

Third-Party Logistics Provider (3PL) License Checklist & Application

For Resident and Non-Resident Facilities; fee of \$300.00

The licensing requirements for 3PL are described in Minnesota Statute § [151.471](#). Other related regulations also include Minnesota Statutes § [151.43](#), [151.441](#), and [151.46](#).

As defined in Minn. Stats. § 151.441 Subd. 11, "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or disposition of the product.

As defined in Minn. Stats. § 151.441 Subd. 9 "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, but does not include blood or blood components intended for transfusion; radioactive drugs or radioactive biological products as defined in Code of Federal Regulations, title 21, section 600.3(ee), that are regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with such commission under United States Code, title 42, section 2021; imaging drugs; an intravenous product described in subdivision 12, paragraph (b), clauses (14) to (16); any medical gas defined in United States Code, title 21, section 360ddd; homeopathic drugs marketed in accordance with applicable federal law; or a drug compounded in compliance with United States Code, title 21, section 353a or 353b.

In order to operate as a 3PL in Minnesota, a license must be obtained from the Board. The Board will issue a license upon the filing of a complete application, submission of required documents, and payment of any applicable fees specified in section § 151.065. The Board may deny a license if any of the requirements in Minn. Stats. § 151.471 are not met. 3PL licenses expire at midnight on October 31 of each year. The renewal period begins on October 1 of each year. If the license is not renewed by October 31, a 50% late fee will be assessed and the 3PL will no longer be allowed to operate in Minnesota until appropriate paperwork and fees are received.

Please read the following carefully

- Your application will not be reviewed until all required items are received.
- Applicants will be notified of missing items from the application within 4 to 6 weeks of receiving the application packet.
- Allow a minimum of 90 days from the time your application packet is complete (all missing items received), for review and final license issuance.
- Required documents must be submitted with each application, duplicate documents sent in with similar applications will not be retrieved for the completion of this application.
- Applications are considered withdrawn if missing items are not submitted to complete an application within one year of the original application submission date.
- The application will be cancelled and a new application packet, including applicable fee(s) must be submitted if a change in owner or location occurs while the application is under review by the Board.

Tennessen Warning. The Board of Pharmacy is seeking data from you which may be considered private or confidential under the Minnesota Government Data Practices Act, Minn. Stat. § 13.01 et seq. Minn. Stat. § 13.04, subd. 2 which requires the Board to notify you of the following four matters before you are asked to supply such information about yourself: (1) This data is being collected to determine whether you meet the requirements for licensure as well as whether you have violated any statutes or rules the Board is empowered to enforce; (2) You are not legally required to complete and return this application, but failure to do so may result in the denial of this licensure application; (3) If you supply the data requested and it shows a violation of any of the statutes or rules enforced by the Board, you may be subject to disciplinary or other action by the Board. If you refuse to supply the data requested, your licensure application may be denied. In addition, falsification or omission of information may be used by the Board as a basis for disciplinary action; and (4) The data which you supply will be accessible to Board staff. The data you supply may also be released to other persons and/or governmental entities who have statutory authority to review the data, investigate specific conduct, and/or take appropriate legal action. If the Board institutes a formal disciplinary action against you, the information you supply could become public.

Designated Representative or Facility Manager. Each applicant must have a primary designated representative to serve as the responsible manager at the facility. The designated representative serves as a manager and is responsible for ensuring the facility follows all state statutes and rules applicable to the operations. The designated representative or facility manager must complete Facility Manager/Designated Representative Affidavit form **Attachment A**.

Ownership Information. For the purposes of facility licensure, the applicant facility shall provide information to identify the ownership of its business. If the owner of the applicant is a sole proprietor or a partnership, complete form **MN-3PL-002**. If the owner is corporation, s-corporation, or a limited liability company, complete form **MN-3PL-003**.

The Board may require additional documentation to confirm or substantiate the reported ownership structure at any time during the application process. Publicly traded businesses: If the applicant business is owned by an entity, the application shall identify each parent entity that is beneficially interested in the applicant business.

RESIDENT Third Party Logistics Applicant Checklist

Per MN Statutes § 151.471 Subd. 2, the Board shall not issue an initial license or renew a license for a third-party logistics provider facility unless the facility passes an inspection conducted by an authorized representative of the Board or is inspected and accredited by an accreditation program approved by the Board. In-State Applicants will receive written communication from the Board regarding the scheduling of an inspection unless the applicant can substantiate proof of current accreditation.

The following items must be submitted with your **RESIDENT** application:

- Completed application with all attachments, original signatures, and application fee.
- Completed Facility Manager/Designated Representative Affidavit Form **Attachment A**.
- Ownership Form **MN-3PL-002 OR MN-3PL-003** as it applies to the ownership of the applicant.
- Organizational chart of the owner's business entity.
- Articles of Incorporation as it applies.
- Explanations or supporting documents for any application item that may require additional information.
- Minnesota Statute §176.181 Subd. 2 requires acceptable evidence of workers compensation insurance unless;
 - If you are self-insured and reside in the State of Minnesota, attach a copy of the Certificate of Exemption from the Commissioner of Commerce.
- **Blueprint Checklist, provide a blueprint showing the items below:**
 - Dimension of the designated area which will be licensed space
 - Access parameters
 - Physical security including central alarm area
 - Temperature controls, parameters, and monitoring equipment

NON-RESIDENT Third Party Logistics Applicant Checklist

Per Minn. Stat. § 151.471 Subd 2., the Board shall not issue an initial or renew a license for a third-party logistics provider facility unless the facility passes an inspection conducted by an authorized representative of the Board or is inspected and accredited by an accreditation program approved by the Board. Applicants must furnish the Board with a report issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the Board or furnish the Board with proof of current accreditation.

All applicants must submit evidence that any deficiencies noted in any inspection or investigatory report have been corrected, including any documents that you have provided to state agencies in response to inspections or investigations. The Minnesota Board of Pharmacy determines whether or not a facility has passed an inspection conducted by someone other than a representative of the Board.

The following items must be submitted with your **NON-RESIDENT** application:

- Completed application with all attachments, original signatures, and application fee.
- Completed Facility Manager/Designated Representative Affidavit Form **Attachment A**.
- Ownership Form **MN-3PL-002 OR MN-3PL-003** as it applies to the ownership of the applicant.
- Organizational chart of the owner's business entity.
- Articles of Incorporation as it applies.
- Explanations or supporting documents for any application item that may require additional information.
- A copy of the current applicable license from the state in which the facility is located, the current Food and Drug Administration registration if that state does not license third-party logistics providers, or an explanation for why a license is not being submitted.
- A complete copy of any and all inspections conducted within the past 24 months immediately preceding application for licensure in the State of Minnesota, OR if NABP accredited, you may attach the certificate in place of an inspection (MN Statute § 151.471 Subd 2). Please note that 'Notices of Inspections' and/or Self-Inspections **do not** meet the Board's inspection requirements.
- Submit documentation of all corrective actions on all deficiencies and observations made during the inspection. Include all related documents.

MINNESOTA RESIDENT Facility Worker's Compensation Insurance

(Complete only if your facility is in Minnesota)

Minnesota Statute § 176.181 Subd. 2 requires that you supply us with information concerning your worker's compensation Insurance for this firm prior to issuance of the license. Check the appropriate box:

Not Applicable - facility is not located in Minnesota

Self-Insured: Attach a copy of the certificate of exemption from the Insurance Commissioner.

I DO NOT employ anyone.

I have paid or otherwise compensated employees. **I am furnishing the following information:**

Name of Insurance Company	Insurance Policy Number	Expiration Date	
Address	City	State	Zip

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 and when the licensure is granted, and, at that time, copies may be issued to anyone.

Acknowledgement

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. I agree to operate in compliance with all state and federal requirements applicable to third-party logistics providers. In addition, I, the undersigned, do hereby certify that all the information contained in this application is true and correct and that the firm will be operated in compliance with all applicable laws and regulations.

Signature of Applicant

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. |

Minnesota Board of Pharmacy

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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)