MINNESOTA BOARD OF PHARMACY

Protecting the Public Since 1885 | pharmacy.board@state.mn.us

335 Randolph Ave., Suite 230 | St. Paul, MN 55102

Drug Manufacturer/Outsourcing Facilities New Application - *Instructions*

For Resident and Non-Resident Applicants

Licensure as a manufacturer is required for all parties involved in the manufacturing of a drug product. This includes but is not limited to virtual manufacturers, contract manufacturers, repackager, and labelers. The exception is if the manufacturer is located outside of the United States or its territories. **Manufacturers who distribute the drugs of *other manufacturers* must also be licensed as drug wholesalers.**

Application fees

- A Non-Opiate Manufacturer and a Non-Opiate Outsourcing Facility application fee is $5,500.
- An Opiate Manufacturer and an Opiate Outsourcing Facility application fee is $55,500.

Licenses are mailed to the facility's physical address. The completed application, supporting documentation, and correct payment must be received by the Board before the application can be processed. All fees are non-refundable. State of Minnesota Tax ID: 4405717, Federal ID: 41-6007162.

Mail the completed renewal form, documents, and payment to Minnesota Board of Pharmacy, 335 Randolph Avenue, Suite 230, St. Paul, MN 55102. Checks should be payable to the Minnesota Board of Pharmacy. All payments are non-refundable.

Checklist for All Applicants

All applicants are required to complete and submit the following information:

√ **Application.** Complete the application in its entirety and submit with original signatures and all documents. Do not leave any leave blanks. If an item or question is not applicable, indicate N/A.

√ **Ownership forms and supporting documents.** Submit the following forms to provide information about the applicant licensee's ownership.

- **Secretary of State - NON-RESIDENT ONLY.** Submit a current Certificate of Good Standing issued by the state in which the facility is located, obtained within the last 24 months.
- **Minnesota Secretary of State - RESIDENT ONLY.** Submit a current Certificate of Good Standing from the Minnesota Secretary of State. For resident pharmacies operating under an Assumed Name, also submit a Certificate of Assumed Name Registration."
- **Organizational Chart.** Provide an organizational chart that shows the multi-levels of ownership and the percentage owned. Individual shareholders, partners, members or parent entity of applicant licensee must be disclosed in full.

√ **List of Officers.** The officers must be identified by name, title and percentage owned if applicable. **Attachment A.**

√ **List of all Shareholders.** Include the shareholder's name, title, address, city, state, and zip code along with their ownership percentage. **Attachment B.**

√ **Facility Manager/Designated Representative affidavit. Attachment C.**

√ **List of dosage forms** proposed to manufacture, re-label, or repackage.

√ **FDA Registration.** Provide proof of current FDA Drug Establishment Registration. You must have an FDA registration or we will not issue or renew a license. A printout of your current FDA registration showing the expiration date from the FDA clearing house is acceptable.

- Outsourcing facilities must hold a current FDA registration as an Outsourcing facility and provide proof of such.

√ **Workman Compensation Requirements** (RESIDENTS ONLY). Minnesota Statute 176.182 requires the applicant to provide acceptable proof of compliance with the workers' compensation coverage provisions before the Board of Pharmacy shall issue a license.

√ **Current Home State License** (NON-RESIDENTS ONLY). A copy of your current license/registration from the state your facility is located, or a letter from your home state explaining that your state does not require a license.

√ **Inspection Report** (NON-RESIDENTS ONLY). Provide a copy of a full inspection report and any corrective actions on deficiencies or observations made during the inspection, with all related documents, from your state or the FDA, obtained within the last 24 months. Please note that 'Notices of Inspections' and/or Self-Inspections **do not** meet the Board's inspection requirements.

Additional Requirements for Virtual Manufacturers

Virtual manufacturers of legend and/or OTC drugs are required to be licensed as a manufacturer (MN Stats. § 151.252). A virtual manufacturer is an entity that holds the approved New Drug Application (NDA) or the Abbreviated New Drug Application (ANDA) for a drug and contracts with a contract manufacturing organization (CMO) for the physical manufacture of the drug.

In addition to the checklist items under checklist for all applicants, the following must be included.

- √ Provide the Minnesota license numbers of all contract manufacturers and 3PLs on the application.
- √ Provide a business summary including all contract manufacturers and distributors of the drugs.
- √ An FDA issued Labeler Code is a form of FDA registration and is required for virtual manufacturers.

Additional Requirements for Outsourcing Facilities

In addition to the checklist items under checklist for all applicants, the following must be included.

- √ Outsourcing facilities must be licensed as wholesalers. Provide the Minnesota wholesaler license number on the application, or include the Minnesota Drug Wholesaler application along with this submission.
- √ Outsourcing facilities dispensing patient specific prescriptions must be licensed as a non-resident pharmacy. Provide the Minnesota pharmacy license on the application.
- √ Outsourcing facilities must hold a current FDA registration as an Outsourcing Facility and provide proof of such.
- √ Inspection reports conducted to current good manufacturing practices that has occurred while the facility is actively engaged in production of product, **and** within the 24 months preceding receipt of the application by the board. This inspection should be issued by the appropriate regulatory agency of the state in which the facility is located *or* by the FDA MS 151.252 Subd 1a (g).
- √ Corrective actions on deficiencies or observations made during the inspection with all related documents.

Officer Forms

Officer Form FAC-002 is available to report officers, and Officer Change Form is available to report a change in officers. Officer changes should be reported to the Board within 30 days of change.

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Drug Manufacturer New Application – *Resident and Non-Resident*

Facility Type (Choose one of the two types below)

☐ Non-Opiate Manufacturer or Non-Opiate Outsourcing Facility (fee $5,500) ☐ Opiate Manufacturer or Opiate Outsourcing Facility (fee $55,500)

Opiate manufacturers that own more than one facility are only subject to one $55,500 fee. If this applies, list the license numbers of all facilities under one ownership and indicate which facility will pay the $55,500 fee. All other facilities listed below must apply separately and pay the appropriate fee.

Name of Facility to appear on license	If DBA, Legal Name	MN Tax ID	Federal Tax ID	FDA Registration	DEA Number

Physical Address				City	Mailing Address				City
State	Zip	Phone	Square Footage	Effective Date of Change	State	Zip	Phone	Email Address	

Hours of Operation

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Open 24 Hours
							☐

Categories

Check each category you will sell drugs to:

- ☐ Home Health Agency
- ☐ Dentist
- ☐ Pharmacy
- ☐ Nursing Home
- ☐ Medical Doctor
- ☐ Veterinarian
- ☐ Wholesaler
- ☐ Other _____

Check all categories of drugs you propose to handle:

- ☐ Human Prescription
- ☐ Human Non-prescription (OTC)
- ☐ API
- ☐ Veterinary Prescription
- ☐ Veterinary Non-prescription (OTC)
- ☐ Other: _____
- ☐ Controlled Substances
- ☐ Medical Gases
- ☐ Human/Vet drug products made by Outsourcing Facility

Does the applicant have the required equipment necessary to comply with good manufacturing practices? ☐ YES ☐ NO ☐ N/A

Individual Completing Application

Must be authorized to discuss application materials.

Name	Title	Phone	Email

Ownership Contact Information

Person authorized to speak on behalf of the owner.

Name	Title	Phone	Email

Facility Contact Information

Contact Name	Phone	Email

Outsourcing Facilities

Outsourcing facilities must also be licensed as wholesalers. Minnesota wholesaler license number _____. Enter "Pending" in the blank to signify that you have submitted an application.

Outsourcing facilities dispensing patient specific prescriptions must also be licensed as a non-resident pharmacy.

Minnesota pharmacy license number _____.

Virtual Manufacturer

Provide the MN License Numbers for the Contract Manufacturers and 3PLS you use.

Name	License #	Name	License #

Qualifications of personnel: (production and quality control)

Name	Qualifications	Position

Ownership Information

Owner (Legal Name) _____ State of Incorporation _____ Number of Share/Stock issued _____

Address _____ City _____ State _____ Zip _____

Phone _____ Email _____ Square Footage _____ NABP Profile Number _____

☐ LLC ☐ Partnership ☐ Publicly Traded

☐ Corporation ☐ Limited Partnership

☐ S Corporation ☐ Proprietorship

Insurance Coverage for Facilities Residing in MN

Minnesota Statute 176.182 requires the applicant to provide acceptable proof of compliance with the workers' compensation coverage provisions before the Board of Pharmacy shall issue a license. **If your facility is <u>not</u> located in the state of Minnesota, <u>do not</u> complete this section. If your facility is in Minnesota, please check the appropriate box below.**

☐ This facility does not employ anyone and therefore will not supply workers' compensation coverage documents.

☐ This facility is self-insured and has attached a **Certificate of Exemption.**

☐ This facility has paid, or compensated employees and has attached a **Certificate of Insurance.**

☐ This facility has paid or compensated employees and is supplying the insurance company information:

Insurance Co Name _____ Policy Number _____ Policy Expiration Date _____

Address _____ Phone Number _____

Read each statement carefully, following the instructions below.

1. Are you or the applying entity, or any of its owners, members, shareholders*, Facility Managers, Designated Representatives or other employees, currently under investigation, or have you or the applying entity, or any of its owners, members, shareholders*, Facility Managers, Designated Representatives or other employees ever been charged, plead guilty to, or convicted of an offense that if committed in this state would be deemed a felony without regard to its designation elsewhere? **Does not apply to the shareholders of applying corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market.*

   ☐ Yes ☐ No

   - If yes, provide copies of all relevant court documents, including but not limited to guilty pleas, records of conviction, final disposition or adjudication, and orders for probation and their terms.

2. Are you or the applying entity, or any of its owners, members, shareholders*, Facility Managers, Designated Representatives or other employees, currently under investigation, or have you or the applying entity, or any of its owners, members, shareholders*, Facility Managers, Designated Representatives or other employees ever been charged, pled guilty to, or convicted of violating any federal or state statute, law or administrative rule, relating to drug samples, drugs, medical gases, or controlled substances, or the manufacturing, distribution, storage, handling, or dispensing of drugs, controlled substances, or medical gases? **Does not apply to the shareholders of applying corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market.*

   ☐ Yes ☐ No

   - If yes, provide copies of all relevant court documents, including but not limited to guilty pleas, records of conviction, final disposition or adjudication, and orders for probation and their terms.

3. Are you or the applying entity, or any of its owners, members, or shareholders*, Facility Managers, Designated Representatives or other employees (collectively as "you") currently the subject of a complaint investigation by, or have you ever had disciplinary action taken against you or any license you've held, by another federal or state agency, or by one of this state's health licensing agencies? This includes the revocation, suspension, restriction, limitation, agreements for corrective action, or other disciplinary action against a license or registration you've held in another state or jurisdiction. **Does not apply to the shareholders of applying corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market.*

   ☐ Yes ☐ No

   - If yes, provide copies of all relevant documents, including but not limited to final disciplinary orders or agreements for corrective action.

4. Has the applicant ever had an application denied by a Board of Pharmacy or any other licensing agency, either in the State of Minnesota or in a different state or jurisdiction?

   ☐ Yes ☐ No

   - If yes, upload documentation which includes an explanation.

The data you supply on this form will be used to assess your qualifications for licensure. You are not legally required to provide this data, but we will not be able to grant the license without it. This data will constitute a public record when the licensure is granted, and, at that time, copies may be issued to anyone.

Acknowledgment

I have read the above statement and I agree to supply the data on this form with full knowledge of the information provided in that statement. In addition, I, the undersigned, do hereby certify that all the information above is true and correct and that the firm will be operated in compliance with all applicable laws and regulations.

_____ _____

Signature of Owner, Partner, Managing Officer, or Authorized Individual Date

Officer Reporting Form

Use this form to report the current, complete list of corporate officers of the licensee. Include additional pages if necessary.

Effective Date	Federal Tax ID	Full Legal Name of Licensee		
Physical Mailing Address		City	State	Zip
MN License Number (list at least one)				

List of Officers:

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Name	Title	License/Registration # (RPH, MD, RN)
Email		Phone

Signature of Designated Authority: Owner, Partner, or Corporate Officer

Date

Printed Name

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Shareholder/Member/Partner Form

Instructions: Select the appropriate checkbox below. If your business is a Non-Profit Corporation or is Publicly Traded you do not need to complete the Shareholders/Members/Partners table below. If part of the parent owner(s) is an ESOP, please list the ESOP and the representative's name. If the space available is insufficient, use a separate sheet. Do not misstate or omit any material fact(s), each statement is subject to verification. All applicants are advised that this record is an official document and misrepresentation or failure to reveal information requested may be deemed to be enough cause for the refusal or revocation of a license this form is submitted for.

☐ Privately Owned ☐ Non-Profit Corporation ☐ Publicly Traded

List All Shareholders/Members/Partners – Attach Additional Sheets if Necessary

Legal Name	Address, City, State, Zip Code	Phone Number	% Owned

The data you supply on this form will be used to assess your qualifications for licensure. You are not legally required to provide this data, but we will not be able to grant the license without it. This data will constitute a public record if the licensure is granted, and at that time, copies may be issued to anyone.

Acknowledgment

I have read the above statement and I agree to supply the data on this form with full knowledge of the information provided in that statement. In addition, I, the undersigned, do hereby certify that all the information above is true and correct and that the firm will be operated in compliance with all applicable laws and regulations.

Signature of Designated Rep., Facility Mgr., or Authorized Individual

Date

Type or Print Full Name Above

Title

Facility Manager or Designated Representative Affidavit

This form is to be completed by the primary designated representative. This designated representative serves as a manager and is responsible for ensuring the facility follows all state statutes and rules applicable to the operations.

Instructions: Complete each section, if a section does not apply, put N/A in the space available. If the space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s), each statement is subject to verification. All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be enough cause for the refusal or revocation of a license for the facility named in this application.

Complete the information below for the Facility

(name and address of business for which designated representative is requested)

Legal Name of Licensee	Address	City	State	Zip

Email	Minnesota License #	e-Profile #	Phone

Applicant Information

Facility Manager or Designated Representative responsible for operations and compliance of applicant facility

Full Legal Name	Title	Academic Credentials	Date of Birth	Email

Mailing Address	City	State	Zip	Last 4 Digits of Social Security #

The Facility Manager or Designated Representative for the Applicant Facility must personally complete and attest to the following points of fact regarding this facility's operations.

Read each statement carefully, following the instructions below

- If the statement is true, review and attest to each statement below by marking YES.
- If the statement is not true, mark NO **and** provide a detailed explanation on a separate document referencing the statement.

I certify the following:

○ Yes	○ No	I am the Facility Manager or Designated Representative for the Applicant Facility.
○ Yes	○ No	I have never been convicted of, or plead guilty to any felony violation.
○ Yes	○ No	I have no convictions under federal, state, or local law relating to distribution of prescription drugs or controlled substances.
○ Yes	○ No	The Applicant Facility has adequate storage conditions to allow for the safe receipt, storage, handling, and transfer of drugs.
○ Yes	○ No	The Applicant Facility has sufficient policies and procedures in place for the inspection of all incoming and outgoing drug shipments.
○ Yes	○ No	There is a functioning security system that includes an after-hours central alarm or comparable entry detection capability.
○ Yes	○ No	There are security policies and procedures that include provisions for restricted access to the premises, comprehensive employee applicant screening, and safeguards against all forms of employee theft.
○ Yes	○ No	The Applicant Facility maintains records of the handling of drugs, which shall be kept for a minimum of two years and be made available to the board upon request.
○ Yes	○ No	I will ensure that all personnel have sufficient education, training, and experience, in any combination, so that they may perform assigned duties in a manner that maintains the quality, safety, and security of drugs.

Read each statement carefully, following the instructions below.

- If the statement is true, review and attest to each statement below by marking YES.
- If the statement is not true, mark NO and provide a detailed explanation on a separate document referencing the statement.

I certify the following:

○ Yes	○ No	I will ensure that all employees of the Applicant Facility will be evaluated and supervised sufficiently to protect and maintain the quality, safety, and security of drugs.
○ Yes	○ No	I will develop and, as necessary, update written policies and procedures that ensure reasonable preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or drug shipping and receiving, outdated drug, appropriate handling of returned goods, and drug recalls.
○ Yes	○ No	I am regularly on-site and actively involved in and aware of the Applicant Facility's actual daily operations.
○ Yes	○ No	I am physically present at the Applicant Facility during normal business hours except when absence is authorized, including but not limited to sick leave and vacation leave.
○ Yes	○ No	I will operate in compliance with all state and federal laws and regulations applicable to Applicant Facility.

Acknowledgment

I, the undersigned, do hereby certify that all the information contained in form and the accompanying application and documents is true and correct and that the Applicant Facility will be operated in compliance with all applicable laws and regulations.

FURTHER AFFIANT SAYETH NOT.

_____ _____ _____
Facility Manager or Designated Representative Signature | Print Name | Date

Notary Acknowledgment

State of _____. I certify the following person personally appeared before me on this day, acknowledging that he or she signed the foregoing document _____.
Name of Facility Manager/Designated Representative

Subscribed and sworn to before me on this _____ day of _____, 20____.

_____
Notary Signature

_____
Print Name of Notary

_____
Date Notary Commission Expires

(Seal)