

MINNESOTA BOARD OF PHARMACY
2829 University Ave. SE, #530, Minneapolis, MN 55414
Phone: (651) 201-2825 Fax: (651) 201-2837
E-Mail: pharmacy.board@state.mn.us Web Site: www.phcybrd.state.mn.us

CHECKLIST OF LEGAL REQUIREMENTS TO BE FOLLOWED IN OPENING A PHARMACY

1. Applications must be considered by the full board at regular meetings. The Board meets approximately monthly. At least 60 days before the planned opening date submit:
 - A. Completed pharmacy application;
 - B. \$165.00 fee made payable to the "Minnesota Board of Pharmacy." No return or refund of fees;
 - C. Blueprint or sketch of new facility, including elevations showing the consultation area where required;
 - D. Articles of Incorporation, if a corporation or limited liability corporation **or** partnership papers, if a partnership or a limited liability partnership. (If the time period from your date of application until your date of opening spans two licensing periods, July 1- June 30, then it will be necessary to submit two fees, or a total of \$330, for both the opening fee and the renewal fee.)
2. The Board recommends that you check local ordinances for sanitary and other requirements.
3. Review Rules 6800.0700 through 6800.1050 for security, access and minimum equipment requirements. (Rules 6800.0700 and 6800.1050 are shown on pages 2 and 3.)
4. Request DEA Form-224, "Application for Registration under the Controlled Substances Act", from the local or regional DEA office or on-line at www.deadiversions.usdoj.gov. Place the word "Pending" under State License Number and mail the application to the Washington address, allowing eight to ten weeks for issuance of the DEA registration. You may also complete this application on line as well.

U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION

MINNEAPOLIS OFFICE

Towle Bldg., Ste. #450
330 2nd Ave. S
Minneapolis, MN 55401-2224
Phone: (612) 344-4136

REGIONAL OFFICE

1800 Dirksen Federal Bldg.
230 S. Dearborn Street
Chicago, IL 60604
Phone: 312-353-9166

WASHINGTON OFFICE

Registration Branch
PO Box 28083, Cent'l Stat.
Washington, D.C. 20005
Phone: 202-254-8255

The DEA registration will not be issued until the Board of Pharmacy verifies the issuance of a state pharmacy license to the DEA Minneapolis office, following final inspection showing full compliance.

5. Request inspection of the new pharmacy by a Board of Pharmacy surveyor (651-201-2839) approximately two weeks prior to the opening date. Copies of the current laws and rules will be given to you at this time.
6. Make certain no legend drugs are received on the premises before the pharmacy license is issued.
7. Make application for other local and state licenses and permits as needed.

6800.0700 PHARMACY, SPACE, AND SECURITY.

Subpart 1. **Minimum requirements.** No person shall be issued a license to conduct a pharmacy located in Minnesota unless the pharmacy:

- A. contains more than 250 square feet in the dispensing and drug storage area;
- B. maintains a prescription dispensing counter at least 18 inches deep that provides two linear feet, which must be kept clear and free of all merchandise and other materials not currently in use in the practice of compounding and dispensing, for each pharmacist and each technician working concurrently on compounding and dispensing; this counter shall provide an additional space for computers if they are used in the dispensing process;
- C. maintains an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter, which shall be kept free of obstruction at all times;
- D. is surrounded by a continuous partition or wall extending from the floor to the permanent ceiling, containing doors capable of being securely locked to prevent entry when the pharmacy is closed;
- E. in the case of a community/retail pharmacy, contains an area where consultation between the patient and the pharmacist may be conducted with an assurance of privacy.

{The recommendations for an adequate patient counseling area are:

- A designated area that provides for a confidential discussion between the patient and the pharmacist using sound dulling partitions **at least** 7 feet high and **at least** 24 inches deep.
- Consideration must be given to the proximity of the check-out or cash register, the volume of pedestrian traffic in and around the counseling area, the drive-thru from both inside and outside, and the presence of chairs, blood pressure machines and other items, so that all patients will be able to obtain counseling without being overheard by others in the area.
- The area must not contain any item for sale apart from the articles needed for counseling sessions. An accessible computer terminal for patient profile review and clinical documentation is also recommended.
- The area must be accessible to the patient from the outside of the prescription dispensing area and be open at all times when the pharmacy is open. }

...and

- F. is lighted to a level of not less than 75-foot candles measured in the major work areas.

Subp. 2. **Satellite waiver.** In the interest of public health, the board may waive subpart 1, item A, for satellite pharmacies located in hospitals.

6800.1050 REQUIRED REFERENCE BOOKS AND EQUIPMENT.

Subpart 1. **Reference books.** Except as indicated, the references in this subpart may be in electronic or hard copy form. In addition to the most recent editions of the laws relating to the practice of pharmacy, the rules of the Board of Pharmacy, and a current copy of the Drug Enforcement Agency regulations, Code of Federal Regulations, Title 21, parts 1300 to 1316, each pharmacy in Minnesota must have on file at least one current reference from each of the categories in items A to C. At least one dosage and toxicology reference must be in hard copy form that is appropriate to the majority of the patient base of the pharmacy. An equivalent reference approved by the board in writing may be used in an appropriate category.

A. Examples of pharmacotherapy references are:

- (1) Pharmacology in Medicine;
- (2) Pharmacological Basis of Therapeutics;
- (3) Applied Therapeutics;
- (4) Pharmacotherapy: A Pathophysiologic Approach;
- (5) United States Pharmacopeia - Dispensing Information; and
- (6) Conn's Current Therapy.

B. Examples of dosage and toxicology references are:

- (1) American Hospital Formulary Service;
- (2) Facts and Comparisons; and
- (3) Drug Information Handbook.

C. Examples of general references are:

- (1) Handbook of Nonprescription Drugs;
- (2) Physician's Desk Reference;
- (3) Remington's Pharmaceutical Sciences;
- (4) United States Pharmacopeia - National Formulary;
- (5) United States Pharmacopeia - Pharmacists' Pharmacopeia;
- (6) Orange Book; and
- (7) Merck Manual.

In addition to items A to C, long-term care pharmacies must have on file the most recent edition of Minnesota Department of Health rules pertaining to medication handling in long-term care facilities and a current general reference on geriatric pharmacotherapy. In addition to items A to C, specialty pharmacies serving a unique population must have a current general reference appropriate to the patient base served.

Subp. 2. **Equipment.** Each pharmacy must have the following minimum equipment, clean and in good working order:

- A. one prescription balance, Class A as defined in United States Pharmacopeia - National Formulary, with one set of accurate metric weights from 50 mg to 100 g, or an electronic balance of equal or greater accuracy;
- B. measuring devices capable of accurately measuring volumes from 1 ml to at least 500 ml;
- C. mortars, pestles, spatulas, funnels, stirring rods, and heating apparatus as necessary to meet the needs of that pharmacy;
- D. other equipment as necessary to comply with the requirements of United States Pharmacopeia, chapter 795;
- E. a refrigerator used only for drug storage or a separate compartment used only for drug storage within a general use refrigerator, manual, electromechanical, or electronic temperature recording equipment, devices, or logs shall be used to document proper storage of prescription drugs every business day;
- F. a sink with hot and cold running water; and
- G. a toilet with a hand-washing lavatory and disposable towels in a location that is reasonably accessible.

Subp. 3. **Required resources.** In addition to the requirements of subparts 1 and 2, pharmacies preparing compounded sterile products are required to have:

- A. minimum equipment to comply with the United States Pharmacopeia, chapter 797, appropriate to risk-level requirements;
- B. current reference materials or books for sterile products or intravenous incompatibilities; and
- C. a current copy of United States Pharmacopeia, chapter 797.