CHAPTER 6800
MINNESOTA BOARD OF PHARMACY
LICENSING AND OPERATION

6800.0100 DEFINITIONS.

Subpart 1. **Scope.** The terms in this chapter have the meanings given in this part and in Minnesota Statutes, section 151.01.

Subp. 2. **Community/retail pharmacy.** "Community/retail pharmacy" means an established place in which prescriptions, drugs, medicines, chemicals, and poisons are prepared, compounded, dispensed, vended, distributed, or sold to or for the use of nonhospitalized patients and from which related pharmaceutical care services are provided. Practitioners, as defined in Minnesota Statutes, section 151.01, subdivision 23, dispensing prescription drugs to their own patients in accordance with parts 6800.9950 to 6800.9954 are not included within this definition.

Subp. 3. **Hospital pharmacy.** "Hospital pharmacy" means an established place located in a licensed hospital in which prescriptions, drugs, medicines, chemicals, and poisons are prepared, compounded, dispensed, vended, distributed, or sold to hospitalized patients and from which related pharmaceutical care services are delivered.

Subp. 4. **Long-term care pharmacy.** "Long-term care pharmacy" means an established place, whether or not in conjunction with a hospital pharmacy or a community/retail pharmacy, in which prescriptions, drugs, medicines, chemicals, or poisons are prepared, compounded, dispensed, vended, distributed, or sold on a regular and recurring basis to or for the use of residents of a licensed nursing home, boarding care home, or supervised living facility and from which related pharmaceutical care services are delivered.

Subp. 5. **Nuclear pharmacy.** "Nuclear pharmacy" is an 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 and from which related clinical services are provided.

Subp. 6. **Parenteral-enteral/home health care pharmacy.** "Parenteral-enteral/home health care pharmacy" means an established place, whether or not in conjunction with a hospital pharmacy, long-term care pharmacy, or a community/retail pharmacy, in which parenteral or enteral drugs or medicines are prepared, compounded, and dispensed for the use of nonhospitalized patients and from which related pharmaceutical care services are provided.

Subp. 7. **Pharmaceutical care.** "Pharmaceutical care" means the responsible provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve definite outcomes related to the cure or prevention of a disease, the elimination or reduction of a patient's symptoms, or the arresting or slowing of a disease process.

Subp. 8. **Pharmacist-in-charge.** "Pharmacist-in-charge" means a pharmacist licensed in Minnesota who has been so designated.

Subp. 9. **Pharmacist-intern; intern.** "Pharmacist-intern" and "intern" has the meaning given in part 6800.5100, subpart 5.

Subp. 10. **Poisons.** "Poisons" means any substance except drugs or medicines which has the inherent capability to produce bodily harm, injury, or morbidity to humans or animals 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," or "Danger," intended to signal a use alert.

Subp. 11. **Prescription drug order.** "Prescription drug order" means a lawful written or oral order of a practitioner for a drug for a specific patient.

Subp. 12. **Prospective drug review.** "Prospective drug review" means a review of a patient's drug therapy record and prescription drug order prior to the time of dispensing for purposes of promoting therapeutic appropriateness.

Subp. 13. **Satellite pharmacy.** "Satellite pharmacy" means a site in a licensed hospital, which is not physically connected with the centrally licensed pharmacy, but is within the same facility or building and is dependent on the centrally licensed pharmacy for administrative control, staffing, and drug procurement. A satellite pharmacy must be under the direction of a licensed pharmacist and provide pharmacy services to hospitalized patients only.

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

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*

LICENSING PHARMACIES

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 PHARMACY LICENSE AND FEE REQUIRED.

No person or persons shall conduct a pharmacy in or outside of Minnesota that dispenses medications for Minnesota residents and mails, ships, or delivers the prescription medications into this state unless the pharmacy is licensed by the Board of Pharmacy. A fee set by the board and indicated in part 6800.0400 shall be charged for a license.

A completed new pharmacy license application together with a blueprint of the proposed pharmacy showing size, layout, and security and a check for the proper fee must be received in the board office at least 60 days prior to the proposed opening date of the pharmacy.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.0350 LICENSE CATEGORIES.

A pharmacy must be licensed in one or more of the following categories:

A. community/retail;

B. hospital;

C. parenteral–enteral/home health care;

D. long–term care; and

E. nuclear.

Licensing of a pharmacy in more than one category shall not result in an increase in the license fee.

No pharmacy may engage in providing products or services in categories for which it is not licensed. A pharmacy must designate its category or categories on license renewal or application for an initial license.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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

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

E. the addition, deletion, or change of categories of licensure.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 PHARMACY, SPACE, AND SECURITY.

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

A. contains more than 400 square feet;

B. is surrounded by a continuous partition or wall extending from the floor to the permanent ceiling, containing doors capable of being securely locked to prevent entry when the pharmacy is closed; and

C. in the case of a community/retail pharmacy, contains an area where consultation between the patient and the pharmacist may be conducted with a reasonable expectation of privacy. Community/retail pharmacies in existence on November 1, 1993, have until January 1, 1994, to comply with this item.

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

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES.

Subpart 1. **Change in location.** Before a 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 the changes and shall submit the information and documents required in an initial application for license. The new application and supporting documents shall be submitted at least 60 days before the proposed change in location. If the Board of Pharmacy approves the application, no additional charge shall be made for the new license.

Subp. 2. **Change in dimension or security.** No licensed pharmacy in Minnesota 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. The documents and plans

shall be submitted at least 60 days before 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. Failure of the board to respond in writing within 30 days shall be considered to be approval of the proposed changes.

Subp. 3. **Establishment of satellite pharmacy.** No licensed pharmacy in Minnesota shall establish a satellite pharmacy until it has submitted documents and plans for the proposed satellite to the Board of Pharmacy. The documents and plans must be submitted at least 60 days before the proposed establishment of the satellite. The board must, within 60 days after receipt of the proposal, notify the licensee that the proposed satellite either complies or does not comply with parts 6800.0100, subpart 13, and 6800.0700. Failure of the board to respond in writing within 60 days shall be considered to be approval of the proposed satellite.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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]

6800.0910 PATIENT ACCESS TO PHARMACIST.

Subpart 1. **Patient consultation procedure required.** Each licensed pharmacy in Minnesota required to provide patient counseling under this part must develop and maintain a written patient consultation procedure providing for direct oral communication between the patient and the pharmacist designed to improve the patient's understanding of and compliance with the patient's drug therapy to enhance or optimize the outcome of the patient's drug therapy.

Subp. 2. **Description of procedure.** When dispensing a prescription for a Medicaid patient, a pharmacist must offer to consult with the patient or the patient's agent or caregiver and inquire about the patient's understanding of the use of the medication. The pharmacist's designee may make the offer of counseling on the pharmacist's behalf, but the pharmacist must personally initiate and conduct the counseling if the offer is accepted.

Upon receipt of a new prescription or a new prescription drug order, following a review of the patient's record, and upon acceptance of an offer to consult, a pharmacist shall personally initiate discussion of matters which in the professional judgment of the pharmacist will enhance or optimize drug therapy with each patient receiving Medicaid benefits or the agent or caregiver of the patient. The discussion shall be in person, whenever practicable, may be supplemented with written material, and shall include appropriate elements of patient counseling. These elements include the following:

A. the name and description of the drug;

B. the dosage form, dose, route of administration, and duration of drug therapy;

C. intended use of the drug and expected action;

D. special directions and precautions for preparation, administration, and use by the patient;

E. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

F. techniques for self–monitoring of drug therapy;

G. proper storage;

H. prescription refill information;

I. action to be taken in the event of a missed dose; and

J. pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

If a prescription drug has been previously dispensed to a patient, the pharmacist or the pharmacist's designee shall attempt to determine if the patient has experienced any unexpected or unusual reactions or changes in health, whether the patient has experienced the ex-

pected outcome, whether the patient is using the medication as prescribed, and whether the patient has been using any over–the–counter or prescription drugs not in the patient's record since the last visit to the pharmacy. If the pharmacist's review of the patient's record or discussions with the patient reveal any of the conditions listed in part 6800.3110, subpart 4, the pharmacist or the pharmacist's designee must offer counseling by the pharmacist to the patient or the patient's agent or caregiver regarding those conditions or problems. The consultation must be in person whenever practicable.

If a prescription drug has been previously dispensed to a patient and the patient's record shows no change in the dose, dosage form, strength, or directions for use, and if none of the conditions listed in part 6800.3110, subpart 4, are present, the pharmacist or the pharmacist's designee must offer counseling by the pharmacist to the patient or caregiver.

A pharmacist may vary or omit the patient information if, in the pharmacist's professional judgment, the variation or omission serves the best interest of the patient because of the particular individual circumstances involved. If there is any material variation from the minimal information required by this subpart in the information provided or, if consultation is not provided, that fact and the circumstances involved shall be noted on the prescription, in the patient's records, or in a specially developed log.

Personal communication by the pharmacist is not required for hospitals dispensing Medicaid–covered outpatient drugs, using the hospital's drug formulary system and billed at no more than the hospital's purchasing costs, for inpatients of a hospital or other institution, such as a licensed nursing home, where other licensed health care professionals are authorized to administer the drugs, or where a patient or patient's agent or caregiver has expressed a desire not to receive the consultation. When a new prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions, and through the provision of a toll–free phone number for long distance calls.

Nothing in this part shall prohibit pharmacists from charging for these services.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.0950 SALE RESTRICTED TO LIMITED AREA UNDER SUPERVISION.

The Board of Pharmacy shall refuse to grant a license to any pharmacy or proposed pharmacy unless there is provided in the pharmacy a prescription department and a drug area which is 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 humans or other animals.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 17 SR 1279; 18 SR 1145*

6800.1000 [Renumbered 6800.1150]

6800.1010 CLOSING A PHARMACY.

Subpart 1. **Before closing.** At least 14 days before a licensed pharmacy closes and ceases operation it shall:

A. notify the board of the intended closing; and

B. notify the Drug Enforcement Administration, 110 South 4th Street #402, Minneapolis, Minnesota 55401, (612) 348–1700, in person or by registered or certified mail with the return receipt requested, of the following information:

(1) name, address, registration number, and authorized business activity of the licensee discontinuing the business;

(2) name, address, registration number, and authorized business activity of the person acquiring the business, if any;

(3) whether the business activities will be continued at the same location or moved to another location, and if moved, the address of the new location; and

(4) the date on which the transfer of controlled substances will occur.

Subp. 2. **At time of closing.** Effective with the closing date, the pharmacist–in–charge shall:

A. return the pharmacy license to the board office, noting the closing date;

B. notify the board as to the disposition of the prescription files, prescription drugs, insulin, hypodermic syringes and needles, contraceptive drugs and devices, and nonprescription drugs;

C. if the pharmacy that is closing has been computerized, give a printout of all patient profiles to the pharmacy that is receiving the prescription files;

D. ensure that all legend drugs are removed from the pharmacy at the time of closing and stored in a licensed pharmacy; legend drugs must not be stored elsewhere, including in the custody of a pharmacist;

E. return the pharmacy's Drug Enforcement Administration Certificate and any unused narcotic order forms to the Drug Enforcement Administration, 110 South 4th Street #402, Minneapolis, Minnesota 55401;

F. inform the succeeding business occupying the premises and the landlord, if any, that it is unlawful to use the words "drugs," "drug store," or "pharmacy," or similar words in connection with the place of business unless it is a licensed pharmacy; and

G. take a controlled substances inventory as described in subitems (1) to (4). The inventory shall serve as the final inventory of the closing pharmacy and the initial inventory of the pharmacy receiving the controlled substances, and a copy of the inventory shall be included in the records of both. It is not necessary to file a copy of the inventory with the Drug Enforcement Administration unless requested by the regional administrator.

(1) If controlled substance drugs are to be destroyed, the pharmacist–in–charge must contact the local Drug Enforcement Administration for instructions.

(2) If controlled substance drugs, Schedule III–V, are being transferred, they shall be transferred on duplicate invoices, with each pharmacy keeping a copy.

(3) If Schedule II narcotics are being transferred, the transferee must submit a new Drug Enforcement Administration 222 Form to the transferor for the Schedule II substances only.

(4) If the Drug Enforcement Administration responds to the previous notice in subpart 1, item B, and does not approve of the transfer, instructions must be given to the pharmacy that is closing to dispose of the drugs according to the written instructions provided by the regional director.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 in Minnesota must have on file at least one current reference, either hard copy or electronically accessible, from each of the categories in items A to C. An equivalent reference approved by the board in writing may be used in an appropriate category.

A. Examples of pharmacotherapy references are:

(1) Pharmacology in Medicine;

(2) Pharmacological Basis of Therapeutics;

(3) Applied Therapeutics;

(4) Pharmacotherapy: A Pathophysiologic Approach;

(5) United States Pharmacopeia – Dispensing Information; and

(6) Conn's Current Therapy.

B. Examples of dosage and toxicology references are:

(1) Hazards of Medications;

(2) American Hospital Formulary Service;

(3) Facts and Comparisons;

(4) Pediatric Dosage Handbook;

(5) Evaluation of Drug Interactions; and

(6) American Medical Association Drug Evaluations.

C. Examples of general references are:

(1) Handbook of Nonprescription Drugs;

(2) Handbook on Injectable Drugs;

(3) Physician's Desk Reference;

(4) Remington's Pharmaceutical Sciences;

(5) United States Pharmacopeia – National Formulary; and

(6) Merck Manual.

In addition to items A to C, long–term care pharmacies must have on file the most recent edition of Minnesota Department of Health rules pertaining to medication handling in long–term care facilities and a current general reference on geriatric pharmacotherapy.

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 used only for drug storage or a separate compartment used only for drug storage within a general use refrigerator;

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.

Subp. 3. **Equipment for parenteral–enteral/home health care and hospital pharmacies.** In addition to the requirements of subparts 1 and 2, a pharmacy licensed as a parenteral–enteral or hospital pharmacy and involved in an intravenous therapy program must have the following minimum equipment, clean and in good working order:

A. appropriate environmental control devices capable of maintaining an atmospheric environment with less than 100 particles 0.5 microns in diameter per cubic foot of air in the workspace where critical objects are exposed and critical activities performed and during normal activity. Examples of appropriate devices include laminar or vertical airflow hoods and zonal laminar flow of HEPA filtered air;

B. sterile disposable equipment for compounding the parenteral or enteral product such as administration sets, filters, needles, and syringes;

C. disposable items for personnel such as gloves, masks, hats, and gowns;

D. cleaning equipment;

E. appropriate disposal containers for used needles, syringes, and, if applicable, cytotoxic waste from preparation of chemotherapy agents, and infectious wastes from patients' homes consistent with Occupational Safety and Health Administration standards; and

F. two current intravenous reference materials or books for sterile products or intravenous incompatibilities such as "Handbook on Injectable Drugs" (ASHP), "Cutter's Guide to Parenteral Admixtures" or "Procedures for Handling Cytotoxic Drugs" (ASHP).

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

LICENSING PHARMACISTS

6800.1100 [Renumbered 6800.1250]

6800.1150 ANNUAL RENEWAL, FEES, AND POSTING.

A pharmacist license expires 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 $75. A pharmacist license renewal application received after March 1 is subject to a late filing fee of an amount equal to 50 percent of the renewal fee in addition to the renewal fee.

A pharmacist shall post the license or renewal most recently issued by the board or a copy of it in a conspicuous place within the pharmacy in which the pharmacist is practicing. For community pharmacies, this place shall be a place which is readily visible to the public.

Statutory Authority: *MS s 16A.128; 151.03; 151.06; 151.13; 214.06*

History: *9 SR 1656; 13 SR 1775; 16 SR 2239; 18 SR 1145*

6800.1200 [Renumbered 6800.1300]

6800.1210 INACTIVE STATUS AND EMERITUS LICENSE.

Subpart 1. **Inactive status.** A pharmacist currently licensed in Minnesota who is not in active practice in Minnesota may apply for an inactive status license with the board. Requests for inactive status licensure shall be made at the time of license renewal.

The board shall grant an inactive status license to a pharmacist making the request on submission of a sworn statement stating that the pharmacist is not in active practice in Minnesota.

A pharmacist granted an inactive status license must continue to pay the renewal fee for licensure but shall not be required to comply with the continuing education requirements of the board. A pharmacist granted inactive status is not authorized to practice pharmacy in Minnesota while on inactive status.

If an individual's license is on inactive status and that individual maintains an active status license in good standing in another state that requires continuing education, the individual may reactivate the Minnesota license by showing compliance with the continuing education requirements of the other state. If an individual in this category has been on inactive status in Minnesota for longer than five years, the individual must also take and pass the jurisprudence examination described in part 6800.1300, subpart 5, offered to candidates for licensure by reciprocity.

If an individual's license is on inactive status in Minnesota and that individual is not licensed in another state that requires continuing education and now seeks to reactivate the license in Minnesota, the individual must show that continuing pharmaceutical education has been completed at a rate of 15 hours per year for each year that the license has been on inactive status up to a maximum of 75 hours. If the license has been on inactive status for longer than five years, the individual must also take and pass the jurisprudence examination described in part 6800.1300, subpart 5, offered to candidates for licensure by reciprocity.

An individual whose license has lapsed before November 1, 1993, and who wishes to be relicensed must apply under Minnesota Statutes, section 151.14.

Subp. 2. **Emeritus.** A pharmacist who is completely retired from active pharmacy practice may apply to the board for an emeritus license providing the pharmacist has not been disciplined by the board. An emeritus license is not a license to practice, but is a formal recognition of completion of that individual's pharmacy career in good standing.

An emeritus pharmacist is not subject to renewal fees or continuing education requirements.

A pharmacist interested in an emeritus license may obtain an application form by requesting it on the annual renewal form or by writing or calling the board office.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. **Submitting.** An applicant 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. An applicant 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. The evidence shall be shown by submitting an official final transcript showing the date on which degree was conferred. The above listed documents together with a check for $250 must be received by the board at least 45 days prior to the examination. An applicant who is a graduate of a school or college of pharmacy located outside the United States, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, is considered to have satisfied the requirements of graduation if the applicant verifies to the board the applicant's academic record and the applicant's graduation. Before taking the licensing examination, a foreign graduate applicant shall pass the Foreign Pharmacy Graduate Equivalency Examination, which is recognized and approved by the board, given by the Foreign Pharmacy Graduate Examination Commission and demonstrate proficiency in the English language by passing the Test of English as a Foreign Language, which is recognized and approved by the board, given by the Educational Testing Service as a prerequisite to taking the licensure 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 the 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 45 days before an examination, notify the board in writing of the intention 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 $250 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 16A.128; 151.06; 151.07; 152.02; 214.06*

History: *9 SR 1656; 11 SR 335; 12 SR 2393; 16 SR 2239; 18 SR 1145*

6800.1300 RECIPROCITY.

Subpart 1. **Applications.** An application for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of $175 shall be filed with the director of the board at least 30 days before the date the 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. an 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 the applicant will be considered eligible to reciprocate to Minnesota;

B. an applicant, if examined and licensed before January 1, 1973, shall show that the applicant has acquired 2,080 hours of practical pharmacy experience under the instruction of a licensed pharmacist;

C. an applicant, if examined and licensed after January 1, 1973, shall show that the applicant has acquired 1,500 hours of practical pharmacy experience under the instruction of a licensed pharmacist, to be acquired after the successful completion of the third year of the standard five–year or six–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 the applicant applies.

Subp. 3. **Substitution for internship.** Defects in internship experience will not preclude an applicant from being considered eligible provided that the applicant has practiced as a licensed pharmacist for one week at 40 hours per week for each week or portion of a week that the applicant is deficient in internship experience, for example, the number of weeks the

applicant has practiced as a licensed pharmacist before applying for reciprocity must be equal to or greater than the number of weeks or portions of weeks that the applicant 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 16A.128; 151.06; 151.12; 214.06*

History: *9 SR 1656; 13 SR 1775; 16 SR 2239; 18 SR 1145*

LICENSING MANUFACTURERS AND WHOLESALERS

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee of $150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $100 for manufacturing or wholesale distribution of prescription medical gases only; and $75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or wholesale distributor. 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 at midnight 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 the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of one–half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. **Prohibition.** No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. **Separate licenses required.** A separate license is required for each separate location where drugs are stored within this state. Out–of–state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

Statutory Authority: *MS s 151.06; 151.25; 151.42*

History: *16 SR 1913*

6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.

The following information is required from each wholesale drug distributor applying for licensure or renewal:

A. the name, full business address, and telephone number of the licensee;

B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

Statutory Authority: *MS s 151.06; 151.42*

History: *16 SR 1913*

6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

A. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local laws;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

Statutory Authority: *MS s 151.06; 151.42*

History: *16 SR 1913*

6800.1430 PERSONNEL.

Each wholesale drug distributor shall require each person employed in any prescription drug wholesale activity to have enough education, training, and experience, in any combination, sufficient for that person: (1) to do assigned work in a manner that maintains the quality, safety, and security of the drug products in accordance with parts 6800.1400 to 6800.1440; and (2) to assume responsibility for compliance with the licensing requirements of parts 6800.1400 to 6800.1440.

Statutory Authority: *MS s 151.06; 151.42*

History: *16 SR 1913*

6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

Subpart 1. **Application.** The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United

States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

Subp. 4. **Security.** The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well–controlled;

(2) the outside perimeter of the premises shall be well–lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Subp. 5. **Storage.** Items A to D govern storage of drugs.

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

Subp. 6. **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7. **Returned, damaged, and outdated drugs.** Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded, or adulterated drugs.

Subp. 8. **Record keeping.** Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

(2) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall

provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. **Salvaging and reprocessing.** Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and Minnesota Statutes, section 151.39.

Statutory Authority: *MS s 151.06; 151.42*

History: *16 SR 1913*

6800.1460 MANUFACTURING PROCEDURES.

A person engaged in the manufacturing of drugs, medicines, chemicals, or poisons for medicinal purposes whose place of business is located in Minnesota must comply with the current Good Manufacturing Practices regulations for finished pharmaceuticals published by the United States Food and Drug Administration.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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.** Beginning March 4, 1975, no annual license renewal shall be issued to a pharmacist under Minnesota Statutes, section 151.13, until the pharmacist has submitted to the board satisfactory evidence that the pharmacist has completed at least 30 hours of approved continuing education during the previous two–year period. Thereafter, a pharmacist shall submit the 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, on application, an extension of time not to exceed one year to comply with the requirements of this subpart. The extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two–year period. Each pharmacist is responsible for maintaining a complete record of the pharmacist's continuing education participation during each continuing education reporting cycle.

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 record keeping 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 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 60 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.** A pharmacist 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 3a, 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. 6a. **Credit for preceptor training program.** A pharmacist who applies shall be given continuing education credit for participation in the Board of Pharmacy's instructional program for pharmacist preceptors.

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 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*

History: *10 SR 2007; 18 SR 1145*

6800.1600 CONTINUING EDUCATION ADVISORY TASK FORCE.

The continuing education advisory task force shall consist of not more than ten members. Three members of the advisory task force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the Minnesota Society of Hospital Pharmacists, two 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 chair and vice chair 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 (7),(9); 151.07; 152.02 subds 7,8; 214.06*

History: *10 SR 2007; 12 SR 2393*

6800.2000 [Renumbered 6800.2150]

6800.2100 [Renumbered 6800.1050]

OPERATION OF PHARMACIES

6800.2150 PHARMACIST ON DUTY.

A pharmacy or satellite 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 except that brief absences of the pharmacist arising out of and in the course of pharmacy practice are allowable.

Except as provided in part 6800.7530, when a pharmacy is closed and there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

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, national origin, or disease.

F. Refusing to consult with patrons or patients, attempting to circumvent the consulting requirements, or discouraging the patient from receiving consultation concerning contents, therapeutic values, uses, and prices 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 the patient's 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 the pharmacist knows or should have known of their intended use in illegal activities.

Subp. 4. **Drug diversion.** It is unprofessional conduct for a pharmacist to sell, purchase, or trade, or offer to sell, purchase, or trade, any drug that was purchased by a public or private hospital or other health care entity or that was donated or supplied at a reduced price to a charitable organization. This subpart does not apply to:

A. a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

B. a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

C. a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; or

D. the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug between members of a group purchasing organization as described in Minnesota Statutes, section 151.44, paragraph (a), clause (2).

For purposes of this subpart, "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed by the board, and "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

Statutory Authority: *MS s 151.06*

History: *9 SR 260; 9 SR 1656; 10 SR 2007; 17 SR 1279; 18 SR 1145*

6800.2300 SANITATION.

A pharmacy shall maintain orderly, clean, and sanitary conditions at all times.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 is the pharmacist–in–charge's 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 assure that all persons participating in an internship, residency, or fellowship program at the pharmacy are appropriately licensed or registered with the board;

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

E. to develop appropriate detailed written procedures directing activities of supportive personnel and to submit these procedures to the board in accordance with part 6800.3850;

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

G. to establish and supervise the record keeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs;

H. to notify the board immediately upon receiving knowledge that his or her services as pharmacist–in–charge have been or will be terminated; and

I. 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*

History: *9 SR 1656; 17 SR 1279; 18 SR 1145*

6800.2500 NOTIFICATION OF CHANGE OF BUSINESS OR RESIDENCE ADDRESS.

A pharmacist or pharmacist–intern shall notify the Board of Pharmacy immediately of any change in location of employment or any change of residence address.

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

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, (United States Pharmacopeial Convention, Inc., Rockville, Maryland);

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 Pharmacopeia, (United States Pharmacopeial Convention, Inc., Rockville, Maryland), 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 rerent thereof.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.2800 [Repealed, 13 SR 1775]

6800.2810 PRESCRIPTION NUMBERS.

Prescriptions dispensed from a pharmacy, other than prescriptions dispensed to hospital inpatients, must be numbered sequentially and the prescription blanks must be filed sequentially by number after dispensing.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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; FAX TRANSMISSION OF PRESCRIPTIONS.

Subpart 1. **Acceptance of order.** 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 applies to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this part prohibits a licensed pharmacist 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.

Subp. 2. **Fax machines.** Prescriptions and drug orders may be transmitted to a pharmacy via the use of a fax machine only in accordance with this subpart. For a pharmacy other than a hospital pharmacy that is transmitting solely within the institution, the procedures must provide for the identification of the person sending the prescription or drug order. Unless the fax transmission is received on a machine generating a copy that is readily readable for at least five years, all fax transmissions of drug orders shall be followed up within 72 hours with the original hard copy of the order or the pharmacist shall reduce the order received by fax to writing that is of permanent quality. Orders for Schedule II–IV controlled substances received by fax shall be handled according to the rules of the federal Drug Enforcement Administration. Prescriptions faxed to the pharmacy by the patient are not to be filled or dispensed.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 pharma-

cist, practitioner, 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 or in the electronically maintained record 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 clerical personnel in limited nonprofessional duties such as looking up prescription refills, filing prescriptions, record keeping, nonprofessional aspects of presenting completed medications to patients, and completing the transaction; and

I. supervising supportive personnel utilized in the performance of certain pharmacy tasks not requiring professional judgment 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, verbal, or electronically produced, is not acceptable except as provided in parts 6800.3000, subpart 2, and 6800.3120, subpart 7.

Subp. 3. **Certification.** In certifying and documenting the completed prescription order under subpart 1, item F, the pharmacist, practitioner, or pharmacist–intern 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. reviewing the patient's medication profile for purposes of conducting a prospective drug review and checking the accuracy of the addition to the profile of the medication dispensed; and

E. initialing of the prescription by the individual 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*

History: *9 SR 1656; 10 SR 2007; 18 SR 1145*

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; generally.** A reasonable effort must be made by the pharmacy to obtain, record, and maintain at least the following information regarding individuals obtaining prescription services at the pharmacy:

A. name, address, telephone number, date of birth or age, and gender; and

B. individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices being used showing the prescription number, the name and strength of the drug or device, the

quantity and date received by the patient, and the name of the prescriber; if this information is obtained by someone other than the pharmacist, the pharmacist must review the information with the patient.

Subp. 2a. **Minimum information required; Medicaid patients.** For Medicaid patients, a reasonable effort must be made by the pharmacy to obtain, record, and maintain at least the following information regarding individuals obtaining prescription services at the pharmacy:

A. name, address, telephone number, date of birth or age, and gender;

B. individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices being used, showing the prescription number, the name and strength of the drug or device, the quantity and date received by the patient, and the name of the prescriber; if this information is obtained by someone other than the pharmacist, the pharmacist must review the information with the patient; and

C. pharmacist comments relevant to the individual's drug therapy, including, where appropriate, documentation of the following for each prescription:

(1) the pharmaceutical care needs of the patient;

(2) the services rendered by the pharmacist; and

(3) the pharmacist's impression of the patient's drug therapy.

This documentation is not required for residents of a licensed nursing home where a consultant pharmacist is performing regular drug regimen reviews.

Subp. 3. **Drug interactions, generally.** 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 resolve the problem which shall, if necessary, include consultation with the prescriber.

Subp. 4. **Drug use review for Medicaid patients.** Upon receiving a prescription, prescription drug order, or prescription refill request for a Medicaid patient, a pharmacist shall examine the patient's profile record and conduct a prospective drug review to identify:

A. overutilization or underutilization;

B. therapeutic duplication;

C. drug–disease contraindications;

D. drug–drug interactions;

E. incorrect drug dosage or duration of drug treatment;

F. drug–allergy interactions; or

G. clinical abuse or misuse.

Upon recognizing any of these drug–related problems, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

For the purpose of meeting the requirements of this subpart, a pharmacist may rely on computerized medication profile review. The review must scan all prescriptions received by the patient at the pharmacy during the previous six months and conduct the prospective review required in this subpart. The pharmacist–in–charge must develop procedures restricting "override" decision making regarding computer–identified drug problems at the pharmacy and include these procedures in the written procedures required under part 6800.3950.

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*

History: *10 SR 2007; 18 SR 1145*

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 prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another. Schedule II prescriptions may not be transferred. Schedule III–V prescriptions may only be transferred once.

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

A. write the word "VOID" across the face of the current prescription to make the prescription invalid and, if records are electronically maintained, void all remaining refills previously authorized;

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 record keeping system.** A computerized prescription record keeping 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*

History: *10 SR 2007; 18 SR 1145*

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 or distributor of the finished dosage form of the drug;

D. except as provided in part 6800.3350, subpart 1, an expiration date of not more than one-fourth of the period of time from the prepackaging date to the manufacturer's expiration date, up to a maximum of six months, 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*

History: *18 SR 1145*

6800.3300 BULK COMPOUNDING.

Subpart 1. **Master formula record.** A pharmacy may compound drugs in bulk quantities for its own use. The 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; and initials of pharmacist supervising each process;

C. a batch number; and

D. total yield.

Subp. 3. **Labeling.** 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; and auxiliary labels, as needed.

Subp. 4. **Raw materials.** Pharmacists shall receive, store, or use drug substances for use in compounding that have been made in an FDA–approved facility. Pharmacists shall also receive, store, or use drug components in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

Subp. 5. **Supply.** The size of batches of bulk compounded drugs must not exceed a three–month average supply, based on historical dispensing records, of the prescription formula that serves as the impetus for the compounding.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.3350 EXPIRATION DATES.

Subpart 1. **Pharmaceuticals prepackaged into prescription vials.** An expiration date of not more than one year from the prepackaging date or the time remaining to the manufacturer's expiration date, whichever is less, shall be placed on every container of drugs prepackaged into prescription vials by the pharmacist.

Subp. 2. **Bulk compounded pharmaceuticals.** An expiration date of not more than one year from the compounding date shall be placed on every container of bulk compounded pharmaceuticals. A longer expiration date may be used if stability studies have been done on the individual products justifying an expiration date longer than one year in length.

Subp. 3. **Unit–of–use and blister card packages.** An expiration date of not more than one–fourth of the period of time from the packaging date to the manufacturer's expiration date, up to a maximum of six months, shall be placed on all unit–of–use and blister card packaging whether prepared by the pharmacist at the time of dispensing or prepared earlier in anticipation of the dispensing.

Subp. 4. **Prescription vials.** Prescription drugs dispensed in traditional prescription vials and labeled with an expiration date shall bear an expiration date of not more than one year from the dispensing date or the time remaining to the manufacturer's expiration date, whichever is less.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.3400 PRESCRIPTION LABELING.

Subpart 1. **Requirements applicable to all drugs.** 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 or distributor 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.

Subp. 2. **Small container labeling.** In cases where the physical characteristics of the immediate container of the medication do not permit full labeling, a partial label containing, at a minimum, the patient name and the prescription number may be placed on the container and the complete labeling applied to an appropriate outer container.

Statutory Authority: *MS s 151.06; 151.212*

History: *18 SR 1145*

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

Subpart 1. **Requirements applicable to intravenous admixture drugs.** Intravenous admixture drugs dispensed to or for a patient, other than a hospitalized patient, shall be labeled according to the requirements of part 6800.3400, and in addition shall contain the following:

A. date of compounding;

B. expiration date and time of product;

C. storage requirements if other than room temperature;

D. infusion or administration rate;

E. sequential number of unit, if appropriate;

F. initials of the dispensing pharmacist personally placed on the label; and

G. other accessory cautionary information which in the professional judgment of the pharmacist is necessary or desirable for proper use by and safety of the patient.

Subp. 2. **Additions to admixtures.** When an additional drug is added to intravenous admixtures, the admixtures shall be labeled on the original label or with a distinctive supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and initials of person adding the drug.

Subp. 3. **Audit trail.** A pharmacy engaged in the dispensing of outpatient intravenous admixtures shall develop a five–year audit trail system that will identify the dispensing pharmacist for each unit dispensed.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.3500 [Renumbered 6800.4150]

6800.3510 REFILL LIMITATIONS.

No prescription may be filled or refilled more than 12 months after the date on which the prescription was issued. Refills originally authorized in excess of 12 months are void 12 months after the original date of issuance of the prescription. After 12 months from the date of issuance of a prescription, no additional authorizations may be accepted for that prescription. If the prescriber desires continued therapy, a new prescription must be generated and a new prescription number assigned.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 being satisfied that such purchaser has produced proof of identity and legal age.

Economic poisons and simple proprietory 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; 17 SR 1279*

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 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, commonly known as pharmacy technicians, may be used in performing pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist, practitioner, 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, practitioner, or pharmacist–intern 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 in a pharmacy 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 in this chapter 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; the name, address, and social security number of the supportive person; that the supportive

person will be identified to the public by the use of a name tag giving both the supportive person's name and title; 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 in this subpart. Procedures shall be updated and resubmitted every five years.

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. A change in personnel filling the approved position does not require resubmission of procedures but does require notification of the board of the names, addresses, and social security numbers of the individuals involved.

Subp. 5. **Supervision.** Supportive personnel shall be supervised by a licensed pharmacist, practitioner, or pharmacist–intern 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 to pharmacists in a pharmacy is 1:1. Specific functions are excepted from the 1:1 ratio as follows:

A. patient counseling and drug use review applied to all patients, not just Medicaid patients, 2:1;

B. intravenous admixture preparation (parts 6800.7510 to 6800.7530), 3:1;

C. unit dose dispensing (part 6800.3750), 3:1;

D. prepackaging (part 6800.3200), 3:1; and

E. bulk compounding (part 6800.3300), 3:1.

Subp. 7. **Persons not included.** Personnel used solely for clerical duties such as typing, other than prescription data entry, and record keeping 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*

History: *9 SR 1656; 18 SR 1145*

6800.3900 [Renumbered 6800.3850]

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE.

Subpart 1. **Policy and procedures.** Up–to–date written policy and procedures shall be developed and maintained that explain the operational aspects of the automated system and shall:

A. include examples of output documentation provided by the automated system that pertain to dispensing or drug control records;

B. outline steps to be followed when the automated system is not operational due to scheduled or unscheduled system interruption;

C. outline regular and routine backup file procedures and file maintenance; and

D. outline audit procedures, personnel code assignments, and personnel responsibilities.

Subp. 1a. **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 must be retained in the computer 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. produce a hard copy daily summary of controlled substance transactions and be capable of producing a hard copy printout of legend drug transactions going back two years, except that if this information is already available in hard copy form it is not necessary to duplicate the data through computer–generated hard copy;

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 and quantities of refills of these prescriptions and:

(1) in the case of hospital or long–term care inpatients, these records shall be kept in the computer system or on hard copy and be immediately retrievable for two years;

(2) in all other cases the data shall be kept in the computer system and be immediately retrievable for at least two years;

E. be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank;

F. be capable of producing a printout providing a refill–by–refill audit trail for any specified strength and dosage form of any controlled substance. The audit trail must include the name of prescribing practitioner, the name and location of patient, the quantity dispensed on each refill, the date of dispensing of each refill, the name or identification code of the dispensing pharmacist, and the prescription number;

G. be capable of identifying any authorized changes in drug, quantity, or directions for use of any order including the date of change, the identity of the individual making the change, and what the original information was; alternatively a new prescription may be created for each change; and

H. be capable of preventing unauthorized access, modification, or manipulation of patient prescription data.

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.

Subp. 4. **Prescription refills.**

A. On the first refill of any prescription whose data is stored electronically, the pharmacist must retrieve the hard copy original of the prescription, compare the data to the data in the computer, and date and initial the back of the hard copy. On subsequent refills, the original hard copy need not be consulted.

B. As an alternative to the requirements of item A, a pharmacy may elect instead to develop and implement a written quality assurance plan that will provide safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer. This written quality assurance plan shall be made available to board surveyors on request.

Subp. 5. **Report to Board of Pharmacy.** If dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 72 hours.

Subp. 6. **Computer–generated material.** Any computer–generated material, such as labels, receipts, duplicate prescriptions, or other printed matter, that is intended to be attached to the hard copy prescription to meet legal requirements shall be affixed so that the face of the prescription is unobstructed.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

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.

Drugs administered systemically as controlled substances under Minnesota Statutes, chapter 152, and parts 6800.4200 to 6800.4250, 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."

Controlled substances shall also be labeled:

"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

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 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) Allylprodine;

(3) Alphacetylmethadol;

(4) Alphameprodine;

(5) Alphamethadol;

(6) Alpha–methylfentanyl (N–[1–(alpha–methyl–beta–phenyl) ethyl–4–piperidyl] propionanilide; 1–(1–methyl–2–phenylethyl)–4–(N–propanilido) piperidine);

(7) Benzethidine;

(8) Betacetylmethadol;

(9) Betameprodine;

(10) Betamethadol;

(11) Betaprodine;

(12) Clonitazene;

(13) Dextromoramide;

(14) Diampromide;

(15) Diethylthiambutene;

(16) Difenoxin;

(17) Dimenoxadol;

(18) Dimepheptanol;

(19) Dimethylthiambutene;

(20) Dioxaphetyl butyrate;

(21) Dipipanone;

(22) Ethylmethylthiambutene;

(23) Etonitazene;

(24) Etoxeridine;

(25) Furethidine;

(26) Hydroxypethidine;

(27) Ketobemidone;

(28) Levomoramide;

(29) Levophenacylmorphan;

(30) MPPP; 1–Methyl–4–Phenyl–4–Propionoxypiperidine;

(31) 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–phenylpro–panamide

(g) 3–Methylthiofentanyl;
N–[3–Methyl–1–(2–(2–thienyl)ethyl)–4–piperidyl]–N–phenylpropana– mide

(h) Thenylfentanyl;
N–[1–(2–thienyl)Methyl–4–piperidyl]–N–phenylpropanamide

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

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

(32) Morpheridine;
(33) Noracymethadol;
(34) Norlevorphanol;
(35) Normethadone;
(36) Norpipanone;
(37) PEPAP; 1–(2–Phenylethyl)–4–Phenyl–4–Acetyloxypiperidine
(38) Phenadoxone;
(39) Phenampromide;
(40) Phenomorphan;
(41) Phenoperidine;
(42) Piritramide;
(43) Proheptazine;
(44) Properidine;
(45) Propiram;
(46) Racemoramide;
(47) Tilidine; and
(48) 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) Hydromorphinol;
(14) Methyldesorphine;
(15) Methylhydromorphine/Methyldihydromorphine;
(16) Morphine Methylbromide;
(17) Morphine Methylsulfonate;
(18) Morphine–N–Oxide;
(19) Myrophine;
(20) Nicocodeine;
(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–Methylenedioxymeth–amphetamine	
(8) 3,4–Methylenedioxy–N–ethylamphetamine	MDMA N–ethyl–alpha–methyl–3,4(Methylenedioxy) phenethylamine; N–ethyl MDA; MDE; MDEA
(9) N–hydroxy–3,4–Methylenedioxy–amphetamine	N–hydroxy–alpha–methyl–3,4(Methylenedioxy) phenethylamine; N–hydroxy MDA
(10) 3,4,5–Trimethoxy Amphetamine	TMA
(11) Bufotenine	3–(b–Dimethylaminoethyl)–5–hydroxyindole; 3–(2–dimethylaminoethyl)–5–indolol; N, N–dimethylserotonin; 5–hydroxy–N,N–dimethyltryptamine; mappine
(12) Diethyltryptamine	N,N–Diethyltryptamine; DET
(13) Dimethyltryptamine	DMT
(14) 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
(15) Lysergic acid diethylamide	LSD
(16) Marijuana	
(17) Mescaline	
(18) Parahexyl	3–Hexyl–1–hydroxy–7,8,9,10–tetrahydro–6,6,9–trimethyl–6H–dibenzo[b,d]pyran; Synhexyl
(19) Peyote Meaning all parts of 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	
(20) N–ethyl–3–piperidyl Benzilate	JB–318
(21) N–methyl–3–piperidyl Benzilate	JB–336
(22) Psilocybin	
(23) Psilocyn	
(24) Tetrahydrocannabinols 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 sesame 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.)	THC
(25) Ethylamine analog of phencyclidine	N–ethyl–1–phenylcyclohexylamine, (1–phenylcyclohexyl)ethylamine, N–(1–phenylcyclohexyl)ethylamine, cyclohexamine, PCE

(26) Pyrrolidine analog of phencyclidine	1–(1–phenylcyclohexyl)–pyrrolidine, PCPy, PHP
(27) Thiophene analog of phencyclidine	1–[1–(2–thienyl)–cyclohexyl]–piperidine, 2–thienyl analog of phencyclidine, TPCP, TCP
(28) 2–thienyl Pyrrolidine analog of Phencyclidine	1–[1–(2–thienyl)cyclohexyl]–pyrrolidine, TCPy

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) Fenethylline;

(2) 4–Methylaminorex (2–Amino–4–methyl–5–phenyl–2–oxazoline);

(3) N–ethylamphetamine.

Statutory Authority: *MS s 151.06; 151.07; 152.02*

History: *9 SR 1656; 11 SR 1113; 12 SR 2393; 18 SR 1145*

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	
(f) Tincture of opium	Laudanum
(g) Codeine	Methylmorphine
(h) Ethylmorphine	Dionin
(i) Etorphine hydrochloride	
(j) Hydrocodone	Dihydrocodeinone
(k) Hydromorphone	Dihydromorphinone, Dilaudid

(l) Metopon	
(m) Morphine	Chlor–Anodyne
(n) Oxycodone	Dihydrohydroxycodeinone, Percodan, Nucodan
(o) Oxymorphone	Dihydrohydroxymorphinone, Numorphan
(p) Thebaine	

(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 of coca leaves and any salt, 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.
(1)	Alfentanil	Alfenta
(2)	Alphaprodine	Nisentil
(3)	Anileridine	Leritine
(4)	Bezitramide	
(5)	Bulk Dextropropoxyphene (nondosage forms)	
(6)	Carfentanil	
(7)	Dihydrocodeine	Paracodin
(8)	Dihydromorphinone	Dilaudid
(9)	Diphenoxylate	
(10)	Fentanyl	Sublimaze, Innovar
(11)	Isomethadone	
(12)	Levomethorphan	
(13)	Levorphanol	Levo–Dromoran
(14)	Metazocine	
(15)	Methadone	Dolophine, Amidone, Adanon
(16)	Methadone–Intermediate 4–cyano–2–dimethylamino–4, 4–diphenylbutane	
(17)	Moramide–Intermediate 2–methyl–3–morpholino–1, 1–diphenyl–propane–carboxylic acid	
(18)	Pethidine (meperidine)	Meperidine, Demerol, Isonipecaine, Mepadin, Mepergan
(19)	Pethidine–Intermediate–A, 4–cyano–1–methyl–4–phenylpiperidine	
(20)	Pethidine–Intermediate–B, ethyl–4–phenylpiperidine–4–carboxylate	

(21)	Pethidine–Intermediate–C, 1–methyl–4–phenylpiperidine–4–carboxylic acid	
(22)	Phenazocine	Prinadol
(23)	Piminodine	Alvodine
(24)	Racemethorphan	
(25)	Racemorphan	Dromoran
(26)	Sufentanil	Sufenta

D. 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:

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	Amphetamine, its salts, optical isomers, and salts of its optical isomers;	Dexedrine, Dexamyl, Benzedrine, Raphetamine, Biphetamine,
(2)	Methamphetamine, its salts, isomers, and salts of its isomers;	Desoxyn, Methedrine, Drinalfa, Desoxyephedrine Hydrochloride, Syndrox, Efroxine, Norodin, Obedrin, Ambar
(3)	Phenmetrazine and its salts;	Preludin
(4)	Methylphenidate	Ritalin, Plimasin, Ritonic

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 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)	Amobarbital	Amytal
(2)	Pentobarbital	Nembutal, Tuinal
(3)	Phencyclidine	Sernyl, Sernylar
(4)	Secobarbital	Seconal

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

(1) Immediate precursor to amphetamine and methamphetamine:

Statutory Name	Some trade or other names
(a) Phenylacetone	phenyl–2–propanone, P2P, benzyl methyl ketone, methyl benzyl ketone

(2) Immediate precursor to phencyclidine (PCP):

(a) 1–phenylcyclohexylamine

(b) 1–piperidinocyclohexane carbonitrile (PCC)

G. Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product.

(2) Nabilone [another name for Nabilone: (±)–trans–3–(1,1–dimethylheptyl)–6,6a,7,8,10,10a–hexahydro–1–hydroxy–6, 6–dimethyl–9H–dibenzo [b,d] pyran–9–one].

Statutory Authority: *MS s 151.06; 151.07; 152.02; 214.06*

History: *9 SR 1656; 11 SR 1113; 12 SR 2393; 18 SR 1145*

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

The following items are listed in Schedule III:

A. Schedule III 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. 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 potential for abuse associated with a stimulant effect on the central nervous system, 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 within the specific chemical designation:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Amphetamine, Methamphetamine, Methylphenidate and Phenmetrazine, when required by federal law to be labeled with either of the following symbols: C–III or III	
(2) Benzphetamine	Didrex
(3) Chlorphentermine	Pre–Sate
(4) Clortermine	Voranil
(5) Phendimetrazine	Plegine, Stim–35, Melfiant, Barcarate

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 having a potential for abuse associated with a depressant effect on the central nervous system:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Any compound, mixture, 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:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital
(4) Chlorhexadol	
(5) Glutethimide	Doriden
(6) Lysergic acid	
(7) Lysergic acid amide	
(8) Methyprylon	Noludar
(9) Sulfondiethylmethane	
(10) Sulfonethylmethane	
(11) Sulfonmethane	
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, Pronicodeine, 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.

(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.

F. Anabolic Steroids.

	Clostebol, Chorionic gonadotropin, Dehydrochlor–methyltestosterone, Ethylestrenol, Fluoxymesterone, Human growth hormones, Mesterolone, Methandienone, Methandrostenolone, Methenolone, Methyltestosterone, Nandrolone, Nandrolone phenpropionate, Norethandrolone, Oxandrolone, Oxymesterone, Oxymetholone, Stanozolol, Testosterone propionate, Testosterone–like related compounds

Statutory Authority: *MS s 151.06; 152.02*

History: *9 SR 1656; 18 SR 1145*

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) Barbital	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) Ethclorvynol	Placidyl
(17) Ethinamate	Valmid
(18) Ethyl Loflazepate	
(19) Fludiazepam	
(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	Mebaral, 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
(1) Fenfluramine	Pondamin

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
(1) Diethylpropion	Tenuate, Tepanil
(2) Mazindol	Sanorex
(3) Pemoline (including organometallic complexes and chelates thereof	Cylert
(4) Phentermine	Wilpo, 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; 152.02*

History: *9 SR 1656; 11 SR 1113; 18 SR 1145*

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.	

D. **Stimulants.** Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone.

Statutory Authority: *MS s 151.06; 152.02*

History: *9 SR 1656; 11 SR 1113; 18 SR 1145*

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.** A 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. On the filing of an application, payment of a fee of $25, and authentication of the application by the board, the board shall issue a permit.

Subp. 2. [Repealed, 18 SR 1145]

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145*

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 to a practitioner unless the 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 or distributor for dispensing to a patient.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145*

6800.4600 PERPETUAL INVENTORY.

Each pharmacy located in this state shall maintain a perpetual inventory system for Schedule II controlled substances. The system shall be established in a manner that will provide total accountability in all aspects of Schedule II drug distribution. The inventory shall be reconciled with the actual inventory monthly and the reconciliations shall be documented. Reconciliation documentation shall be retained for at least two years.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.4700 CONTROLLED SUBSTANCE VERIFICATION.

Each hospital pharmacy shall develop and implement a written quality assurance plan that provides for pharmacist verification of drug distribution records relating to the distribution of controlled substance drugs from the pharmacy to the nursing stations or other drug storage locations within the hospital.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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, fifth, and sixth academic years only, while a person is a full–time student carrying, in any given school term, 12 or more quarter credits.

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

Subp. 5. **Pharmacist–intern; 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;

C. a qualified applicant awaiting examination for licensure; or

D. a participant in a residency or fellowship program who is a licensed pharmacist in another state or who is a graduate of the University of Minnesota College of Pharmacy or another pharmacy college approved by the board.

Subp. 6. **Preceptor.** "Preceptor" means a natural person licensed as a pharmacist by the Board of Pharmacy who participates in instructional programs approved by the board and is providing instruction and direction to pharmacist–interns related to their practical experience.

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.** Except as provided in subpart 9, "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 the intern's internship.

Subp. 9. **Supervision in approved clinical programs.** Direct supervision for interns is not required for drug information gathering for the purpose of patient assessment. Direct supervision is required when making drug therapy recommendations to other health professionals when the recommendations may affect patient therapy.

Subp. 10. **Supervision in patient counseling situations.** Direct supervision is not required for interns in patient counseling, patient education, or staff in–service situations. The preceptor for the intern is responsible for the accuracy and completeness of statements made by the intern.

Statutory Authority: *MS s 151.06; 151.101*

History: *17 SR 1279; 18 SR 1145*

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 parts take effect immediately but do not nullify any period of internship service by any individual previous to their adoption if the period of internship is filed in a proper manner with the director of the Board of Pharmacy.

Statutory Authority: *MS s 151.06; 151.101*

History: *18 SR 1145*

6800.5300 REGISTRATION AND REPORTING.

Subpart 1. **Registration.** Every person shall register with the board before beginning an internship, residency, or fellowship in Minnesota. Applications for the registration of a pharmacist–intern shall be on a form or forms the Board of Pharmacy prescribes and shall be accompanied by a fee of $20. Registration remains 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. Registration for purposes of participating in a residency or fellowship program remains in effect until the individual obtains licensure as a pharmacist, for two years, or until the completion of the residency or fellowship program, whichever occurs first. 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 professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall on proper registration issue to the intern a pocket registration card for purposes of identification and verification of the intern's role as an intern, and the card shall be surrendered to the director of the board on 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 the intern's 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 that the board designates. These examinations shall be of a pretest and posttest nature bracketing the 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. Candidates for licensure by examination who are licensed as pharmacists in another state are exempt from this requirement.

Subp. 6. **Termination.** No person who terminates 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; 151.101*

History: *17 SR 1279; 18 SR 1145*

6800.5350 PRECEPTORS.

Subpart 1. **Certificates.** Pharmacists intending to act as preceptors for pharmacist–interns in licensed pharmacies shall first obtain preceptor certificates from the board. Certificates shall be renewed every other year on the anniversary of their issuance. The board shall grant certificates or renewals to applicants who fulfill the requirements of subparts 2 and 3.

Subp. 2. **Training and practice.** Applicants must show that:

A. they are participating in the college–based externship program of the University of Minnesota College of Pharmacy as an approved preceptor; or

B. they have completed at least 4,000 hours of pharmacy practice after licensure, with at least 2,000 hours of that pharmacy practice after licensure as a pharmacist in Minnesota.

Subp. 3. **Other requirements.** In addition to fulfilling the requirements of subpart 2, item A or B, applicants must show that:

A. they are currently in practice at least 20 hours per week as a pharmacist;

B. they have a history of exemplary practice with respect to compliance with state and federal laws;

C. they will provide at least 12 hours per calendar quarter of scheduled, uninterrupted time, in segments of not less than 30 minutes, for the intern for purposes of education and discussion; and

D. for renewal of a certificate only, they have participated in the board's instructional programs on pharmacy law for preceptors within the previous 24 months.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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.

Subp. 3. **Training in other state.** When an intern desires to obtain credit for training received in a state other than Minnesota, the intern shall abide by the internship rules in that state, and shall provide evidence from that state's Board of Pharmacy that the intern's 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 part and the requirements of the state in which the intern is training, the intern shall contact the director of the Board of Pharmacy in Minnesota 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 the intern's 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 or six–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, fifth, and sixth year; participation in approved clinical pharmacy programs; or participation in approved internship demonstration projects such as industrial or research experiences;

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

C. 800 hours of internship credit may be acquired through Pharm D clinical rotations on condition that the remaining 700 hours of the 1,500–hour total requirement is of a traditional compounding and dispensing nature.

Statutory Authority: *MS s 151.06; 151.101*

History: *17 SR 1279; 18 SR 1145*

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, pharmacist–interns, and representatives of the board.

Statutory Authority: *MS s 151.06; 151.101*

History: *18 SR 1145*

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, except that part 6800.3000, subpart 2, shall continue to apply, a li-

censed pharmacist, registered nurse, or licensed practical nurse who is employed by a licensed nursing home, boarding care home, or supervised living 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 does 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 in accordance with part 6800.3000, subpart 2.

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*

History: *18 SR 1145*

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 additional information: quantity of drug dispensed; date of original issue, or in the case of a refill, the most recent date; 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 the prescriber's agent. Personnel of the facility may affix supplemental labels alerting staff to a change in the directions for use when a corresponding change is made on the appropriate medication administration record, in accordance with procedures approved by the facility's quality assurance and assessment committee. Subsequent refills of the medication shall be appropriately labeled with the directions for use in effect at the time of dispensing.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 17 SR 1279; 18 SR 1145*

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 CONSULTING SERVICES TO LICENSED NURSING HOMES.

Subpart 1. **Written agreement.** A pharmacist providing pharmacy consultative services to a licensed nursing home shall devote a sufficient number of hours during regularly scheduled visits to the facility for the purpose of reviewing the quality of the pharmaceutical services provided to the facility residents. There shall be a written agreement, separate and apart from that provided to pharmacists supplying prescription drug services to residents, for the pharmaceutical consultative services between the facility and the consulting services provider 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 including 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, 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 the quality assurance and assessment 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;

G. providing in–service training to nursing personnel; and

H. developing policies for the issuance of medications to residents who are going on leave from the facility. These policies may allow the preparation, by facility personnel responsible for overseeing medication administration, of a supply of medications, not to exceed a 72–hour supply, in paper envelopes or other more suitable containers for use by a resident temporarily leaving the facility at times when the resident's pharmacy is closed or cannot supply the needed medication in a timely manner. A container may hold only one medication. A label on the container shall include the date, the resident's name, the facility, the name of the medication, its strength, dose, and time of administration, and the initials of the person preparing the medication and label.

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 unused portion of other prescribed 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.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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.** A pharmacy may provide, upon a written or oral request from the quality assurance and assessment committee, limited supplies of drugs for use in an emergency kit. The drugs remain the property of the pharmacy.

Subp. 2. **Emergency drug supplies.** Only emergency drug supplies determined by the quality assurance and assessment committee 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 in this subpart. The emergency drug supplies shall comply with the following:

A. The drugs shall be limited to the extent possible to a 72–hour supply of any one emergency drug in either sealed ampules, vials, or prefilled syringes. If an emergency drug is

not available in parenteral form, a supply in an alternate dosage form may be provided. Notwithstanding these restrictions, if the quality assurance and assessment committee considers it necessary, up to a 72–hour supply of each of a maximum of ten different oral pharmaceuticals restricted to therapeutic categories related to symptomatic patient distress or emergencies may be stocked. Inclusion of other oral legend drugs is permissible only through the granting of a variance by the board. Drugs in the supply shall be properly labeled, including expiration dates and lot numbers.

B. The emergency drug supply shall be stored in a container which is sealed by the pharmacist or the pharmacist's agent 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 by submitting a prescription for the used item to the pharmacist within 72 hours and the supply shall be resealed by the pharmacist or the pharmacist's agent.

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

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 for two years, 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.

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 part are violated, the board may suspend or revoke a pharmacy's privilege to maintain an emergency kit of drug supplies at the noncompliant facility.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 and related pharmaceutical care services 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*

History: *9 SR 1656; 18 SR 1145*

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.

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 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. [Repealed, 18 SR 1145]

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

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;

F. the use of drugs brought into the hospital by or with the patient. If the 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;

G. the use of investigational drugs; and

H. the preparation, use, and disposal of chemotherapy drugs.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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. Developing a system to assure that outpatient drug dispensing through the emergency room after regular pharmacy hours complies with all laws and board rules relating to prepackaging, labeling, dispensing, and record keeping. The system shall limit dispensing done in the absence of the pharmacist and physician to an amount not exceeding a 72–hour supply. No controlled substances may be dispensed in this manner.

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

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

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

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

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

M. Providing for a system of accountability for inpatient dispensing meeting the intent of the certification requirement of part 6800.3100.

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

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

P. Assuring that precautionary measures, including quality control documentation, for the safe admixture of parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, pharmacist–interns, 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, and must be prepared in a laminar or vertical flow hood whenever possible. Chemotherapy admixtures shall be prepared in a vertical flow hood whenever possible.

Q. 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).

R. 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.

S. Developing, implementing, and maintaining a system of controlled substance and narcotic control in accordance with subitems (1) to (7).

(1) Controlled substances must be accounted for by either:

(a) a "proof–of–use" sign–out sheet where each dose given is accounted for by the nurse administering the drug. No controlled substance may be kept on floor stock unless it is accompanied by the sign–out sheet and each dose is documented by the nurse at

the time the drug is procured from the nursing station stock. The proof–of–use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed nurse's signature; or

(b) the dispensing of the drug to a specific patient after the pharmacy receives an individual drug order.

(2) Wasted doses must be documented and witnessed by the signature of two individuals who are nurses or pharmacists.

(3) There must be a system for reconciling the proof–of–use sheets in the pharmacy to assure accountability of all sheets sent to the various nursing stations.

(4) Controlled substances must be stored under lock on the nursing stations.

(5) Access to the main supply of Schedule II controlled substances in the pharmacy must be restricted to a limited number of persons in the pharmacy. The main supply of Schedule II controlled substances in the pharmacy must be kept locked when not being used.

(6) Single unit–of–use dosage forms should be used when possible.

(7) A perpetual inventory of Class II controlled substances must be accurately maintained.

T. Developing policies for the issuance of medications to patients who are going on leave from the facility. These policies may allow the preparation, by facility personnel responsible for overseeing medication administration, of a supply of medications, not to exceed a 72–hour supply, in paper envelopes or other more suitable containers for use by a patient temporarily leaving the facility at times when the facility's pharmacy is closed or cannot supply the needed medication in a timely manner. A container may hold only one medication. A label on the container shall include the date, the patient's name, the facility, the name of the medication, its strength, dose, and time of administration, and the initials of the person preparing the medication and label.

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

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 two years.

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 for two years;

(5) receipted invoices for drugs, chemicals, and pharmaceutical service supplies purchased and received over the immediately preceding two years; and

(6) any agreement or contract between an off–premises pharmacy and the hospital.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 to inpatients 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 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*

History: *18 SR 1145*

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. name of patient;

B. name of drug;

C. route of administration of drug when necessary for clarification;

D. strength of drug;

E. auxiliary labels as needed;

F. expiration date, if applicable; and

G. date dispensed.

Subp. 3. **Drugs prepackaged 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 supplemental label should be placed 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.** Intravenous admixtures must 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, if appropriate;

D. name and quantity of each additive;

E. infusion or administration rate, if appropriate;

F. storage requirements if other than room temperature;

G. identity of the pharmacist preparing or certifying the admixture;

H. date and time of administration;

I. expiration date and date and time of compounding; and

J. ancillary precaution labels.

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

Statutory Authority: *MS s 151.06; 151.212*

History: *9 SR 1656; 18 SR 1145*

6800.7950 EXTENSION OF PHARMACY SERVICES UNDER LICENSE.

A licensed pharmacy in a hospital may utilize additional locations within the hospital in conformity with part 6800.0800, subpart 3, without the necessity of securing additional licenses provided, however, that the pharmacist–in–charge of the hospital pharmacy informs the board of the location of each satellite and assumes professional responsibility, in accordance with parts 6800.2400 and 6800.3850, for the practice of pharmacy and for staffing in each additional location.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

OPERATION OF PARENTERAL–ENTERAL/HOME HEALTH CARE PHARMACIES

6800.8000 SCOPE AND PURPOSE.

The purpose of parts 6800.8000 to 6800.8008 is to provide standards for the preparation, labeling, and distribution of sterile products by licensed parenteral–enteral/home health care pharmacies pursuant to an order or prescription. The standards are intended to apply to sterile products compounded by the pharmacist, notwithstanding the location of the patient, such as a private home, nursing home, hospice, or doctor's office.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8001 POLICY AND PROCEDURES MANUAL.

To obtain a pharmacy license as a parenteral–enteral home health care pharmacy, a policy and procedures manual relating to sterile products shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis. The manual shall include the policy and procedures for:

A. clinical services;

B. cytotoxics handling, storage, and disposal;

C. disposal of unused supplies and medications;

D. drug destruction and returns;

E. drug dispensing;

F. drug labeling and relabeling;

G. drug storage;

H. duties and qualifications for professional and nonprofessional staff;

I. equipment;

J. handling of infectious wastes;

K. infusion devices and drug delivery systems;

L. investigational drugs;

M. obtaining a protocol on investigational drugs from the principal investigator;

N. public safety;

O. quality assurance procedures, including:

(1) recall procedures;

(2) storage and dating;

(3) educational procedures for professional staff, nonprofessional staff, and patients;

(4) sterile procedures including a log of the temperature of the refrigerator, routine maintenance, and report of hood certification; and

(5) sterility testing of the product;

P. record keeping;
Q. reference materials;
R. sanitation;
S. security;
T. sterile product preparation procedures; and
U. transportation.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8002 PHYSICAL REQUIREMENTS.

Subpart 1. **Space.** The pharmacy licensed under parts 6800.8000 to 6800.8008 shall have a designated area with entry restricted to designated personnel for preparing compounded, sterile parenteral products. The area shall be structurally isolated from other areas, with restricted entry or access, and must be designed to avoid unnecessary traffic and air flow disturbances from activity within the controlled facility. The area shall be used only for the preparation of parenteral or enteral specialty products. It shall be of sufficient size to accommodate a laminar air flow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

Subp. 2. **Equipment.** The licensed pharmacy preparing sterile parenteral products shall have equipment as required by part 6800.1050.

Subp. 3. **Time for compliance.** Licensed pharmacies providing services to parenteral–enteral home health care patients on November 1, 1993, shall have 90 days to comply with subparts 1 and 2.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8003 PERSONNEL.

Subpart 1. **Pharmacist–in–charge.** In addition to the pharmacist–in–charge requirements of part 6800.2400, the section of the pharmacy providing home health care pharmacy services must be managed by a pharmacist licensed to practice pharmacy in Minnesota who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile parenteral products, including the principles of aseptic technique and quality assurance. The knowledge is usually obtained through residency training programs, continuing education programs, or experience in an intravenous admixture facility. The pharmacist–in–charge is responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of drugs and pharmaceuticals and for the development and continuing review of policies and procedures, training manuals, and quality assurance programs. The pharmacist–in–charge may be assisted by additional pharmacists adequately trained in this area of practice.

Subp. 2. **Supportive personnel.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services may be assisted by supportive personnel. The personnel must have specialized training in the field and must work under the immediate supervision of a licensed pharmacist. The training provided to the personnel must be described in writing in a training manual. Their duties and responsibilities must be consistent with their training and experience and must remain in conformity with the requirements of part 6800.3850.

Subp. 3. **Staffing.** A pharmacist must be accessible at all times to respond to patients' and other health professionals' questions and needs.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8004 DRUG DISTRIBUTION AND CONTROL.

Subpart 1. **General.** This part governs the mechanism by which a physician's prescription is executed, from the time the drug is ordered and received in the pharmacy to the time the prescribed drug is dispensed to the patient.

Subp. 2. **Prescription.** The pharmacist, or pharmacist–intern acting under the immediate supervision of a pharmacist, must receive a written or oral prescription from a physician before dispensing any compounded, sterile parenteral product. Prescriptions must be filed as required by law or rules of the board.

Subp. 3. **Labeling.** Each compounded intravenous admixture product must be labeled in accordance with part 6800.3450.

Subp. 4. **Delivery.** The pharmacist–in–charge shall assure the environmental control of all products shipped as follows:

A. compounded, sterile pharmaceuticals must be shipped or delivered to a patient in appropriate temperature–controlled delivery containers, as defined by United States Pharmacopeia standards, and stored appropriately in the patient's home; and

B. chain of possession for the delivery of Schedule II controlled substances via courier must be documented, and a receipt obtained.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8005 CYTOTOXIC AGENTS.

Licensed pharmacies that prepare cytotoxic drugs must comply with the requirements in items A to F in addition to the requirements in parts 6800.8000 to 6800.8004.

A. Cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet.

B. Protective apparel, such as disposable masks, gloves, and gowns with tight cuffs, shall be worn by personnel compounding cytotoxic drugs.

C. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

D. Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

E. Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedures manual.

F. Prepared doses of cytotoxic drugs must be dispensed and shipped in a manner that will minimize the risk of accidental rupture of the primary container.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8006 DRUG USE REVIEW.

Systematic processes of drug use review must be designed, followed, and documented to assure that appropriate patient outcomes occur from drug therapy on an ongoing basis.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8007 PATIENT CARE GUIDELINES.

Subpart 1. **Primary provider.** The pharmacist who assumes the responsibilities under this part must ensure that there is a designated physician primarily responsible for the patient's medical care and that there is a clear understanding between the physician, licensed home care agency, if any, the patient, and the pharmacist of the responsibilities of each in the areas of the delivery of care and the monitoring of the patient. Compliance with this subpart shall be documented in the patient's profile.

Subp. 2. **Patient training.** The pharmacy must demonstrate or document the patient's training and competency in managing this type of therapy in the home environment. A pharmacist must be involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility.

Subp. 3. **Patient monitoring.** The pharmacist shall request access to clinical and laboratory data concerning each patient and, if the data is obtained, monitor each patient's re-

sponse to drug therapy. Any unexpected or untoward response shall be reported to the prescribing physician. If the data is not obtained and the pharmacist is not doing the monitoring, the identity of the health care provider who has assumed the responsibility shall be documented in the patient's profile.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8008 QUALITY ASSURANCE.

Subpart 1. **Quality control program.** There must be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. The end product must be examined on a sampling basis as determined by the pharmacist–in–charge to assure that it meets required specifications.

Subp. 2. **Hood certification.** All laminar flow hoods must be inspected by a qualified individual for operational efficiency at least every 12 months. Appropriate records of the inspection must be maintained.

Subp. 3. **Prefilters.** Prefilters for the clean air source must be replaced on a regular basis and documented.

Subp. 4. **Bulk compounding.** If bulk compounding of parenteral solutions is performed using nonsterile chemicals, extensive end–product testing must be documented before release of the product from quarantine. The process must include testing for sterility and pyrogens.

Subp. 5. **Expiration dates.** If the product is assigned an expiration date that exceeds seven days from its compounding date, there must be in–house data or data in the literature to assure the sterility and stability of the product when it is used by the patient.

Subp. 6. **Quality control audits.** There must be documentation of quality assurance audits at regular, planned intervals.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

RADIOACTIVE DRUGS

6800.8100 DEFINITIONS.

Subpart 1. **Manufacturers of radiopharmaceuticals.** Any person, firm, or hospital compounding, mixing, deriving, repackaging, or otherwise preparing a radioactive drug shall be licensed as a manufacturer, unless the drug is prepared for use by:

A. the medical facility to which the facility preparing the product is physically attached; or

B. an individual patient when the drug is being dispensed on the order of a licensed practitioner.

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. **Radiopharmaceutical.** A radiopharmaceutical 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.

Subp. 4. **Nuclear pharmacy practice.** "Nuclear pharmacy practice" refers to a patient–oriented pharmacy service that embodies the scientific knowledge and professional judgment required for the assurance of the safe and effective use of radiopharmaceuticals and other drugs.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8200 SCOPE.

Parts 6800.8100 to 6800.8700 are applicable to pharmacies and manufacturers dealing with radiopharmaceuticals; 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 with them, in which case parts 6800.8100 to 6800.8700 apply.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 radiopharmaceuticals, 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, 6800.0910, 6800.0950, 6800.1050, and 6800.2150 if the board finds it is in the public interest.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

6800.8400 PHARMACISTS HANDLING RADIOPHARMACEUTICALS.

A pharmacist handling radiopharmaceuticals must be competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radiopharmaceuticals. The pharmacist 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, the programs provide a level of competence substantially the same as approved programs.

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

6800.8500 PHARMACIST–IN–CHARGE.

A pharmacy handling radiopharmaceuticals shall not function without having a pharmacist who is competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radiopharmaceuticals in charge of the licensed premises. A qualified nuclear pharmacist shall be a currently licensed pharmacist in Minnesota and either be certified as a nuclear pharmacist by the board of pharmaceutical specialties or meet the following standards:

A. have received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy, with emphasis in the following areas:

(1) radiation physics and instrumentation;

(2) radiation protection;

(3) mathematics of radioactivity;

(4) radiation biology; and

(5) radiopharmaceutical chemistry;

B. attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist; and

C. submit an affidavit of experience and training to the Board of Pharmacy.

Personnel performing tasks within the pharmacy shall be under the immediate and direct supervision of the pharmacist competent in handling radiopharmaceuticals.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8600 ACQUISITION, STORAGE, AND DISTRIBUTION OF RADIOPHARMACEUTICALS.

Only radiopharmaceuticals 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.

Radioactive materials shall be kept locked and secure from unauthorized personnel.

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

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.8700 RECORD KEEPING.

A pharmacist handling radiopharmaceuticals shall maintain records of acquisition and disposition of radiopharmaceuticals for at least two years.

In the case of investigational radiopharmaceuticals, the pharmacy records shall include an investigators protocol for the preparation of radiopharmaceuticals, 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 radiopharmaceutical 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*

History: *18 SR 1145*

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, when its investigation discloses probable grounds for disciplinary action; the board president or director may act for the board in initiating proceedings under this part.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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 a 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*

History: *17 SR 1279*

6800.9600 ORDER FOR AND NOTICE OF HEARING.

Notices of hearing shall be addressed to the respondent at the 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*

History: *17 SR 1279*

6800.9700 SERVICE AND FILING OF PAPERS.

Unless otherwise provided by law, all orders, notices, and other papers may be served by the director of the board by first class, certified, or registered mail addressed to the party at the last known post office address, or to the attorney of record. Papers required to be filed with the board may be mailed to the following address: 2700 University Avenue West #107, St. Paul, Minnesota 55114–1079.

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

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:

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.

Subp. 6. **Research projects.** Pharmacists desiring to participate in research or studies not presently allowed by or addressed by rules of the board may apply for approval of the projects through waivers or variances in accordance with subparts 1 to 4.

Statutory Authority: *MS s 151.06*

History: *10 SR 2007; 18 SR 1145*

LEGEND MEDICAL GASES

6800.9920 DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES.

Parts 6800.9920 to 6800.9924 apply to the retail sale and distribution of legend medical gases.

Statutory Authority: *MS s 151.06 subd 1; 151.19 subd 3*

History: *14 SR 617*

6800.9921 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or establishment selling or distributing legend medical gases in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in Minnesota Statutes, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration, and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and must be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The registration certificate must be displayed at the location for which it was issued. A change in the location of a registered facility will require reregistration.

Statutory Authority: *MS s 151.06 subd 1; 151.19 subd 3*

History: *14 SR 617*

6800.9922 RESTRICTED SALES.

No person or establishment shall sell or distribute legend medical gases at retail to anyone other than:

A. a patient on the basis of a prescription from a practitioner; or

B. a hospital, a practitioner as defined in Minnesota Statutes, section 151.01, subdivision 23, a licensed pharmacy, or other institution or person licensed to possess these drugs for use in the usual course of practice. The distributor of these items shall determine if the purchaser is licensed to possess them.

Statutory Authority: *MS s 151.06 subd 1; 151.19 subd 3*

History: *14 SR 617*

6800.9923 LABELING.

No person or distributor may sell or distribute any legend medical gas product at retail without the manufacturer's intact federally required labeling.

Statutory Authority: *MS s 151.06; 151.19*

History: *14 SR 617; 18 SR 1145*

6800.9924 RECORDS.

A sale or distribution of legend medical gases by registered distributors of these items at retail must be limited to the prescription or order of a licensed practitioner. The orders or prescriptions must be maintained for at least two years, must be filed by patient name or date, and must be readily retrievable and available for inspection by the Board of Pharmacy. The prescription must bear at least the patient's name and address, date, name and quantity of legend medical gas distributed, and name and address of the prescriber. Refills of legend medical gases must be recorded and the record must be maintained for at least two years.

Statutory Authority: *MS s 151.06; 151.19*

History: *14 SR 617; 18 SR 1145*

DISPENSING BY PRACTITIONERS

6800.9950 DISPENSING BY PRACTITIONERS.

Parts 6800.9951 to 6800.9954 apply to medical, dental, veterinary, and other licensed practitioners engaged in dispensing drugs and controlled substances.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.9951 DRUG STORAGE.

Practitioners engaged in dispensing drugs shall have a separate locked drug storage area for the safe storage of drugs. Access to the drug supply shall be limited to persons who have legal authority to dispense and to those under their direct supervision.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.9952 DISPENSING.

Subpart 1. **Who may dispense.** A dispensing practitioner shall personally perform all dispensing functions described in part 6800.3100 that are required of a pharmacist when the dispensing is being done in a pharmacy. A practitioner may delegate functions that may be delegated to supportive personnel in accordance with part 6800.3850.

Subp. 2. **Written prescriptions required.** A practitioner shall reduce all drug orders to a written prescription that shall be numbered and filed in an organized manner when dispensed. Patient chart records do not qualify as a prescription record.

Subp. 3. **Tight containers.** Drugs dispensed shall be packaged in prescription containers meeting United States Pharmacopeia requirements for "tight" or "well closed" containers.

Subp. 4. **Child–resistant containers.** Drugs dispensed shall be packaged in child–resistant containers as required by the federal Poison Prevention Packaging Act unless the patient specifically requests the use of non–child–resistant containers. Any such request must be documented.

Subp. 5. **Controlled substances.** Controlled substance prescriptions shall be filed in accordance with federal and state laws relating to controlled substances.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.9953 LABELING.

Prescription containers, other than those dispensed in unit dose under part 6800.3750, shall be labeled in accordance with part 6800.3400.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

6800.9954 RECORDS.

A practitioner engaged in dispensing drugs shall keep on file at each location from which dispensing is taking place a record of drugs received, administered, dispensed, sold, or

distributed. The records shall be readily retrievable, shall be maintained for at least two years, and shall include:

A. a record or invoice of all drugs received for purposes of dispensing to patients;

B. a prescription record of drugs dispensed, filed by prescription number or date, showing the patient's name and address, date of the prescription, name of the drug, strength of the drug, quantity dispensed, directions for use, signature of practitioner and, if it is a controlled substance, practitioner's Drug Enforcement Administration number;

C. a record of refills recorded on the back of the prescriptions showing date of refill, quantity dispensed, and initials of dispenser; and

D. the patient profile requirements of part 6800.3110, if all data required by that part is not already included in the patient's chart.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*