MINNESOTA
BOARD OF PHARMACY

Pharmacy License Category Change Notification

In-State and Out-State Pharmacies

This change notification should be submitted 30 days prior to your pharmacy adding or deleting the products or services on your current license. **See MN Rules 6800.0350 for license categories and requirements.** No pharmacy may engage in providing products or services that they are not licensed for by the Board of Pharmacy. There is no fee for the reprinted license with new categories.

Special considerations apply to pharmacies that wish to be licensed in hospital and limited services categories. Review Minnesota Rule 6800.9900 to determine if your request will require a variance.

Pharmacy Information

Current Name/DBA Name as listed on the License	Effective Date	Current MN License #	Federal Tax ID	DEA Number

Street Address	City	State	Zip	Contact Number

Check all categories of licensure of service(s) for which you are currently licensed to serve Minnesota residents.

License categories are listed on your current license. A license verification will also provide you with your current license categories.

- ☐ A. Community/Outpatient
- ☐ B. Nuclear
- ☐ C. Central Services
- ☐ D. Hospital
- ☐ E. Long Term Care
- ☐ F. Home Health Care
- ☐ G. Veterinary
- ☐ H. Sterile Compounding
- ☐ I. Nonsterile Compounding
- ☐ J. Limited Services

Other category not listed above:

Indicate the type of change to the services on your license below

Category	Add This Category	Delete This Category	Briefly Explain Reason for the Change
A. **Community/Outpatient**	☐	☐	
B. **Nuclear**	☐	☐	
C. **Central Services***	☐	☐	
D. **Hospital** *include MDH license	☐	☐	
E. Long Term Care	☐	☐	
F. **Home Health Care**	☐	☐	
G. Veterinary	☐	☐	
H. **Sterile Compounding†**	☐	☐	
I. **Nonsterile Compounding††**	☐	☐	
J. **Limited Services****	☐	☐	
K. **Other (Indicate type)**	☐	☐	

The Board may contact you for additional information if necessary.

t **Sterile Compounding pharmacies:** By initialing here, you attest that the pharmacy follows Minnesota Rule 6800.3300, Minnesota Statute §151.253, the current United States Pharmacopeia (USP) 797 standard, and USP 825 standard (if applicable.)_____

- Include a copy of the blueprint indicating the location of the sterile compounding area including type and location of primary engineering controls (PEC), location and ISO classification of secondary engineering controls, location of pressure monitors and pressure differentials between ISO classified spaces, and types of material on floors, ceilings, and doors in all classified spaces.

Does your pharmacy plan to dispense CATEGORY 2 or CATEGORY 3 preparations which are prepared either from one or more nonsterile starting components, terminally sterilized Compounded Sterile Preparations (CSPs), or created from CSPs, to Minnesota residents?

☐ **No** ☐ **Yes** *provide a list of all Category 2 and/or Category 3 compounded preparations proposed or made within the previous year*

tt **Nonsterile Compounding pharmacies:** By initialing here, you attest that the pharmacy follows Minnesota Rule 6800.3300, Minnesota Statute §151.253, and the current United States Pharmacopeia (USP) 795 standard._____

- Include a copy of a blueprint indicating the location of the dedicated non-sterile compounding area. Include an indication of the types of materials within the space. Provide the types of primary and secondary engineering controls if engaging in hazardous, non-sterile compounding.
- Resident compounding pharmacies must provide copies of detailed policies and procedures to meet Minnesota Rule 6800.3300.

t/ tt **Non-resident compounding pharmacies** must provide a copy of a full operational inspection report including the compounding operation, and any corrective actions on deficiencies or observations made during the inspection. The inspection must have occurred within the previous 24 months. Note: the Board of Pharmacy will only accept inspections conducted by your home state, the CA Board of Pharmacy for sterile inspections, and/or NABP Verified Pharmacy Program (VPP).

t/ tt All compounding pharmacies: By initialing here, you acknowledge the pharmacy will comply with all requirements for compounding drug products under applicable law, including the following:___

1. **Use of Bulk Drug Substances;** The pharmacy will only compound using bulk drug substances that:
   i. Meet an applicable **USP or NF monograph**, including USP chapters on pharmacy compounding; **or**
   ii. If no monograph exists, are components of **FDA approved drugs**; **or**
   iii. If neither of the above applies, appear on the **FDA 503A Bulk Substances List** issued under Section 503A of the FD&C Act. The pharmacy further attests that all bulk drug substances used:
   iv. Are manufactured by an establishment **registered with FDA** under section 360 of the FD&C Act (including foreign establishments), and
   v. Are accompanied by **valid Certificates of Analysis**.
2. **Prohibition on Essentially Copies of Commercially Available Drugs:** The pharmacy will **not** compound drug products that are **essentially copies** of commercially available drug products. See also 21 USC 353a and MN Stat 151.253.
3. **Exception for Significant Clinical Difference:** The pharmacy acknowledges that a compounded drug is **not** considered "essentially a copy" if the prescribing practitioner documents a **specific change** that produces a **significant clinical difference** for an identified individual patient. The pharmacy will ensure such documentation is obtained and maintained.
4. **Comply with all state and federal regulations related to compounding and dispensing prescriptions.**

Alternatively, the pharmacy can choose to forgo the compounding categories on the Minnesota Pharmacy license which would allow the pharmacy to dispense only commercially available drugs into Minnesota for Minnesota Residents.

Does the pharmacy plan to compound HAZARDOUS drugs for Minnesota patients?

☐ **No** ☐ **Yes, sterile hazardous drugs †††** ☐ **Yes, non-sterile hazardous drugs †††**

††† **Hazardous Compounding Pharmacies:** By initialing here, you attest that the pharmacy follows current United States Pharmacopeia (USP) 800 standard _____

All Applicants, briefly describe the service(s) that you propose to provide to Minnesota residents:

If Central Services or Limited Services are selected, the following are required:

*****Pharmacies that are providing **central services** for a Minnesota resident pharmacy need Board approval **prior to** engaging in these services. Please ensure the pharmacy has obtained board approval of any variance(s) and policies related to the services offered.

- Upload a list of the pharmacies located in Minnesota that central services are performed on behalf of, or complete Attachment A.

Pharmacies that are providing **limited services for residents of Minnesota need Board approval **prior to** engaging in these services. Please ensure the pharmacy has obtained board approval of any variance(s) related to the services offered. *If the Limited Services category is selected, no other category should be selected. You are required to submit a detailed description of the services that will be provided.*

I, the undersigned, do hereby certify that all of the information contained in notification is true and correct, and that the firm will be operated in compliance with all applicable laws and regulations.

Pharmacist-In-Charge Signature	Printed Name	Date

Mail, Fax, or E-mail this form to the Board of Pharmacy 30 days prior to the change in services.

Minnesota Board of Pharmacy
335 Randolph Ave, Suite 230 | Saint Paul, MN 55102
Fax: (651) 215-0951 | E-mail: pharmacy.board@state.mn.us

MINNESOTA
BOARD OF PHARMACY

Attachment A

Please list all pharmacies located in Minnesota that central services are performed on behalf of.

MN License #	Name of Pharmacy

Minnesota Board of Pharmacy
335 Randolph Ave, Suite 230 | Saint Paul, MN 55102
Fax: (651) 215-0951 | E-mail: pharmacy.board@state.mn.us