



## REQUEST FOR AUTHORITY TO COMPOUND PHARMACEUTICALS IN A LIMITED QUANTITY WITHOUT A PRESCRIPTION

**\* Please read application instructions carefully and answer all questions completely.  
Failure to do so may cause a delay in your application process.\***

Section 333.17748b of the Michigan Public Health Code (PA 368 of 1978, as amended) requires the Department of Licensing and Regulatory Affairs to establish and maintain a list of pharmacies and pharmacists who are authorized to compound limited quantities of sterile or non-sterile pharmaceuticals without a prescription. These compounded pharmaceuticals must be prepared for use by the patients of a prescriber or health facility or agency that is licensed under Article 17. The pharmacy or pharmacist must be in compliance with the most recent guidance on pharmacy compounding of human drug products under 21 USC 353a. This section does not apply to the compounding of topical nonsterile pharmaceuticals.

To apply for the authority to compound pharmaceuticals in a limited quantity without a prescription, please complete the enclosed application in its entirety. You will be required to provide the following.

1. A completed affidavit (enclosed) from the prescriber or the agent of the health facility or agency licensed under Article 17 that verifies the need for the compounded pharmaceuticals and that these pharmaceuticals will only be administered to patients located in Michigan or in states immediately adjacent to Michigan.
2. A list of the pharmaceuticals to be compounded and the reason for the need to compound the pharmaceuticals.
3. A description of the anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound before a prescription or documentation supporting the anticipated quantities is received.
4. A description of the conditions of operation including practices consistent with USP standards and requirements for sterility testing.

If approved, a new pharmacist or pharmacy license will be issued that indicates that the authority to compound pharmaceuticals in limited quantities without a prescription has been granted. The license number of the pharmacist or pharmacy will not change. The authorization is granted for a two-year period consistent with the two-year license cycle of the pharmacist or pharmacy. The authorization may be extended upon submitting a new application and required documentation. Once the authorization is granted, the pharmacist or pharmacy shall maintain complete and accurate records on a monthly basis of requests from and pharmaceuticals compounded for each prescriber or health facility or agency. This information must be provided to the Department upon request.

Authorization will not be granted if the pharmacist or pharmacy is under investigation, is in the process of being disciplined, or is in a disciplinary status. The Department may immediately revoke this authorization if there is a confirmed deviation or violation of the compounding process or if an adverse event directly related to sterility or integrity of the product and associated with a compounded nonsterile or sterile pharmaceutical is detected. The authorized pharmacist or pharmacy shall report any adverse event attributed to the integrity of the product of a compounded pharmaceutical to the Department no later than 10 calendar days after becoming aware of the adverse event. An adverse event does not include an isolated allergic reaction to a substance included in the compound if the allergic reaction is treated and relieved with standard protocol.

If you have questions on pharmacy-related issues, please contact the Pharmacy Services Unit at (517) 373-1737 during regular business hours.

For questions regarding licensing and filing your application, please contact us at (517) 335-0918 or visit our website at [www.michigan.gov/healthlicense](http://www.michigan.gov/healthlicense).

Michigan Department of Licensing and Regulatory Affairs  
Board of Pharmacy  
PO Box 30670  
Lansing MI 48909  
(517) 335-0918  
[www.michigan.gov/healthlicense](http://www.michigan.gov/healthlicense)

For Board Use Only
License #:
Issue Date:

<b>APPLICATION FOR AUTHORIZATION TO COMPOUND LIMITED QUANTITIES WITHOUT A PRESCRIPTION</b>
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<b>INFORMATION TO BE INCLUDED WITH APPLICATION</b>
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All Applicants:

Affidavit from Prescriber or Designated Agent (Attached)

Name of Pharmaceuticals and Reason Needed

Anticipated Quantities/Frequency of Need

Compliance with USP Standards/Requirements for Sterility Testing

<b>1. Demographic Information</b>
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First Name:	Middle Name:	Last Name:
U.S. Social Security #:		Birth Date:
Business Name:		
Street Address:		Apt/Bldg #:
City:	State:	Zip Code:
Country: United States		
Phone Number:	Email Address:	
Health Professional Permanent I.D./ License Number:		Expiration Date:
County:	Federal Employer #	

Full Name:

## 2. Certification

I certify that I have read Section 333.17748b of the Michigan Public Health Code and will comply with all of the legal requirements for compounding pharmaceuticals in limited quantities without a prescription.

I understand that it is the policy of this agency to secure a criminal conviction history as part of the pre-licensure screening process. I authorize this agency to use the information provided in this application to obtain a criminal conviction history file search from the Central Records Division of the Michigan Department of State Police, law enforcement, or judicial record-keeping organization.

I further consent to the release of information to this agency regarding any disciplinary investigations conducted by a similar licensure, registration, or specialty certification board of this or any other state, of the United States military, of the federal government, or of another country.

The statements in this application are true and correct. I have not withheld information that might affect the decision to be made on this application. In signing this application, I am aware that a false statement or dishonest answer may be grounds for denial of my application or revocation of my license and that such misrepresentation is punishable by law.

## 3. Signature

Printed Name of Pharmacist or Authorized Agent for Health Facility or Agency

Signature of Pharmacist or Authorized Agent for Health Facility or Agency

Date

Michigan Department of Licensing and Regulatory Affairs  
 Bureau of Health Care Services  
 Health Licensing Division  
 PO Box 30670  
 Lansing, MI 48909  
 (517) 335-0918  
[www.michigan.gov/healthlicense](http://www.michigan.gov/healthlicense)

**AFFIDAVIT FOR RECEIPT OF COMPOUNDED PHARMACEUTICALS**

**1. Demographic Information**

Name of Prescriber, Health Facility or Agency Requesting Compounded Pharmaceuticals:

Name of Compounding Pharmacist or Pharmacy:

License Number of Compounding Pharmacist or Pharmacy:

**2. Certification**

I certify that I am a prescriber or designated agent for a health facility or agency licensed under Article 17 that is in need of a limited quantity of compounded pharmaceuticals. The compounded pharmaceuticals will only be administered to patients located in Michigan or in states immediately adjacent to Michigan.

**3. Signature**

Printed Name of Prescriber or Authorized Agent for Health Facility or Agency

Signature of Prescriber or Authorized Agent for Health Facility or Agency	Date
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