BUREAU OF PROFESSIONAL LICENSING

MICHIGAN WHOLESALE DISTRIBUTOR LICENSING GUIDE

OVERVIEW:

The wholesale distributor license type allows a licensee to engage in wholesale distribution of 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 wholesale distributor license.)

APPLICATION AND FEES

Online Application For a Wholesale Distributor License - Complete all fields, answer all questions, and upload
any supporting documentation.

	Online application	can be completed	yd b	/ visiting	www.michigan.	<u>.gov/miplus</u> .
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Application Fee + 2-	-year license fe	ee (Must be	e paid by Visa	, Mastercard,	Discover, or	American	Express	credit
or debit card.):								

Wholesale Distributor License – \$127.50 Controlled Substance License – \$176.40

Wholesale Distributor 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 wholesale distributor 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.

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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, wholesale distributor or wholesale distributor-broker 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 wholesale distributor 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 wholesaler holds a current wholesaler 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 wholesale distributor 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 wholesale distributor of drugs must have a pharmacist in charge (PIC) licensed in or outside of Michigan or a facility manager. If you will be utilizing a facility manager, you must submit the Facility Manager Affidavit form with the application. If you will be utilizing a PIC, 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 distribute 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 wholesale distributor address. If you do not apply for a controlled substance license on your initial application, you must wait for the wholesale distributor 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. If you are applying for a wholesale distributor license and will not physically touch prescription drugs or devices, the pharmacist in charge or facility manager must submit the Virtual Entity Affidavit with the application.
A pharmacy that is applying for licensure as a wholesale distributor must show a clear delineation between the pharmacy and wholesale distributor stock, records, policies, and procedures at the time of inspection.

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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 wholesale distributor with a current Michigan license that is moving the facility to a new address must complete the Online Application For a Wholesale Distributor 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 license number.
REQUIREMENTS FOR LICENSE MODIFICATIONS
A wholesale distributor of drugs salable on prescription only must notify the department of a change in pharmacist-in-charge or facility manager within 30 days of the change. This can be done by visiting www.michigan.gov/miplus and submitting a modification to the license. Choose the Compliance Person Change option.
A facility 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 wholesale distributor 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 license. Choose the Company Information Change option.
A wholesale distributor that previously filed an affidavit attesting that they do not physically touch prescription drugs and devices shall not obtain custody and control of prescription drugs or devices until the licensee provides written notification to the department of physical custody and are inspected by the department.

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RENEWAL REQUIREMENTS CHECKLIST
Online Application For a Wholesale Distributor Renewal – Can be completed by visiting www.michigan.gov/miplus .
Renewal Application Fee (Must be paid by Visa, Mastercard, Discover credit, or American Express credit or debit card.):
Wholesale Distributor Renewal Fee: \$51.00 Controlled Substance Renewal Fee: \$165.40
Renewal Cycle: 2 years
Your controlled substance license will renew along with the wholesale distributor license unless <u>you uncheck</u> 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