

Michigan Department of Licensing and Regulatory Affairs

Board of Pharmacy

P.O. Box 30670

Lansing, Michigan 48909

(517) 335-0918

www.michigan.gov/healthlicense

PHARMACY LICENSURE INSTRUCTIONS

Authority: P.A. 368 of 1978, as amended
This form is for information only

NOTE: It is your responsibility to have all required documentation sent to the Board of Pharmacy. Questions regarding your application can be directed to the Michigan Board of Pharmacy at (517) 335-0918 three weeks after the date you sent the application. Please allow 6-8 weeks processing time. 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to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid.

OPENING A NEW PHARMACY

1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with appropriate fees.
2. Applicants that are partnerships, corporations, or operating under an assumed name must file their application for a pharmacy license along with copies of:
 - 1) Partnership Certificates
 - 2) Articles of Incorporation and/or Assumed Name Certificates.
3. Complete the information on the application as to the opening date of the pharmacy, name and telephone number of person to contact.

Upon receipt of fees and all pertinent documents, your application will be reviewed for compliance with Administrative Rules 11 and 12 of the Michigan Board of Pharmacy. If the application and checklist are satisfactory, a permanent identification number will be assigned, and a pharmacy and controlled substance license will be issued.

NOTE TO OUT-OF-STATE APPLICANTS - The Michigan Board of Pharmacy requires pharmacy applicants to designate a licensed pharmacist to be responsible for compliance with the licensing requirements. The responsible pharmacist must hold a full pharmacist's license in the state where the pharmacy is located. A Michigan pharmacy license will not be issued without complying with this requirement.

SALE OR TRANSFER OF A PHARMACY

The following changes constitute a transfer:

1. Complete (100%) change of ownership in existing pharmacy.
2. Sale of stock from original owner to new owner.
3. Widow/widower of owner who is not listed as an owner in existing pharmacy.

If one of the above applies to your situation, you must submit the following:

1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with appropriate fees. You are not required to file a new controlled substance application and fee.
2. Affidavits from both buyer and seller stating the actual consummation date of the sale or transfer. Please submit name and telephone number of person to contact.

3. If the application indicates that the pharmacy ownership will be a partnership, corporation, or operating under an assumed name, the applicant must submit copies of:

- 1) Partnership Certificates
- 2) Articles of Incorporation and/or Assumed Name Certificates

Upon receipt of fees and all pertinent documents, including the Affidavit that states when the sale or transfer will occur, your application will be reviewed for compliance with Administrative Rules 11 and 12 of the Michigan Board of Pharmacy. If the application and checklist are satisfactory, a permanent identification number will be assigned, and pharmacy and controlled substance licenses will be issued.

NOTE TO OUT-OF-STATE APPLICANTS - The Michigan Board of Pharmacy requires pharmacy applicants to designate a licensed pharmacist to be responsible for compliance with the licensing requirements. The responsible pharmacist must hold a full pharmacist's license in the state where the pharmacy is located. A Michigan pharmacy license will not be issued without complying with this requirement.

RELICENSURE OF A PHARMACY (PREVIOUSLY LICENSED IN MICHIGAN)

The application for Pharmacy Relicensure should be completed in its entirety and returned to the board office with the appropriate fee.

RELOCATION OF A PHARMACY

1. The application, ADP System Approval Request form, and Self-Inspection form should be completed in their entirety and returned to the board office with the \$55.00 fee.
2. Complete the information on the application about the proposed date of change of location, person to contact and telephone number.

Upon receipt of the fee and all pertinent documents, your application will be reviewed. If the application and checklist are satisfactory, the same permanent identification number will be retained, and a new pharmacy and controlled substance license will be issued to reflect the new address.

If a pharmacy area is moving within the same building and there is no change in address, no fee is required and notification to the board office is not necessary.

MISCELLANEOUS PHARMACY CHANGES

The following changes constitute miscellaneous changes, which may require a fee:

1. Partner or stockholder change.
2. Change in name of store/corporation where no change in ownership occurs.
3. Change in pharmacist-in-charge designation.

If one of the above applies to your situation, you must contact the board office at (517) 335-0918 to request an Application for Miscellaneous Pharmacy Change.

CLOSING OF A PHARMACY

The owner of a pharmacy being closed must notify the Michigan Board of Pharmacy of the effective closing date of the pharmacy and must return the current pharmacy license and controlled substance license to the Board office. The Board of Pharmacy must be notified about the disposition of the prescription files and prescription drugs for both controlled substances and non-controlled substances.

Upon receipt of the above information, our files for your pharmacy will indicate that it is closed.

For information concerning **Federal Drug Enforcement Administration** (DEA) requirements for pharmacy closings, contact the DEA at their Detroit office, 1-800-882-9539.

DEA INFORMATION

You may also apply to the Drug Enforcement Administration (DEA) for registration under the Federal Controlled Substances Act at the same time you apply for the Board of Pharmacy application. A federal application may be obtained from the Department of Justice Drug Enforcement Administration, 431 Howard Street, Detroit, Michigan 48226. The telephone number is 1-800-882-9539. All questions concerning the federal license should be directed to that office.

GENERAL INFORMATION

1. **REFUND POLICY:** If you wish to withdraw your application, you may be eligible for a partial refund. You must notify the Board of Pharmacy in writing to request a refund.
2. **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.

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APPLICATION FOR PHARMACY 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 1-800-882-9539).

Board Use Only
License Number
Date of Licensure

SECTION I - Pharmacy Information - Complete this section in its entirety.

Type or Print Only

I AM APPLYING FOR THE FOLLOWING:

New Store License/Controlled Substance - Fee: \$180.00 71-5301-375701 Proposed Opening Date of Pharmacy: _____

Store Transfer - Fee: \$180.00 71-5301-375701 Proposed Date of Store Transfer: _____

Pharmacy Relicensure - Fee: \$200.00 71-5301-375706 Proposed Date of Relocation: _____

Relocation - Fee: \$70.00 71-5301-33 _____

Your check or money order drawn on a US 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.

I AM APPLYING AS (check one from each category):

<u>Type of Pharmacy</u>		<u>Type of Ownership</u>	
<input type="checkbox"/> Retail	<input type="checkbox"/> HMO	<input type="checkbox"/> Partnership	<input type="checkbox"/> Individual Owner
<input type="checkbox"/> Hospital	<input type="checkbox"/> Educational Institution Pharmacy	<input type="checkbox"/> Private Corporation	<input type="checkbox"/> Public Corporation

Name of Pharmacy	*If Transfer, Give Name of Former Pharmacy and MI permanent I.D. Number		
Name of Contact Person	Phone Number of Contact Person		
Street Address	City	State	ZIP Code
If Relocation, Give New Street Address	City	State	ZIP Code
Business Telephone Number	County	Federal Employer (Tax) I.D. Number	
Name of Corporation (If Applicable)	If Relicensure or Relocation, List Pharmacy MI Permanent I.D. Number		

SECTION II

List the names, MI Permanent I.D. Numbers, and percentage of stock owned by each individual who is a Pharmacist licensed in Michigan. If none, indicate "none" below.

Pharmacist's Name	MI Permanent I.D./License Number	Percentage of Stock Owned

The Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

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PHARMACY ADP SYSTEM APPROVAL REQUEST

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

PRESCRIPTION RECORDS: Checklist for Automated Data Processing (ADP) System. If a computer (ADP) system is used, please answer the following questions:

Type or Print

Only of Pharmacy		Michigan Permanent I.D. Number and Expiration Date	
Street Address of Pharmacy		Pharmacy Telephone Number	
City		State	ZIP Code
Name of ADP Software System		The Terminal System is (Check One) <input type="checkbox"/> On Line <input type="checkbox"/> Stand Alone	
Company Name	Company Telephone Number	Company Representative Name	
Street Address of Company			
City		State	ZIP Code

1. The information entered on the ADP record must include, but is not limited to, the following (check appropriate box):

CR = Computer Record	L = Rx Label		
Prescription Number	<input type="checkbox"/> CR <input type="checkbox"/> L	Manufacturer or Supplier of Drug Dispensed	<input type="checkbox"/> CR <input type="checkbox"/> L
Patient's Name	<input type="checkbox"/> CR <input type="checkbox"/> L	Name, strength, dosage form, quantity of drug, prescribed and dispensed originally and refilled	<input type="checkbox"/> CR <input type="checkbox"/> L
Patient's Address	<input type="checkbox"/> CR <input type="checkbox"/> L	Is drug dispensed DAW?	<input type="checkbox"/> CR <input type="checkbox"/> L
Prescriber's Name	<input type="checkbox"/> CR <input type="checkbox"/> L	Date and initials of dispensing pharmacist on original and each refill	<input type="checkbox"/> CR <input type="checkbox"/> L
Prescriber's DEA Number	<input type="checkbox"/> CR <input type="checkbox"/> L	Date of Rx issuance	<input type="checkbox"/> CR <input type="checkbox"/> L
Number of Authorized refills	<input type="checkbox"/> CR <input type="checkbox"/> L		

2. Are computer prescription records retained at the pharmacy for five years subject to inspection of Board agents? Yes No

3. Is a R.Ph security code required to activate the ADP System in the A.M.? Yes No

Do any other pharmacy or store personnel have access to the individual R.Ph. codes? Yes No

If yes, who? _____

4. Are ALL prescriptions entered into the ADP system including those that are not refillable? Yes No

5. Does the ADP system provide for immediate on-line retrieval of all original and refilled prescription data that is 16 months old or less and retrieval within 72 hours for data older than 16 months? Yes No

NAME _____

6. Is the ADP system capable of producing a hard copy printout of all original and refilled prescription data? Yes No

Does this include

Prescription-by-prescription audit trail (specific patient)? Yes No

Refill-by-refill audit trail (specific prescription)? Yes No

Could a controlled substance audit be done on:

A drug by each strength (15 mg, 10 mg, 5 mg) Yes No

A drug by dosage form (tablets, capsules)? Yes No

Drugs written by specific prescriber? Yes No

Are hard copy printouts available for immediate review for all computer entries since the last controlled substance inventory? Yes No

7. Does the pharmacy maintain a computer generated daily log for new and refill controlled substance prescriptions that includes a statement signed by the pharmacist at the end of each working day that the ADP information on Rx's he/she filled:

Has been reviewed? Is correct? Is complete? Has R.Ph signature?

Contains the pharmacist's identifying designation?

Is this log maintained at the pharmacy for five years? Yes No

8. Describe the system of recording new prescriptions and refill information in the event of downtime on the ADP system.

9. Describe the arrangements made with the ADP system supplier for continuity of records in the event of contract termination.

10. Are prescription records subject to confidentiality? Yes No

Explain: _____

11. Is there a safeguard built into the system in case of power failure? Yes No

Explain: _____

CERTIFICATION

I, _____, R.Ph., certify that my responses to this checklist are true and accurate

Print or Type Name

and that I am employed as the Responsible Fully Licensed Pharmacist or the Owner of this pharmacy.

Signature of Responsible Fully Licensed Pharmacist/Owner _____

Date _____

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PHARMACY SELF-INSPECTION FORM

Authority: Public Act 368 of 1978, as amended
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Type or Print

Name of Pharmacy		Date Opening, Transferring and Relocating	
Street Address		City	
State	ZIP Code	County	
Pharmacy Telephone Number		Pharmacy Hours	
Non-Pharmacist Owner of Pharmacy		Name of Responsible Fully Licensed Pharmacist and MI License #	
Non-Pharmacist Owner of Pharmacy		Employee Pharmacist and MI License #	
Non-Pharmacist Owner of Pharmacy		Employee Pharmacist and MI License #	
Owner of Pharmacy		Employee Pharmacist and MI License #	
Is the pharmacy approved for Intern Training? <input type="checkbox"/> No <input type="checkbox"/> Yes - If Yes, Please complete the following:			
Name of Intern and MI License # _____		Name of Intern and MI License # _____	
Name of Intern and MI License # _____		Name of Intern and MI License # _____	
Name of Preceptor _____		Name of Preceptor _____	
Pharmacy Department Staff	# of Full time Staff	# of Part Time Staff	
Pharmacists	_____	_____	
Interns	_____	_____	
Other	_____	_____	

ANY NEW PHARMACY, ANY PHARMACY THAT IS MOVING FROM ONE LOCATION TO ANOTHER, OR ANY PHARMACY TRANSFERRING OWNERSHIP, MUST COMPLY WITH THE FOLLOWING PROVISIONS:

Each pharmacy must be equipped with proper pharmaceutical utensils so that prescriptions can be properly filled and compounded and U.S. Pharmacopoeia and National Formulary preparations properly prepared.

PHARMACY CHECKLIST

Instructions: Please indicate by placing a check in the appropriate box as indicated.

1. Does the pharmacy have the necessary technical equipment to compound and dispense prescription drugs?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
a. Are three separate prescription files maintained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Schedule 2 Schedules 3,4, and 5 Other Legend Drugs		
b. Prescription medication containers available in appropriate sizes?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. Safety closure prescription containers available in appropriate sizes and used routinely?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. Schedule 5 OTC sales record book is maintained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

NAME

<p>2. Is there a well lighted, ventilated area of 150 square feet minimum devoted entirely to the pharmacy area?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>3. Clean and sanitary conditions?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>4. Prescription counter has at least 10 square feet work area plus 4 square feet for each additional pharmacist on duty, free of obstruction?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>5. Does the pharmacy occupy less than the entire area controlled by the licensee? If no, does the licensee control the entire area in which the pharmacy is located? If yes, does the pharmacy have a permanent partition enclosure from floor to ceiling that is lockable?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>6. Sink with hot and cold running water?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>7. Refrigerator of adequate capacity?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>8. List the names of two (2) pharmacy reference texts or electronic media on site that pertain to drug interactions, drug product composition, and pharmacology.</p> <p>_____</p> <p>_____</p>	
<p>9. Current copy of the Michigan Public Health Code - Dated: _____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>10. Current Michigan Pharmacy Administrative Rules - Dated: _____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>11. Are all licenses of pharmacists conspicuously displayed?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>12. Will all prescription labels indicate brand name, generic name, and name of manufacturer or distributor if drug product selection is utilized?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>13. Do pharmacists number, initial, and date all original prescriptions?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>14. Will the manufacturer's or distributor's name be indicated on all prescriptions where drug product selection is utilized or if prescription is written generically?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>15. Are all prescriptions retained for five years?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>16. Have all outdated drugs been removed from the prescription department shelves?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>17. Has DEA Registration been applied for?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>18. Have DEA Registration and Order Forms been received?</p> <p>DEA Registration Number _____</p> <p>Expiration date of DEA Registration _____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>19. Have you applied for central record keeping with DEA and the Board of Pharmacy? If applying, at what address will the records be kept?</p> <p>_____</p> <p>Street Address</p> <p>_____</p> <p>City State Zip Code</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>20. Are controlled substances stored in a cabinet?</p> <p>Is this cabinet secured to the floor or wall?</p> <p>Is this cabinet substantially constructed and securely lockable?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

NAME

21. Security provided for the pharmacy area - Explain alarm system:

- 22. Are controls in effect in the pharmacy department to prevent theft and diversion of controlled substances? Yes No
- 23. Has a controlled substances inventory been taken? Yes No
 Is it on site and properly documented? Date taken: _____ Yes No
- 24. Are all controlled substance purchase records to be kept on site? Yes No
- 25. Will all controlled substances invoices be initialed and dated by a pharmacist? Yes No
- 26. Are Schedule 2 invoices filed separately from all other purchase invoices? Yes No
- 27. Are Schedules 3,4, and 5 controlled substance invoices filed separately or readily retrievable? Yes No
- 28. Will DEA-222 Schedule 2 Order Forms be maintained as required? Yes No
- 29. How are prescription refill records maintained? Check one:
 - Initialed and dated on back of Rx
 - Paper profile maintained (See Below)
 - Computer

IF PAPER PROFILE IS TO BE MAINTAINED, PLEASE ANSWER THE FOLLOWING:

- 30. Does the profile system indicate the drug name, strength, and directions for use of all drugs entered? Yes No
- 31. Are all prescriptions entered on the system - new Rx's and refills? Yes No
- 32. Are DAW prescriptions so designated? Yes No
- 33. Is the manufacturer's or distributor's name indicated if drug product selection is used or if prescription is written generically? Yes No
- 34. Is the pharmacist who filled or refilled the prescription initialing each entry? Yes No
- 35. Are the profiles maintained for five years? Yes No

CERTIFICATION

I, _____, R.Ph., certify that my responses to this checklist are true and accurate
Print or Type Name
 and that I am employed as the Responsible Fully Licensed Pharmacist or the Owner of this pharmacy.

Signature of Responsible Fully Licensed Pharmacist	Date
Signature of Owner	Date