



# MAINE BOARD OF PHARMACY

## Manufacturer

Stop  Stop

If this company manufactures opioid medication products, you must complete the Opioid Prescription Drug Manufacturer (MFO) application using the online services located at

<https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy/online-services>

### **Exception:**

The manufacturer opioid medication fee does not apply if all opioid medication manufactured is approved by the United States Food and Drug Administration for use only in veterinary medicine. In addition, please visit our website and complete the Opioid Prescription Drug Manufacturer (MFO) form online

Do not return the following informational pages with your application; it is for your information only

Department of Professional and Financial Regulation  
Office of Professional and Occupational Regulation  
(Mailing address) 35 State House Station, Augusta, ME 04333  
(Office location) Gardiner Annex, 76 Northern Avenue, Gardiner, Maine 04345

Office Direct Line (207) 624-8686 or (207) 624-8620  
TTY users call Maine relay 711  
FAX (207) 624-8637

Web address: [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing)  
Email: [pharmacy.lic@maine.gov](mailto:pharmacy.lic@maine.gov)

**Check here to demonstrate you have read this notice.**

**NOTICE:**

If this entity manufactures opioid medication products you must complete the Opioid Prescription Drug Manufacturer (MFO) application online. You must submit this manufacturer (MF) application before applying online for the Opioid Prescription Drug Manufacturer license.

Once the Board has received your application for the MF license, a pending license number will be assigned and be available for you to obtain using this link

<https://www.pfr.maine.gov/almsonline/almquery/SearchCompany.aspx>

You may then apply online for the MFO registration using the following link

[https://licensing.web.maine.gov/cgi-bin/online/licensing/begin.pl?board\\_number=4380](https://licensing.web.maine.gov/cgi-bin/online/licensing/begin.pl?board_number=4380)

A Manufacturer of opioid medication (MFO) will be assessed for a total fee of \$55,000. IF the entity only manufactures an opioid medication(s) that is approved by the United States Food and Drug Administration for use only in veterinary medicine, the \$55,000 assessment does not apply, but the MFO registration is still required.

A Manufacturer of opioid medication (MFO) that sells, delivers, or distributes an opioid medication within Maine shall pay an annual product registration fee of \$250,000 to the board at the time of renewal (licenses expire December 31 annually).

**Exception:** A manufacturer that does not sell, deliver or distribute 2,000,000 million or more units of an opioid medication within Maine in the year in which a registration fee is due the manufacturer is exempt from the product registration fee. To qualify for the exception, the manufacturer must demonstrate proof to the board, by January 31<sup>st</sup> of the following year in which the registration fee is due.

**Example:** Registration due December 31, 2020, request for an exception must be submitted by January 31, 2021, and so on.)

## INFORMATIONAL

- ✓ Receipt of your application does not constitute entitlement to distribute your product in any manner into Maine until such time as a license has been issued. While applications are logged in as 'pending' this does not mean a license has been issued.

**You must hold an ACTIVE license in order for your prescription products to be shipped into Maine.** Your application may be subject to denial or discipline imposed as a condition to licensure if you ship into Maine prior to licensure.

- ✓ Processing time depends greatly on the completeness of your application. Applications that are incomplete and/or missing supporting documents may be returned where you will be required to reapply and pay a new fee. PLEASE FILE A COMPLETE APPLICATION TOGETHER WITH ALL SUPPORTING DOCUMENTS REQUIRED.
- ✓ Please visit our website if you wish to monitor progress. If your application status appears as Pending, this means that your application was received by this office and it is pending or under review. Once reviewed and if everything about your application is complete and complies with requirements, the license will be issued and the status will show as ACTIVE. If incomplete your application may be returned, which may required you to reapply, together with a new fee. We will attempt to work with you to bring an application to completeness for items that are not expected to require a significant amount of time. We suggest you monitor the website for any communications.
- ✓ Please refrain from calling our office to “check” on your application status as these calls only serve to slow our ability to review and process applications. Information regarding the status of applications may be found at the Office of Professional and Occupational Regulation’s website [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing). We appreciate your thoughtful attention to this request.
- ✓ If there is an urgent need to contact us, please be advised that we will only discuss your application with the contact person named in the application. This is done not only for your protection, but to also avoid complications when multiple individuals are involved and generally lead to miscommunication or misunderstandings. Our goal is to streamline your process, not complicate it.
- ✓ Once your license is issued it is immediately visible online with an “active” status and you may begin to conduct business in Maine.
- ✓ Incomplete applications or documents that have been modified or altered in any way, including use of a white out substance will not be accepted and will be returned. Please write your information legibly.

## LAW AND BOARD RULE REFERENCE

Information contained in this application is not a substitute for carefully reviewing applicable laws and rules. You may obtain a copy of the laws and board rules online at [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing)—Click on “list of licensed professions”, click on “Pharmacy” under “Board of Pharmacy Home” click on “Laws & Rules.” Notwithstanding, please pay particular attention to the following:

- 32 MRSA Chapter 117 <http://www.mainelegislature.org/legis/statutes/32/title32ch117sec0.html>
- Board Rules <https://www.maine.gov/sos/cec/rules/02/chaps02.htm#392>

**READY TO SUBMIT YOUR APPLICATION - CHECK, DID YOU COMPLETE THE APPLICATION FULLY AND INCLUDE ALL NECESSARY ATTACHMENTS/ ENCLOSURES:**

*Do not submit your application unless it is completed fully and all attachments/ enclosures are included.*

*An incomplete application may be subject to being returned requesting that you file a new fully completed application w/attachments together with a new fee. All fees are non-refundable.*

- ⇒ Did you respond to all questions and provide a response to all information requested?
- ⇒ Did you affix signatures in all areas noted?
- ⇒ Payment is enclosed and is it made payable to Treasurer, State of Maine
- ⇒ You must submit a copy of the most recent inspection report from the state in which the facility is located. Contact your State of jurisdiction to obtain a copy if you don't have it, OR, if the State of jurisdiction does not inspect facilities, you must attach a letter from the State of jurisdiction that confirms this. Your application cannot be processed solely on the basis of you saying you do not have a current facility inspection or that your State of jurisdiction does not inspect.
- ⇒ Is your company's Organizational Chart attached?
- ⇒ Is a complete list of Jurisdictions licensed attached? *(in the format given in section 6 above)*
- ⇒ If there is disciplinary action reported, is a copy of all necessary documents attached?
- ⇒ Certificate of Existence or Authority from your home state and/or the Maine Secretary of State, whichever applies.



**STATE OF MAINE  
DEPARTMENT OF PROFESSIONAL  
AND FINANCIAL REGULATION  
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION  
COMPANY APPLICATION**

APPLICANT INFORMATION (please print)			
NAME OF MANUFACTURER			
FEIN OR SSN			
PHYSICAL LOCATION OF THE MANUFACTURING FACILITY <i>(STREET)</i>			
<i>(CITY)</i>	<i>(STATE)</i>	<i>(ZIP)</i>	<i>(COUNTY)</i>
CONTACT ADDRESS			
<i>(CITY)</i>	<i>(STATE)</i>	<i>(ZIP)</i>	<i>(COUNTY)</i>
PHONE # (    )		FAX # (    )	

Maine Board of Pharmacy  
Manufacturer (MF)

MF License Fee: \$200.00;  
**(Non Refundable)**

<i>Office Use Only:</i>
Check # _____
Amount: _____
Cash # _____
Lic. # _____
Issue Date _____
Exp. Date _____

<i>Office Use Only:</i>
MF1421 - \$200.00

<b>PAYMENT OPTIONS:</b>	
Make checks payable to "Maine State Treasurer" - If you wish to pay by MasterCard or Visa, fill out the following:	
NAME OF CARDHOLDER (please print name on card)	
I authorize the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation to charge my <input type="checkbox"/> VISA <input type="checkbox"/> MASTERCARD <input type="checkbox"/> AMERICAN EXPRESS <input type="checkbox"/> DISCOVER the following amount: \$ _____	
<input type="checkbox"/> I understand that fees are non-refundable	
Card number: _____	Expiration Date    /
<b>SIGNATURE</b>	<b>DATE</b>

**SECTION 1: TYPE OF APPLICATION**

**Initial Application**

**Change of Ownership - Important, please read** - Reference 32 MRSA §13752, Sec. 3. A license is not transferrable to another owner and is subject to a new application and license under the new owner(s) before operation may begin and product shipment into Maine.

**Maine License No. of Prior Owner(s)** \_\_\_\_\_ **Exp. Date** \_\_\_\_\_

**Date Ownership Changed or Anticipated:** \_\_\_\_\_  
(You may be requested to demonstrate legal proof of the date of change, please be accurate.)

**Change of Location** - A license is not transferrable to a new location and is subject to a new Application. The new location must hold an ACTIVE license before operation can begin at the new Location. *The former location license will be terminated.*

Maine License No. for Prior Location \_\_\_\_\_ Exp. Date \_\_\_\_\_

Anticipated Date of Location Change: \_\_\_\_\_

**Is this company publicly traded?**  Yes  No

**SECTION 2: APPLICATION CONTACT PERSON**

Last Name	First Name	Middle Name
Contact Person's Title and email address		

Name of Manufacturer	
Manufacturer Phone Number / Fax Number	24-Hour Phone Number
( ) ( )	( )
E-mail Address—License will be emailed to this address	Web Address
DEA # (Required pursuant to 32 MRSA §13758 (4)), if not applicable, you must provide a written statement	Date Executed
FDA # (Required pursuant to 32 MRSA §13758 (4)), if not applicable, you must provide a written statement	Date Executed
All Trade Names or Business Names of the Manufacturer	

**SECTION 3: FACILITY CONTACT PERSON**

Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code
24-Hour Telephone Number	E-mail Address of Facility Contact		

**SECTION 4: OWNERSHIP.** Please check one and complete the appropriate block below.

- Sole Proprietor (complete section A)**
- Partnership (complete section B)** - If your partnership consists of 2 or more corporations, you must submit a list of officers and an organizational chart.
- Corporation (complete section C)** - If you are a corporation, you must **submit a Certificate of Existence from the State of origin. For Corporations not organized under Maine law, a Certificate of Authority from the Maine Secretary of State is required including assumed name or DBA.** For assistance, call (207) 624-7752. Please be aware the application to file for a certificate of existence is not evidence of having been issued a Certificate of Authority.
- Limited Liability Company (complete section D)** - If you are a limited liability company, you must submit the names and mailing addresses of each member and manager; **you must submit a Certificate of Existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a Certificate of Authority or Certificate of Qualification from the Maine Secretary of State is required including assumed name or DBA;** and the name of the member or manager who will be representing the applicant in matters before the board.

<b>Section A - Sole Proprietor:</b> (Please type or print legibly)			
Owner Last Name	First Name	Middle Name	
Social Security Number			
Name of Business Entity			
Contact Address	City	State	Zip Code
Telephone Number	Fax Number		
( )	( )		
E-mail Address Website Address			

**SECTION 4 (Continued):**

**Section B - Partnership:** List the name and address of each partner (please type or print legibly).  
*Please see Chapter 12, Sec. 2(5)(A) (If you need more space please use separate sheet)*

<b>PARTNERSHIP INFORMATION:</b>			
Name of partnership			
Contact Address	City	State	Zip Code
Telephone Number		FEIN Number	
(     )			
E-mail Address			

**NAME AND CONTACT INFORMATION OF EACH PARTNER**

<b>Person</b> Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		(     )	

<b>Person</b> Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		(     )	

<b>Person</b> Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		(     )	



<b>Section C - Corporation Ownership:</b> Please include an organizational chart. (Please type or print legibly) Please see Board Rule, Chapter 12, Sec. 2(5)(B)			
Name of Corporation			
Assumed Name (d/b/a)			
Name of Parent Company, if any			
FEIN # of Parent Company, if any			
Applicant Contact Address of Corporation	City	State	Zip Code
Applicant Physical Address of Corporation	City	State	Zip Code
Applicant Telephone Number applicant			
(      )			
E-mail Address for contacting company			

Registered Agent Name for Maine			
Contact Address for Registered Agent <i>If different from Corporation</i>	City	State	Zip Code
Physical Address for Registered Agent <i>If different from Corporation</i>	City	State	Zip Code
Registered Agent Email Address/Web Address		Telephone	
		(      )	

Name of Designated Officer			
Mailing Address of Representative	City	State	Zip Code
Telephone Number	E-mail Address		
(      )			

**SECTION 4-C (Con't): CORPORATION OWNERSHIP**

Please see Board Rule, Chapter 12, Section 2(5)(B).

Is this corporation's stock traded on a major stock exchange and not over-the-counter

YES

NO

If, no complete the section below—List the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock. Use a separate sheet of paper if needed.

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
(    )		(    )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
(    )		(    )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
(    )		(    )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
(    )		(    )	

**SECTION 4-C (Con't): CORPORATE OFFICER(S) AND DIRECTOR**

1. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

2. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

3. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

4. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

**SECTION 4 (Continued):****Section D - Limited Liability Company:**

(Please type or print legibly)

*Please see Chapter 12, Sec. 2(5)(C)*

Name of Limited Liability Company

Assumed Name (d/b/a)

Name of Parent Company, if any

FEIN # of Parent Company

Contact Address of Company

City

State

Zip Code

Physical Address of Company

City

State

Zip Code

Telephone Number

Fax Number

( )

E-mail Address

Website Address

Name of Designated Officer

Mailing Address of Representative

City

State

Zip Code

Telephone Number

E-mail Address

( )

Corporate Registration Certificate Number

Issued Under What Jurisdiction

Date

Name of Registered Agent

Contact Address for Registered Agent  
*If different from Corporation*

City

State

Zip Code

Physical Address for Registered Agent  
*If different from Corporation*

City

State

Zip Code

Telephone Number

E-mail Address/ Website Address

( )

**SECTION 4-D (Con't): LIMITED LIABILITY COMPANY** Please see Chapter 12, Section 2(5)(C). Please list the names and mailing addresses of each member and manager. You may copy this page if more space is needed.

<b>1. Last Name</b>	<b>First Name</b>	<b>Middle Name</b>	
<b>Address</b>	<b>City</b>	<b>State</b>	<b>Zip Code</b>
<b>E-mail Address</b>		<b>Telephone Number</b>	
		(      )	
<b>2. Last Name</b>	<b>First Name</b>	<b>Middle Name</b>	
<b>Address</b>	<b>City</b>	<b>State</b>	<b>Zip Code</b>
<b>E-mail Address</b>		<b>Telephone Number</b>	
		(      )	
<b>3. Last Name</b>	<b>First Name</b>	<b>Middle Name</b>	
<b>Address</b>	<b>City</b>	<b>State</b>	<b>Zip Code</b>
<b>E-Mail Address</b>		<b>Telephone Number</b>	
		(      )	
<b>4. Last Name</b>	<b>First Name</b>	<b>Middle Name</b>	
<b>Address</b>	<b>City</b>	<b>State</b>	<b>Zip Code</b>
<b>E-mail Address</b>		<b>Telephone Number</b>	
		(      )	
<b>5. Last Name</b>	<b>First Name</b>	<b>Middle Name</b>	
<b>Address</b>	<b>City</b>	<b>State</b>	<b>Zip Code</b>
<b>E-mail Address</b>		<b>Telephone Number</b>	
		(      )	

**SECTION 5: DISCLOSURE**

<p>Has any state or territory of the U.S., province/territory of Canada, or any other jurisdiction <b>ever</b> denied to <b>this entity</b> an application for license, certificate or registration, <b>or</b> taken any disciplinary action in that jurisdiction (including, but not limited to, warning, reprimand, fine, suspension, revocation or restrictions in permitted practice, probation with or without monitoring)?</p> <p>1. List the jurisdiction(s) that denied your license or issued discipline and date of action:</p> <p>State/Jurisdiction _____ Date _____</p> <p>State/Jurisdiction _____ Date _____</p> <p>State/Jurisdiction _____ Date _____</p> <p>2. Attach with this application a copy of the consent agreement or decision and order for each of the above, with this application.</p> <p>3. Attach with this application - Describe, on a separate sheet of paper, a <u>detailed</u> explanation in your own words, the nature of the incident.</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, Complete requested information AND <u>attach with this application all</u> information requested; application will not be accepted otherwise.</p>
<p>Has the US Drug Enforcement Administration (DEA) ever denied registration or had a DEA Registration modified, restricted, suspended or revoked?</p> <p>1. Attach with this application - Copy of the official document related to the DEA action taken against entity.</p> <p>2. Attach with this application - Describe, on a separate sheet of paper, a <u>detailed</u> explanation in your own words, the nature of the incident.</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, as stated in the block above attach all information requested with this application</p>
<p>Has this entity ever been issued a citation, warning letter or untitled letter by FDA or similar action taken by any governmental board?</p> <p>1. Attach with this application - Copy of the official document related to the FDA action taken against entity.</p> <p>2. Attach with this application - Describe, on a separate sheet of paper, a <u>detailed</u> explanation in your own words, the nature of the incident.</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, as stated above attach all information requested with this application</p>

**SECTION 6: LIST OF JURISDICTIONS IN WHICH YOU HOLD OR HAVE EVER HELD A MANUFACTURER LICENSE.**

On a separate sheet, list each state or jurisdiction the applicant has at any time held a pharmaceutical license, including controlled substance licenses. **The information must include the following in the same format please:**

State, Territory, Country	License Number & Lic Type	Date Issued	Expiration Date	Was discipline ever imposed? Yes / No
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**FORM:** For your convenience a form to report this information is available online from our applications and forms section entitled "Reporting Jurisdictions of Licensure."

If discipline was imposed, you **must attach with this application** a copy of the consent agreement, order or legal document issued.

**SECTION 7: Opioid Medications Manufacturing—Statement/Affirmation**

1) Does this entity manufacture opioid medications for distribution in the state of Maine?

**Check:**  **YES** —You must complete the MFO form for the Opioid Prescription Drug Manufacturer. (Once your MF (Manufacturer) application is received by this office, you will be sent the tracking Pending License number and Access Code to the email address provided on this application, which will be needed to access the online MFO form that you must complete.

**No**

A Manufacturer of opioid medication (MFO) will be assessed for a total fee of \$55,000.

If the entity only manufactures an opioid medication(s) that is approved by the United States Food and Drug Administration for use only in veterinary medicine, the \$55,000 assessment does not apply, but the MFO form must be completed

**SECTION 8: APPLICANT’S CERTIFICATION AND SIGNATURE**

Read the statement below and sign where indicated as your certification of the information provided on this application. Applications that are incomplete, altered (including use of any white out), defaced, or compromised will not be accepted and will be returned. This includes, but is not limited to, unanswered questions, lack of appropriate signature, information is illegible, missing required supporting documents, and/or missing or wrong fee.

By my signature, I hereby certify that the information provided on this application is true and accurate to the best of my knowledge and belief. By submitting this application I understand that the Maine Board of Pharmacy will rely upon this information for issuance of my license and that this information is truthful and factual. I further understand that sanctions may be imposed, including denial, suspension or revocation of my license, if this information is found to be false.

<b>Printed Name of Owner or Officer of the Entity (32 MRS §13758(4))</b>	<b>Title</b>
<b>Signature</b>	<b>Date</b>
	