

MINNESOTA BOARD OF PHARMACY  
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**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. \$190.00 fee plus a \$19.00 OET surcharge for a total of \$209.00 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 \$418.00, 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. Review Minnesota Statute 152.126 which in part, requires all pharmacies licensed in Minnesota to report to the Prescription Monitoring Program (PMP) the dispensing of all schedule II, III, and IV controlled substances to a secure central database. (See pages 4 and 5)
5. Request DEA Form-224, "Application for Registration under the Controlled Substances Act", from the local or regional DEA office or on-line at [www.deadiversion.usdoj.gov](http://www.deadiversion.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.

6. Request inspection of the new pharmacy by a Board of Pharmacy surveyor (651-201-2839) approximately two weeks prior to the opening date.
7. Make certain no legend drugs are received on the premises before the pharmacy license is issued.
8. 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. Community/retail pharmacies in existence on February 1, 1999, have until February 1, 2001, to comply with this item; 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.

{The recommendations for an adequate patient counseling area are:

- That there is 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.}

## 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 the 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.

## **Excerpt from 152.126 CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM.**

### **Subdivision 1. Definitions.**

For purposes of this section, the terms defined in this subdivision have the meanings given.

- (b) "Controlled substances" means those substances listed in section [152.02](#), subdivisions 3 to 5, and those substances defined by the board pursuant to section [152.02, subdivisions 7, 8, and 12](#).
- (c) "Dispense" or "dispensing" has the meaning given in section [151.01, subdivision 30](#). Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.
- (d) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section [156.18](#).
- (f) "Prescription" has the meaning given in section [151.01, subdivision 16](#).

### **Subd. 2. Prescription electronic reporting system.**

- (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.
- (b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

### **Subd. 4. Reporting requirements; notice.**

- (a) Each dispenser must submit the following data to the board or its designated vendor, subject to the notice required under paragraph (d):
  - (1) name of the prescriber;
  - (2) national provider identifier of the prescriber;
  - (3) name of the dispenser;
  - (4) national provider identifier of the dispenser;
  - (5) prescription number;
  - (6) name of the patient for whom the prescription was written;
  - (7) address of the patient for whom the prescription was written;
  - (8) date of birth of the patient for whom the prescription was written;
  - (9) date the prescription was written;
  - (10) date the prescription was filled;
  - (11) name and strength of the controlled substance;
  - (12) quantity of controlled substance prescribed;
  - (13) quantity of controlled substance dispensed; and
  - (14) number of days supply.
- (b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for:

- (1) individuals residing in licensed skilled nursing or intermediate care facilities;
- (2) individuals receiving assisted living services under chapter 144G or through a medical assistance home and community-based waiver;
- (3) individuals receiving medication intravenously;
- (4) individuals receiving hospice and other palliative or end-of-life care; and
- (5) individuals receiving services from a home care provider regulated under chapter 144A.

(d) A dispenser must not submit data under this subdivision unless a conspicuous notice of the reporting requirements of this section is given to the patient for whom the prescription was written.

**Subd. 7. Disciplinary action.**

(a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

Reporting to the Minnesota Prescription is required unless an exemption is on file with the Board of Pharmacy.

Detailed information on reporting to the MN PMP can be found in the “Dispenser’s Implementation Guide” which is available on the MN PMP website at [www.pmp.pharmacy.state.mn.us](http://www.pmp.pharmacy.state.mn.us) on the “Other Forms and Documents” page.