Pharmacy Application - *Instructions*

For Resident and Non-Resident Pharmacies

A Pharmacy is a place of business in which prescription drugs are prepared, compounded, or dispensed by or under the supervision of a pharmacist and from which related clinical pharmacy services are delivered. Any establishment that falls under this definition needs to be licensed by the state of Minnesota as a pharmacy. To successfully apply for a pharmacy license, the applicant must follow the instructions and submit all the required documents with payment. Failure to do so will result in a delay of licensure.

Use this application for a new pharmacy, change of ownership, and/or relocation.

Checklist of Requirements to Be Followed to License a Pharmacy

Resident Pharmacy

The following must be submitted to the Board **at least 60 days prior to the planned opening date or relocation:**
The information must also be submitted for changes of ownership, prior to the effective date of change. Upon a change of ownership, the licensee can continue operation of the pharmacy under the original license for 14 days after the effective date of the change or until the Board issues a new license, whichever is earlier. After the 14-day period, the original license issued is void and must be surrendered by the licensee to the director of the Board.

- ☐ **A completed pharmacy application.** Make sure that you check all categories of licensure or services that apply to your pharmacy and indicate whether you prepare sterile or non-sterile compounded preparations.
- ☐ **Fee.** A $450.00 fee made payable to the "Minnesota Board of Pharmacy." NOTE: Fees are nonrefundable.
- ☐ **Proof of Federal Tax ID.**
- ☐ **Blueprint or sketch of new pharmacy.** 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.
  - ☐ The 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.
  - ☐ The location of the refrigerator and sink.
  - ☐ Confirmation that the lighting will be a minimum of 75-foot candles in all major work areas.
  - ☐ The location of the non-sterile compounding area with an indication of the types of materials within the space, if applicable. Provide the types of primary and secondary engineering controls if engaging in hazardous, non-sterile compounding.

  <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.
- ☐ **DEA Requirement.** Once you have completed all of the Board of Pharmacy's requirements, please contact the Minneapolis DEA office at either www.deadiversion.usdoj.gov or call (612) 344-4136 for their requirements.
- ☐ **Category Form.** See attachment F.
- ☐ **Make certain** no prescription drugs are received on the premises before the pharmacy license is issued. Once a license is issued and prescription drugs are received, other individuals are not allowed in the pharmacy unless a pharmacist is present.
- ☐ **Ownership forms and supporting documents.** Provide information about the applicant licensee's ownership. NOTE: The applicant licensee is legally responsible for the operation of the pharmacy, and it must match any and all Secretary of State and IRS filings and must be identified on the application.
- ☐ **Organizational Chart.** Provide an organizational chart that shows the ownership of the licensee and the percentages owned. Individual shareholders, members or parent entity of applicant licensee must be disclosed

in full. If the business is a non-profit corporation or is publicly traded on any securities exchange, indicate so in the organizational chart.

- ☐ **Minnesota Secretary of State – Resident Pharmacies. For resident pharmacies operating under an assumed name,** submit a Certificate of Assumed Name Registration. Also submit a Certificate of Good Standing from the Minnesota Secretary of State. This document shows that the applicant licensee is filed and authorized to conduct business in Minnesota.
- ☐ **Prescription Monitoring Program.** Review Minnesota Statutes Section 152.126, which requires dispensers (pharmacies) licensed by the MN Board of Pharmacy to report daily to the Prescription Monitoring Program (PMP) the dispensing of all schedule II-V controlled substances, butalbital, and gabapentin. Information regarding the submission of data can be found on the PMP website under "PMP Data Uploader" section.
- ☐ **Workers' Compensation Requirements.** Minnesota Statute 176.182 requires the applicant to provide acceptable proof of compliance with the workers' compensation coverage provisions before the Board of Pharmacy will issue a license. Submit this certification with the application.
- ☐ **List of Current Pharmacists and Technicians**. Attach a list of current pharmacists and technicians with their full name, license or registration number, and whether they are full or part-time. **See Attachment A**

Checklist of Requirements to Be Followed to License a Pharmacy

Non-resident Pharmacy

The following must be submitted to the Board ONLY AFTER the home state regulatory agency has issued a license and an inspection has been conducted at the location. The completed application, supporting documentation, and correct payment must be submitted as one complete submission. For an existing license holder that undergoes a relocation, a new pharmacy application must be submitted no later than 30 days after the change has occurred. The information must also be submitted for changes of ownership, prior to the effective date of change. Upon a change of ownership, the licensee can continue operation of the pharmacy under the original license for 14 days after the effective date of the change, or until the board issues a new license, whichever is earlier. After the 14-day period, the original license issued is void and must be surrendered by the licensee to the director of the board.

- ☐ **A completed pharmacy application.** Make sure that you check all categories of licensure or service(s) that apply to your pharmacy and indicate whether you prepare sterile or non-sterile compounded preparations.
- ☐ **Fee.** A $450.00 fee made payable to the "Minnesota Board of Pharmacy." NOTE: Fees are nonrefundable.
- ☐ **Blueprint or sketch of new pharmacy.** (Not needed for change of ownership only)The following must be clearly shown on the document:
  - ☐ Dimensions and layout of the proposed licensed space. Include a diagram to establish the location of the licensed space within the building, as applicable.
  - ☐ The location of the refrigerator and sink.
  - ☐ The location of the compounding area.

  <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.
- ☐ **Proof of Federal Tax ID.**
- ☐ **Certificate of Good Standing** from the state in which the pharmacy is located, obtained within the last 24 months.
- ☐ **Current Home State License.** A copy of your current license/registration from the state your facility is located.
- ☐ **Pharmacists.** A list of all pharmacists involved in dispensing drugs. **See attachment B**
- ☐ **Category Form. See attachment F.**

- ☐ **Ownership forms and supporting documents.** Provide information about the applicant licensee's ownership. NOTE: The applicant licensee is legally responsible for the operation of the pharmacy, and it must match any and all Secretary of State and IRS filings and must be identified on the application.
- ☐ **Organizational Chart.** Provide an organizational chart that shows ownership of the licensee and the percentages owned. Individual shareholders, members or parent entity of applicant licensee must be disclosed in full.
- ☐ **Prescription Monitoring Program.** Review Minnesota Statutes Section 152.126, which requires dispensers (pharmacies) licensed by the MN Board of Pharmacy to report daily to the Prescription Monitoring Program (PMP) the dispensing of all schedule II-V controlled substances, butalbital, and gabapentin. Information regarding the submission of data can be found on the PRESCRIPTION MONITORING PROGRAM website.
    - ☐ **Prescription Monitoring Program – EXEMPTION FORM.** A dispenser is not required to submit data for those controlled substance prescriptions distributed through the use of an automated drug distribution system according to section 151.58 or dispensed for inpatient hospital care only. If this applies to your pharmacy, you are required to request an exemption from reporting. The exemption form is found on the PMP website at https://mn.gov/boards/pharmacy-pmp/forms-help/forms/forms-disp.jsp.
- ☐ **For Central Service and Limited Service Categories.** Pharmacies that are providing central services for a Minnesota resident pharmacy or limited services for residents of Minnesota need Board approval **prior to** engaging in these services:
    - ☐ **Variances.** Obtain board approval of any variance(s) related to the services offered.
    - ☐ **Technicians**. For those employees engaged in central service or limited service, provide a list of technicians along with their Minnesota issued license or registration number. **See attachment A.**
    - ☐ **Central Service Pharmacies ONLY.** Provide a list of the pharmacies located in Minnesota that central services are performed on behalf of. **See Attachment C.**
- ☐ **Copy of Current Inspection Report(s).** Provide copies of all inspections conducted by your home state and/or the U.S. Food and Drug Administration within the 24 months immediately preceding the application submission. A full operational inspection report that covers all of the services (i.e. community, hospital, sterile compounding, non-sterile compounding, and hazardous compounding) the pharmacy engages in is required for licensure. Corrective actions on any deficiencies or observations made during the inspections, with all related documents must also be provided. Per MN Statutes §151.19, the Board may not issue a license unless the facility passes an inspection conducted by an authorized representative of the board. The inspection must have occurred within the 24 months immediately preceding receipt of the application. 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 or the FDA in response to inspections or investigations. The Minnesota Board of Pharmacy determines if a facility has passed an inspection conducted.
  Note: Some states do not conduct inspections within the necessary time frame. In this case a nonresident pharmacy must work with its home state regulatory body or a board approved third-party inspection program to get an inspection conducted.

The Board shall not issue an initial license for a pharmacy located outside of the state unless the applicant discloses and certifies:

- The location, names, and titles of all principal corporate officers **(Attachment E)** and all pharmacists who are involved in dispensing drugs to residents of this state.
- That it maintains its records of drugs dispensed to residents of this state so that the records are readily retrievable from the records of other drugs dispensed.
- That it agrees to cooperate with, and provide information to, the board concerning matters related to dispensing drugs to residents of this state.
- That, during its regular hours of operation, but no less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state.
- That, upon request of a resident of a long-term care facility located in this state, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision 5.

Pharmacies also Operating as an Outsourcing Facility

A pharmacy also operating an outsourcing facility must have the outsourcing facility separately licensed as a manufacturer and a wholesaler. An outsourcing facility may not ship drug products into Minnesota before obtaining a Minnesota manufacturer license and Minnesota wholesaler license.

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 Application

For Resident and Non-Resident Pharmacy - *Application Fee: $450*

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:

☐ New Pharmacy

☐ Relocation: Date of proposed change:_____

Former Address:_____

MN License Number:_____

☐ Change of Ownership:
Date of proposed change:_____

Former Owner:_____

MN License Number_____

Note: Previous variances and/or Board approved policies **do not automatically transfer to new ownership.** PICs will need to reapply.

Applicant Business Information

Fictitious, Trade or Business Name to Appear on License	Applicant's full Legal Name	Check below if outsourcing or telepharmacy ☐ Outsourcing ☐ Telepharmacy

Date proposed to begin services in MN	Federal Tax ID	MN Tax ID	DEA Number	Square Footage to be Licensed

Physical Address of the Facility				Mailing Address of the Facility (if different than the physical)			
City	State	Zip Code	Phone Number	City	State	Zip Code	Phone Number

Public Email Address (this will be for all communication, including licensing)	Organization Email Address (this is for licensing information only)

Hours of Operation

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Operate 24/7

Business Structure of the Applicant Business

Complete the questions below and **Attachment D** as it applies to the ownership of the applicant.

☐ Sole Proprietor ☐ Partnership ☐ Limited Liability Company ☐ Corporation ☐ Publicly Traded

Answer the following:

◯ **Yes** ◯ **No** Does the owner of this pharmacy own 4 or more pharmacies under this ownership?

◯ **Yes** ◯ **No** Does the pharmacy plan to extend drugs storage/distribution to off-site locations? If yes, list.

◯ **Yes** ◯ **No** Does the pharmacy have all the required equipment listed in MN Rule 6800.1050?

◯ **Yes** ◯ **No** Are all prescriptions labeled and dispensed pursuant to a valid, patient specific prescription order that is received in advance of the dispensing? If no, 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 thepharmacist-in-charge.

_____ Signature of Pharmacist-in-Charge

_____ Date

Prescription Monitoring Program

Minnesota Statute 152.126 requires dispensers (pharmacies) licensed by the MN Board of Pharmacy to report daily to the Prescription Monitoring Program the dispensing of all schedule II-V controlled substances, butalbital and gabapentin. A dispenser is not required to submit data for those controlled substance prescriptions distributed through the use of an automated drug distribution system according to section 151.58 or dispensed for inpatient hospital care only. If this applies to your pharmacy, you are required to request an exemption from reporting.

◯**Yes** ◯**No** Is this application for a pharmacy that will dispense controlled substance schedules II-V, gabapentin and/or butalbital in, or into the state of MN?

If No, you are required to request an exemption from reporting. This form must be submitted with the application.

NON-RESIDENT PHARMACIES ONLY

Minnesota rules require a toll-free telephone number to facilitate communication between patients in Minnesota and a pharmacist, who has access to the patients' records, at the pharmacy.
Please provide the number: _____

◯**Yes** ◯**No** Does the applicant comply with all lawful directions and requests for information from the Board of Pharmacy in all states in which it is licensed or registered?

◯**Yes** ◯**No** Does the applicant agree to respond directly to all communications from the Minnesota Board of Pharmacy concerning emergency circumstances arising from the dispensing of drugs to residents of this state?

◯**Yes** ◯**No** Does the applicant maintain its records of drugs dispensed to residents of Minnesota so that the records are readily retrievable from the records of other drugs dispensed?

◯**Yes** ◯**No** Does the applicant agree to cooperate with the Minnesota Board of Pharmacy by providing information to the Board of Pharmacy of applicant's home state concerning matters related to the dispensing of drugs to residents in Minnesota?

◯**Yes** ◯**No** Does the applicant intend to place emergency drug kits in facilities located in Minnesota?
- If yes, see Minnesota Rule 6800.6700 for requirements prior to placement

◯**Yes** ◯**No** Does the applicant intend to place automated drug distribution systems in facilities located in Minnesota?
- If yes, See Minnesota Statute 151.58, Minnesota Rule 6800.2600 for requirements. Applicant needs to obtain Minnesota Board of Pharmacy approval prior to placement in Minnesota located facilities

◯**Yes** ◯**No** Has the facility listed on the application shipped drugs into Minnesota in the previous 12 months?
- If yes, provide the specific drugs shipped, and the locations they were sent to.

RESIDENT PHARMACIES ONLY - Insurance Coverage

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 not located in the state of Minnesota, do not complete this section. If your facility is in Minnesota, please select the appropriate choice 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	Address	
Policy Number	Policy Expiration Date	Phone Number

Contact Information

Individual Completing Application

Must be authorized to discuss application materials.

Name	Phone
Email Address (this is used for questions during renewal)	

Ownership Contact

Authorized individual to speak on the behalf of the owner.

Name	Phone
Email (this is used for questions during renewal, or if an ownership question arises)	

Practice Questions

1. Has the applicant 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?
   If yes, attach a separate document with an explanation.

   ☐ Yes ☐ No

2. Are you or the applying entity or any of its owners, members, shareholders* currently under investigation, or has the applying entity or any of its owners, members, shareholders*, 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.*
   If yes, provide copies of all relevant documents, including but not limited to guilty pleas, records of conviction, final disposition or adjudication, and orders for probation and their terms.

   ☐ Yes ☐ No

3. Are you or the applying entity, or any of its owners, members, shareholders* (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.*
   If yes, provide copies of all relevant documents, including but not limited to guilty pleas, records of conviction, final disposition or adjudication, and orders for probation and their terms.

   ☐ Yes ☐ No

Acknowledgement

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. 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 State and Federal laws and regulations.

_____ _____
Signature of Applicant Date

_____
Type or Print Full Name Above

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

Attachment B

Non-Resident Pharmacy List of Current Pharmacists

Minnesota Statute section 151.19 requires pharmacies to report all pharmacists involved in dispensing drugs to residents of this state.

MN Pharmacy License Number:

Name of Pharmacist	Title	State of Licensure	License #	Full Time	Part Time

MINNESOTA
BOARD OF PHARMACY

Attachment C

Non-Resident Pharmacy CENTRAL SERVICE

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

Attachment D

Shareholder/Member/Partner Form

Instructions: Select the appropriate checkbox below, as related to the parent-level ownership. 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. An **organizational chart** as described in the application instructions should accompany this form.

☐ 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

Attachment E

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

Officer Reporting Form

Use this form to report the current, complete list of corporate officers or managing members 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 Administrative Officer

Date

Printed Name

MINNESOTA
BOARD OF PHARMACY

New Pharmacy Application Category Notification

Attachment F

In-State and Out-State Pharmacies

See MN Rule 6800.0350 for license categories and requirements. No pharmacy may engage in providing products or services not licensed by the Board of Pharmacy. Note that a pharmacy also operating as an outsourcing facility must submit separate manufacturer and wholesale distributor license applications.

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

Pharmacy Legal Business Name/DBA		Federal Tax ID		DEA Number
Street Address	City	State	Zip	Contact Number

Check all categories of licensure of service(s) that apply to the pharmacy for MN residents:

- ☐ 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**

Other category not listed above:_____

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)
   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 _____

***For HOSPITAL PHARMACIES:**

Check the scope of services that will be provided:

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

_____

****For CENTRAL SERVICES or LIMITED SERVICES:**

Pharmacies that are providing central services for a Minnesota resident pharmacy or 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) and policies related to the services offered.

- **Variances.** Obtain board approval of any variance(s) related to the services offered.
- **Technicians.** For those employees engaged in central service or limited service, provide a list of technicians along with their Minnesota issued registration number. See **Attachment A.**
- **Central Service Pharmacies ONLY**. Provide a list of the pharmacies located in Minnesota that central services are performed on behalf of. **See Attachment C.**
- **Limited Services ONLY**. 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.

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

I, the undersigned, do hereby certify that all of the information contained in this 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**_____

Minnesota Board of Pharmacy
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