, an outsourcing facility must submit

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the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form.

ADDITIONAL REQUIREMENTS FOR THOSE APPLYING FOR RELICENSURE

- Online application can be completed by visiting 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 pharmacy with a current Michigan pharmacy license that is moving the pharmacy to a new address must complete the Online Application For a Pharmacy 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 pharmacy license number.

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

- A pharmacy 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 pharmacy license. Choose the Pharmacy PIC Change option. Please note that your pharmacist-in-charge must have a Michigan pharmacist license and if you will be dispensing controlled substances, the PIC must also have a Michigan controlled substance license.
- A pharmacy 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 pharmacy 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 pharmacy license. Choose the Company Information Change option.

RENEWAL REQUIREMENTS CHECKLIST

- Online Application For a Pharmacy Renewal – Can be completed by visiting www.michigan.gov/miplus

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- Renewal Application Fee (Must be paid by Visa, Mastercard, Discover or American Express credit or debit card.):

Pharmacy Renewal Fee: \$102.00

Controlled Substance Renewal Fee: \$165.40

- Renewal Cycle: 2 years

- Your controlled substance license and any controlled substance automated device licenses will renew along with the pharmacy 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.
- Sterile compounding pharmacies located in Michigan and pharmacies located outside of Michigan that ship sterile compounded products into Michigan must, prior to the end of the renewal period, upload a copy of a current accreditation certificate (if applicable) AND an inspection report completed within the last 18 months showing compliance with USP standards in a manner approved by the Michigan Board of Pharmacy. Approved entities include:
 - Gates Healthcare Associates, Inc.
 - HFAP
 - Joint Commission Home Care Accreditation Program
 - Joint Commission Medication Compounding Certification Program
 - National Association of Boards of Pharmacy Verified Pharmacy Program (VPP)
 - National Association of Boards of Pharmacy – Multistate Pharmacy Inspection Blueprint Program
 - Pharmacy Compounding Accreditation Board (PCAB)
 - The Compliance Team, Inc.
 - Outsourcing facilities may upload their latest FDA-483 form and the plan of corrections.
- Outsourcing facilities must upload verification that the facility is in compliance with requirements of the FDA applicable to compounding services for sterile pharmaceuticals and a copy of the report provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug’s active ingredients, strength, and dosage form. Documentation may include the FDA-483 form and the plan of corrections.

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](#)