MINNESOTA BOARD OF PHARMACY
Protecting the Public Since 1885 | pharmacy.board@state.mn.us
335 Randolph Ave., Suite 230 | St. Paul, MN 55102

Pharmacy Remodel Application - *Instructions*

For Resident Pharmacies
***Non-resident pharmacies do not need to notify the Board of a remodel**

Minnesota Rule 6800.0800 requires pharmacies to submit proposed remodel plans to the Board of Pharmacy a minimum of 60 days before the project is to begin. Additional time may be needed, depending on the scope of the project. Consideration should be given to variance and/or policy approvals and should allow for additional time as applicable.
There is no fee associated with a remodel application provided the pharmacy is not also relocating to a new physical location. Relocations along with remodel require submission of a new pharmacy application and fee.

Checklist of Requirements to Be Followed to Remodel a Pharmacy

The following must be submitted to the Board at least 60 days prior to the planned remodel.

- ☐ **A completed Pharmacy Remodel Application.** Make sure that you check all categories of licensure or services that currently apply to your pharmacy and indicate whether you prepare sterile or non-sterile compounded preparations.
- ☐ **Blueprint or sketch of current pharmacy and proposed remodeled space.** The following must be clearly shown on the document:
  - ☐ Dimensions of proposed licensed space. Include a diagram to establish the location of the licensed space within the building, as applicable.
  - ☐ Layout, physical security, and access parameters; including confirmation that the exterior walls extend to the permanent ceiling, patient counseling area indicating the dimensions, elevations, and sound dulling material specifications/properties to meet rule 6800.0700, subpart 1 E.
  - ☐ Location of the refrigerator and sink. The sink must be plumbed.
  - ☐ Confirmation that the lighting will be a minimum of 75-foot candles in all major work areas.
  - ☐ The location of the compounding area with an indication of the types of materials within the space, if applicable. Indicate whether you plan to engage in hazardous compounding and if so provide the type of engineering controls and space to establish compliance with USP 800.

  <u>For sterile compounding provide an enlarged floorplan of the compounding spaces, including:</u>
    - ☐ Type of primary engineering controls (PECs).
    - ☐ Locations of the PECs.
    - ☐ Whether the PEC is vented to the outside.
    - ☐ Location and ISO classification of all secondary engineering controls (e.g., ante, buffer/clean rooms.
    - ☐ Location of pressure monitors and pressure differentials between ISO classified spaces.
    - ☐ Indication and location of any pass-through(s) with specifications (e.g., interlocking HEPA filtered).
    - ☐ Types of material on floors, ceilings, and doors in all classified space.

Link to our rules: https://www.revisor.mn.gov/rules/?id=6800
Link to laws 151: https://www.revisor.mn.gov/statutes/?id=151
Link to laws 152: https://www.revisor.mn.gov/statutes/?id=152

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.

Pharmacy Remodel Application

For Resident Pharmacies

NOTE: There is no fee for remodels.

Instructions: Complete each section, if a section does not apply, put N/A in the space available. 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 for the facility named in this application. Application is applicable for:

Remodel: Date of proposed change:_____
Attach blueprint as indicated in instructions.

Applicant Business Information

Fictitious, Trade or Business Name to Appear on License	Applicant's full Legal Name			Licensed square footage (current)
Minnesota License Number	Federal Tax ID	MN Tax ID	DEA Number	Licensed Square Footage (if change)

Physical Address of the Facility			
City	State	Zip Code	Phone Number
Email Address (this will be for all communication related to the remodel)			

Hours of Operation *indicate if this is a change from previous open/close hours provided

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Operate 24/7

Briefly describe the service(s) that you propose to provide to Minnesota residents:

Check all categories of licensure of service(s) that you are currently licensed for.

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

Indicate a 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**t	☐	☐	
I. **Nonsterile Compounding**tt	☐	☐	
J. **Limited Services****	☐	☐	
K. Other (indicate type)	☐	☐	

The Board may contact you for additional information if necessary.

t/tt **If you are proposing to add a compounding category**, confirm the blueprint identifies the proposed space requirements and provide policies and procedures to establish compliance with the applicable USP chapters.

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

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

Hazardous Drug Compounding pharmacies: By initialing here, you attest that the pharmacy follows Minnesota Rule 6800.3300 and the United States Pharmacopeia (USP) 800 standard. _____

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) 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.*

For HOSPITAL PHARMACIES ONLY

Check the scope of services that are provided.

☐ Hospital In-Patient ☐ Emergency Out-Patients ☐ Long-term care residents ☐ Other, explain: _____

Pharmacist-in-Charge Information

Name	Email Address	MN License Number	Phone Number	Are you the permanent PIC? ◯ Yes ◯ No

As the Pharmacist-in-charge, I hereby certify that I am a licensed pharmacist in the state of_____, holding license number_____. I have been designated as pharmacist-in-charge of the pharmacy named in this application, and I do hereby assume professional responsibility for said pharmacy as the pharmacist-in-charge.

_____ _____
Signature of Pharmacist-in-Charge Date

Individual Completing Application

Must be authorized to discuss application materials.

Name	Phone
Email Address (this is used for questions related to the remodel)	

Acknowledgement

The data you supply on this form will be used to assess approval for remodel. You are not legally required to provide this data, but we will not be able to grant the approval to remodel without it. This data will constitute a public record, if and when approval is granted, and, at that time, copies may be issued to anyone. 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 contained in this application is true and correct and that the firm will be operated in compliance with all applicable State and Federal laws and regulations.

_____ _____
Signature of Applicant Date

_____ _____
Type or Print Full Name Above Title

Attachment A

RESIDENT PHARMACIES and NON-RESIDENT CENTRAL SERVICE OR LIMITED-SERVICE CATEGORIES

DO NOT Complete if neither of the above apply to your pharmacy.

Please list all pharmacists and pharmacy technicians currently employed by the pharmacy.

MN License #	Name of Pharmacist/Technician	Fulltime	Part-time