

CHAPTER 6800
MINNESOTA BOARD OF PHARMACY
PHARMACISTS' LICENSING AND OPERATION

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6800.0100 DEFINITIONS.

Subpart 1. **Pharmacist-in-charge.** The term "pharmacist-in-charge" means a duly licensed pharmacist in the state of Minnesota who has been so designated.

Subp. 2. **Pharmacy.** The term "pharmacy" means an established place regularly licensed by the board of pharmacy in which prescriptions, drugs, medicines, chemicals, and poisons are compounded, dispensed, vended, or sold to the consuming public.

Subp. 3. **Poisons.** For the purpose of parts 6800.0100 to 6800.9700, "poisons" shall be deemed to mean any substance except drugs or medicines which has the inherent capability to produce bodily harm, injury, or morbidity to man or beast through ingestion, inhalation, or absorption through or from any body organ or surface and shall include, but not be limited to, substances that are toxic, caustic, corrosive, sensitizing, extremely flammable or explosive, alone or in mixtures, and whose label bears the signal word "Poison" or cautionary words such as "Caution," "Warning," "Danger," etc., intended to signal a use alert.

Statutory Authority: MS s 151.06 subd 1

6800.0110 RESPONSIBILITY FOR ACTION BY A PHARMACY.

Whenever an applicable rule requires or prohibits action by a pharmacy, responsibility for said action shall be that of the owner and pharmacist-in-charge thereof, whether said owner is a sole proprietor, partnership, association, corporation, or otherwise.

Statutory Authority: MS s 151.06 subd 1

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6800.0200 FORM OF APPLICATION AND LICENSE.

Applications for the licensing of a pharmacy and renewal thereof shall be on such form or forms as the board of pharmacy may from time to time prescribe, and the license of such pharmacy shall be issued by the board of pharmacy in such form as it may from time to time prescribe.

Statutory Authority: MS s 151.06 subd 1

6800.0300 LICENSE AND FEE REQUIRED.

No person or persons shall conduct a pharmacy in the state of Minnesota unless such pharmacy is licensed by the board of pharmacy. A fee set by the board and indicated in part 6800.0400 shall be charged for each license.

Statutory Authority: MS s 151.06 subd 1

6800.0400 ANNUAL LICENSE RENEWAL DATE AND FEES.

Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application for license renewal, on or before June 1 of each year, together with a fee of \$100. Renewal applications received on or after July 1 are subject to a late filing fee of \$50 in addition to the renewal fee.

Statutory Authority: MS s 151.06 subd 1 cl (7),(9); 151.07; 151.19; 214.06

History: 9 SR 1656; 11 SR 335

6800.0500 SEPARATE LICENSE REQUIRED.

A separate license shall be required for each pharmacy and is not transferable. The following shall be deemed a transfer requiring relicensure:

- A. the sale of all or substantially all of the assets of the pharmacy;
- B. the addition or deletion of one or more partners in a partnership, to which a pharmacy license has been issued;
- C. the change of ownership of 20 percent or more of the issued voting stock of a corporation pharmacy since the issuance of the license or the last

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renewal thereof, this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market; or

D. the change in ownership from one form to another: sole proprietor, partnership, or corporation.

Statutory Authority: MS s 151.06 subd 1

6800.0600 POSTING LICENSE.

Each pharmacy license shall be posted in a conspicuous place in the pharmacy for which the license has been issued.

Statutory Authority: MS s 151.06 subd 1; 151.19

6800.0700 ACCESS, SPACE, AND SECURITY.

Subpart 1. **Minimum requirements.** No person shall be issued a license to conduct a pharmacy unless such pharmacy:

A. has an entrance which affords the public reasonable access to the pharmacy;

B. contains more than 400 and less than 12,500 square feet; and

C. is surrounded by a continuous partition or wall extending from floor to ceiling, which wall shall contain doors capable of being securely locked to prevent entry when the pharmacy is closed.

Subp. 2. **Hospital waiver.** In the interest of public health the board may waive any of these provisions for pharmacies located in hospitals.

Statutory Authority: MS s 151.06 subd 1

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES.

Subpart 1. **Change in location.** Before a duly licensed pharmacy changes the location of its business it shall first submit to the board of pharmacy a new application for a license setting forth such changes, and shall submit therewith the information and documents required in an initial application for license. The new application and supporting documents shall be submitted at least 60 days prior to the proposed change in location. If the board of pharmacy approves such application, no additional charge shall be made for such new license.

Subp. 2. **Change in dimension or security.** No duly licensed pharmacy shall change its physical dimensions or elements of physical security until it has submitted documents and plans of the proposed changes to the board of pharmacy. Such documents and plans shall be submitted at least 60 days prior to the proposed changes. The board shall within 30 days after receipt of the proposed changes notify the licensee that the proposed changes either comply or do not comply with part 6800.0700. The failure of the board to respond in writing within said 30 days shall be deemed to be approval of the proposed changes.

Statutory Authority: MS s 151.06 subd 1

6800.0900 Subpart 1. [Renumbered 6800.2250, subpart 1]

Subp. 2. [Renumbered 6800.2250, subp 2]

Subp. 3. [Repealed, 9 SR 260]

Subp. 4. [Renumbered 6800.2250, subp 3]

6800.0950 SALE RESTRICTED TO LIMITED AREA UNDER SUPERVISION.

Hereafter, the board of pharmacy shall refuse to grant a license to any pharmacy or proposed pharmacy unless there is provided in such pharmacy a prescription department and a drug area which shall be used exclusively for the display, sale, compounding, and dispensing of drugs, medicines, chemicals, and poisons, and for the display and sale of other items used in the cure, mitigation, treatment, or prevention of disease in man or other animals.

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Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.1000 [Renumbered 6800.1150]

6800.1050 REQUIRED REFERENCE BOOKS AND MINIMUM EQUIPMENT FOR PHARMACIES.

Subpart 1. **Reference books.** In addition to the most recent editions of the laws relating to the practice of pharmacy and the rules of the board of pharmacy, each pharmacy must have on file at least one current reference from each of the categories in items A to C. An equivalent reference approved by the board in writing may be utilized in an appropriate category.

A. Examples of pharmacology references are:

- (1) Pharmacology in Medicine;
- (2) Pharmacological Basis of Therapeutics;
- (3) Merck Manual;
- (4) Pharmindex;
- (5) United States Dispensatory; and
- (6) United States Pharmacopeia - Dispensing Information.

B. Examples of dosage and toxicology references are:

- (1) Hazards of Medications;
- (2) American Hospital Formulary Service;
- (3) Facts and Comparisons;
- (4) Pediatric Dosage Handbook; and
- (5) Evaluation of Drug Interactions.

C. Examples of general references are:

- (1) Handbook of Non-Prescription Drugs;
- (2) Modern Drug Encyclopedia;
- (3) Physician's Desk Reference;
- (4) Remington's Pharmaceutical Sciences; and
- (5) United States Pharmacopeia - National Formulary.

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

A. one prescription balance, as specified in rules of the Department of Public Service, Weights and Measures Division;

B. one set of accurate metric weights from 50 mg to 100 g;

C. measuring devices capable of accurately measuring volumes from 1 ml to at least 500 ml;

D. mortars, pestles, spatulas, funnels, stirring rods, and heating apparatus as necessary to meet the needs of that pharmacy;

E. refrigerator with a thermometer suitable for drug storage;

F. sink with hot and cold running water; and

G. toilet with a hand-washing lavatory and disposable towels in a location which is reasonably accessible.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

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6800.1100 [Renumbered 6800.1250]

6800.1150 ANNUAL RENEWAL, FEES, AND POSTING.

Each pharmacist license shall expire on March 1 of each year and shall be

renewed annually by filing an application for license renewal on or before February 1 of each year, together with a fee of \$50. Any pharmacist license renewal application submitted after March 1 shall be subject to a late filing fee of \$25 in addition to the renewal fee.

Each pharmacist shall post his license or renewal thereof in a conspicuous place within the pharmacy in which he is practicing his profession. For community pharmacies, this place shall be a place which is readily visible to the public.

Statutory Authority: *MS s 151.03; 151.06 subd 1 cl (9); 151.13 subd 1; 214.06*

History: 9 SR 1656

6800.1200 [Renumbered 6800.1300]

6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. Submitting. Applicants for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicant's birth certificate, and a recent photograph. All applicants shall show evidence of graduation with a bachelor of science degree or doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy, from a college of pharmacy or a department of pharmacy of a university approved by the board and meeting at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual. Such evidence shall be shown by submitting a final transcript showing the date on which degree was conferred. The above-listed documents together with a check for \$125 must be submitted to the board at least 30 days prior to the examination.

Subp. 2. Retaking exam. Any applicant who has failed to pass the examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake such examination within the next ensuing 14 months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the board. The applicant shall, at least 30 days before an examination, notify the board in writing of his or her intentions to retake the examination, certifying that information furnished on the original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of \$125 payable to the Minnesota Board of Pharmacy. The board reserves the right to request a full and complete application.

Subp. 3. Fees not refunded. Examination or license fees paid to the board shall not be returned or refunded.

Statutory Authority: *MS s 151.06 subd 1 cl (7),(9); 151.07; 151.19; 214.06*

History: 9 SR 1656; 11 SR 335

6800.1300 RECIPROCITY.

Subpart 1. Applications. Applications for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of \$150 shall be filed with the secretary of the board at least 30 days prior to the date said application is to be considered by the board. The board will consider applications for reciprocity in at least January and June of each calendar year.

Subp. 2. Eligibility. To be found eligible for consideration by the board:

A. Applicant must have practiced in the profession for at least one year after licensure in another state which is an active member of the National Association of Boards of Pharmacy before he will be deemed eligible to reciprocate to Minnesota.

B. Applicant, if examined and licensed prior to January 1, 1973, shall show that he has acquired 2,080 hours of practical pharmacy experience under the instruction of a licensed pharmacist.

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C. Applicant, if examined and licensed after January 1, 1973, shall show that he has acquired 1,500 hours of practical pharmacy experience under the instruction of a licensed pharmacist; said 1,500 hours to be acquired after the successful completion of the third year of the standard five-year pharmacy curriculum, 400 hours of which may be acquired: concurrently with college attendance, in clinical pharmacy programs, or in demonstration projects which have been approved by the Tripartite Committee on Internship and the board of the active member state from which he applies.

Subp. 3. **Substitution for internship.** Defects in internship experience will not preclude an applicant from being deemed eligible provided that said applicant shall have practiced as a licensed pharmacist for one year, plus one week at 40 hours per week for each week or portion thereof that he is deficient in internship experience, (i.e., the number of weeks in excess of one year the applicant has practiced as a licensed pharmacist prior to applying for reciprocity must be equal to or greater than the number of weeks or portions thereof that he is deficient in internship experience).

Subp. 4. **Practical examination.** The board may compel applicants who have not engaged in practice as a licensed pharmacist for the two years immediately preceding the time of filing of their application for reciprocity to take a practical examination.

Subp. 5. **Written and oral examination.** Applicants for reciprocal licensure shall be required to display their familiarity with the laws regulating the practice of pharmacy in Minnesota by submitting to a written and oral examination on the Minnesota laws and rules and the federal laws and regulations governing the practice of pharmacy.

Subp. 6. **Prior examination failure.** An applicant who has failed to successfully pass the Minnesota Board of Pharmacy licensure examination shall not be eligible for licensure by reciprocity.

Statutory Authority: *MS s 151.06 subd 1; 151.12*

History: *9 SR 1656*

LICENSING MANUFACTURERS AND WHOLESALERS

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Every person engaged in manufacturing or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public shall annually be licensed by the board. Upon the filing of an application therefor, and upon payment of a fee of \$100, the board may issue a license in such form as it may prescribe to the manufacturer or wholesaler. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with a fee of \$100. Renewal applications received after June 1 shall be subject to a late filing fee of \$25 in addition to the renewal fee.

Statutory Authority: *MS s 151.06 subd 1; 151.25*

CONTINUING EDUCATION

6800.1500 CONTINUING PHARMACEUTICAL EDUCATION.

Subpart 1. **Definitions.** Definitions:

A. "Approved continuing education" means those continuing pharmacy education programs approved by the board or made available by an approved provider. These programs may take the form of classes, conferences, correspondence study courses, institutes, lectures, professional meetings, programmed learning courses, journal readings, seminars, study groups, or other program formats commonly accepted by educators as legitimate adult educational activities.

B. "Approved provider" means any association, corporation, educational institution, organization, group, or person who has been recognized by the Board of Pharmacy, in accordance with subpart 3, as having met its criteria indicative of the ability to provide quality continuing education programs or who has been recognized by the board as being approved by the American Council on Pharmaceutical Education for the provision of quality continuing education programs.

C. "Continuing pharmaceutical education" is a planned learning experience beyond a formal undergraduate degree program designed to promote the continual development of professional knowledge, professional skills, and professional attitudes on the part of the practitioners and shall include but is not limited to professional postgraduate education in any of the following subjects:

- (1) properties and actions of drugs and drug dosage forms;
- (2) etiology, characteristics, and therapeutics of the disease state;
- (3) pharmacy practice; or
- (4) legal, psychological, and socioeconomic aspects of health care

delivery.

Subp. 2. **Minimum hours required; reporting.** Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minnesota Statutes, section 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he or she has completed at least 30 hours of approved continuing education during the previous two-year period. Thereafter, each pharmacist shall submit such evidence every two years. Beginning with the 1981-1983 reporting period, participation in continuing education shall be reported on October 1 of each even-numbered year. The board may grant a pharmacist, upon application, an extension of time not to exceed one year to comply with the requirements of this subpart. Such extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period.

Subp. 3. **Approval of providers.** Application may be made by an association, corporation, educational institution, organization, or person to be designated as an approved provider on forms provided by the board. The applicant shall provide, at a minimum, information regarding administrative and recordkeeping procedures used for past programs; a history of the content, methods of delivery, and faculty qualifications for past programs; methods of program needs assessment and development that the applicant has used; and evaluation mechanisms that the applicant has used. The applicant shall agree to maintain records of program content, evaluation summary, and attendance for at least three years following completion of each program. The application must cover the two-year reporting period for which provider approval is sought.

The board shall approve an applicant as a continuing education provider based on the applicant's compliance with the following criteria:

A. The continuing education programs must have had an identifiable administrative authority who was responsible for meeting all quality criteria and for maintaining records of program content, planning, delivery, evaluation, and attendance.

B. The programs' administrative requirements must have included:

(1) promotion and advertising of continuing education activities in a responsible fashion clearly indicating in promotional material the educational objectives of the particular activity, the nature of the audience that may best benefit from the activity, the schedule of the activity, the cost of the activity to the participant and the items covered by that cost, the amount of continuing education credit that can be earned through participation in the activity, and the credentials of the faculty;

(2) maintenance and availability of records of participation in

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continuing education activities adequate to serve the needs of the participants and others requiring this information; and

(3) provision of evidence to the participant, in the form of a certificate or other document, of satisfactory completion of a continuing education activity as reasonably required by the participant.

C. The educational content development must have included:

(1) Advance planning that includes a statement of educational goals, behavioral objectives, or both, that are measurable.

(2) Activities designed to satisfy educational needs which the board has determined to be appropriate.

(3) Involvement of members of the intended audience in identifying their own continuing education needs.

(4) Activities designed to explore one subject or a group of closely related subjects. If an activity involves multiple components, such as a lecture series, all segments must be devoted to integrally related subjects.

(5) Appropriate mediated material and supportive instructional material. Previously offered activities, including those in mediated forms, must have been reviewed by the provider prior to being offered to new audiences, with a view toward maintaining technical quality, timeliness, and currency of content, and faculty must have had the opportunity to update material, if they desired, before an activity was offered to a new audience.

D. The methods of delivery must have been consistent with the special needs of the program.

E. The teaching staff for a particular continuing education activity must have been competent in the subject matter and qualified by experience or preparation to the tasks and method of delivery.

F. An evaluation mechanism must have been provided to allow the participants to assess their achievement of program objectives.

G. The provider must have developed and employed evaluation techniques that assess the effectiveness of the continuing education activities, and the level of fulfillment of the stated objectives, for the purpose of provider and activity improvement if indicated.

Applicants with no history of program development in compliance with items A to G or with an incomplete history will be judged on their willingness and ability to comply with these criteria in the future.

Subp. 3a. Approval of programs. Application may be made by an association, corporation, educational institution, organization, group, or person, not presently approved as a provider, to have a program designated as an approved program. The board shall approve a continuing education program if it complies with the following criteria:

A. The provider shall submit evidence that promotion and advertising of the program will be done in a responsible fashion. For example, the promotional material should state the educational objectives of the program, the nature of the audience for which the program is intended, the program schedule, the cost of the program and the items covered by that cost, the amount of continuing education credit that can be earned through the program, and the credentials of the program faculty.

B. The provider agrees to maintain records of participation in or attendance at the program for not less than three years and agrees to make them available to the board upon request.

C. The provider agrees to provide evidence to the participant of satisfactory completion of the program.

D. The program provider submits evidence that:

(1) program planning involved members of the intended audience;

(2) the program is designed to satisfy identified educational needs;
(3) the program includes a statement of educational goals, behavioral objectives, or both, that are measurable;

(4) the program, if it involves multiple components, is devoted to integrally related subjects; and

(5) any mediated and supportive instructional material is designed to be used in a suitable and appropriate manner.

E. The method of program delivery is consistent with the special needs of the program.

F. The teaching staff appears to be competent in the subject matter and is qualified by experience or preparation to the task and method of delivery.

G. An evaluation mechanism is provided for the purpose of allowing the participants to assess their achievement of program objectives.

H. The provider has developed and will employ evaluation techniques that assess the effectiveness of the continuing education activities, and the level of fulfillment of the stated objectives for the purpose of provider and activity improvement if indicated.

Applications for program approval must be submitted not less than 45 days prior to the commencement of the program. The board shall assign the number of credit hours to each program and shall grant approval or deny approval of such application within 30 days of receiving the application.

Subp. 4. Revocation or suspension of approval. The board may deny, refuse to renew, revoke, or suspend authorization, recognition, or approval previously furnished to programs or providers if the program or provider fails to conform to its application approved by the board, fails to furnish program content as publicized, or if the program or provider violates any provision of Minnesota Statutes, section 214.12, or this rule.

Subp. 4a. Programs not previously submitted for approval. Pharmacists may apply for credit for attendance at programs not previously submitted to the board for approval provided that the pharmacist completes a continuing education program approval form, obtainable from the board, and submits it to the board within 45 days after completing the program. The applicant shall provide, at a minimum, the title, site, date, type, and length of the program being proposed for approval, a program outline, and a description of the type of evaluation mechanism used at the program. Approval of the program is subject to all the standards of Minnesota Statutes, section 214.12 and subparts 1, item C, and 4, items B to G.

Subp. 5. Hours of credit. Credit shall be earned on the basis of attendance at or, in the case of correspondence courses, completion of a program. Credit for an identical program may be given only once to any individual during any reporting period.

Subp. 6. Credit for presentation of professional lectures. Pharmacists may apply for credit for presentation of in-service training programs or lectures consisting of subjects included in the definition of Continuing Pharmaceutical Education. Credit for these presentations will be granted only once to any individual during any reporting period.

Subp. 7. Record of approved programs. The board shall maintain a record of approved providers and approved programs including the hours of credit assigned to each program.

Subp. 8. [Repealed, 10 SR 2007]

Subp. 9. Program promotion. No reference shall be made by a program provider in publicizing a program that it is an "approved program provider" unless the provider is so approved by the board or the American Council on Pharmaceutical Education. No other reference indicating endorsement by the

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board may be made except as follows: "This program is approved by the Minnesota Board of Pharmacy for ___ hours of continuing education credit."

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.1600 CONTINUING EDUCATION ADVISORY TASK FORCE.

The continuing education advisory task force shall consist of not more than ten members. Five members of the advisory task force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the College of Pharmacy of the University of Minnesota, and two members shall be designated by the board. The continuing education advisory task force shall meet at least quarterly and shall annually elect a chairman and vice-chairman from its membership. The executive director of the board of pharmacy shall act as secretary to the task force.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

OPERATION OF PHARMACY

6800.2000 [Renumbered 6800.2150]

6800.2100 [Renumbered 6800.1050]

6800.2150 PHARMACIST ON DUTY.

Each pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business.

Statutory Authority: *MS s 151.06 subd 1*

History: *9 SR 1656*

6800.2200 [Renumbered 6800.0950]

6800.2250 UNPROFESSIONAL CONDUCT.

Subpart 1. **Prohibited conduct.** Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.

B. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.

C. Refusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists.

D. Participation in agreements or arrangements, with any person, corporation, partnership, association, firm, or others involving rebates, "kickbacks," fee-splitting, or special charges in exchange for professional pharmaceutical services, including but not limited to the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility as compensation or inducement for placement of business with that pharmacy or pharmacist. Monetary rebates or discounts which are returned to the actual purchaser of drugs as a cost justified discount or to meet competition are permitted if the rebates or discounts conform with other existing state and federal rules and regulations.

E. Discriminating in any manner between patients or groups of patients, for reasons of religion, race, creed, color, sex, age, or national origin.

F. Refusing to consult with patrons or patients concerning contents,

therapeutic values, and uses of prescription or nonprescription drugs, chemicals, or poisons.

G. Requiring an individual patient to be a member of any organization, association, or other group as a condition for obtaining the professional services of a pharmacist.

H. The violation of any law, rule, regulation, or ordinance of the state or any of its political subdivisions, including the board of pharmacy, or the United States government, or any agency thereof relating to the practice of pharmacy.

I. Divulging or revealing to others the nature of professional pharmaceutical services rendered to a patient without his expressed consent orally or in writing or by order or direction of a court (this shall not prevent pharmacies from providing information copies of prescriptions to other pharmacies or to the person to whom the prescription was issued and shall not prevent pharmacists from providing drug therapy information to physicians for their patients).

J. Participation in institutional drug distribution as a consultant without providing pharmaceutical services in accordance with accepted principles of pharmacy practice and in compliance with federal and state laws or rules.

Subp. 2. **Improper advertising.** Prescription drug price information may be provided to the public only by a pharmacy, so long as it is not violative of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

A. No representation or suggestion concerning the drug's safety, effectiveness, indications for use, or competitive comparison shall be made.

B. No reference shall be made to controlled substances listed in schedule II-IV of the latest revision of the Federal Controlled Substances Act, and the rules of the Minnesota Board of Pharmacy.

C. The termination date for the prices listed shall be stated in the ad.

Subp. 3. **Accessories to illegal drug traffic.** The selling, giving away, or otherwise disposing of accessories (i.e., glassine papers, empty capsules, quinine, lactose, or similar products), chemicals, or drugs found in illegal drug traffic is unprofessional conduct by a pharmacist when he or she knows or should have known of their intended use in illegal activities.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *9 SR 260; 9 SR 1656; 10 SR 2007*

6800.2300 SANITATION.

Each pharmacy shall maintain clean and sanitary conditions at all times.

Statutory Authority: *MS s 151.06 subd 1*

6800.2400 PHARMACIST-IN-CHARGE.

Subpart 1. **Responsibilities and duties.** No person shall conduct a pharmacy without a pharmacist-in-charge, who shall be a pharmacist regularly employed in the pharmacy department and shall be designated in the application for license, each renewal thereof or pursuant to subpart 4. It shall be his duty and responsibility, consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws:

A. to establish policies and procedures for the employees of the pharmacy for the procurement, storage, compounding, and dispensing of drugs and the communication of information to the public in relation to drug therapy;

B. to supervise all of the professional employees of the pharmacy;

C. to supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the procurement, sale, and/or storage of drugs;

D. to develop appropriate detailed written procedures directing activi-

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ties of supportive personnel and to submit these procedures to the board in accordance with part 6800.3850;

E. to establish and supervise the method and manner for the storing and safekeeping of drugs;

F. to establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs;

G. to notify the board immediately upon his knowledge that his services as pharmacist-in-charge have been or will be terminated; and

H. to respond to deficiency reports.

Subp. 2. **Deficiency reports.** The pharmacist-in-charge of any pharmacy wherein deficiencies are noted upon inspection by the board or its staff shall, within 30 days of receiving notice of such deficiency, submit in writing to the board the steps taken or proposed to eliminate the deficiency. Failure to submit such report or to eliminate deficiency shall be grounds for the institution of disciplinary action by the board.

Subp. 3. **More than one location.** No pharmacist shall be designated pharmacist-in-charge of more than one pharmacy. In the interest of public health, this requirement may be waived in the case of a pharmacist serving a hospital pharmacy on a part-time basis.

Subp. 4. **Termination of service.** Each pharmacy shall notify the board of pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the board of pharmacy of such designation. The board of pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the board of pharmacy within ten days after receipt thereof.

Statutory Authority: *MS s 151.06 subd 1*

History: *9 SR 1656*

6800.2500 NOTIFICATION OF CHANGE OF BUSINESS OR RESIDENCE ADDRESS.

Each pharmacist, assistant pharmacist, and registered pharmacist-intern shall notify the board of pharmacy immediately of any change in location of his employment or any change of his residence address.

Statutory Authority: *MS s 151.06 subd 1*

6800.2600 VENDING MACHINES.

It shall be deemed unlawful to distribute, dispense, or vend any legend drug by automatic or vending machine. Provided, however, that nothing in this rule shall prohibit a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises from utilizing such a device in an emergency, after regular pharmacy hours, when the hospital's pharmacist shall have complete control over the monitoring of drug therapy, packaging, labeling, filling, record keeping, and security of the drugs involved and of the device, and when such device is utilized in compliance with all other state and federal laws and regulations regarding the distribution of legend drugs.

Statutory Authority: *MS s 151.06 subd 1*

6800.2700 RETURN OF DRUGS AND DEVICES.

Subpart 1. **Reuse.** Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any drugs, prescribed medications, chemicals, poisons, or medical devices; except that in a hospital with a licensed pharmacy, drugs, devices, or other items dispensed for hospital inpatient use may be returned to the pharmacy for disposition by a pharmacist in accordance with good professional practice.

Subp. 2. **Drugs from nursing homes.** Drugs from nursing homes may be returned to the dispensing pharmacy if:

A. the consultant pharmacist can assure proper storage conditions for the drugs in the facility as specified in the United States Pharmacopeia, (Rockville, Maryland: United States Pharmacopoeial Convention, Inc.);

B. the drugs are returned to the pharmacy which dispensed the drugs;

C. the integrity of such packaging remains intact (no reconstituted drugs, drugs requiring refrigeration, or controlled substances may be so returned); and

D. the drugs are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's unit-dose, unit-of-use, or strip packaging with each tablet or capsule individually wrapped and labeled, or in blister cards, which indicate the drug name and strength, the packager's name, and the manufacturer's or packager's lot or batch number. Drugs packaged by a pharmacy may be returned only if the pharmacy can demonstrate to the board that its packaging material and procedures will provide a package that will meet or exceed the criteria for class B packaging established by the United States Pharmacopoeia, (Rockville, Maryland: United States Pharmacopoeial Convention, Inc.), and that procedures have been developed and implemented to prevent the commingling of dosage units of different lot numbers.

Subp. 3. **Commingling.** Commingling of returned medication or mixing of lot numbers of returned medication, upon or prior to repackaging, shall result in such medication being deemed misbranded and subject to embargo under Minnesota Statutes, section 151.38. This prohibition shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale, or reent thereof.

Statutory Authority: MS s 151.06 subd 1

6800.2800 MAIL ORDER SALE.

Hereafter no pharmacist or pharmacy shall solicit or participate in the solicitation by advertising of any kind, the sale or distribution of drugs requiring a prescription by any mail order plan of any form. The mail order sale or distribution of drugs requiring a prescription is prohibited whenever such sale has been solicited by advertising of any kind by any person or persons. No pharmacist or pharmacy shall accept or fill a prescription which has been received by mail and that has been written by a practitioner not licensed to practice his profession in this state.

Statutory Authority: MS s 151.06 subd 1

6800.2900 PRESCRIPTION BLANKS.

No licensed pharmacy or pharmacist shall accept, furnish, or cause to be furnished to any practitioner authorized by law to prescribe drugs and medicines prescription blanks referring to any specific licensed pharmacy or pharmacist in any manner whatsoever. No licensed pharmacy or pharmacist shall actively or passively participate in any arrangement or agreement whereby prescriptions are prepared, written, or issued in a manner which refers to a specific pharmacy or pharmacist.

Statutory Authority: MS s 151.06 subd 1

6800.3000 ACCEPTANCE OF ORDER AND DISTRIBUTION OF MEDICATION.

No licensed pharmacist shall participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. This shall apply to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this part shall prohibit a licensed pharma-

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cist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or medical care facility in which a patient is confined.

Statutory Authority: *MS s 151.06 subd 1*

6800.3100 COMPOUNDING AND DISPENSING.

Subpart 1. Duties. The practice of compounding and dispensing a prescription includes, but is not limited to, the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist:

- A. determination of brands and suppliers;
- B. receipt of verbal prescriptions;
- C. verifying the prescription order;
- D. selecting the drug to be used in filling the prescription;
- E. extemporaneous compounding on an individual basis;
- F. certifying the completed prescription;

G. assuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized prescribers or their agents, and then noting on the reverse side of the prescription the following data: date refilled; name of practitioner authorizing refill (if different from original prescriber); quantity of drug dispensed (if different from the original prescription); and initials of the pharmacist refilling the prescription;

H. supervising nonpharmacist clerical personnel in limited nonprofessional duties such as looking up prescription refills, filing prescriptions, recordkeeping, nonprofessional aspects of presenting completed medications to patients, and completing the transaction; and

I. supervising nonpharmacist supportive personnel utilized in the performance of certain pharmacy tasks (the use of such supportive personnel shall be in accordance with part 6800.3850).

Subp. 2. Verification. Verification of validity and propriety under subpart 1, item C, must be of the original prescription order. A copy, rewritten or verbal, is not acceptable.

Subp. 3. Certification. In certifying and documenting the completed prescription order under subpart 1, item F, the pharmacist shall include:

A. checking of the original labeled container from which the medication was withdrawn;

B. checking of the labeling on the prescription medication container;

C. checking the contents of the prescription medication container and the appearance of the total product;

D. checking the patient's medication profile for possible therapeutic incompatibilities and the accuracy of the addition to the profile of the medication dispensed; and

E. initialing of the prescription by the pharmacist performing the certification.

Subp. 4. Exception. The provisions of this rule shall apply to all pharmacies. Provided, however, that nothing in this rule shall prevent pharmacists in hospitals from dispensing to hospital inpatients according to parts 6800.7100 to 6800.7950.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: 9 SR 1656; 10 SR 2007

6800.3110 PATIENT MEDICATION PROFILES.

Subpart 1. **System required.** A patient profile record system must be maintained in all pharmacies for persons for whom prescriptions are dispensed. The patient profile record system must be designed for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record may be maintained for all members of a family living at the same address and possessing the same family name.

Subp. 2. **Minimum information required.** The following information, at a minimum, must be recorded:

- A. the family name and the first name of the person for whom the medication is intended;
 - B. the address of the patient;
 - C. an indication of the patient's age group, such as infant, child, or adult;
- and

D. a list of all prescriptions obtained by the patient at the pharmacy maintaining the profile during the two years immediately preceding the most recent entry showing the prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber.

Subp. 3. **Recording allergies.** The pharmacist shall request from the patient or the patient's agent and shall record any allergies, idiosyncrasies, and chronic conditions of the patient and the identity of any other medications being taken by the patient which may relate to drug utilization. If there are none, this must be indicated on the profile.

Subp. 4. **Drug interactions.** Upon receiving a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potentially harmful interaction or reaction, the pharmacist shall take appropriate steps to avoid or minimize the problem which shall, if necessary, include consultation with the prescriber.

Subp. 5. **Duration of recordkeeping.** A patient profile record must be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be in a hard copy or a computerized form.

Subp. 6. **Certain profiles not required.** Patient profiles are not required in the following circumstances:

A. If a patient does not want a patient profile established, the patient shall state it in writing to the pharmacist. The pharmacist shall not then be required to prepare a profile as otherwise would be required by this part.

B. Hospital pharmacies serving only inpatients of the hospital are not required to prepare patient profiles for those patients being discharged or receiving discharge prescriptions.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

Subpart 1. **Authorization to dispense transferred prescription.** A prescription label, a written copy of the prescription, or a telephone report of a prescription from another pharmacy may be used for informational purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription from another pharmacist shall either contact the prescribing practitioner for authorization to dispense the prescription or shall comply with subparts 2 to 6.

Subp. 2. **Conditions of transfer.** A pharmacy may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.

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Subp. 3. Duties of transferring pharmacist. The transferring pharmacist shall:

- A. write the word "VOID" across the face of the original prescription to make the prescription invalid;
- B. record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and
- C. record the date of the transfer.

For controlled substances in Schedules III-V, parts 6800.4230 to 6800.4250, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.

Subp. 4. Duties of receiving pharmacist. The pharmacist receiving the transferred prescription information shall write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription, and shall provide all information required by law to be on a prescription, including:

- A. the date of issuance and of filling of the original prescription;
- B. the original number of refills authorized;
- C. the number of valid refills remaining;
- D. the date of last refill from original prescription;
- E. the original prescription number from which the prescription information was transferred; and
- F. the transferring pharmacy's name and address and, in the case of a controlled substance in Schedules III-V, parts 6800.4230 to 6800.4250, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

Subp. 5. Retention of prescription. The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

Subp. 6. Notice to patient of prescription invalidation. The pharmacist conferring with the patient at the time of the transfer request shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

Subp. 7. Computerized prescription recordkeeping system. A computerized prescription recordkeeping system must satisfy all the requirements of subparts 2 to 6 including invalidation of the original prescription. Pharmacies accessing a common electronic file or data base used to maintain required dispensing information are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however, that any such common file must contain complete records of each prescription and refill dispensed and further, that a hard copy record of each prescription transferred or accessed for purposes of refilling must be generated and maintained at the pharmacy refilling the prescription or to which the prescription has been transferred.

Subp. 8. Transfer of prescription by presentation of container. Except as provided in subpart 7, when the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by subparts 2 to 6 must be exchanged.

Subp. 9. Unprofessional conduct. The board shall consider it evidence of unprofessional conduct to reveal to others the nature of professional pharmaceutical services rendered to a patient without the express oral or written consent of the patient or without an order or direction of a court. A pharmacy may, however, provide informational copies of a prescription to another pharmacy or to the

person to whom the prescription was issued as provided in this part. A pharmacist may also provide drug therapy information to a physician for the patient.

The board shall consider it evidence of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is making a legal request for this information under this part.

Subp. 10. Schedule II controlled substances. Nothing in this part authorizes the transfer of a prescription for a Schedule II controlled substance. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3200 PREPACKAGING AND LABELING.

Subpart 1. Prepackaging. Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall cause to be prepared and kept a packaging control record containing the following information:

- A. date;
- B. identification of drug: name, dosage form, manufacturer, manufacturer's lot number, strength, and manufacturer's expiration date if any;
- C. container specification;
- D. copy of the label;
- E. initials of the packager;
- F. initials of the supervising pharmacist;
- G. quantity per container; and
- H. internal control number or date.

Subp. 2. Labeling. Each prepackaged container shall bear a label containing the following information:

- A. name of drug;
- B. strength;
- C. name of the manufacturer of the finished dosage form of the drug;
- D. manufacturer's expiration date if any, or any earlier date which, in the pharmacist's professional judgment, is preferable; and
- E. internal control number or date.

Statutory Authority: *MS s 151.06 subd 1*

6800.3300 BULK COMPOUNDING.

Subpart 1. Master formula record. Pharmacies may compound drugs in bulk quantities. Such drugs shall be compounded by or under the direct supervision of a pharmacist. For each drug product compounded in bulk quantities a master formula record shall be prepared containing the following information: name of the product; specimen or copy of label; list of ingredients and quantities; description of container used; and compounding instructions, procedures, and specifications.

Subp. 2. Production record. For each batch of drug product compounded a production record shall be prepared and kept containing the following information:

- A. a copy of the information on the master formula record;
- B. records of each step in the compounding process including: dates; identification of ingredients (including lot numbers); quantities of ingredients used; initials of person preparing each process; initials of pharmacist supervising each process; and a batch number.

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Subp. 3. **Total yield.** For each batch of drug product compounded, labels shall be prepared and affixed to each container containing the following information: identifying name or formula; dosage form; strength; quantity per container; internal control number or date; expiration date (if any); and auxiliary labels, as needed.

Statutory Authority: *MS s 151.06 subd 1*

6800.3400 PRESCRIPTION LABELING.

All drugs dispensed to or for a patient (other than an inpatient of a hospital) shall be labeled with the following information:

- A. name, address, and telephone number of pharmacy;
- B. patient's name;
- C. prescription number;
- D. name of prescribing practitioner;
- E. directions for use;
- F. name of manufacturer of the finished dosage form of the drug;
- G. auxiliary labels as needed;
- H. date of original issue or renewal; and

I. generic or trade name of drug and strength, except when specified by prescriber to the contrary. In the case of combining premanufactured drug products, the names of the products, or a category of use name shall suffice. In the case of compounding basic pharmaceutical ingredients, the common pharmaceutical name (if such exists), the names and strengths of the principle active ingredients or a category of use label shall suffice.

Statutory Authority: *MS s 151.06 subd 1; 151.212 subd 1*

6800.3500 [Renumbered 6800.4150]

6800.3550 SALE OF POISONS.

Sales of poisons or hazardous substances shall be made only by a licensed pharmacist or by a pharmacist-intern under the direct supervision of a pharmacist. Each such transaction shall be entered into a poison register with pen and each entry shall show the date and time of day, the name and quantity of substance, the proposed use, the name, address, and signature of the purchaser, and signature of the seller. No such substance shall be sold without the pharmacist first determining the propriety of the purported use and satisfying himself that such purchaser has produced proof of identity and legal age.

Economic poisons and simple proprietary preparations in the original manufacturer's container may be entered into the poison register pursuant to the above requirement if called for by the best professional judgment of the pharmacist.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.3600 [Renumbered 6800.3550]

6800.3650 LABELING OF POISONS.

All poisons sold, except when in the original manufacturer's container or on the written prescription of a licensed practitioner, shall bear a label containing the word "Poison," the name and quantity of the substance, and the name and business address of the seller. In addition the package labeling shall contain the following information in accordance with the Hazardous Substance Labeling Act:

- A. name of substance;
- B. the name and business address of the manufacturer or repackager;
- C. the word "POISON" in letters no smaller than the largest point on the label (for extremely dangerous substances this must be accompanied by the "skull and crossbones");

D. the word "Caution," "Warning," "Danger," or some such signal word of warning together with the specific indication necessitating its use;

E. the name and quantity of each toxic, poisonous, caustic, or corrosive constituent together with directions for treatment in case of accidental injury; and

F. the added warning "Keep Out of the Reach of Children."

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: 9 SR 1656; 10 SR 2007

6800.3700 [Renumbered 6800.3650]

6800.3750 UNIT DOSE DISPENSING.

Subpart 1. **Control.** A unit dose system shall be under the control of the pharmacist-in-charge. The act of drug dispensing is reserved for licensed pharmacists and registered pharmacist-interns acting under the supervision of licensed pharmacists, as set forth in part 6800.3100. A unit dose system may be used as an alternative to part 6800.3100, items D, F, and G, according to the following subparts.

Subp. 2. **Unit dose packaging.** Unit dose packaging is the packaging of individual doses of medication in containers which will preserve the identity and integrity of the drug from the point of packaging to the point of administration to the patient. Packaging may be accomplished by a manufacturer or by a pharmacy in accordance with part 6800.3200.

Individual doses of medication shall be properly labeled from the manufacturer with the name of the drug, dosage form and strength, manufacturer's name and lot number, and expiration date of all time dated drugs, or labeled in accordance with part 6800.3200 if prepackaged by the pharmacy.

Unit dose packaging may provide individual doses of medication attached to each other by placement in a card or other container. Such packaging shall be labeled in accordance with part 6800.3200 in such a manner as to provide continuous identification of the contents and, when dispensed, the name and location of the patient, name of the prescribing practitioner, prescription number, date, the directions for use, and identification of the pharmacy.

Subp. 3. **Unit dose system.** The unit dose system is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stocks from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled.

The system must provide and the pharmacist must utilize:

A. a means of separating medications by patient name and bed number;

B. a means of separating medications by day of administration;

C. a means of identifying individual doses dispensed, doses administered, and doses returned;

D. a means of identifying the dosage regimen of each drug, including the date of the original order and the date of changes, if any, in the prescriber's drug order;

E. a means of identifying the total dosage regimen of each patient;

F. a means of identifying the time of administration of each drug;

G. a means for the pharmacist to verify the original prescriber's order;

and

H. a means for the pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient.

Subp. 4. **Written policies.** Each pharmacy utilizing a unit dose dispensing system shall establish written policies specifying the categories of drugs which

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will or which will not be dispensed under the unit dose distribution system. Such policies shall be available in the pharmacy for inspection by the board.

Subp. 5. Unit dose preferred. Proper utilization of the unit dose system requires that in as far as is practicable all medications be in unit dose packaging when dispensed.

Subp. 6. Controlled substances. Schedule II, III, and IV controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

Subp. 7. Legend drugs. Legend drugs not dispensed under the unit dose dispensing system must be dispensed in accordance with part 6800.3100 and labeled in accordance with parts 6800.3400 and 6800.4150.

Subp. 8. Who may perform. Selection of individual unit dose packaging for placement in individual patient containers, bins, compartments, or drawers is not dispensing under part 6800.3100, and may be performed by supportive personnel. Dispensing occurs upon the certification of the accuracy of the selected unit dose packages, which shall be done by the pharmacist before the dose is delivered for administration to the patient.

Subp. 9. Storage. All medication shall be stored in a locked area or locked cart.

Subp. 10. Compliance. Unit dose system shall comply with existing law with respect to provisions of pharmaceutical services to hospitals and nursing homes and as set forth in parts 6800.6100 to 6800.7950.

Statutory Authority: *MS s 151.06 subd 1*

History: *9 SR 1656*

6800.3800 [Renumbered 6800.3750]

6800.3850 SUPPORTIVE PERSONNEL.

Subpart 1. Nonspecified tasks. Supportive personnel may be used in performing pharmacy tasks not specifically reserved in these rules to a licensed pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

Subp. 2. Permissible duties. Supportive personnel may perform functions which do not involve professional pharmaceutical judgment.

Subp. 3. Certifying. Pharmaceutical products prepared by supportive personnel must be certified for accuracy by a licensed pharmacist, as provided for in part 6800.3100, item F, prior to release for patient use.

Subp. 4. Written procedures. Written procedures for the use of supportive personnel shall be prepared by the pharmacist-in-charge, shall be submitted to the board, and a copy shall be kept on file in the pharmacy. These procedures must comply with the standards set forth in this rule and will be approved on that basis. Approval must be obtained prior to implementation of the procedures.

These procedures shall indicate in detail the tasks performed by the supportive person and the certification steps performed by the licensed pharmacist. New procedures or changes in procedures shall be submitted to the board for approval as specified above.

The submitted procedures shall be automatically approved 90 days after receipt by the board unless the pharmacist-in-charge is notified by the board of the specific reasons the procedures are unacceptable.

Subp. 5. Supervision. Supportive personnel shall be supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the action of the supportive person.

Subp. 6. Ratios. The basic ratio of supportive personnel allowed by this rule to work with one pharmacist shall be 1:1. Specific functions shall be excepted from the 1:1 ratio as follows:

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- 3:1;
- A. intravenous admixture preparation (parts 6800.7510 to 6800.7530), 3:1;
 - B. unit dose dispensing (part 6800.3750), 3:1;
 - C. prepackaging (part 6800.3200), 3:1; and
 - D. bulk compounding (part 6800.3300), 3:1.

Subp. 7. **Persons not included.** Personnel used solely for clerical duties such as typing, looking up refills, filing prescriptions, record keeping, etc. need not be included in the ratios of the functions performed by supportive personnel.

A pharmacist-intern submitting hours toward completion of the 1,500-hour requirement is not considered a supportive person for the purpose of determining the number of supportive persons supervised by a licensed pharmacist.

Subp. 8. **Petition for different ratio.** A pharmacist-in-charge of any pharmacy may petition the board for use of supportive personnel in ratios in excess of those allowed under these rules or for functions not specified in these rules. This petition for the use of additional personnel must be based on evidence that patient care and safety is maintained. The burden of persuasion is on the pharmacist-in-charge. Such a petition shall be automatically approved 90 days after receipt by the board unless the board shall send to the pharmacist-in-charge notification of the specific reasons why the petition is unacceptable.

Subp. 9. **Penalty.** The use of supportive personnel in the performance of delegated tasks not included in approved written procedures may be considered to be unprofessional conduct on the part of the pharmacist supervising the supportive personnel and the pharmacist-in-charge.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.3900 [Renumbered 6800.3850]

6800.3950 ELECTRONIC DATA PROCESSING.

Subpart 1. **Entering orders.** When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed by a physician or a pharmacist. If orders are entered by other personnel the pharmacist must certify the accuracy of the information entered and verify the prescription order prior to the dispensing of the medication. The identity of the person entering the order and the pharmacist verifying the order must be retained in the record.

Subp. 2. **Minimum requirements.** Electronic data processing equipment, when used to store prescription information, must:

- A. guarantee the confidentiality of the information contained in the data bank;
- B. be capable of producing a hard copy daily summary of controlled substance transactions;
- C. be capable of recording and carrying in the record all dates of refills of any prescription and initials of the pharmacist which shall act in lieu of the requirements of part 6800.3100, item G (initials);
- D. be capable of producing a patient profile indicating all drugs being taken and the dates of refills of these prescriptions; and
- E. be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank.

Subp. 3. **Original prescription retained.** In all cases where electronic data processing equipment is used the original prescription must be retained on file according to law to assure access to the information contained thereon in the event of a computer breakdown.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

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6800.4000 [Renumbered 6800.3950]

6800.4050 DRUG IDENTIFICATION.

Subpart 1. **Minimum requirement.** The finished dosage form of any legend drug in solid oral dosage form manufactured, packaged, or distributed for sale in this state after January 1, 1983, shall be clearly marked or imprinted with a symbol, number, name, word, letter, national drug code number, or other mark identifying the drug and the manufacturer or distributor of the drug.

Subp. 2. **Imprints.** Each manufacturer and distributor shall publish and provide to the board printed material which will identify each imprint or mark currently used by the manufacturer or distributor. The board shall also be notified of any changes in the published list.

Subp. 3. **Exemptions.** Drug manufacturers, packagers, or distributors seeking an exemption from the requirements of subpart 1 or 2 shall submit to the board a documentation of facts related to the product which would make impractical compliance with the imprinting required by Minnesota Statutes, section 151.361, subdivision 2. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

Statutory Authority: *MS s 152.02*

History: *9 SR 1656*

6800.4100 [Renumbered 6800.4050]

CONTROLLED SUBSTANCES

6800.4150 LABELING OF CONTROLLED SUBSTANCES AND CERTAIN OTHER DRUGS.

All drugs administered systemically as controlled substances under Minnesota Statutes, chapter 152 and parts 6800.4200 to 6800.4250, antihistamines, psychotherapeutic agents, and other drugs deemed appropriate in the professional judgment of the pharmacist and dispensed to or for an adult patient (other than an inpatient of a hospital or nursing home) shall be labeled according to the requirements of part 6800.3400 and in addition shall contain the following:

“Caution: Taking this drug alone or with alcohol may impair your ability to drive.”

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *9 SR 1656*

6800.4200 INCLUSIONS AND EXCEPTIONS.

Subpart 1. **Substances included.** The substances in parts 6800.4210 to 6800.4250 are, because of their potential for abuse, defined and controlled in the following schedules and are, therefore, subject to the provisions of Minnesota Statutes, chapter 152.

Subp. 2. **Exceptions.** Drugs which are not required by federal law to bear any one of the following symbols, C-I, C-II, C-III, C-IV, or C-V, I, II, III, IV, or V, are exempt from the provisions of Minnesota Statutes, section 152. Provided, however, that drugs containing any quantity of phenobarbital shall be dispensed only on prescription.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *9 SR 1656*

6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this part.

A. Opiates. Unless specifically excepted or unless listed in another

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schedule, any of the following opiates, including their isomers (whether optical, positional, or geometric), esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, or salts is possible within the specific chemical designation:

- (1) Acetylmethadol;
- (2) Alfentanil;
- (3) Allylprodine;
- (4) Alphacetylmethadol;
- (5) Alphameprodine;
- (6) Alphamethadol;
- (7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);
- (8) Benzethidine;
- (9) Betacetylmethadol;
- (10) Betameprodine;
- (11) Betamethadol;
- (12) Betaprodine;
- (13) Clonitazene;
- (14) Dextromoramide;
- (15) Diampromide;
- (16) Diethylthiambutene;
- (17) Difenoxin;
- (18) Dimenoxadol;
- (19) Dimepheptanol;
- (20) Dimethylthiambutene;
- (21) Dioxaphetyl butyrate;
- (22) Dipipanone;
- (23) Ethylmethylthiambutene;
- (24) Etonitazene;
- (25) Etoxeridine;
- (26) Furethidine;
- (27) Hydroxypethidine;
- (28) Ketobemidone;
- (29) Levomoramide;
- (30) Levophenacylmorphan;
- (31) MPPP; 1-Methyl-4-Phenyl-4-Propionoxypiperidine
- (32) Methyl substituted isomers of Fentanyl;
 - (a) 3-Methylfentanyl; N-[3-Methyl-a-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide
 - (b) Acetyl-alpha-methylfentanyl; N-[1-(Methyl-2-phenyl)ethyl-4-piperidyl]-N-phenylacetamide
 - (c) Alpha-methylthiofentanyl; N-[1-benzyl-4-piperidyl]-N-phenylpropanamide
 - (d) Benzylfentanyl; N-[1-benzyl-4-piperidyl]-N-phenylpropanamide
 - (e) Beta-hydroxyfentanyl; N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide
 - (f) Beta-hydroxy-3-Methylfentanyl; N-[3-Methyl-1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide

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(g) 3-Methylthiofentanyl; N-[3-Methyl-1-(2-(2-thienyl)ethyl)-4-piperidyl]-N-phenylpropanamide

(h) Thenyfentanyl; N-[1-(2-thienyl)Methyl-4-piperidyl]-N-phenylpropanamide

(i) Thiofentanyl; N-[1-(2-(2-thienyl)ethyl)-4-piperidyl]-N-phenylpropanamide

(j) N-[1-(2-phenylethyl)-4-piperidyl]-N-(4-fluorophenyl)-propanamide (para-fluorofentanyl), its optical isomers, salts and salts of isomers

(33) Morpheridine;

(34) Noracymethadol;

(35) Norlevorphanol;

(36) Normethadone;

(37) Norpipanone;

(38) PEPAP; 1-(2-Phenylethyl)-4-Phenyl-4-Acetyloxypiperidine

(39) Phenadoxone;

(40) Phenampromide;

(41) Phenomorphan;

(42) Phenoperidine;

(43) Piritramide;

(44) Proheptazine;

(45) Properidine;

(46) Propiram;

(47) Racemoramide;

(48) Tilidine; and

(49) Trimeperidine.

B. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Acetylcodone;

(4) Benzylmorphine;

(5) Codeine methylbromide;

(6) Codeine-N-Oxide;

(7) Cyprenorphine;

(8) Desomorphine;

(9) Dihydromorphine;

(10) Drotebanol;

(11) Etorphine (except hydrochloride salt);

(12) Heroin;

(13) Hydromorphanol;

(14) Methyldesorphine;

(15) Methylhydromorphine/Methyldihydromorphine;

(16) Morphine Methylbromide;

(17) Morphine Methylsulfonate;

(18) Morphine-N-Oxide;

(19) Myrophine;

(20) Nicocodeine;

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- (21) Nicomorphine;
- (22) Normorphine;
- (23) Pholcodine; and
- (24) Thebacon.

C. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers (whether optical, positional, or geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) 4-Bromo-2,5-Dimethoxyamphetamine	4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA
(2) 2,5-Dimethoxyamphetamine	2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA
(3) 4-Methoxyamphetamine	4-methoxy-a-Methylphenethylamine; paramethoxyamphetamine, PMA
(4) 5-Methoxy-3,4-Methylenedioxyamphetamine	MMDA
(5) 4-Methyl-2,5-Dimethoxyamphetamine	4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP"
(6) 3,4-Methylenedioxy Amphetamine	MDA
(7) 3,4-Methylenedioxymethamphetamine	MDMA
(8) 3,4,5-Trimethoxy Amphetamine	TMA
(9) Bufotenine	3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(10) Diethyltryptamine	N,N-Diethyltryptamine; DET
(11) Dimethyltryptamine	DMT
(12) Ibogaine	7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga
(13) Lysergic acid diethylamide	LSD
(14) Marijuana	
(15) Mescaline	
(16) Parahexyl	3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl
(17) Peyote	
Meaning all parts of	

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- the plant presently
classified botanically
as *Lophophora williamsii*
Lemaire, whether growing
or not, the seeds thereof,
any extract from any part
of such plant, and every
compound, manufacture,
salt, derivative,
mixture, or preparation
of such plant, its
seeds or extracts
- (18) N-ethyl-3-piperidyl
Benzilate JB-318
- (19) N-methyl-3-piperidyl
Benzilate JB-336
- (20) Psilocybin
- (21) Psilocyn
- (22) Tetrahydrocannabinols THC
Synthetic equivalents
of the substances
contained in the plant,
or in the resinous
extractives of
cannabis, sp. and/or
synthetic substances,
derivatives, and their
isomers with similar
chemical structure
and pharmacological
activities such as
the following:
1 cis or trans
tetrahydrocannabinol,
and their optical
isomers, excluding
dronabinol in sasame oil
and encapsulated in a
soft gelatin capsule in
a drug product approved
by the U.S. Food and Drug
Administration.
6 cis or trans
tetrahydrocannabinol, and
their optical isomers;
3,4 cis or trans
tetrahydrocannabinol,
and its optical isomers
(Since nomenclature of
these substances is not
internationally
standardized, compounds
of these structures,
regardless of numerical
designation of atomic
positions covered.)
- (23) Ethylamine analog of N-ethyl-1-

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phencyclidine	phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(24) Pyrrolidine analog of phencyclidine	1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(25) Thiophene analog of phencyclidine	1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP

D. Peyote. The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church; and members of the Native American Church, however, are required to obtain federal registration annually and to comply with all other requirements of law.

E. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system including its salts, isomers, and salts of isomers:

- (1) Mecloqualone;
- (2) Methaqualone.

F. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

- (1) Fenethylamine;
- (2) N-ethylamphetamine.

Statutory Authority: *MS s 151.06 subd 1 para (9); 152.02 subds 7,8*

History: *9 SR 1656; 11 SR 1113*

6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

The following items are listed in schedule II:

A. Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this part.

B. Substances, vegetable origin, or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

Statutory Name

Some examples of common names, trade names, or names of products which contain a controlled substance.

- (a) Raw opium
- (b) Opium extracts
- (c) Opium fluidextracts
- (d) Powdered opium
- (e) Granulated opium

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- | | |
|---|---|
| <ul style="list-style-type: none"> (f) Tincture of opium (g) Codeine (h) Ethylmorphine (i) Etorphine hydrochloride (j) Hydrocodone (k) Hydromorphone (l) Metopon (m) Morphine (n) Oxycodone
 (o) Oxymorphone
 (p) Thebaine | <ul style="list-style-type: none"> Laudanum Methylmorphine Dionin
 Dihydrocodeinone Dihydromorphone, Dilaudid
 Chlor-Anodyne Dihydrohydroxycodeinone,
Percodan, Nucodan Dihydrohydroxymorphone,
Numorphan |
|---|---|

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subitem (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, cocaine compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

C. Opiates. Unless specifically excepted or unless listed in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

Statutory Name

Some examples of common names, trade names, or names of products which contain a controlled substance.

- | | |
|---|--|
| <ul style="list-style-type: none"> (1) Alphaprodine (2) Anileridine (3) Bezitramide (4) Bulk Dextropropoxyphene
(nondosage forms) (5) Dihydrocodeine (6) Dihydromorphone (7) Diphenoxylate (8) Fentanyl (9) Isomethadone (10) Levomethorphan (11) Levorphanol (12) Metazocine (13) Methadone
 (14) Methadone-Intermediate
4-cyano-2-dimethylamino-4,
4-diphenylbutane (15) Moramide-Intermediate
2-methyl-3-morpholino-1, | <ul style="list-style-type: none"> Nisentil Leritine
 Paracodin Dilaudid
 Sublimaze, Innovar
 Levo-Dromoran
 Dolophine, Amidone,
Adanon |
|---|--|

- or preparation containing:
 - (a) Amobarbital;
 - (b) Secobarbital;
 - (c) Pentobarbital, or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
- (2) Any suppository dosage form containing:
 - (a) Amobarbital;
 - (b) Secobarbital;
 - (c) Pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
- (3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically excepted or listed in other schedules:
- (4) Chlorhexadol
- (5) Glutethimide
- (6) Lysergic acid
- (7) Lysergic acid amide
- (8) Methyprylon
- (9) Sulfondiethylmethane
- (10) Sulfonethylmethane
- (11) Sulfonmethane

Butobarbital,
 Vinbarbital,
 Delvinal, Talbutal,
 Lotusate,
 Pentothal, Brevital

Doriden

Noludar

D. Nalorphine

Nalline

E. Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium: Copavin.

(2) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cheracol, Elixir, Terpin Hydrate and Codeine, Cosadein, Prunicodeine, Robitussin A.C.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Ambenyl, Tussend, Hycomine, Tussionex.

(5) Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

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(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cidicol.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Paregoric, Camphorated Opium Tincture.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

Statutory Authority: *MS s 151.06 subd 1 cl (9); 152.02*

History: *9 SR 1656*

6800.4240 SCHEDULE IV CONTROLLED SUBSTANCES.

The following items are listed in schedule IV:

A. Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this part.

B. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) Not more than one milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane), for example, Darvon, Darvocet.

C. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Statutory Name

Some examples of common names, trade names, or names of products which contain a controlled substance.

(1) Alprazolam	Xanax
(2) Barbitol	Barbitone
(3) Bromazepam	
(4) Camazepam	
(5) Chloral betaine	Beta-Chlor
(6) Chloral hydrate	Noctec, Somnos
(7) Chlordiazepoxide	Librium, Libritabs
(8) Clobazam	
(9) Clonazepam	Clonopin
(10) Clorazepate	Tranxene
(11) Clotiazepam	
(12) Cloxazolam	
(13) Delorazepam	
(14) Diazepam	Valium
(15) Estazolam	
(16) Ethchlorvynol	Placidyl
(17) Ethinamate	Valmid
(18) Ethyl Loflazepate	
(19) Fludiazepam	

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(20) Flunitrazepam	
(21) Flurazepam	Dalmane
(22) Halazepam	Paxipam
(23) Haloxazolam	
(24) Ketazolam	
(25) Loprazolam	
(26) Lorazepam	Ativan
(27) Lormetazepam	
(28) Mebutamate	
(29) Medazepam	
(30) Meprobamate, except when in combination with the following drugs in the following or lower concentrations: conjugated estrogens 0.4 mg tridihexethyl chloride 25 mg pentaerythritol tetranitrate 20 mg	Equanil, Miltown, Equagesic, Equalysen
(31) Methohexital	Brevital
(32) Methylphenobarbital	Mebral, Mephobarbital
(33) Midazolam	
(34) Nimetazepam	
(35) Nitrazepam	
(36) Nordiazepam	
(37) Oxazepam	Serax
(38) Oxazolam	
(39) Paraldehyde	Paral
(40) Petrichloral	Periclor
(41) Phenobarbital	Luminal, Phenobarbitone, Eskabarb
(42) Pinazepam	
(43) Prazepam	Centrax
(44) Quazepam	
(45) Temazepam	Restoril
(46) Tetrazepam	
(47) Triazolam	Halcion

D. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
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(1) Fenfluramine	Pondamin
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E. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
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(1) Diethylpropion	Tenuate, Tepanil
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- | | |
|--|-------------------------|
| (2) Mazindol | Sanorex |
| (3) Pemoline (including organometallic complexes and chelates thereof) | Cylert |
| (4) Phentermine | Wilpro, Fastin, Ionamin |
| (5) Pipradrol | |
| (6) SPA ((-)-1-dimethylamino-1, 2-diphenylethane) | |

F. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

Statutory Name

Some examples of common names, trade names, or names of products which contain a controlled substance

- | | |
|-----------------|--------|
| (1) Pentazocine | Talwin |
|-----------------|--------|

Statutory Authority: *MS s 151.06 subd 1 para (9); 152.02 subds 7,8*

History: *9 SR 1656; 11 SR 1113*

6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The following items are listed in schedule V:

A. Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this part.

B. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine

C. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

Statutory Names

Some examples of common names, trade names, or names of products which contain a controlled substance.

(1) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(3) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

Lomotil

(4) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

Parapectolin,
Donnagel P.G.

(5) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

Statutory Authority: *MS s 151.06 subd 1 para (9); 152.02 subds 7,8*

History: *9 SR 1656; 11 SR 1113*

6800.4300 DISPENSING SCHEDULE II CONTROLLED SUBSTANCES FOR PATIENTS IN LONG-TERM CARE FACILITIES.

Subpart 1. **Authorization.** Prescriptions for schedule II controlled substances written for patients in long-term care facilities may be dispensed in partial quantities, including individual dosage units.

Subp. 2. **Records.** For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate record uniformly maintained and readily retrievable, the date of the partial dispensing, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

Subp. 3. **Quantity dispensed.** The total quantity of schedule II controlled substances dispensed in all partial dispensings must not exceed the total quantity prescribed.

Subp. 4. **Validity of prescription.** Schedule II prescriptions for patients in a long-term care facility shall be valid for a period not to exceed 60 days from the issue date unless terminated sooner by the discontinuance of medication.

Subp. 5. **Computerization of information.** Information pertaining to current schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized recordkeeping system if the system has the capability to permit:

A. output by display or printout of the original prescription number; date of issue; identification of prescribing individual practitioner; identification of patient; identification of long-term care facility; identification of medication authorized, including dosage form, strength, and quantity; listing of partial dispensings that have been dispensed under each prescription; and the information required in subpart 2;

B. immediate or real time updating of the prescription record each time a partial dispensing of the prescription is conducted; and

C. retrieval of partially dispensed schedule II prescription information, the same as required by federal law for schedule III and IV prescription refill information.

Statutory Authority: *MS s 152.02*

6800.4400 REGISTRATION OF CONTROLLED SUBSTANCE RESEARCHERS.

Subpart 1. **Application; fee; permit.** Every person who engages in research, teaching, or educational projects involving the use, study, or testing of controlled substances shall annually, on or before June 1 of each year, apply for registration by the board. Upon the filing of an application therefor, and upon payment of the fee of \$25, the board shall issue a permit.

Subp. 2. **Exemption.** Registration under subpart 1 shall not be required of any physician conducting research involving controlled substances who is other-

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wise licensed by the state and who has complied with federal laws covering research projects of controlled substances.

Statutory Authority: *MS s 152.02*

6800.4500 CONTROLLED SUBSTANCE SAMPLES.

A manufacturer, distributor, or agent of a manufacturer or distributor of a controlled substance as defined in Minnesota Statutes, section 152.01, subdivision 4 or parts 6800.4200 to 6800.4250, may not distribute controlled substance samples directly or by other means without charge or at a charge below fair market value unless a practitioner signs a written request for a designated quantity of the controlled substance. The request must also indicate that the controlled substance is to be distributed to the practitioner by the manufacturer, distributor, or agent or distributed to a pharmacist for dispensing to a patient.

Statutory Authority: *MS s 152.02*

INTERNSHIP

6800.5100 DEFINITIONS.

Subpart 1. Approved clinical program. "Approved clinical program" means a clinical program approved by the Internship Advisory Committee and the board of pharmacy, which is a patient-oriented instructional program involving actual patient contact activities including, but not limited to, patient rounds, medication histories, patient drug education, and clinical conferences.

Subp. 2. Approved externship program. "Approved externship program" means an undergraduate program of practical experience administered by a college of pharmacy approved by the board.

Subp. 3. Concurrent time. "Concurrent time" means internship experience gained during the fourth and fifth academic years only, while a person is a full-time student carrying, in any given school term, at least 75 percent of the average number of credit hours per term needed to graduate within five years.

Subp. 4. Hour. "Hour" means the standard 60-minute division of time.

Subp. 5. Intern; pharmacist-intern. "Pharmacist-intern" and "intern" mean:

A. a natural person satisfactorily progressing toward the degree in pharmacy required for licensure;

B. a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the board of pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

C. a qualified applicant awaiting examination for licensure.

Subp. 6. Preceptor. "Preceptor" means a natural person licensed as a pharmacist by the board of pharmacy, and who participates in instructional programs approved by the board.

Subp. 7. Quarter. "Quarter" means that amount of internship time gained during a three-month period of time, but not to exceed 700 hours.

Subp. 8. Supervision. "Supervision," as used in connection with parts 6800.5100 to 6800.5600, means that in the pharmacy where the intern is being trained, a registered pharmacist designated as preceptor or another registered pharmacist shall be in continuous personal contact with and actually giving instructions to the intern during all professional activities of the entire period of his internship.

Statutory Authority: *MS s 151.06 subd 1; 151.101*

6800.5200 INTERNSHIP.

The purpose of parts 6800.5100 to 6800.5600 is to define and regulate the internship experience of prospective pharmacists as required by Minnesota Statutes, sections 151.10 and 151.101. These rules shall take effect immediately

but the provisions contained herein shall not nullify any period of internship service by any individual previous to its adoption provided such period of internship is filed in a proper manner with the secretary of the board of pharmacy

Statutory Authority: MS s 151.06 subd 1; 151.101

6800.5300 REGISTRATION AND REPORTING.

Subpart 1. Registration. Every person shall register with the board before beginning his internship in this state. Applications for the registration of a pharmacist-intern shall be on such form or forms as the board of pharmacy may from time to time prescribe and shall be accompanied by a fee of \$20. Registration shall remain in effect during successive quarters of internship training if progress reports, examinations, and affidavits of experience as required by the board are submitted promptly upon beginning or terminating employment, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy. Credit for internship time will not be granted unless registration, progress reports, and affidavits of experience for preceding time are completed and received.

Subp. 2. Identification. The pharmacist-intern shall be so designated in his professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall upon proper registration issue to the intern a pocket registration card for purposes of identification and verification of his role as an intern, which card shall be surrendered to the secretary of the board upon termination of the internship program.

Subp. 3. Change of address. All registered interns shall notify the board immediately upon change of employment or residence address.

Subp. 4. Records of professional activities. The intern may be required to maintain additional records of his professional activities. The records, which shall be submitted after the completion of each quarter of internship, are to be prescribed by the board for the purpose of recording details of the scope of internship experience and may include examinations to test the competency of interns.

Subp. 5. Examinations. Examinations shall be administered approximately quarterly at times and locations as the board may designate. These examinations shall be of a pretest and posttest nature bracketing such segments of the intern's experience as the board deems appropriate. Interns will be required to attain a score of 75 percent on the posttest examination as verification of having met the minimum objectives of an internship before qualifying to sit for the examination for licensure as a pharmacist.

Subp. 6. Termination. No person who terminates his efforts toward the completion of the educational or other prerequisites of licensure is entitled to the continued privileges of internship registration.

Subp. 7. Improper use of title. No person not properly registered with the board as a pharmacist-intern shall take, use, or exhibit the title of pharmacist-intern, pharmacist-apprentice, pharmacist-extern, or any other term of similar or like import.

Statutory Authority: MS s 151.06 subd 1; 151.101

6800.5400 TRAINING.

Subpart 1. Intent. The intent of this rule is to provide a proper preceptor-intern (teacher-student) relationship within the context of the employer-employee relationship, provide a broad base of internship experience, and supplement didactic academic training in a manner which prepares the intern for all aspects of the practice of pharmacy.

Subp. 2. Nonreciprocity. Nothing in this rule shall imply that the standards described herein are acceptable to other states on a reciprocal basis.

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Subp. 3. Training in other state. When an intern desires to obtain credit for training received in a state other than Minnesota, he shall abide by all the provisions of the internship rules in that state, and shall provide evidence from the state's board of pharmacy that his internship training has been completed in compliance with the internship standards of the National Association of Boards of Pharmacy and with the standards herein provided. Where a possible conflict may exist between the provisions of this rule and the requirements of the state in which the intern is training the intern shall contact the secretary of the state board of pharmacy in his state and outline any possible problem.

Subp. 4. Maximum trainees. No more than one intern shall be trained by a preceptor at one time.

Subp. 5. Guides and objectives. Upon registration, interns and preceptors will be furnished guides and objectives for internship training. The guides are furnished to suggest appropriate types and order of training experience and shall be used to ensure that the intern's practical experiences are commensurate with his educational level, and broad in scope.

Subp. 6. Evidence of completion. Applicants for licensure as pharmacists who are examined and licensed after September 17, 1973, shall submit evidence that they have successfully completed not less than 1,500 hours of internship under the instruction and supervision of a preceptor. Credit for internship shall be granted only to registered interns who have completed the third year of the five-year pharmacy curriculum, provided, however, that:

A. 400 hours of internship credit may be acquired by any combination of the following: internship experience gained concurrent with attendance at a college of pharmacy during the fourth and fifth year, or participation in approved clinical pharmacy programs or approved internship demonstration projects; and

B. not more than 700 hours of internship credit may be given during any internship quarter.

Statutory Authority: *MS s 151.06 subd 1; 151.101*

6800.5500 RECIPROCITY STANDARDS.

The board may accept internship credit from applicants for licensure by reciprocity who have submitted evidence of completion of internship training in another state, provided that the training is, in the opinion of the board, substantially equivalent to the standards herein provided, and is in compliance with the internship standards of the National Association of Boards of Pharmacy, and provided, further, that the applicant has practiced pharmacy for one year prior to being examined for licensure in this state pursuant to the requirements of part 6800.1300.

Statutory Authority: *MS s 151.06 subd 1; 151.101*

History: *9 SR 1656*

6800.5600 ADVISORY COMMITTEE.

The board shall appoint an advisory committee on internship to advise the board on the administration of parts 6800.5100 to 6800.5600. The committee shall include practicing pharmacists, pharmacist-educators, pharmacy-interns, and representatives of the board.

Statutory Authority: *MS s 151.06 subd 1; 151.101*

OPERATIONS IN LONG-TERM CARE FACILITIES

6800.6100 SCOPE.

The provisions of parts 6800.6100 to 6800.6700 are applicable to pharmaceutical services provided to patients in long-term care facilities, provided, however, that parts 6800.0100 to 6800.5600 shall also be applicable to such pharmaceutical services, unless specifically exempted by parts 6800.6100 to

6800.6700 or are in direct conflict therewith, in which case parts 6800.6100 to 6800.6700 shall apply.

Statutory Authority: *MS s 151.06 subd 1*

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

Subpart 1. Transmitting orders. Notwithstanding any other provisions of parts 6800.0100 to 6800.9700, a licensed pharmacist, registered nurse, or licensed practical nurse who is employed by a duly licensed skilled care, intermediate care, or other licensed health care facility, and who is authorized by the facility's administrator, may transmit to the pharmacy provider a prescription lawfully ordered by a practitioner authorized to prescribe drugs or devices pursuant to Minnesota Statutes, section 151.37. The pharmacy provider shall record on the prescription the name of the person who transmits the order in addition to the other required information. This subpart shall not apply to orders for schedule II controlled substances as defined by part 6800.4220.

Subp. 2. Written orders. Orders in subpart 1 may be in writing or, except for schedule II controlled substances, an oral order reduced to writing by the pharmacist, and may include authorization for multiple refills consistent with good practice and legal limitations. A facsimile copy of the prescriber's medication order may be accepted and filed as a prescription by the pharmacy.

Subp. 3. Schedule II orders. Schedule II controlled substances shall be dispensed only upon receipt of an original written order signed by the prescribing individual practitioner or upon an oral order reduced to writing given in emergency situations as allowed by these criteria:

A. immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;

B. no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of Minnesota Statutes, section 152 and parts 6800.4200 to 6800.4250; and

C. it is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the person dispensing the substance, prior to dispensing.

Statutory Authority: *MS s 151.06 subd 1*

6800.6300 PRESCRIPTION LABELING.

Subpart 1. Minimum information. All prescription containers, other than those dispensed pursuant to part 6800.3750, shall be properly labeled in accordance with part 6800.3400 and shall also contain at least the following information: quantity of drug dispensed; date of original issue, or in the case of a refill, the most recent date thereof; and expiration date of all time dated drugs.

Subp. 2. Directions for use. Directions for use on labels of medications shall be changed only by a pharmacist acting on the instructions of the prescriber or his agent. Such medications shall be returned to the pharmacist provider to be so relabeled or a pharmacist shall relabel such medications at the facility.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.6400 LABELING INSULIN.

Insulin shall be dispensed with a label affixed to the vial showing at least the patient's full name and location.

Statutory Authority: *MS s 151.06 subd 1*

6800.6500 CONSULTATIVE SERVICES TO LONG-TERM CARE FACILITIES.

Subpart 1. Written agreement. A pharmacist providing pharmacy consulta-

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tive services to a long-term care facility shall devote a sufficient number of hours during regularly scheduled visits to the long-term care facility for the purpose of reviewing the quality of the pharmaceutical services provided to the long term care facility residents. There shall be a written agreement, separate and apart from that provided to pharmacists supplying prescription drug services to residents, for such pharmaceutical consultative services between the facility and the pharmacist which shall be available for review by the board.

Subp. 2. Responsibilities. The pharmacist shall be responsible for but not limited to the following:

A. preparation and revision of policies and procedures governing the pharmaceutical services;

B. development, coordination, and direction or supervision of all pharmaceutical services provided in the facility;

C. review of the drug regimen of each resident and preparation of appropriate reports and recommendations. This shall include at least a review of all drugs currently ordered; information concerning the patient's condition as it relates to drug therapy; and medication administration records and, where appropriate, physician progress notes, nurses' notes, and laboratory test results;

D. reporting, in writing, irregularities in the storage, dispensing, and administration of drugs and other matters relating to the review of the drug regimen, to the administrator, and other appropriate health professionals as may be determined by the administrator and consultant pharmacist;

E. preparing, at least quarterly, a written report on the status of the pharmaceutical service and staff performance and submitting this report to the administrator and patient care policy committee and/or the pharmaceutical services committee;

F. developing policies for destroying, in the prescribed manner, any unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued; and

G. providing in-service training to nursing personnel.

Subp. 3. Unused portions. Unused portions of controlled substances shall be handled by contacting the Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the facility for two years.

Any other unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued shall be destroyed by the facility in the presence of a pharmacist or registered nurse who shall witness such destruction or shall be handled in accordance with part 6800.2700.

The drugs shall be destroyed by flushing them into the sewer system or by incineration.

Statutory Authority: *MS s 151.06 subd 1*

6800.6600 FREEDOM OF CHOICE.

No pharmacist shall participate in any agreement or plan which infringes on any patient's right to freedom of choice as to the provider of prescription services.

Statutory Authority: *MS s 151.06 subd 1*

6800.6700 DRUGS FOR USE IN EMERGENCY KITS.

Subpart 1. Authorization upon request. Pharmacists may provide, upon a written or oral request from a licensed practitioner, limited supplies of drugs for use in an emergency kit.

Subp. 2. Emergency drug supplies. Only emergency drug supplies determined

by the patient care policy committee or pharmaceutical service committee to be necessary for patient care in life threatening emergencies may be made available. The drugs in the emergency kit are the responsibility of the pharmacist and, therefore, shall not be used or altered in any way except as outlined herein. The emergency drug supplies shall comply with the following:

A. The drugs shall be limited to the extent possible to a maximum of six single doses of any one emergency drug in either sealed ampuls, vials, or prefilled syringes. If an emergency drug is not available in parenteral form, a supply of the drug in inhalation or sublingual form may be obtained in the smallest sealed manufacturer's package. Inclusion of other oral legend drugs is discouraged. All drugs in this supply shall be properly labeled.

B. The emergency drug supply shall be stored in a portable container which is sealed with a tamper-proof seal that must be broken to gain access to the drugs, and shall be placed in a locked area.

C. The pharmacist shall be notified by the health care facility when drugs from the emergency kit have been used or when the seal has been broken.

D. Drugs used from the kit shall be replaced within 72 hours and the supply shall be resealed.

E. The pharmacist shall see that the contents of the kit are accurately listed on the container.

F. The supply shall be checked and inventoried monthly by the pharmacist who is responsible for control of the kit.

Subp. 3. Controlled substances. Emergency kits may contain limited supplies of controlled substances only if:

A. the controlled substances are supplied by a licensed pharmacy duly registered with the Federal Drug Enforcement Administration;

B. the emergency kit is kept in a locked medicine room or medicine cabinet;

C. access to the emergency kit is limited to the following individuals:

(1) a licensed professional nurse who is employed by the facility and who has been directed by a physician to administer a drug from the kit;

(2) a consultant pharmacist or other licensed pharmacist designated by the facility's pharmaceutical services committee; or

(3) a licensed medical practitioner;

D. the emergency kit does not contain more than six single doses of any controlled substance narcotic analgesic;

E. the dispensing pharmacy keeps a complete record of each controlled substance stored in the emergency kit, including the name of the drug, the strength of the drug, and the number of doses provided;

F. the facility keeps a complete record of the use of controlled substances from the kit, including the patient's name, the date of use, the name of the drug used, the strength of the drug, the number of doses used, and the signature of the person administering the dose; and

G. the controlled substances stored in the emergency kit are used only in a situation deemed an emergency by a licensed practitioner in conformity with the following provisions:

(1) immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;

(2) no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance; and

(3) it is not reasonably possible for the prescribing practitioner to provide prior to administration a written prescription order to be presented to a pharmacist for dispensing of the controlled substance.

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Subp. 4. **Excluded controlled substances.** Controlled substance sedatives and stimulants in oral dosage forms may not be included in emergency kits.

Subp. 5. **Penalty.** If any of the provisions of this rule are violated, the board may suspend or revoke a facility's right to maintain an emergency kit of drug supplies.

Statutory Authority: *MS s 151.06 subd 1*

OPERATIONS IN HOSPITALS

6800.7100 DEFINITIONS.

Subpart 1. **Credentialed.** "Credentialed" means registered with, certified by, or similarly recognized by a health-related agency or department of the state of Minnesota.

Subp. 2. **Drug administration.** "Drug administration" means to deliver by or pursuant to the lawful order of a licensed practitioner a single dose of a drug to a patient by injection, inhalation, ingestion, or by any other immediate means and shall include:

- A. preparing the individual dose from a previously dispensed, properly labeled container;
- B. verifying the dose as prescribed;
- C. giving the individual dose by the proper route to the correct patient at the proper time;
- D. assuring that the dose is taken; and
- E. promptly recording the time and dose given.

Subp. 3. **Drug dispensing.** "Drug dispensing" means to deliver one or more doses of a drug for subsequent administration to, or use by a patient or human research subject. Such drug dispensing shall be performed by the pharmacist in compliance with part 6800.3100 or 6800.3750, subparts 2 to 10, with delivery being made in a suitable container properly labeled.

Subp. 4. **Pharmaceutical service.** "Pharmaceutical service" means the control of the utilization of drugs, biologicals, and chemicals including procuring, manufacturing, compounding, dispensing, distribution, and storing of drugs, biologicals, and chemicals under the conditions prescribed by this part. The provision of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

Subp. 5. **Supervision.** "Supervision," as used in connection with parts 6800.7100 to 6800.7950, means stationed within the same work area, coupled with the ability to control and responsibility for an action.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.7200 SCOPE.

The provisions of parts 6800.7100 to 6800.7950 are applicable to pharmaceutical services provided to patients in hospitals, including state hospitals, provided, however, that parts 6800.0100 to 6800.5600 and 6800.8100 to 6800.9700 shall also be applicable to such pharmaceutical services, unless specifically exempted by parts 6800.7100 to 6800.8100 or unless in direct conflict therewith, in which case parts 6800.7100 to 6800.8100 shall apply.

Statutory Authority: *MS s 151.06 subd 1*

6800.7300 PHARMACISTS AND SUPPORT PERSONNEL.

Pharmaceutical services in hospitals shall be organized and directed by a pharmacist. Pharmaceutical services shall be provided only by pharmacists and other personnel under a pharmacist's supervision. The use of supportive personnel shall be in accordance with the provisions of part 6800.3850.

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Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.7400 HOSPITAL PHARMACIST-IN-CHARGE.

Subpart 1. **Qualifications.** The pharmacist-in-charge, regardless of his title or designation, shall be a pharmacist licensed in this state.

Subp. 2. **On-site pharmacies.** A pharmacist providing pharmaceutical services to a hospital maintaining an on-site pharmacy shall be engaged by the hospital and shall provide at least part-time, five-day-per-week services.

Subp. 3. **Drug room.** A pharmacist providing pharmaceutical services from off-site to a hospital maintaining a drug room shall schedule on-premises visits on at least a weekly basis.

Subp. 4. **Responsibilities.** The responsibilities and duties of the hospital pharmacist-in-charge include at least the following specific duties in addition to the duties of the pharmacist-in-charge found in part 6800.2400:

A. the procurement, identification, security, storage, and distribution of all drugs, as well as the disposition of drugs whose effectiveness has expired or which, for other reasons, are deemed no longer usable;

B. the development, implementation, coordination, supervision, and review of pharmaceutical services in the hospital and policies related thereto;

C. the supervision of the preparation and sterilization of parenteral drugs in the hospital;

D. the supervision of bulk compounding of pharmaceuticals;

E. the establishment of specifications for procurement of drugs and chemicals for direct patient use;

F. the development of a hospital formulary system;

G. the dispensing of drugs and chemicals for direct patient use;

H. the maintaining of a stock of antidotes and emergency drugs in the hospital;

I. the maintaining of pharmaceutical service records; and

J. cooperating in the teaching and research programs of the hospital.

Subp. 5. **Span of control.** The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than every two months inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the required emergency drug supply.

Subp. 6. **Director's absence.** In the absence of the director of the pharmaceutical service, pharmaceutical services shall be directed by a pharmacist designee.

Statutory Authority: *MS s 151.06 subd 1*

HOSPITAL SERVICE POLICIES

6800.7510 PATIENT CARE.

Pharmaceutical service policies shall cover at least the following:

A. the providing of drug information to patients and health professionals;

B. the limiting of drug administration;

C. the immediate reporting of drug-related errors;

D. the immediate reporting of adverse drug reactions;

E. the self-administration of drugs by patients; and

F. the use of drugs brought into the hospital by or with the patient. If such drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored, and returned to the patient at the time of discharge.

Statutory Authority: *MS s 151.06 subd 1*

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6800.7520 ADMINISTRATION.

Subpart 1. **Dispensing drugs.** Pharmaceutical service policies shall cover at least the following measures related to the control, accessibility, dispensing, and administration of drugs:

A. Developing, implementing, and maintaining a system assuring the availability of prescribed drugs at all times.

B. Dispensing of legend drugs.

C. Changing of labels or the transfer of drugs from one container to another.

D. Maintaining security and emergency access in accordance with part 6800.7530.

E. Supplying of prepackaged legend drugs which are accessible for use without entering either the pharmacy or drug room maintained for use when a pharmacist is not available. Such supply may be located in nursing units, with access limited to designated registered nurses. No hospital pharmacy shall utilize a floor stock drug distribution system of this or any other type as its primary system of drug delivery.

F. Maintaining a supply of drugs for use in medical emergencies.

G. Specifying the maintenance of permissible supplies of nonprescription drugs in nursing service units.

H. Assuring that unused patient drugs, discontinued and outdated drugs, and containers with worn, illegible, or missing labels be returned to a pharmacist for disposition.

I. Maintaining a drug recall procedure which can be implemented no more than 24 hours after recall notification by the manufacturer.

J. Permitting the dispensing of drugs only pursuant to orders initiated by a licensed practitioner.

K. Assuring that all orders for drugs are transmitted to the pharmacy by the prescriber or by means of an order format which produces a direct copy or an electronically reproduced facsimile.

L. Requiring authorization for a standing order to be noted on the patient's medical record. Such orders shall specify the circumstances under which the drug is to be administered, the drug, dosage, route, frequency of administration, and duration.

M. Assuring that when drug therapy is not renewed on an established regular basis such therapy is limited either by the prescriber's specific indication or by automatic stop orders.

N. Assuring that precautionary measures for the safe admixture of parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, supportive personnel under the supervision of a pharmacist, licensed practitioners, and licensed nurses. Furthermore, admixtures shall be labeled as in part 6800.7900, subpart 4.

O. Assuring that investigational drug use is in accordance with state and federal law: basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of such drugs shall be available in the pharmacy (investigational drugs shall be distributed only from the pharmacy).

P. Assuring that the practice of drug reconstitution is performed only by pharmacists, licensed practitioners, licensed nurses, or hospital-authorized personnel under the supervision of licensed pharmacists, licensed practitioners, or licensed nurses.

Subp. 2. **Maintenance of documents.** Pharmaceutical service policies shall cover at least the following measures related to the maintenance of documents.

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A. The pharmacist-in-charge shall maintain at least the following written documents:

- (1) a statement of service philosophy and objectives;
- (2) a job description for each classification of personnel;
- (3) a list of pharmaceutical service committees, and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;
- (4) procurement records for controlled substances for two years or as required by law;
- (5) prescriptions or other forms initiated by the prescriber, for two years or as required by law;
- (6) records of packaging, bulk compounding, or manufacturing for two years or as required by law;
- (7) records of action taken pursuant to drug recalls for two years or as required by law;
- (8) special reports concerning narcotics and other drugs for two years or as required by law;
- (9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room, as permitted under subpart 1, items E and F, for two years; and
- (10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room, as permitted under subpart 1, item D and part 6800.7530, for one month.

B. The following documents relative to pharmaceutical services shall also be maintained:

- (1) a current organization chart delineating intra-service structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff, and other relevant hospital services;
- (2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;
- (3) a record of the number of persons, by job description, employed full-time and part-time in the pharmaceutical services;
- (4) copies of current staffing patterns and weekly work schedules;
- (5) receipted invoices for all drugs, chemicals, and pharmaceutical service supplies purchased and received over the immediately preceding two years; and
- (6) any agreement between an off-premises pharmacy and the hospital.

Statutory Authority: *MS s 151.06 subd 1*

6800.7530 MAINTAINING SECURITY AND EMERGENCY ACCESS.

Subpart 1. **Limited access.** Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth in subparts 2 and 3.

Subp. 2. **Disaster.** In the case of disaster, the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.

Subp. 3. **Emergencies.** For purposes of withdrawing limited doses of drugs for administration in emergencies when the pharmacy is closed, a designated registered nurse may make emergency withdrawal of a dose required by a patient. Only a designated registered nurse in any given shift may have emergency access.

The person withdrawing from a bulk stock container the limited doses for

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administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing the patient's name, the name of the drug and dose prescribed, drug strength, the amount taken, the time and date, and the signature of nurse withdrawing drug.

The person withdrawing the drug from a bulk stock container or unit dose packaging bin shall place upon the record of withdrawal the container from which the limited doses were taken so that the withdrawal may be verified by the pharmacist.

Subp. 4. **Emergency access procedure.** The pharmacist-in-charge shall develop an emergency access procedure and may make provisions for prepackaged drugs for emergency withdrawal, provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.

Statutory Authority: *MS s 151.06.subd 1*

6800.7600 PHARMACEUTICAL SERVICE EQUIPMENT AND SUPPLIES.

In addition to the requirements of part 6800.1050, equipment and supplies shall be maintained by the pharmacy as necessary to fulfill the further needs of patients and the scope of services offered.

Statutory Authority: *MS s 151.06 subd 1*

History: 9 SR 1656

6800.7700 DRUG HANDLING AND STORAGE.

At least the following provisions for the safe handling and secure storing of drugs shall be observed. Storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security. Drugs shall be protected from contamination. Drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

Statutory Authority: *MS s 151.06 subd 1*

6800.7800 PHARMACEUTICAL SERVICE SPACE.

The pharmacy or drug room shall be surrounded by a continuous partition or wall extending from floor to ceiling. All doors and windows shall be securely locked when the pharmacy or drug room is closed, so as to prevent entry by unauthorized persons.

When drugs are stored on nursing service units space shall be available at each unit for the storage, safeguarding, and preparation of medication doses, and shall include provision of at least the following:

A. A well-illuminated, locked drug cabinet or room shall be equipped with clearly labeled cubicles to ensure physical separation of individual patient prescribed medications. Medications may be stored in secured individual patient storage areas or secured portable storage carts providing separate compartments for individual patients.

B. A container or compartment that is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

Statutory Authority: *MS s 151.06 subd 1*

6800.7900 LABELING.

Subpart 1. **Outpatient prescriptions.** Labels for outpatient prescriptions shall comply with parts 6800.3400 and 6800.4150. Labels for outpatient nonprescription drugs shall comply with the federal regulations. Drugs originally dispensed to an inpatient shall be returned to the pharmacy for proper labeling before leaving the hospital premises.

Subp. 2. **Inpatient prescriptions.** All prescriptions dispensed to inpatients, other than those dispensed pursuant to part 6800.3750, shall be labeled with the following information:

- A. identification of pharmacy;
- B. name of patient;
- C. name of drug;
- D. route of administration of drug when necessary for clarification;
- E. strength of drug;
- F. auxiliary labels as needed;
- G. expiration date, if applicable; and
- H. date dispensed.

Subp. 3. **Drugs repackaged for emergency use.** All drugs dispensed under part 6800.7520, subpart 1, item E shall be labeled with the following information:

- A. identification of pharmacy or other source;
- B. name of drug or list of ingredients;
- C. strength of drug or amount of ingredients;
- D. auxiliary labels as needed;
- E. expiration date, if any;
- F. usual dose; and
- G. control number or date of issue.

Subp. 4. **Supplemental label.** Whenever a drug is added to a parenteral solution a distinctive supplemental label shall be firmly affixed to the container. The label shall indicate the name and amount of drug added, the date and time of the addition, the date and time of the expiration of the admixture, and the identity of the person preparing or certifying the integrity of the admixture.

The information in subpart 5, except for lot number, should be recorded on a supplemental label. If the large volume parenteral contains no additives, the same label may be used, omitting those items which do not apply. If, at some later time an additive might be added, then a suitable space should be available for recording the additive.

The supplemental label should be placed so as to permit visual inspection of the infusion contents and to allow the name, type of solution, and lot number on the manufacturer's label to be read.

Subp. 5. **Intravenous admixtures.** It is recommended that all intravenous admixtures be labeled with the following information:

- A. name of solution, lot number, and volume of solution;
- B. patient's name;
- C. bottle sequence number or other control number system;
- D. name and quantity of each additive;
- E. date of preparation;
- F. beyond-use time and date of intravenous admixture; and
- G. ancillary precaution labels.

Subp. 6. **Responsibility.** The hospital pharmacy service is responsible for labeling all medications.

Statutory Authority: *MS s 151.06 subd 1; 151.212*

History: 9 SR 1656

6800.7950 EXTENSION OF PHARMACY SERVICES UNDER LICENSE.

A licensed pharmacy in a hospital may utilize additional locations within the hospital without the necessity of securing additional licenses provided, however, that the pharmacist-in-charge of any such hospital pharmacy shall designate another licensed pharmacist to assume professional responsibility, in accordance with part 6800.2400, for the practice of pharmacy in each such additional location.

Statutory Authority: *MS s 151.06 subd 1*

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RADIOACTIVE DRUGS

6800.8100 DEFINITIONS.

Subpart 1. **Manufacturers of radioactive drugs.** Any person, firm, or hospital compounding, mixing, deriving, repackaging, or otherwise preparing a radioactive drug for use, other than in the medical facility of which it may be physically attached, shall be licensed as a manufacturer.

Subp. 2. **Nuclear pharmacy.** A nuclear pharmacy is any area, place, or premises described in a license issued by the board with reference to plans approved by the board where radioactive drugs are stored, prepared, manufactured, derived, manipulated, compounded, or dispensed.

Subp. 3. **Radioactive drug.** A radioactive drug is any substance defined as a drug in section 201 (g) (1) of the Federal Food, Drug, and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

Statutory Authority: *MS s 151.06 subd 1*

6800.8200 SCOPE.

The provisions of parts 6800.8100 to 6800.8700 are applicable to pharmacies and manufacturers dealing with radioactive pharmaceuticals; provided, however, that parts 6800.0100 to 6800.5600 shall also be applicable to such pharmacies, unless specifically exempted by parts 6800.8100 to 6800.8700 or are in direct conflict therewith, in which case parts 6800.8100 to 6800.8700 shall apply.

Statutory Authority: *MS s 151.06 subd 1*

6800.8300 MINIMUM STANDARDS.

Proof of adequate space and equipment for storage, manipulation, manufacture, compounding, dispensing, safe handling, and disposal of radioactive material must be submitted to and approved by the board before a pharmacy license is issued by the board.

Compliance with all laws and regulations of the U.S. Nuclear Regulatory Commission and other applicable federal and state agencies shall be deemed minimal compliance with this part. Further requirements, as the board in its opinion finds necessary and proper for health and safety in the production, compounding, dispensing, and use of radioactive drugs, may be imposed as a condition of licensure. A pharmacy exclusively handling radioactive materials may be exempt from the building and equipment standards of parts 6800.0700, 6800.0800, 6800.0950, 6800.1050, and 6800.2150 if the board finds it is in the public interest.

Statutory Authority: *MS s 151.06 subd 1*

History: *9 SR 1656*

6800.8400 PHARMACISTS HANDLING RADIOACTIVE DRUGS.

A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the board. Education and experience in nonapproved programs may be accepted if, in the opinion of the board, such programs provide a level of competence substantially the same as approved programs.

Statutory Authority: *MS s 151.06 subd 1*

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6800.8500 PHARMACIST-IN-CHARGE.

A pharmacy handling radioactive drugs shall not function without having a pharmacist who is competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radioactive drugs in charge of the licensed premises. All personnel performing tasks within such pharmacy shall be under the immediate and direct supervision of the pharmacist competent in handling radioactive drugs.

Statutory Authority: MS s 151.06

6800.8600 ACQUISITION, STORAGE, AND DISTRIBUTION OF RADIOACTIVE DRUGS.

Only radioactive drugs which are approved by the U.S. Food and Drug Administration or which are investigational drugs having IND or NDA status may be dispensed by a nuclear pharmacy.

All radioactive materials shall be kept locked and secure from unauthorized personnel.

Radioactive drugs shall not be transferred, distributed, or dispensed to any person or firm not licensed or authorized to receive or possess such drugs.

Statutory Authority: MS s 151.06 subd 1

6800.8700 RECORD KEEPING.

Pharmacists handling radioactive drugs shall maintain records of acquisition and disposition of all radioactive drugs for a period of not less than two years.

In the case of investigational radioactive drugs, such pharmacy records shall include an investigators protocol for the preparation of radioactive drugs, a copy of the Human Use Committee approval, a copy of the approved patient consent form, and a letter from the "manufacturer-sponsor" indicating that the physician requesting the radioactive drug is a qualified investigator.

Additional records shall be maintained as required by statute or rule of any other state or federal agency.

Statutory Authority: MS s 151.06 subd 1

DISCIPLINARY PROCEEDINGS

6800.9100 DEFINITIONS.

Subpart 1. **Board.** "Board" means the Minnesota Board of Pharmacy.

Subp. 2. **Hearing.** "Hearing" includes a joint hearing of the board and any other administrative agency.

Subp. 3. **License.** "License" means any license, permit, certificate of registration, or other grant of authority issued or subject to suspension or revocation by the board.

Subp. 4. **Revocation or suspension.** "Revocation or suspension" of license includes refusal to renew the same.

Statutory Authority: MS s 151.06 subd 1

6800.9200 INITIATING PROCEEDINGS.

Proceedings to revoke or suspend licenses may be initiated in one of two ways, except insofar as any order of suspension or revocation may be issued pursuant to a statute not requiring hearing:

A. on a verified complaint by an individual or an agency required by law to enforce the law in question, filed with the board of pharmacy; or

B. by the board on its own motion, whenever its investigation discloses probable grounds for disciplinary action; the board president or secretary may act for the board in initiating proceedings under this part.

Statutory Authority: MS s 151.06 subd 1

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6800.9300 PROCEDURE UPON FILING COMPLAINT.

All complaints received pursuant to the provisions of part 6800.9200 shall be dealt with in accordance with the requirements of Minnesota Statutes, section 214.10.

Statutory Authority: *MS s 151.06 subd 1*

6800.9400 STYLE OF PLEADINGS.

All pleadings, notices, orders, and other papers filed in such proceedings shall be captioned "BEFORE THE MINNESOTA BOARD OF PHARMACY," and shall be entitled "IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE _____ OF _____ RESPONDENT." The party whose license is involved shall be known and designated as the "Respondent."

Statutory Authority: *MS s 151.06 subd 1*

6800.9500 FORM OF CHARGES.

If the alleged offense is a continuing one, its general nature and the approximate time covered shall be stated in the complaint or notice of hearing. If a specific incident is relied on, it shall be alleged with such particularity as to time, place, and circumstances as may be necessary to enable the respondent to prepare his defense. In either case, the offense may be alleged in the language of the statute or rule claimed to have been violated. Separate charges shall be stated in separate paragraphs and numbered consecutively.

Statutory Authority: *MS s 151.06 subd 1*

6800.9600 ORDER FOR AND NOTICE OF HEARING.

Notices of hearing shall be addressed to the respondent at his last known post office address. All hearings shall be conducted pursuant to Minnesota Statutes, chapter 14 and the rules for contested cases of the Office of Administrative Hearings.

Statutory Authority: *MS s 151.06 subd 1*

6800.9700 SERVICE AND FILING OF PAPERS.

Unless otherwise provided by law, all orders, notices, and other papers may be served by the secretary or the board by first class, certified, or registered mail addressed to the party at his last known post office address, or to his attorney of record. Papers required to be filed with the board may be mailed to the following address: 717 Delaware Street SE, #351, Minneapolis, Minnesota 55414.

Statutory Authority: *MS s 151.06 subd 1*

WAIVERS AND VARIANCES

6800.9900 VARIANCES.

Subpart 1. Right to request variance. A person subject to the rules of the Board of Pharmacy may request that the board grant a variance from any rule of the Board of Pharmacy.

Subp. 2. Submission and contents of request. A request for a variance must be submitted to the board in writing. Each request must contain the following information:

- A. the specific rule for which the variance is requested;
- B. the reason for the request;
- C. the alternative measures that will be taken if a variance is granted;
- D. the length of time for which a variance is requested; and
- E. any other relevant information necessary to properly evaluate the request for the variance.

Subp. 3. Decision on variance. The board shall grant a variance if it determines that:

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A. the variance will not adversely affect directly or indirectly, the health, safety, or well-being of the public;

B. the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the variance is requested; and

C. compliance with the part for which the variance is requested would impose an undue burden upon the applicant.

The board shall deny, revoke, or refuse to renew a variance if the board determines that item A, B, or C has not been met.

Subp. 4. Notification. The board shall notify the applicant in writing within 60 days of the board's decision. If a variance is granted, the notification shall specify the period of time for which the variance will be effective and the alternative measures or conditions, if any, to be met by the applicant.

Subp. 5. Renewal. Any request for the renewal of a variance shall be submitted in writing prior to the expiration date of the existing waiver. Renewal requests shall contain the information specified in subpart 2. A variance shall be renewed by the board if the applicant continues to satisfy the criteria contained in subpart 3 and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance was granted.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*