CHAPTER 6800
BOARD OF PHARMACY
PHARMACIES AND PHARMACISTS

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. 1a. **Board.** "Board" means the Board of Pharmacy.

Subp. 1b. **Beyond-use date.** "Beyond-use date" means the date after which a drug should not be used.

Subp. 1c. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that may provide dispensing functions, drug utilization review (DUR), packaging, labeling, or delivery of a filled prescription for another pharmacy.

Subp. 2. **Community/outpatient pharmacy.** "Community/outpatient 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. 2a. **Community satellite.** "Community satellite" means a site affiliated with a licensed community pharmacy, which is dependent on the licensed community pharmacy for administrative control, staffing, and drug procurement. A community satellite must be under the direction of a licensed pharmacist and comply with the requirements of part 6800.0800, subpart 3.

Subp. 2b. **Expiration date.** "Expiration date" means the date placed on the container or label of a drug product designating the time during which the product is expected to remain within the approved shelf life specifications if stored under defined conditions, and after which it may not be used.

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. 3a. **Hospital satellite.** "Hospital satellite" 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 hospital satellite must be under the direction of a licensed pharmacist, comply with the requirements of part 6800.0800, subpart 3, and provide pharmacy services to hospital patients only.

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/outpatient 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, assisted living facility, or supervised living facility and from which related pharmaceutical care services are delivered.

Subp. 4a. **Assisted living facility.** For the purposes of this chapter, the term "assisted living facility" means a registered housing with services establishment, as defined in Minnesota Statutes, section 144D.01, subdivision 4, that provides central storage of medications for residents.

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. **Home health care pharmacy.** "Home health care pharmacy" means an established place, whether or not in conjunction with a hospital pharmacy, long-term care pharmacy, or a community/outpatient 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. [Repealed, 23 SR 1597]

Subp. 11. **Prescription drug order.** "Prescription drug order" means a lawful written, oral, or electronic order of a practitioner for a drug for a specific patient. A prescription drug order must contain the information specified in this chapter and in Minnesota Statutes, section 151.01, subdivision 16.

Subp. 11a. **Prescription.** "Prescription" means a prescription drug order that is written or printed on paper, an oral order reduced to writing by a pharmacist, or an electronic order. To be valid a prescription must be issued for an individual patient by a practitioner within the scope and usual course of the practitioner's practice, and must contain the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, the name and address of the practitioner, and a telephone number at which the practitioner can be reached. A prescription written or printed on paper that is given to the patient or an agent of the patient, or transmitted facsimile-to-facsimile must contain the practitioner's manual signature. An electronic prescription must contain the practitioner's electronic signature.

Subp. 11b. **Chart order.** "Chart order" means a prescription drug order for a drug that is to be dispensed by a pharmacist, or by a pharmacist-intern under the direct supervision of a pharmacist, and administered by an authorized person only during the patient's stay in a hospital or long-term care facility. The chart order shall contain the name of the patient, another patient identifier such as a birth date or medical record number, the drug ordered,

and any directions as the practitioner may prescribe concerning strength, dosage, frequency, and route of administration. The manual or electronic signature of the practitioner must be affixed to the chart order at the time it is written or at a later date in the case of verbal chart orders.

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. [Repealed, 31 SR 1673]

Subp. 14. **Nonsterile preparation compounding.** "Nonsterile preparation compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a nonsterile drug preparation, according to United States Pharmacopeia Chapter 795.

Subp. 15. **Sterile preparation compounding.** "Sterile preparation compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug preparation that achieves sterility, according to United States Pharmacopeia Chapter 797.

Subp. 16. **Limited service pharmacy.** "Limited service pharmacy" means a pharmacy to which the board may assign a restricted license to perform a narrow range of the activities that constitute the practice of pharmacy.

Subp. 17. **Unique identifier.** "Unique identifier" means a manual signature or initials, a biometric identifier, or a board-approved electronic means of identifying only one individual.

Subp. 18. **High-alert drug.** "High-alert drug" means a drug that bears a heightened risk of causing significant patient harm when it is used in error.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *17 SR 1279; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

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*

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*

6800.0300 PHARMACY LICENSE AND FEE REQUIRED.

No person or persons shall conduct a pharmacy in or outside of Minnesota that dispenses legend drugs for Minnesota residents and mails, ships, or delivers the legend drugs into this state unless the pharmacy is licensed by the Board of Pharmacy. A fee established in Minnesota Statutes, chapter 151, 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.

An application for a pharmacy license which has not been completed within 12 months of the date on which the board received the application is no longer valid.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145; 36 SR 237*

6800.0350 LICENSE CATEGORIES.

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

A. community/outpatient;

B. hospital;

C. home health care;

D. long-term care;

E. nuclear;

F. central service;

G. nonsterile preparation compounding;

H. sterile preparation compounding;

I. veterinary; and

J. limited service.

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. Effective July 1, 2012: an initial or renewed license issued by the board shall list each license category for which the pharmacy has received board approval; a pharmacy must receive board approval before providing services in a license category not listed on its license; a pharmacy must notify the board if the pharmacy no longer provides services in a license category; and the board shall issue a revised license without imposing an additional fee, if it approves a pharmacy's request to provide services in additional license categories or if a pharmacy no longer provides services in one or more license categories.

The board may establish special conditions for licensure, appropriate to the situation, before approving a license application for a pharmacy with a limited service license category. Such pharmacies must also apply for and receive any necessary variances, according to part 6800.9900, before an application for licensure is approved.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

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 established in Minnesota Statutes, chapter 151. Renewal applications received on or after July 1 are subject to a late filing fee of an amount equal to 50 percent of the renewal fee in addition to the renewal fee.

Statutory Authority: *MS s 16A.128; 151.06; 151.07; 151.12; 151.13; 151.19; 151.25; 151.47; 151.48; 151.49; 214.06*

History: *9 SR 1656; 11 SR 335; 22 SR 1547; 25 SR 81; 36 SR 237*

6800.0500 SEPARATE LICENSE REQUIRED.

Subpart 1. **Transfer of license restrictions.** A separate license shall be required for each pharmacy and is not transferable. The following shall be considered a transfer of ownership 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; or

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

Subp. 2. **Transfer of ownership.** For a transfer of ownership, the new owner must submit a completed pharmacy license application prior to the effective date of the transfer. Upon a transfer of ownership, the new owner can continue operation of the pharmacy under the license issued to the prior owner for 14 days after the effective date of the change of ownership or until the board issues a new license, whichever is earlier. After the 14-day period, the license issued to the prior owner is void and must be surrendered to the director of the board.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145; 36 SR 237*

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; 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 250 square feet in the dispensing and drug storage area;

B. maintains a prescription dispensing counter at least 18 inches deep that provides two linear feet, which must be kept clear and free of all merchandise and other materials not currently in use in the practice of compounding and dispensing, for each pharmacist and each technician working concurrently on compounding and dispensing; this counter shall provide an additional space for computers if they are used in the dispensing process;

C. maintains an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter, which shall be kept free of obstruction at all times;

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

E. in the case of a community/outpatient pharmacy, contains an area where consultation between the patient and the pharmacist may be conducted with a reasonable assurance of privacy. All new and remodeled community/outpatient pharmacies must meet the standards of this item. A pharmacy licensed before January 1, 2011, must meet the standards within two years of that date, unless the pharmacy has an existing counseling area that has been deemed by the board to provide a reasonable assurance of privacy. If pharmacies use partitions to create a consultation area in which the patient will typically remain standing, the partitions must be sound-dulling and at least seven feet high and 24 inches deep. The patient must be able to enter the partitioned area so that the partitions are on each side

of the patient. Consultation areas without partitions may be approved if the board deems the consultation area will provide a reasonable assurance of privacy. Consultation areas must not contain any item for sale apart from the articles needed for counseling sessions. Pharmacists must have access to patient profiles in order to comply with part 6800.0910. Consultation areas must be accessible to the patient from the outside of the prescription dispensing area and be open at all times when the pharmacy is open; and

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

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

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *18 SR 1145; 23 SR 1597; 27 SR 260; 36 SR 237*

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.** No licensed pharmacy in Minnesota shall establish a community or hospital satellite until it has submitted documents, plans, and operational policies and procedures 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 part 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; 152.02*

History: *18 SR 1145; 31 SR 1673*

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 filled prescription for a patient, a pharmacist must consult with the patient or the patient's agent or caregiver and inquire about the patient's understanding of the use of the drug according to this part.

A. Upon receipt of a new prescription, following a review of the patient's record, 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 or the agent or caregiver of the patient. The discussion shall be in person, whenever applicable, may be supplemented with written material, and shall include appropriate elements of patient counseling. These elements include the following:

(1) the name and description of the drug;

(2) the dosage form, dose, route of administration, and duration of drug therapy;

(3) intended use of the drug and expected action;

(4) special directions and precautions for preparation, administration, and use by the patient;

(5) 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;

(6) techniques for self-monitoring of drug therapy;

(7) proper storage;

(8) prescription refill information;

(9) action to be taken in the event of a missed dose; and

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

B. The pharmacist must counsel the patient on a refilled prescription if deemed necessary according to the pharmacist's professional judgment. The consultation must be in person whenever applicable.

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 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 filled 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; 152.02*

History: *18 SR 1145; 27 SR 260; 31 SR 1673; 36 SR 237*

6800.0950 REQUIREMENT FOR A SUPERVISED PHARMACY AREA.

The Board of Pharmacy shall refuse to grant a pharmacy license to any existing or proposed facility or place of business unless the facility or place of business has an area that meets the definition of and the requirements for a pharmacy according to this chapter.

The pharmacy area must be under the supervision of a licensed pharmacist. The board may issue a pharmacy license for a limited service pharmacy according to part 6800.0350.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 17 SR 1279; 18 SR 1145; 36 SR 237*

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 notify the board of the intended closing.

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, legend drugs, insulin, hypodermic syringes and needles, contraceptive drugs and devices, chemicals, 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. 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

F. 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 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.

Subp. 3. **Public notification.** A licensed pharmacy must provide the following public notification when closing a pharmacy: distribution, by at least one of the following means, of a notice that informs patients that the pharmacy will close on a specified date and that gives the name, address, and telephone number of the pharmacy to which prescription files will be transferred:

A. publication of the notice in a local newspaper for one week prior to the date on which the pharmacy is to be closed;

B. a direct mailing to patients who have had at least one prescription filled at that pharmacy during the six months preceding the date of closing, with the mailing designed to reach patients no later than one business day prior to the closing; and

C. distribution of the notice to patients who are picking up prescriptions at least 30 days prior to the date on which the pharmacy will be closed.

In the case of patients who are residents of long-term care facilities, the pharmacy shall provide a written notice to the patients, the caregivers of the patients, or the long-term care facilities in which the patients reside at least 30 days prior to the date on which the pharmacy will be closed.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

6800.1050 REQUIRED REFERENCE BOOKS AND EQUIPMENT.

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

A. Examples of pharmacotherapy references are:

(1) Goodman and Gilman's The Pharmacological Basis of Therapeutics;

(2) Applied Therapeutics: The Clinical Use of Drugs;

(3) Pharmacotherapy: A Pathophysiologic Approach; and

(4) Conn's Current Therapy.

B. Examples of dosage and toxicology references are:

(1) American Hospital Formulary Service;

(2) Facts and Comparisons; and

(3) Drug Information Handbook.

C. Examples of general references are:

(1) Handbook of Nonprescription Drugs;

(2) Physician's Desk Reference;

(3) Remington: The Science and Practice of Pharmacy;

(4) United States Pharmacopeia - National Formulary;

(5) United States Pharmacopeia - Pharmacists' Pharmacopeia;

(6) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations; and

(7) The Merck Manual.

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

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

A. one prescription balance, Class A as defined in United States Pharmacopeia - National Formulary, with one set of accurate metric weights from 50 mg to 100 g, or an electronic balance of equal or greater accuracy;

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

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

D. other equipment as necessary to comply with the requirements of United States Pharmacopeia, chapter 795;

E. a refrigerator used only for drug storage or a separate compartment used only for drug storage within a general use refrigerator, manual, electromechanical, or electronic temperature recording equipment, devices, or logs shall be used to document proper storage of legend drugs every business day;

F. a sink with hot and cold running water; and

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

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

A. minimum equipment to comply with the United States Pharmacopeia, chapter 797, appropriate to risk-level requirements;

B. current reference materials or books for sterile products or intravenous incompatibilities; and

C. a current copy of United States Pharmacopeia, chapter 797.

Statutory Authority: *MS s 151.06; 152.02*

History: *9 SR 1656; 18 SR 1145; L 2001 1Sp4 art 6 s 1; 31 SR 1673; 36 SR 237*

6800.1100 [Renumbered 6800.1250]

LICENSING PHARMACISTS

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 $105. 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; 151.07; 151.12; 151.13; 151.19; 151.25; 151.47; 151.48; 151.49; 214.06*

History: *9 SR 1656; 13 SR 1775; 16 SR 2239; 18 SR 1145; 22 SR 1547; 25 SR 81*

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. **Graduates of colleges or schools of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE).** An applicant for licensure by examination who is a graduate of a college or school of pharmacy accredited by ACPE shall submit a completed eligibility application, affidavits of internship, a copy of the applicant's official and certified birth record, and a recent photograph. An applicant shall provide the board with an official certified final transcript from an ACPE accredited college or school of pharmacy showing the date on which the applicant graduated with a bachelor of science degree or doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy. The documents in this subpart, together with a check for the application fee under Minnesota Statutes, chapter 151, and made payable to the Minnesota Board of Pharmacy, must be received by the board prior to approval being granted to sit for the examinations. Applicants must register with and pay the required fees to the National Association of Boards of Pharmacy for the North American Pharmacy Licensing Exam and the Multistate Pharmacy Jurisprudence Exam, both of which must be passed before licensure as a pharmacist is granted.

Subp. 1a. **Graduates of colleges or schools of pharmacy accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).**

A. Applicants who graduated between 1993 and June 30, 2004, from a CCAPP-accredited pharmacy program with a curriculum taught in English must:

(1) submit a letter to the Board of Pharmacy which outlines work experience as an intern or pharmacist in Canada. The board shall determine if the reported experience is comparable to the experience gained by individuals completing the internship requirement specified in part 6800.5400. If the board finds that the reported experience is not comparable, the board shall require the applicant to obtain additional experience as an intern or pharmacist prior to permitting the applicant to sit for the required licensure examinations;

(2) submit to the board a completed eligibility application, a copy of the applicant's official certified birth record, a recent photograph, an official certified final transcript

from a CCAPP-accredited college or school of pharmacy showing the date on which the applicant graduated with a first professional pharmacy degree, and a check for the application fee under Minnesota Statutes, chapter 151; and

(3) register with and pay the required fees to the National Association of Boards of Pharmacy for the North American Pharmacy Licensing Exam and the Multistate Pharmacy Jurisprudence Exam, both of which must be passed before licensure as a pharmacist is granted.

B. Applicants who graduated before 1993 or after June 30, 2004, from a CCAPP-accredited pharmacy program with a curriculum taught in English or who graduated from a CCAPP-accredited pharmacy program with a curriculum that is not taught in English or licensed Canadian pharmacists who graduated from a college of pharmacy located outside of the United States or Canada must:

(1) pass the Foreign Pharmacy Graduate Equivalency Examination and become certified by the Foreign Pharmacy Graduate Equivalency Commission (FPGEC), including demonstrating proficiency in the English language by passing the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English, or the TOEFL Internet-based Test;

(2) obtain 1,600 hours of internship after becoming certified by the FPGEC. Applicants obtaining their internship in Minnesota must register as interns according to part 6800.5300 and complete the internship manual as specified in that part. Applicants obtaining their internship outside of Minnesota must have the licensing agency of the state in which the internship was completed certify to the board completion of the internship hours;

(3) submit to the board a completed eligibility application form, a copy of the applicant's official certified birth record, a recent photograph, and a check for the application fee under Minnesota Statutes, chapter 151; and

(4) register with and pay the required fees to the National Association of Boards of Pharmacy for the North American Pharmacy Licensing Exam and the Multistate Pharmacy Jurisprudence Exam, both of which must be passed before licensure as a pharmacist is granted.

Subp. 1b. **Foreign pharmacy graduates.**

A. Except as provided in subpart 2, graduates of foreign schools, colleges, or programs of pharmacy must:

(1) pass the Foreign Pharmacy Graduate Equivalency Examination and become certified by the Foreign Pharmacy Graduate Equivalency Commission (FPGEC), including demonstrating proficiency in the English language by passing the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English, or the TOEFL Internet-based Test;

(2) obtain 1,600 hours of internship after becoming certified by the FPGEC. Applicants obtaining their internship in Minnesota must register as interns according to part 6800.5300 and complete the internship manual as specified in that part. Applicants obtaining their internship outside of Minnesota must have the licensing agency of the state in which the internship was completed certify to the board completion of the internship hours;

(3) submit to the board a completed eligibility application form, a copy of the applicant's official certified birth record, a recent photograph, and a check for the application fee under Minnesota Statutes, chapter 151; and

(4) register with and pay the required fees to the National Association of Boards of Pharmacy for the North American Pharmacy Licensing Exam and the Multistate Pharmacy Jurisprudence Exam, both of which must be passed before licensure as a pharmacist is granted.

B. Graduates of four-year foreign pharmacy schools, colleges, or programs are not eligible for licensure as pharmacists.

Subp. 1c. **Social Security number required.** No license will be issued to an applicant for licensure by any method described in this part who does not supply the board with a valid United States Social Security number as required by Minnesota Statutes, section 270C.72, subdivision 4.

Subp. 1d. **Authorization to practice.** An applicant who obtains a passing score on the required examinations is authorized to practice pharmacy only after paying an original licensure fee under Minnesota Statutes, chapter 151, to the board.

Subp. 2. **Retaking exam.** Any applicant who has failed to pass an examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake the examination within the next ensuing 18 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 board reserves the right to request resubmission of a full and complete application, including the application fee under Minnesota Statutes, chapter 151.

Subp. 2a. **Deadline for completion of licensing process.** The board shall consider an application for licensure or a NAPLEX or MPJE registration to be invalid 18 months after the date that the board receives an application for licensure.

Subp. 3. **Fees not refunded.** Fees paid to the board according to this part will not be returned or refunded.

Statutory Authority: *MS s 16A.128; 151.06; 151.07; 151.12; 151.13; 151.19; 152.02; 214.06*

History: *9 SR 1656; 11 SR 335; 12 SR 2393; 16 SR 2239; 18 SR 1145; 22 SR 1547; L 2001 1Sp9 art 15 s 32; 31 SR 1673; 36 SR 237*

6800.1300 LICENSURE TRANSFER (RECIPROCITY).

Subpart 1. **Applications.** An application for licensure transfer (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with an application fee under Minnesota Statutes, chapter 151, shall be filed with the director of the board. An applicant must register with and pay the required fees to the National Association of Boards of Pharmacy for the Minnesota version of the Multistate Pharmacy Jurisprudence Exam, which must be passed before licensure as a pharmacist is granted.

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

A. 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;

B. an applicant, if examined and licensed between January 1, 1973, and May 1, 2003, 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 first professional academic 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; and

C. an applicant, if examined and licensed after May 1, 2003, shall show that the applicant has acquired 1,600 hours of practical pharmacy experience under the instruction of a licensed pharmacist, acquired after the successful completion of the first professional academic year of the standard six-year pharmacy curriculum, with 800 of the hours being of a traditional compounding, patient counseling, and dispensing nature.

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. **NAPLEX 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 the NAPLEX examination.

Subp. 5. **Examination.** Applicants for licensure transfer shall be required to display their familiarity with the laws regulating the practice of pharmacy in Minnesota by passing the Minnesota version of the Multistate Pharmacy Jurisprudence Exam that is offered by the National Association of Boards of Pharmacy.

Subp. 6. [Repealed, 36 SR 237]

Statutory Authority: *MS s 16A.128; 151.06; 151.07; 151.12; 151.13; 151.19; 151.25; 151.47; 151.48; 151.49; 152.02; 214.06*

History: *9 SR 1656; 13 SR 1775; 16 SR 2239; 18 SR 1145; 22 SR 1547; 25 SR 81; 27 SR 260; 31 SR 1673; 36 SR 237*

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, except as allowed under part 6800.9921, shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee under Minnesota Statutes, chapter 151, 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. An application for a manufacturer or wholesaler license which has not been completed within 12 months of the date on which the board received the application is no longer valid.

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 involved in wholesale drug distribution within this state and each separate out-of-state location from which drugs are shipped into this state. A manufacturer that does not ship drugs into this state from any location that it directly operates must still obtain a license according to Minnesota Statutes, section 151.25, if it does business with accounts in this state. Doing business in this state includes any sale of a manufacturer's drug to any individual or business in Minnesota.

Statutory Authority: *MS s 151.06; 151.12; 151.13; 151.19; 151.25; 151.42; 151.47; 151.48; 151.49; 152.02; 214.06*

History: *16 SR 1913; 25 SR 81; 31 SR 1673; 36 SR 237*

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 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; 36 SR 237*

6800.1440 REQUIREMENTS FOR WHOLESALE DRUG DISTRIBUTORS.

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 Pharmacopeia, 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 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 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 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 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 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 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; 36 SR 237*

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 EDUCATION.

Subpart 1. **Definitions.**

A. "Approved continuing education" means those continuing pharmacy or pharmacy technician 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 Accreditation Council for Pharmacy Education (ACPE) for the provision of quality continuing education programs.

C. "Continuing pharmacy 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 pharmacist 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.

D. "Continuing pharmacy technician education" is a planned learning experience beyond initial technician training designed to promote the continued development of the knowledge, skills, and attitudes that enable a technician to adequately perform the tasks that a technician is allowed to perform under this part.

Subp. 2. **Minimum hours required for pharmacists; 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. Pharmacists exempted from the payment of all renewal fees and from the filing of any application for renewal under Minnesota Statutes, section 326.56, subdivision 2, shall also be exempted from the requirements of this subpart for a concurrent period of time. Beginning with the 1981-1983 reporting period, participation in continuing education shall be reported by September 30 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. 2a. **Minimum hours required for technicians; reporting.**

A. A pharmacy technician's registration renewal for calendar year 2014 shall not be issued unless the technician has completed 20 hours of approved continuing pharmacy technician education during the two-year period between August 1, 2011, and July 31, 2013. Thereafter, no annual pharmacy technician registration renewal shall be issued unless the technician presents the board with satisfactory evidence of completion of 20 hours of approved continuing pharmacy technician education per two-year reporting period. Each reporting period shall end on July 31 of odd-numbered years.

B. Continuing education must focus on the competencies that the technician must carry out and the specific duties that the technician performs. Technicians exempted from the payment of all renewal fees and from the filing of any application for renewal under Minnesota Statutes, section 326.56, subdivision 2, shall also be exempted from the requirements of this subpart for a concurrent period of time. The board may grant a technician, 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 technician from complying with the continuing education requirements for any other two-year period. Each technician is responsible for maintaining a complete record of 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 chapter.

Subp. 4a. **Programs not previously submitted for approval.** A pharmacist or pharmacy technician may apply for credit for attendance at programs not previously submitted to the board for approval provided that the pharmacist or pharmacy technician completes a continuing education program approval form, obtainable from the board, and submits it to the board within 90 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 Pharmacy 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 any instructional program for pharmacist preceptors that is developed or approved by the board.

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 Accreditation Council for Pharmacy Education (ACPE). 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; 152.02*

History: *10 SR 2007; 18 SR 1145; 31 SR 1673; 36 SR 237*

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; 151.07; 152.02; 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. 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.

B. When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800.7530. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.

Statutory Authority: *MS s 151.06; 152.02*

History: *9 SR 1656; 18 SR 1145; 27 SR 260*

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 or dispense prescription drug orders that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists, except as provided for in Minnesota Statutes, sections 145.414 and 145.42.

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 race, color, creed, religion, disability, national origin, marital status, sexual orientation, sex, or age.

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 legend or nonlegend 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.

K. Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of a patient or the public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist and which harms or could harm a patient.

Subp. 2. **Improper advertising.** Legend 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; 151.102*

History: *9 SR 260; 9 SR 1656; 10 SR 2007; 17 SR 1279; 18 SR 1145; 23 SR 1597; 36 SR 237*

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*

6800.2350 PHARMACEUTICAL WASTE.

Hazardous pharmaceutical waste disposal shall comply with chapter 7045 as enforced by the Pollution Control Agency (MPCA) and other authorized state agencies.

Statutory Authority: *MS s 151.06; 152.02*

History: *31 SR 1673*

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 pharmacy technicians and to make these procedures available to the board, and to ensure that all persons working as pharmacy technicians are registered with 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;

I. to respond to deficiency reports; and

J. to ensure that staffing and operational quality assurance policies are developed, implemented, and followed for the purpose of decreasing and monitoring prescription errors.

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. The successor pharmacist-in-charge shall submit, on the approved form, an acknowledgment of an awareness and understanding of any variances that the pharmacy has been granted according to part 6800.9900. The successor pharmacist-in-charge shall be responsible for ensuring that any conditions imposed by the board on granted variances continue to be met.

Statutory Authority: *MS s 151.06; 151.102*

History: *9 SR 1656; 17 SR 1279; 18 SR 1145; 23 SR 1597; 36 SR 237*

6800.2500 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 AUTOMATED COUNTING AND DISTRIBUTION.

Subpart 1. **Generally.** It is unlawful to count, distribute, dispense, or vend any legend drug through the use of an automated counting device or automated drug distribution system, or a vending machine except as provided in this part.

A. **Notification.** The board must be provided with written notification of the location of the automated counting device or automated drug distribution system, the name and address of the pharmacy responsible for control of the device or system, written policies and procedures that govern the operation of the device or system, and the name of the pharmacist-in-charge of the pharmacy. Notification must be provided to the board at least 60 days in advance of the initial use of the device or system. Policies and procedures must address staff training and the requirements listed in subparts 2 and 3. The pharmacy responsible for the control of the automated counting device or automated drug distribution system may proceed with its use unless the board has provided written notification to the pharmacy that the device or system may not be used. The board must provide written notification within 60 days of receiving the documents required under this item. The written notification must specify the steps that the pharmacy must take in order to use the system.

B. **Training.** Training for all staff who use an automated counting device or automated drug distribution system shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that employees remain familiar with the relevant policies and procedures and with the safe operation of the device. Documentation of training must be maintained and must include the names and unique identifiers of staff members trained, the name and unique identifier of the trainer, and the date of training. Training documentation shall be made available to the board or the board's staff upon request.

Subp. 2. **Automated counting devices.** In addition to the requirements in subpart 1, the following requirements apply to automated counting devices.

A. The filling of cells or cassettes is subject to the requirements of part 6800.3200, subpart 1, items A, B, E, F, G, and H, except that item F only applies if the pharmacy's policies and procedures require a pharmacist to verify the accuracy of the filling of the cell or cassette. Only one cell or cassette may be filled at a time.

B. The labeling of cells and cassettes is subject to the requirements of part 6800.3200, subpart 2, items A, B, C, and F. The requirements of part 6800.3200, subpart 2, items D and E, also apply unless the information required under those items is maintained in the packaging control record.

C. The pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a regular basis, consistent with the recommendations of the manufacturer of the device.

D. The pharmacy shall have procedures in place to prevent cross-contamination of cells and cassettes.

E. If the manufacturer's stock container is not available as required in part 6800.3100, subpart 3, a method for verifying that the correct drug is being dispensed must be specified in the policies and procedures. All other certification requirements in part 6800.3100, subpart 3, shall apply.

F. The pharmacy must have continuous quality assurance policies and procedures developed specifically for the automated counting device.

Subp. 3. **Automated drug distribution systems.** In addition to the requirements in subpart 1, the following requirements apply to automated drug distribution systems.

A. A pharmacist employed by the pharmacy, which is responsible for the control of the system, must review, interpret, and approve all prescription drug orders before any drug is distributed from the system to be administered to a patient. Access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.

B. Access to any automated medication distribution system must be limited to pharmacy and nonpharmacy personnel authorized to procure drugs from the system. Each person authorized to access the system must be assigned an individual, specific access code. Alternatively, access to the system may be controlled through the use of biometric identification procedures. A policy specifying time access parameters, such as time-outs, log-offs, and lock-outs must be in place.

C. At a minimum, the system must maintain records of:

(1) the identity of all personnel who access the automated unit, including any personnel who are required to witness a transaction;

(2) the reason for access;

(3) the date and time of access;

(4) the name, strength, dosage form, and quantity of the drug removed, returned, or wasted;

(5) the name of the patient for whom the drug was ordered; and

(6) any additional information the pharmacist in charge may deem necessary.

These records shall be reviewed for discrepancies on a periodic basis. The pharmacist-in-charge is responsible for the quality, accuracy, and timeliness of the review and must ensure that appropriate actions are taken to deal with any discrepancies found.

D. The pharmacy and therapeutics or relevant committee shall develop and regularly review a list of drugs or categories of drugs that are prohibited from being distributed through an automated distribution system. The review must take place at least annually. A high-alert drug may be distributed through an automated distribution system only if the pharmacy and therapeutics or relevant committee has determined that the drug need not be included on the list of drugs prohibited from being distributed through an automated distribution system. Patient-specific drug additions or deletions to the automated distribution device or system shall be determined by a pharmacist.

E. The use of an open matrix drawer that allows access to more than one drug at a time must be limited to noncontrolled substance drugs, unless the entire drawer contains

only one controlled substance drug product. Noncontrolled substance drugs may be stored in the open matrix drawer if they are:

(1) large bulky items such as intravenous infusion bags;

(2) nonlegend drugs that are safely arranged;

(3) legend drugs that are not look-alike products; or

(4) drugs properly packaged and labeled for an individual patient.

F. Removal of a high-alert drug from the system must be checked by a second licensed health care professional to ensure that the prescription drug order is being correctly interpreted and that the correct drug has been removed. This requirement does not apply when:

(1) a pharmacist has reviewed and approved the prescription drug order prior to the removal of the high-alert drug from the system;

(2) a licensed practitioner controls the ordering, preparation, and administration of the medication during a medical procedure; or

(3) the prescribing practitioner has determined that the high-alert drug must be administered before the drug order can be reviewed by a pharmacist or a second licensed health care professional.

G. A pharmacist must certify all packaging, labeling, and stocking associated with the use of an automated drug distribution system. Unless the certification process utilizes a fail-safe bar coding, certification must be performed by a pharmacist. Certification must be documented and records must be retained for at least two years.

H. Automated distribution devices must be secured or kept in a locked medication room when not in actual use.

I. Unused drugs must be returned to the pharmacy or to the system's secure, designated return bin or equivalent area. Restocking of the system may only be performed by designated pharmacy personnel with required certification.

J. Assessments of automated distribution devices must be performed to ensure, at a minimum, that:

(1) drugs are properly stored in their assigned locations and in pharmacy-approved configurations;

(2) outdated drugs are removed and replaced;

(3) only approved drugs are in the device;

(4) inventory levels are appropriate based on usage; and

(5) the device and drugs are secure.

Each of the five requirements in item J must be assessed at least on a monthly basis, but all need not be assessed at the same time.

K. Pharmacy personnel must conduct, at least monthly, an audit of controlled substances to ensure accuracy of distribution and proper record keeping.

L. The system must provide for maintenance of patient confidentiality, so that unauthorized individuals do not have access to patient data.

M. Policies and procedures must be in place for return of unused drugs and for drug wastage and the documentation of drug wastage.

N. Continuous quality assurance must be developed specifically for the automated drug distribution system or device. An ongoing failure mode effect analysis or quality assurance process must be in place and address possible system failures, process failures, high-alert drugs, medication errors, and controlled substance discrepancies.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *23 SR 1597; 31 SR 1673; 36 SR 237*

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 only, which have not left the span of control of the pharmacy, may be returned to the pharmacy for reuse or disposal in accordance with good professional practice.

Subp. 2. **Drugs from nursing homes and assisted living facilities.** Drugs from nursing homes and assisted living facilities may be returned to the dispensing pharmacy. The returned drugs may be redispensed 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) and the drugs are stored within the facility in a secure area;

B. the facility has 24-hour, on-site licensed nursing coverage seven days a week;

C. the drugs are returned to the same pharmacy, which dispensed the drugs;

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

E. 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 or beyond-use dates.

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; 152.02*

History: *18 SR 1145; 31 SR 1673*

6800.2800 [Repealed, 13 SR 1775]

6800.2810 [Repealed, 31 SR 1673]

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*

6800.3000 PRESCRIPTIONS AND DISTRIBUTION OF DRUGS.

Subpart 1. **Acceptance of prescription drug orders and distribution of drugs.**

A. **Restrictions on pickup or delivery of prescription drug orders or filled prescriptions.** No licensed pharmacist shall participate in any arrangement or agreement

whereby prescription drug orders or filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. 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 prescription drug orders or delivering filled prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or long-term care facility in which a patient is confined. A pharmacy may deliver filled prescriptions at the place of employment of the patient or a designated caregiver of the patient only if the pharmacy:

(1) obtains and documents the authorization of the patient or patient's caregiver for delivery at the place of employment;

(2) ensures the filled prescription order is delivered directly to the patient or the patient's caregiver as authorized; and

(3) ensures the security of protected health information.

B. **Direct prescription delivery.** A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must, based on the professional judgment of the pharmacist:

(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes must include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;

(2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;

(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures must address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug has been compromised during shipment. In these instances, the pharmacy must make provisions for the replacement of the drugs; and

(4) provide for an electronic, telephonic, or written communication mechanism for a pharmacist, or a pharmacy intern working under the direct supervision of a pharmacist, to offer counseling to the patient. The patient must receive information indicating what the patient should do if the integrity of the packaging or medication has been compromised during shipment.

C. **Adulteration.** A drug is adulterated if it has been exposed to conditions of fire, water, or extreme temperature, which may have rendered it injurious to health.

Subp. 2. **Fax machines.** Prescription drug orders may be transmitted to a pharmacy via the use of a fax machine only in accordance with this subpart and as permitted by law. 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 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 prescription 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. Prescription drug 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.

Subp. 3. **Electronic prescriptions.** Any electronic prescription transmitted from the prescriber to the pharmacy must comply with Minnesota Statutes, section 62J.497, chapter 325L, and any applicable rules. Electronic prescriptions for controlled substance drugs

must conform to the rules of the federal Drug Enforcement Administration. Except for prescription drug orders for drugs to be administered in an acute care hospital, an electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice.

Subp. 4. **Answering machines and electronic voice recording devices.** Only a practitioner or a practitioner's agent may transmit a prescription to a pharmacy's answering machine or electronic voice recording device. Prescriptions transmitted to a pharmacy's answering machine or an electronic voice recording device shall only be retrieved by a licensed pharmacist or registered pharmacist-intern working under the immediate and direct supervision of a pharmacist. A technician may not retrieve a prescription from these devices, except in the case where the practitioner or authorized agent of the practitioner is approving additional refills of a prescription previously dispensed from the pharmacy and no other changes are made to the prescription. Personnel used for clerical duties according to part 6800.3850, subpart 7, may not retrieve any prescription information from these devices. Prescriptions retrieved from these devices are considered verbal prescription drug orders that must be reduced to writing and are subject to the requirements of part 6800.3100, subpart 1.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

6800.3100 COMPOUNDING AND DISPENSING.

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

A. determination of brands and suppliers;

B. receipt of verbal prescription drug orders which must include documentation of the individual communicating the order and the pharmacist or pharmacist intern receiving the order;

C. verification of the prescription drug order;

D. selection of the drug to be used in filling the prescription drug order;

E. establishment and validation of the initial formulation record of all compounded preparations according to part 6800.3300;

F. certification of the filled prescription drug order;

G. ensuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized practitioners or other individuals allowed to prescribe legend drugs according to Minnesota Statutes, section 151.37, subdivision 2, and then noting on the reverse side of the prescription drug order or in the electronically maintained record of the prescription drug order the following data: date refilled; name of practitioner or other authorized prescriber personally authorizing the refill, and the name of the practitioner's agent transmitting or communicating the refill authorization, if applicable; quantity of drug dispensed, if different from the original prescription; and the unique identifier of the pharmacist refilling the prescription;

H. supervising clerical personnel in limited nonprofessional duties such as typing that does not involve prescription data entry, record keeping, filing, and completing sales transactions; and

I. supervising pharmacy technicians 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 drug order. A rewritten, verbal, or electronically produced copy is not acceptable except as provided in parts 6800.3000, subpart 2, 6800.3120, subpart 7, and 6800.3950, subpart 1a.

Subp. 3. **Certification.** In certifying and documenting the filled prescription under subpart 1, item F, an individual pharmacist, practitioner, or pharmacist-intern shall:

A. check the original labeled container from which the medication was withdrawn, except as provided in part 6800.2600, or when the pharmacy uses a computerized process to identify oral, solid drugs through the use of images;

B. check the labeling on the medication container that will be dispensed;

C. check the contents of the medication container that will be dispensed and the appearance of the total product to ensure that all of the doses that are dispensed are of the correct drug, strength, and dosage form prescribed;

D. review 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. place the pharmacist's, practitioner's, or pharmacist-intern's unique identifier on the prescription drug order or other permanently maintained record. Those pharmacists using automated medication management dispensing systems must develop written policies and procedures which provide that all certification steps are performed and documented before the medication is dispensed to the patient. These policies and procedures must be made available for inspection by the board upon request.

Subp. 3a. **Accountability.** For prescriptions filled in a pharmacy, the unique identifier of each pharmacist, pharmacist-intern, or pharmacy technician who performs any portion of the prescription filling process must be documented, with the documentation maintained for a minimum of two years. The documentation must indicate which portion of the prescription filling process each pharmacist, pharmacist-intern, or pharmacy technician completed. For prescriptions filled by a practitioner, the unique identifier of each practitioner and each individual who assists the practitioner according to part 6800.9952 must be documented and the documentation maintained for a minimum of two years. This subpart does not waive the requirement for an individual pharmacist, practitioner, or pharmacist-intern to certify a filled prescription drug order according to subpart 3.

Subp. 3b. **Notice required.** A pharmacy utilizing a central service pharmacy to provide dispensing functions, drug utilization review, packaging, labeling, delivery of a filled prescription, or other services must notify the pharmacy's patients of that fact.

Subp. 4. **Exception.** This part applies to all pharmacies. Provided, however, that nothing in this part prevents pharmacists in hospitals from dispensing to hospital inpatients according to parts 6800.7100 to 6800.7950.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *9 SR 1656; 10 SR 2007; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

6800.3110 PATIENT MEDICATION PROFILES.

Subpart 1. **System required.** A patient profile record system must be maintained in all pharmacies for persons for whom filled prescription drug orders 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 drug order 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;

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. 2a. [Repealed, 27 SR 260]

Subp. 3. **Drug interactions, generally.** Upon receiving a prescription drug order, 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 patients.** Upon receiving a prescription drug order, or prescription refill request for a 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, provided that it includes all medication dispensed by the pharmacy for the patient during at least the preceding six months. The pharmacist-in-charge must develop procedures for handling alerts generated by the computerized medication profile review and include these procedures in the written procedures required under part 6800.3950. Only a pharmacist or a pharmacist-intern working under the immediate and direct supervision of a pharmacist may override the alerts.

Subp. 5. **Duration of record keeping.** 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. [Repealed, 36 SR 237]

Statutory Authority: *MS s 151.06; 152.02*

History: *10 SR 2007; 18 SR 1145; 27 SR 260; 36 SR 237*

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

Subpart 1. **Label, copy, or report.** 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 drug 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 drug order information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist or registered intern to another licensed pharmacist or registered intern. A pharmacy may transfer prescription drug order information for the purpose of the initial filling of the order only according to subpart 8a. Schedule II prescription drug orders may not be transferred. Schedules III-V prescription drug orders may be transferred in accordance with the limitations placed on such transfers by the Drug Enforcement Administration (DEA).

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

A. write the word "VOID" across the face of the current prescription drug order to make it invalid or, if records are electronically maintained, void all remaining refills previously authorized and carried in the electronic record;

B. record on the reverse side of the invalidated prescription drug order or in the electronically maintained record of the prescription drug order the name, address, and telephone number of the receiving pharmacy and the name of the receiving pharmacist or intern; and

C. record the date of the transfer.

Recording of prescription drug order transfers by cancellation of the electronic version of the prescription drug order is acceptable only when the quality assurance check required by part 6800.3950, subpart 4, has been completed on the prescription drug order being transferred.

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

Subp. 4. **Duties of receiving pharmacist or intern.** The pharmacist or intern receiving the transferred prescription drug order information shall write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription, and shall obtain from the transferring pharmacist or intern all information required by law to be on a prescription, plus:

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, address, and telephone number and the name of the transferring pharmacist or intern. In the case of a controlled substance listed in Schedules III-V, parts 6800.4230 to 6800.4250, the receiving pharmacist or intern must obtain the transferring pharmacy's Drug Enforcement Administration registration number.

Subp. 5. **Retention of prescription.** The transferring pharmacy shall keep the original prescription drug order on file for at least two years from the date of last filling. The receiving pharmacy shall keep the transferred prescription drug order on file 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 drug order. Pharmacies accessing a common electronic file or data base used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file or data base; provided, however, that any such common file or database must contain complete records of each prescription drug order and refill dispensed and further, that a hard copy record of each prescription drug order 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 drug order.** Except as provided in subpart 7, when the transfer of original prescription drug order 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. 8a. **Transfer of nondispensed drug orders.** Prescription drug orders that are entered into a computer system but never dispensed to the patient may be transferred to another pharmacy if all of the following conditions are met:

A. all prescription drug order information has been entered into the computer system of the transferring pharmacy;

B. the information is displayed on the patient's profile in a manner that indicates the prescription drug order was not filled at the transferring pharmacy;

C. there is present, either in the computer system or on the hard copy prescription drug order, the unique identifier of the person who entered the prescription drug order information into the system and of the pharmacist who certified this entry, and of the pharmacist who performed the quality assurance verification as required by part 6800.3950, subpart 4. If the quality assurance verification has not occurred, then the prescription information exchanged must be from the original written prescription drug order;

D. the original prescription drug order is kept on record according to Minnesota Statutes, section 151.211; and

E. all other requirements of this part are met.

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 pharmacist or a pharmacist-intern may provide informational copies of a prescription drug order to another pharmacist or pharmacist-intern who is currently providing services to or acting at the request of the patient, as provided in this part; or to the person for whom the prescription drug order was issued. A pharmacist may also provide drug therapy information to a physician or other licensed, registered, or certified health care professional who is currently providing services to or acting on the behalf of the patient.

The board shall consider it evidence of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription drug order 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 drug order for a Schedule II controlled substance. All prescription drug orders for Schedule II controlled substances must conform to the requirements of the federal Controlled Substances Act and to the regulations of the Drug Enforcement Administration.

Subp. 11. **Shared information.** Prescription drug order information shared between two pharmacies which are accessing the same real-time, online database, according to the operation of a board-approved central service operation shall not be considered a prescription copy and is not subject to the requirements of this part.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *10 SR 2007; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

6800.3200 PREPACKAGING AND LABELING.

Subpart 1. **Prepackaging.** Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Prepackaging into unit-dose containers shall be done according to United States Pharmacopeia, chapter 1146. 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 or distributor, lot number assigned by manufacturer or distributor, strength, and expiration date assigned by manufacturer or distributor, if any;

C. container specification;

D. copy of the label;

E. unique identifier of the packager;

F. unique identifier 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. a beyond-use date as provided in part 6800.3350, or any earlier date which, in the pharmacist's professional judgment, is preferable;

E. internal control number or date;

F. after July 1, 2008, a physical description, including any identification code that may appear on tablets and capsules or a bar code based on the National Drug Code (NDC). Such a description does not need to be placed on individual unit-doses, provided that the pharmacy dispenses the unit-doses in outer packaging that contains a physical description of the drug or the pharmacy dispenses less than a 72-hour supply of the unit-doses; and

G. radiopharmaceuticals must be labeled according to the requirements of part 6800.8550.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

6800.3300 COMPOUNDING STANDARDS.

Subpart 1. **Standards for nonsterile compounding.** All licensed Minnesota pharmacies that compound nonsterile drug preparations must follow United States Pharmacopeia, chapter 795, standards.

Subp. 2. **Standards for sterile compounding.** Any licensed Minnesota pharmacy compounding a sterile product must follow the United States Pharmacopeia, chapter 797, standards.

Subp. 3. [Repealed, 31 SR 1673]

Subp. 4. [Repealed, 31 SR 1673]

Subp. 5. [Repealed, 31 SR 1673]

Subp. 6. **Certifying compounding procedure effective January 2, 2013.** A pharmacy must develop a list of high-alert compounded preparations for which a pharmacist shall certify that each component used in the compounding of the drug preparation has been accurately weighed, measured, or subdivided, as appropriate, at each stage of the compounding procedure in order to verify conformance with the formula being prepared. Subsequent stages of the compounding process may not be completed until this certification occurs. This subpart is effective January 2, 2013.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

6800.3350 PHARMACEUTICALS BEYOND-USE DATES.

Subpart 1. **Prepackaged into prescription vials.** A beyond-use 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. [Repealed, 31 SR 1673]

Subp. 3. **Unit-of-use and blister card packages.** A beyond-use date of not more than one year from the packaging date or the time remaining to the manufacturer's expiration date, whichever is less, 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.** When a drug is dispensed in a prescription vial, a beyond-use date need not be printed on the label. Drugs dispensed in prescription vials that are labeled with a beyond-use date shall bear a beyond-use date of not more than one year from the dispensing date or the time remaining to the manufacturer's expiration date, whichever is less.

Nothing in this part supersedes the pharmacist's professional judgment.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 27 SR 260; 31 SR 1673; 36 SR 237*

6800.3400 PRESCRIPTION LABELING.

Subpart 1. **Requirements applicable to all drugs.** Except for radiopharmaceuticals, all drugs dispensed to or for a patient, other than an inpatient of a hospital must be labeled with the following information:

A. name, address, and telephone number of the pharmacy filling the prescription drug order, except that central service pharmacies shall use the name, address, and telephone number of the pharmacy dispensing the medication to the patient;

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;

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 principal active ingredients or a category of use name shall suffice;

J. prescription drug orders filled as part of a central service operation must bear an identifier that indicates the central service pharmacy at which they were filled; and

K. after July 1, 2008, any dispensed legend drug, or nonlegend drug not dispensed in the manufacturer's original container, must be labeled with its physical description, including any identification code that may appear on tablets and capsules. This requirement does not apply to drugs dispensed as part of an investigational drug study.

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.

Subp. 3. **Customized patient medication packages.** In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package as defined in the United States Pharmacopeia (USP), chapter 661, standards.

Subp. 4. **Veterinary prescription drug label.** The label for a filled veterinary prescription that is dispensed by a licensed pharmacy must include:

A. in the case of non-food-producing animals, the name of the client or animal. In the case of food-producing animals, the name of the owner and the specific name and address of the facility at which the filled prescription will be used;

B. identification of the species for which the drug is prescribed or ordered;

C. the name, strength, and quantity of the drug, except when specified by the prescriber to the contrary. In the case of combining premanufactured drug products, the names of the products, or category of use may suffice;

D. the name of the manufacturer or distributor of the finished dosage form of the drug;

E. the date of issue;

F. directions for use;

G. withdrawal time, excluding non-food-producing animals;

H. cautionary statements if appropriate for the drug;

I. the name, address, and telephone number of the pharmacy, except that central service pharmacies must use the name, address, and telephone number of the pharmacy dispensing the medication to the client;

J. the name and address of the prescribing veterinarian, except that the address of the prescribing veterinarian is not required if the prescription is for a non-food-producing animal; and

K. the prescription number.

When the veterinary drug is in the manufacturer's original package and the information that is required on the label includes the drug or drugs, strength of the drug or drugs, directions for use, withdrawal time for food-producing animals, and cautionary statements, a label will be required on each individual bottle or package.

Subp. 5. **Radiopharmaceutical labeling.** Radiopharmaceutical labeling shall comply with the requirements in part 6800.8550.

Statutory Authority: *MS s 151.06; 151.212; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

Subpart 1. **Labeling requirements.** 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, subpart 1, items A to J, and in addition shall contain the following:

A. date of compounding;

B. beyond-use date;

C. storage requirements if other than room temperature;

D. infusion or administration rate;

E. administration times, administration frequency, or both; and

F. 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 the unique identifier of the 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; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

6800.3500 [Renumbered 6800.4150]

6800.3510 REFILL LIMITATIONS.

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

Statutory Authority: *MS s 151.06*

History: *18 SR 1145; 36 SR 237*

6800.3550 [Repealed, 23 SR 1597]

6800.3600 [Renumbered 6800.3550]

6800.3650 [Repealed, 23 SR 1597]

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, subpart 1, 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 prescription drug order and the date of changes, if any, made to the prescription 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 prescription drug 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 non-dispensing functions.** 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 of medications.**

A. All controlled substances must be stored in a locked area or locked cart at all times.

B. All noncontrolled substances must be stored in a locked area or locked cart when a patient care area is not staffed. An area in which staff is actively providing patient care or preparing to receive patients is considered a secure area and locked storage of noncontrolled substances is not required.

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*

History: *9 SR 1656; 36 SR 237*

6800.3800 [Renumbered 6800.3750]

6800.3850 PHARMACY TECHNICIANS.

Subpart 1. **Technician registration required.** Pharmacy technicians may be used in performing pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist only when the technician is properly registered with the board. An individual may not, under any circumstances, perform pharmacy tasks as a pharmacy technician prior to being registered as a pharmacy technician according to this part. Registration does not include any determination of the competency of the registered individual.

Subp. 1a. **Denial and suspension of registration.** The board may deny, suspend, revoke, refuse to renew, or place conditions and limitations on the registration of a technician for any violation of the rules of the board or the laws of this state, another state, or the United States relating to the practice of pharmacy, prescription drugs, or controlled substances.

Subp. 1b. **Registration, renewals.**

A. A pharmacy technician registration expires each year on December 31 and shall be renewed annually by filing an application for registration renewal on or before December 1 of each year, together with the fee listed in subpart 1c.

B. Initial registration shall not be prorated.

Subp. 1c. **Registration fee, late fee.**

A. The fee for an initial registration is the amount established in Minnesota Statutes, chapter 151.

B. The fee for each annual renewal is the amount established in Minnesota Statutes, chapter 151.

C. The fee must be paid at the time when a new application or a renewal application is submitted to the board.

D. Persons required to renew their registration under this part, who file an application which is received by the board after the date on which it is due, must pay a late fee of 50 percent of the renewal fee in addition to the renewal fee.

Subp. 1d. **Notifications to board.** A pharmacy technician must report any changes in name, residence, or place of employment to the board within ten days of the change.

Subp. 1e. **Identification of technician.**

A. A pharmacy technician must wear a name badge while on duty which clearly identifies the person as a "Pharmacy Technician," except when complying with the requirements of United States Pharmacopeia Chapter 797.

B. Pharmacy technicians must not represent themselves as pharmacists in any manner.

Subp. 1f. **Posting of registration.** A pharmacy technician shall post the registration most recently issued by the board in a conspicuous place within the pharmacy in which the technician is working. For all pharmacies, this place shall be a place which is readily accessible to the board.

Subp. 1g. **Minimum age.** Prior to January 1, 2012, the board shall not register as a pharmacy technician any individual who is less than 16 years of age. Effective January 1, 2012, the board shall not register as a pharmacy technician any individual who is less than 18 years of age. An individual who is less than 18 years of age and who was registered

by the board as a pharmacy technician prior to January 1, 2012, may renew registration provided that all other requirements for renewal are met.

Subp. 1h. **Education and training requirements.**

A. **Initial registration.** Effective January 1, 2013, the board shall not issue an initial pharmacy technician registration to any individual who does not present the board with evidence of high school graduation or possession of a general educational development certificate equivalent. An individual who is not a high school graduate or who does not possess a general educational development certificate equivalent who was registered by the board prior to January 1, 2013, may renew the individual's registration provided that all other requirements for renewal are met and provided the individual maintains a pharmacy technician registration on an uninterrupted basis. Any individual whose registration lapses for a period of more than one year must meet the registration requirements in effect at the time the individual applies for reinstatement of registration.

B. **Renewal of registration.** Effective January 1, 2014, the board shall not renew the registration of a pharmacy technician who was initially registered after January 1, 2013, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual provides the board with evidence of completion of one of the following:

(1) a pharmacy technician training program offered by a board-approved, accredited vocational/technical institution or college;

(2) a pharmacy technician training program accredited by a board-approved, national organization that accredits pharmacy technician training programs;

(3) a pharmacy technician training program provided by a branch of the United States armed forces or Public Health Service; or

(4) an employer-based pharmacy technician training program that includes a minimum total of 240 hours on a one-year period to include both theoretical and practical instruction. An employer utilizing such a program must develop and regularly update a technician training manual that must be available for board inspection upon request. The employer must also supply a technician who completes the training program with written evidence of completion. The employer-based pharmacy technician training program must include written guidelines, policies, and procedures that define the specific tasks the technician will be expected to perform. A pharmacy technician who has not completed this training, but is otherwise eligible for renewal of his or her registration, may apply for renewal provided that: less than six months has elapsed between the date of initial registration as a pharmacy technician and the date of the pharmacy technician's first renewal of registration; or the pharmacy technician shows satisfactory evidence of being enrolled in a pharmacy technician training program offered by a board-approved, accredited vocational/technical institution or college, when the program is longer than six months in length.

C. **Pharmacy-specific training.** Notwithstanding the fact that a technician has completed a training program as specified in item B, it is the responsibility of the pharmacist-in-charge of a pharmacy to ensure that a technician receives adequate training in the tasks performed by technicians working at that pharmacy.

Subp. 2. **Permissible duties.** Pharmacy technicians may perform pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist or pharmacist-intern and that do not involve the use of professional judgment.

Subp. 3. **Certifying.** Pharmaceutical products prepared or processed, in whole or in part, by a pharmacy technician must be certified for accuracy by a licensed pharmacist, practitioner, or pharmacist-intern as provided for in part 6800.3100, subpart 1, item F, prior to release for patient use.

Subp. 4. **Written procedures.** Written procedures for the use of pharmacy technicians in a pharmacy shall be prepared by the pharmacist-in-charge. A copy of the procedures must be given to each technician and a copy must be kept on file in the pharmacy. The written

procedures must be made available for inspection by the board upon request. These procedures must comply with the standards in this chapter and will be reviewed for compliance on that basis.

These procedures must indicate in detail the tasks performed by the pharmacy technician; the name, address, and registration number of the pharmacy technician; and the certification steps performed by the licensed pharmacist in verifying the technician's work. Procedures must be updated at least every five years and whenever a significant change in the way in which pharmacy technicians are utilized occurs. The pharmacist-in-charge shall ensure that each technician has reviewed the procedures when the technician is first employed by the pharmacy as a technician and when any substantial changes to the procedures have been made. The pharmacist-in-charge must ensure that proper documentation of training is maintained in the pharmacy for a period of at least two years after the training occurs.

Subp. 5. **Supervision.** Pharmacy technicians shall be supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the action of the pharmacy technician. The ultimate responsibility for the actions of a pharmacy technician working under a licensed pharmacist's supervision shall remain with the licensed pharmacist.

Subp. 6. **Ratios.** The basic ratio of pharmacy technicians to pharmacists on duty in a pharmacy is two technicians to one pharmacist. Specific functions are excepted from the basic ratio as follows:

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

B. setting up or preparing patient specific prescriptions in unit dose or modified unit dose packaging (part 6800.3750), 3:1;

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

D. compounding (part 6800.3300), 3:1.

Subp. 7. **Persons not included.** Personnel used solely for clerical duties such as typing or keyboarding that does not involve prescription data entry, record keeping, filing, billing, and completing sales transactions need not be included when determining compliance with the ratios listed in this part. Personnel used solely for the delivery of filled prescription drug orders need not be included when determining compliance with the ratios listed in this part.

A pharmacist-intern submitting hours toward completion of the 1,600-hour requirement is not considered a pharmacy technician for the purpose of determining the number of pharmacy technicians supervised by a licensed pharmacist.

Subp. 8. [Repealed, 23 SR 1597]

Subp. 9. **Unprofessional conduct.** The use of pharmacy technicians in the performance of delegated tasks not included in written procedures may be considered unprofessional conduct on the part of the pharmacist supervising the technician, the pharmacist-in-charge, and the pharmacy technician. Falsification of any documents pertaining to the training of pharmacy technicians shall be considered unprofessional conduct on the part of any pharmacist or pharmacy technician involved in such act.

Statutory Authority: *MS s 151.06; 151.102; 151.12; 151.13; 151.19; 151.25; 151.47; 151.48; 151.49; 214.06*

History: *9 SR 1656; 18 SR 1145; 23 SR 1597; 25 SR 81; 36 SR 237; L 2012 c 187 s 74*

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 electronic data processing system and shall:

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

B. outline steps to be followed when the electronic data processing 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 prescription drug orders.** When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed by a prescriber or a pharmacist. If prescription drug orders are entered by other personnel, the pharmacist or the prescriber must certify the accuracy of the information entered and verify the prescription drug order prior to the dispensing of the medication. The unique identifier of the person entering the prescription drug order must be retained in the computer record.

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

A. be structured in such a manner that all prescription drug orders, communicated to a pharmacy by way of electronic transmission, will be transmitted with no intervening person having access to the information contained in the prescription drug order;

B. not infringe on a patient's freedom of choice of pharmacy provider;

C. guarantee the confidentiality of the information contained in the system's storage devices and databases;

D. 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 a computer-generated hard copy;

E. be capable of recording and carrying in the record all dates of refills of any prescription drug order and the unique identifier of the pharmacist;

F. be capable of producing a patient profile indicating all drugs being taken and the dates and quantities of fills or refills of prescription drug orders dispensed for the patient 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; and

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

G. be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the system's storage devices or databases;

H. 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 unique identifier of the dispensing pharmacist, and the prescription number;

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

J. 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. Original prescriptions or any other patient specific records stored outside the licensed pharmacy area must be stored in a secure area accessible only to registered or licensed pharmacy staff, or others delegated by the pharmacist-in-charge and trained on the policies and procedures relating to protected health information.

Subp. 4. **New prescriptions.**

A. A pharmacy must develop and implement a written quality assurance plan that includes a pharmacist, or a pharmacist-intern working under the immediate and direct supervision of a pharmacist, comparing the original written prescription or an image of the original written prescription, to the information entered into the computer, and documenting the completion and accuracy of this comparison with the date and unique identifier of the pharmacist or pharmacist-intern completing the task. This process must not occur prior to two hours after the prescription has been initially certified, unless it is completed by a second individual pharmacist as soon as possible after the initial certification has occurred. The process must be completed within 72 hours.

B. As an alternative to the requirements of item A, hospitals providing inpatient pharmacy services may elect instead to develop a plan to 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 the board surveyors upon 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; 151.102; 152.02*

History: *9 SR 1656; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

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*

6800.4075 CENTRALIZED PRESCRIPTION PROCESSING AND FILLING.

Subpart 1. **Licensure.**

A. A central service pharmacy located in another state that provides any services listed in part 6800.0100, subpart 1c, to a pharmacy located in this state shall be licensed as a nonresident pharmacy according to Minnesota Statutes, section 151.19, subdivision 2.

B. A central service pharmacy located in this state that provides any services listed in part 6800.0100, subpart 1c, to a pharmacy located in any state shall be licensed as a pharmacy according to Minnesota Statutes, section 151.19, subdivision 1.

Subp. 2. **Requirements; policy and procedures.**

A. A pharmacy may perform or outsource centralized prescription drug order filling or centralized prescription drug order processing services provided:

(1) the parties have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

(2) the parties share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order;

(3) the central service pharmacy is licensed according to part 6800.0300; and

(4) the parties provide the board with a copy of the policy and procedures manual described in item B at least 30 days before centralized prescription drug order processing services begin.

B. The parties performing or contracting for centralized prescription drug order processing services shall maintain a policy and procedures manual and documentation that operations are occurring in a manner consistent with the manual. The manual shall be made available to the board for review upon request and shall include, at a minimum, the following:

(1) a description of how the parties will comply with federal and state laws and regulations;

(2) the maintenance of appropriate records to identify the responsible pharmacist in the dispensing and counseling processes;

(3) the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;

(4) the maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order;

(5) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information; and

(6) the maintenance of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

Subp. 3. **Certification and counseling.**

A. A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription drug order to the patient is responsible for certifying the completed prescription drug order, except as provided for in Minnesota Statutes, section 151.215.

B. A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription drug order to the patient is responsible for counseling the patient according to part 6800.0910.

Subp. 4. **Notification.** A pharmacy utilizing a central service pharmacy to provide dispensing functions, drug utilization review, packaging, labeling, delivery of a completed prescription drug order, or other services must notify its patients of that fact.

Statutory Authority: *MS s 151.06; 152.02*

History: *31 SR 1673; 36 SR 237*

6800.4100 [Renumbered 6800.4050]

CONTROLLED SUBSTANCES

6800.4150 LABELING OF CONTROLLED SUBSTANCES AND 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, chapter 152. Provided, however, that drugs containing any quantity of phenobarbital shall be dispensed only according to a prescription drug order.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 36 SR 237*

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 (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

(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) Methyl substituted isomers of Fentanyl:

(a) 3-Methylfentanyl; N-[3-Methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide;

(b) Acetyl-alpha-methylfentanyl; N-[1-(1-methyl-2-phenylethyl)-4-piperidinyl]-N-phenylacetamide;

(c) Alpha-methylthiofentanyl; N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl-N-phenylpropanamide;

(d) Benzylfentanyl; N-[1-benzyl-4-piperidyl]-N-phenylpropanamide;

(e) Beta-hydroxyfentanyl; N-[1-(2-hydroxy-2-phenylethyl-4-piperidinyl]-N-phenylpropanamide;

(f) Beta-hydroxy-3-methylfentanyl; N-[1-(2-hydroxy-2-phenylethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide;

(g) 3-methylthiofentanyl; N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide;

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

(i) Thiofentanyl; N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide;

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

(31) Morpheridine;

(32) MPPP; 1-Methyl-4-phenyl-4-Propionoxypiperidine;

(33) Noracymethadol;

(34) Norlevorphanol;

(35) Normethadone;

(36) Norpipanone;

(37) PEPAP; 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine;

(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) Benzylmorphine;

(4) Codeine methylbromide;

(5) Codeine-N-Oxide;

(6) Cyprenorphine;

(7) Desomorphine;

(8) Dihydromorphine;

(9) Drotebanol;

(10) Etorphine (except hydrochloride salt);

(11) Heroin;

(12) Hydromorphinol;

(13) Methyldesorphine;

(14) Methyldihydromorphine;

(15) Morphine Methylbromide;

(16) Morphine Methylsulfonate;

(17) Morphine-N-Oxide;

(18) Myrophine;

(19) Nicocodeine;

(20) Nicomorphine;

(21) Normorphine;

(22) Pholcodine; and

(23) 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-α-methylphenethylamine;4-bromo-2,5-DMA
(2)	2,5-Dimethoxyamphetamine	2,5-dimethoxy-α-methylphenethylamine; 2,5-DMA
(3)	4-Methoxyamphetamine	4-methoxy-α-Methylphenethylamine; paramethoxyamphetamine, PMA
(4)	5-Methoxy-3, 4-Methylenedioxyamphetamine	MMDA
(5)	4-Methyl-2,5-Dimethoxyamphetamine	4-methyl-2,5-dimethoxy-α-methylphenethylamine; "DOM"; and "STP"
(6)	3,4-Methylenedioxy Amphetamine	MDA
(7)	3,4-Methylenedioxymeth-amphetamine	MDMA
(8)	3,4-Methylenedioxy-N-ethylamphetamine	N-ethyl-alpha-methyl-3,4(Methylenedioxy) phenethylamine; N-ethyl MDA; MDE; MDEA
(9)	N-hydroxy-3, 4-Methylenedioxyamphetamine	N-hydroxy-alpha-methyl-3, 4(Methylenedioxy) phenethylamine; N-hydroxy MDA
(10)	3,4,5-Trimethoxy Amphetamine	TMA
(11)	Alpha-Ethyltryptamine	Etryptamine; monase; α-Ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl)indole; α-ET; and AET
(12)	Bufotenine	3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(13)	Diethyltryptamine	N,N-Diethyltryptamine; DET
(14)	Dimethyltryptamine	DMT
(15)	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

(16)	Lysergic acid diethylamide	LSD
(17)	Marijuana	
(18)	Mescaline	
(19)	Parahexyl	3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6, 6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl
(20)	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	
(21)	N-ethyl-3-piperidyl Benzilate	
(22)	N-methyl-3-piperidyl Benzilate	
(23)	Psilocybin	
(24)	Psilocyn	
(25)	Tetrahydrocannabinols Meaning Tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, 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.	THC

	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)	
(26)	Ethylamine analog of phencyclidine	N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(27)	Pyrrolidine analog of phencyclidine	1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(28)	Thiophene analog of phencyclidine	1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP
(29)	2-thienyl Pyrrolidine analog of Phencyclidine	1-[1-(2-thienyl)cyclohexyl]-pyrrolidine, TCPy
(30)	4-bromo-2,5-dimethoxyphenethylamine	2-(4-bromo-2,5-dimethoxyphenyl) -1-aminoethane;alpha-desmethyl DOB; 2C-B (nexus)
(31)	2,5-dimethoxy-4-ethylamphetamine	DOET
(32)	2,5-dimethoxy-4-(n)-propylthiophenethylamine	2C-T-7
(33)	Alpha-methyltryptamine	AMT
(34)	5-methoxy-N,N-diisopropyltryptamine.	5-MeO-DIPT

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) Flunitrazepam;

(2) Gamma-hydroxybutyric acid, including its esters and ethers (some other names include GHB, gamma-hydroxybutyrate, 4-hydroxybutanoic acid, sodium oxybate, sodium oxybutyrate);

(3) Mecloqualone;

(4) 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:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Aminorex	Aminoxaphen; 2-Amino-5-phenyl-2-oxazoline; 4,5-Dihydro-5-phenyl-2-oxazolamine
(2) Cathinone	2-Amino-1-phenyl-1-propanone; alpha-Aminopropiophenone; 2-Aminopropiophenone; Norephedrone
(3) Fenethylline	
(4) Methcathinone	2-(Methylamino)-Propiophenone; alpha-(Methylamino)-propiophenone; 2-(Methylamino)-1-Phenyl-propan-1-one; alpha-N-Methylamino-propiophenone; monomethylpropion; ephedrone; N-Methylcathinone; Methylcathinone
(5) (±) cis-4-Methylaminorex	(±) cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine
(6) N-ethylamphetamine	
(7) N,N-dimethylamphetamine	N,N-alpha-trimethly-benzene-ethanamine; N,N-alpha-trimethylphenethylamine
(8) N-benzylpiperazine.	BZP, 1-benzylpiperazine

Statutory Authority: *MS s 151.02; 151.06; 151.07; 152.02*

History: *9 SR 1656; 11 SR 1113; 12 SR 2393; 18 SR 1145; 20 SR 2592; 27 SR 260; 34 SR 1205*

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, thebaine-derived butorphanol, 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 fluid	
(d) Powdered opium	
(e) Granulated opium	
(f) Tincture of opium	Laudanum
(g) Codeine	Methylmorphine
(h) Dihydroetorphine	
(i) Ethylmorphine	Dionin
(j) Etorphine hydrochloride	
(k) Hydrocodone	Dihydrocodeinone
(l) Hydromorphone	Dihydromorphinone, Dilaudid
(m) Metopon	
(n) Morphine	
(o) Oxycodone	Dihydrohydroxycodeinone, Percodan, Nucodan, OxyContin
(p) Oxymorphone	Dihydrohydroxymorphinone, Numorphan
(q) Thebaine	
(r) Oripavine.	

(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 (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), 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)	Levo-alpha-acetylmethadol	LAAM
(13)	Levomethorphan	
(14)	Levorphanol	Levo-Dromoran
(15)	Metazocine	
(16)	Methadone	Dolophine, Amidone, Adanon
(17)	Methadone-Intermediate 4-cyano-2-dimethylamino-4, 4-diphenylbutane	
(18)	Moramide-Intermediate 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid	
(19)	Pethidine (meperidine)	Meperidine, Demerol
(20)	Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	Isonipecaine, Mepadin, Mepergan
(21)	Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	
(22)	Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	
(23)	Phenazocine	Prinadol
(24)	Piminodine	Alvodine
(25)	Racemethorphan	

(26)	Racemorphan	Dromoran
(27)	Remifentanil	
(28)	Sufentanil	Sufenta
(29)	Tapentadol.	

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
(5)	Lisdexamfetamine.	Vyvanse

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)	Glutethimide	Doriden
(3)	Pentobarbital	Nembutal, Tuinal
(4)	Phencyclidine	Sernyl, Sernylar
(5)	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
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. 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 151.02; 151.06; 151.07; 152.02; 214.06*

History: *9 SR 1656; 11 SR 1113; 12 SR 2393; 18 SR 1145; 20 SR 2592; 27 SR 260; 34 SR 1205*

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)	Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug, and Cosmetic Act	
(6)	Ketamine, its salts, isomers, salts of isomers	
(7)	Lysergic acid	
(8)	Lysergic acid amide	
(9)	Methyprylon	Noludar
(10)	Sulfondiethylmethane	
(11)	Sulfonethylmethane	
(12)	Sulfonmethane	
(13)	Tiletamine and zolazepam and any salt thereof	Telazol

(14) Embutramide.

D. Nalorphine	Nalline

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

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

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

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

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

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

(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

G. Hallucinogenic substances. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product.

H. Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts: Buprenorphine.

Statutory Authority: *MS s 151.02; 151.06; 152.02*

History: *9 SR 1656; 18 SR 1145; 20 SR 2592; 27 SR 260; 31 SR 1673; 34 SR 1205*

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) Dichloralphenazone	
(16) Estazolam	
(17) Ethchlorvynol	Placidyl
(18) Ethinamate	Valmid
(19) Ethyl Loflazepate	

(20)	Fludiazepam	
(21)	Flurazepam	Dalmane
(22)	Halazepam	Paxipam
(23)	Haloxazolam	
(24)	Ketazolam	
(25)	Loprazolam	
(26)	Lorazepam	Ativan
(27)	Lormetazepam	
(28)	Mebutamate	
(29)	Medazepam	
(30)	Meprobamate	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
(48)	Zaleplon	
(49)	Zolpidem	
(50)	Zopiclone.	

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) Cathine ((+)-Norpseudoephedrine)	
(2) Diethylpropion	Tenuate, Tepanil
(3) Fencamfamine	
(4) Fenproporex	
(5) Mazindol	Sanorex
(6) Mefenorex	
(7) Modafinil	
(8) Pemoline (including organometallic complexes and chelates thereof)	Cylert
(9) Phentermine	Wilpo, Fastin, Ionamin
(10) Pipradrol	
(11) Sibutramine	
(12) 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
(2) Butorphanol (including its optical isomers).	

Statutory Authority: *MS s 151.02; 151.06; 152.02*

History: *9 SR 1656; 11 SR 1113; 18 SR 1145; 20 SR 2592; 27 SR 260; 34 SR 1205*

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 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.	

C. **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.

D. **Depressants.** 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 depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Pregabalin

(2) Lacosamide ((R)-2-acetoamido-N-benzyl-3-methoxy-propionamide).

Statutory Authority: *MS s 151.06; 152.02*

History: *9 SR 1656; 11 SR 1113; 18 SR 1145; 31 SR 1673; 34 SR 1205*

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

Subpart 1. **Authorization.** Prescription drug orders for Schedule II controlled substances written for patients in long-term care facilities and terminally ill patients 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 drug order, 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 unique identifier of the dispensing pharmacist. The pharmacist must record on the prescription drug order whether the patient is "terminally ill" or an "LTCF patient."

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 prescription drug orders for patients in a long-term care facility and terminally ill patients 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 prescription drug orders for patients in a long-term care facility and terminally ill patients may be maintained in a computerized record keeping 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 drug order; and the information required in subpart 2;

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

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

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *23 SR 1597; 36 SR 237*

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, including documentation of an approved protocol, 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]

Subp. 3. **Registrant requirements.** Each registrant must have policies and procedures that address effective controls to protect against theft and diversion of all stocked controlled substances, restricting access, drug wastage, and returns. Adequate records must be maintained to show purchase, receipt, use, transfer, and disposal of controlled substances. An inventory must be done annually to document control of each stocked controlled substance.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673*

6800.4500 [Repealed, 31 SR 1673]

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*

6800.4800 REPORTING CONTROLLED SUBSTANCE LOSSES.

Any pharmacy, drug wholesaler, drug manufacturer, or controlled substance researcher detecting the theft or significant loss of any controlled substance drug, where the loss is attributable to other than inadvertent error, must report the loss, in writing, to the board and to the Drug Enforcement Administration immediately. The report must include a description of how the loss occurred, if known, the date the loss occurred, if known, the steps being taken to prevent future losses, and an inventory of the missing drugs.

Statutory Authority: *MS s 151.06; 151.102*

History: *23 SR 1597*

INTERNSHIP

6800.5100 DEFINITIONS.

Subpart 1. [Repealed, 36 SR 237]

Subp. 2. **Experiential education program.** "Experiential education program" means the pharmacy practice experience component of the professional pharmacy curriculum of an accredited college or school of pharmacy.

Subp. 3. **Concurrent time internship.** "Concurrent time internship " means internship experience gained during the second, third, and fourth professional academic years only, while a person is a full-time student carrying, in any given school term, 12 or more 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, not licensed to practice pharmacy in the state of Minnesota, 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, or a licensed pharmacist working in a federal health care facility, 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. [Repealed, 36 SR 237]

Subp. 8. [Repealed, 36 SR 237]

Subp. 9. [Repealed, 36 SR 237]

Subp. 10. [Repealed, 36 SR 237]

Statutory Authority: *MS s 151.06; 151.101; 152.02*

History: *17 SR 1279; 18 SR 1145; 27 SR 260; 36 SR 237*

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 a pharmacy internship in Minnesota. Every person participating in a pharmacy residency or fellowship shall either register as an intern or be licensed as a pharmacist. 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 established in Minnesota Statutes, chapter 151. Registration remains in effect if notices of employment, progress report affidavits, or similar forms are submitted as required by the board, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy, is a qualified applicant awaiting an examination for licensure, or is completing a pharmacy residency or fellowship. Registration as an intern 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 hours will not be granted unless registration forms and materials, notices of employment, and progress report affidavits are submitted as required by the board.

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 registration.

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

Subp. 4. [Repealed, 36 SR 237]

Subp. 5. **Manual.** Interns completing 400 hours or more of their internship requirement in Minnesota must complete an internship manual, provided by the board, before the board will recognize the completed hours as acceptable for use in meeting the board's internship requirement.

Subp. 6. **Termination.** No person who terminates efforts toward the completion of the educational or other prerequisites of licensure, or of completion of a residency or fellowship, 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; 151.102; 152.02*

History: *17 SR 1279; 18 SR 1145; 23 SR 1597; 27 SR 260; 36 SR 237*

6800.5350 PRECEPTORS.

Subpart 1. **Certificates.** Pharmacists intending to act as preceptors for pharmacist-interns must register as preceptors with the board by submitting an application and any supporting documentation required by the board. A preceptor registration shall expire every other year on the anniversary of its issuance. The board shall grant registrations 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 Experiential Education Program of the University of Minnesota College of Pharmacy as an approved preceptor; or

B. they have completed at least 4,000 hours of practice as a licensed pharmacist, with at least 2,000 hours of that practice occurring within the state of 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 time on a regular basis, at least three times each month, for the purpose of helping their interns meet the competencies of the internship requirement; and

D. for renewal of a registration only, that they have participated in an instructional program specifically for preceptors, provided by or approved by the board, within the previous 24 months.

Statutory Authority: *MS s 151.06; 151.102*

History: *18 SR 1145; 23 SR 1597; 36 SR 237*

6800.5400 TRAINING.

Subpart 1. **Intent.** The intent of this rule is to establish minimum standards for the training of interns so that they are provided with a proper preceptor-intern relationship and a broad base of practical experience that supplements didactic academic training in a manner which prepares them 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 confirming completion of the number of internship hours for which credit is being requested. The board may deny requests for approval of credit for training received in a state other than Minnesota if the training does not meet the standards for internship described in this subpart.

Subp. 4. **Maximum number of interns.** A licensed pharmacist shall not be the preceptor for more than two interns at one time.

Subp. 4a. **Supervision: intern dispensing and compounding.** An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Except in the case of internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may not supervise more than one intern who is performing tasks associated with dispensing or compounding. In the case of an internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may supervise two interns who are performing tasks associated with dispensing or compounding. The ultimate responsibility for the actions of an intern performing tasks associated with dispensing or compounding shall remain with the licensed pharmacist who is supervising the intern.

Subp. 4b. **Supervision, generally.** Immediate and direct supervision by a licensed pharmacist is not required when an intern completes a medication history, gathers information for the purpose of formulating a pharmaceutical care plan or making a drug therapy recommendation, conducts educational activities for patients or staff, provides patient counseling, participates in patient rounds, or performs similar tasks that do not involve dispensing and compounding. However, all drug therapy and related recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made. An intern's supervising pharmacist is responsible for the accuracy and completeness of statements made by the intern while providing counseling to patients or health-related education to patients or staff.

Subp. 5. **Competencies.** Upon registration, interns and preceptors will be furnished a copy of the board's internship manual, which lists the minimum competencies that should be the focus of internship training. The competencies 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. Effective May 1, 2003, candidates for licensure shall submit evidence that they have successfully completed not less than 1,600 hours of internship under the direction 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. no more than 400 hours of concurrent time internship will be granted to an intern; and

B. 800 hours of internship credit may be acquired through experiential education program experiences that do not have as their focus traditional compounding, dispensing, and related patient counseling activities. The remaining 800 hours of the 1,600 hour total requirement must focus on traditional compounding, dispensing, and related patient counseling activities.

Statutory Authority: *MS s 151.06; 151.101; 151.102; 152.02*

History: *17 SR 1279; 18 SR 1145; 23 SR 1597; 27 SR 260; 36 SR 237*

6800.5500 LICENSURE TRANSFER STANDARDS.

The board may accept internship credit from applicants for licensure transfer 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.

Statutory Authority: *MS s 151.06; 151.101*

History: *9 SR 1656; 36 SR 237*

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*

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

Subpart 1. **Verbal or telephone orders.** Notwithstanding any other provisions of parts 6800.0100 to 6800.9700, a licensed pharmacist, registered nurse, or licensed practical nurse who is employed by a licensed facility and who is authorized by the facility's administrator and is acting on the behalf of the prescriber, may communicate to the pharmacy provider

a prescription drug order lawfully ordered by a practitioner authorized to prescribe drugs or devices pursuant to Minnesota Statutes, section 151.37. Whenever possible, these prescription drug orders shall be transmitted via facsimile or secure electronic format, to the pharmacy in an order format which produces a direct copy of the chart order, which the prescriber will sign at a later date. The pharmacy provider shall record on the prescription drug order the name of the person who transmits the order in addition to the other required information. This subpart does not apply to prescription drug orders for Schedule II controlled substances as defined by part 6800.4220.

Subp. 2. **Written orders.** A copy of a written prescription drug order, signed by the prescriber, may be delivered to the pharmacy by an individual authorized by the facility.

Subp. 3. **Schedule II orders.** Except as provided in part 6800.3000, subparts 2 and 3, Schedule II controlled substances shall be dispensed only upon receipt of an original written prescription drug order manually 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, chapter 152 and parts 6800.4200 to 6800.4250; and

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

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

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 [Repealed, 23 SR 1597]

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;

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 the facility's licensed or registered nurses responsible for overseeing medication administration, of up to a 72-hour supply of medications 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; and

I. preparation of policies and procedures for the disposition of medications. The policies and procedures must conform with the requirements of parts 4658.1350 and 6800.2350.

Subp. 3. [Repealed, 36 SR 237]

Statutory Authority: *MS s 151.06*

History: *18 SR 1145; 36 SR 237*

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*

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 in items A to F.

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 15 different oral pharmaceuticals, not counting oral antibiotics, restricted to therapeutic categories related to symptomatic patient distress or emergencies may be stocked. An unlimited number of oral antibiotics may be stocked in 72-hour supplies of each. 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 beyond-use 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 tamperproof 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 drug order 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 drug order to be presented to a pharmacist for dispensing of the controlled substance.

Subp. 4. **Excluded controlled substances.** Controlled substance 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; 151.102*

History: *18 SR 1145; 23 SR 1597; 36 SR 237*

6800.6800 STAFF PROTECTION FROM HIV TRANSMISSION.

A pharmacy may provide to a nursing home a separate supply of medications containing the prophylaxis regimen currently recommended by the Centers for Disease Control for the prevention of HIV due to accidental contact with contaminated body fluids by health care workers.

Statutory Authority: *MS s 151.06; 151.102*

History: *23 SR 1597*

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*

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*

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 month 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; 152.02*

History: *17 SR 1279; 18 SR 1145; 31 SR 1673*

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. an ongoing proactive program to identify risks to patient safety and reducing 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;

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

I. the preparation of compounded sterile products; and

J. the preparation of compounded nonsterile products.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673*

6800.7520 PHARMACEUTICAL SERVICE POLICIES.

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

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

B. dispensing of legend drugs;

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

D. maintaining security and emergency access in accordance with part 6800.7530;

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

F. maintaining a supply of drugs for use in medical emergencies;

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

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

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

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

K. assuring that orders for drugs are transmitted to the pharmacy by the prescriber or by an order format which produces a direct copy of the order as it is documented in the patient chart;

L. providing for a system of accountability for inpatient dispensing meeting the intent of the certification requirement of part 6800.3100;

M. establish a pharmacist monitoring system that reconciles a nurse prepared medication administration record (MAR) to the pharmacy profile;

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, sterile admixtures shall be labeled as required in part 6800.7900 and must be prepared as required in part 6800.3300, subpart 2;

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 licensed health care professional who procures 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 licensed health care professional at the time the drug is procured from the stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed health care professional's signature;

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

(c) a computer system which utilizes electronic distribution records of controlled substance transactions as long as the system complies with the following requirements:

i. allows for retrieval of all information required by this regulation for all distribution and dispensing transactions for two years;

ii. provides for at least weekly transaction printouts, except that this requirement does not have to be met if a secure daily 24-hour backup is performed which allows for restoration of required information in case of a system failure;

iii. maintains a complete online transaction file that is printable on request, or have a "lock-out" feature that prevents editing of distribution or dispensing information; and

iv. allows for the printing of a report of all distribution and dispensing transactions for a minimum of two years. The system must be capable of retrieving and printing a report listing variables which include, but are not limited to: the identity of a user accessing the system; the date and time controlled substances are distributed to or removed from the automated distribution machine; the quantity of a controlled substance distributed to or removed from the automated distribution machine; drug name, strength, and dosage form; patient name; and practitioner name;

(2) wasting of doses must be carried out by two licensed individuals who are authorized to have access to controlled substances. The wasting of doses must be documented, with the accuracy of the documentation being certified by the licensed individuals who carried out the wasting. Certification must include the signature or other unique identifier of the licensed individuals who carried out the wasting;

(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 or other patient care area;

(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; and

(7) a perpetual inventory of Class II controlled substances must be accurately maintained; and

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 the facility's registered nurses 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 intraservice 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; 152.02*

History: *18 SR 1145; 27 SR 260; 31 SR 1673; 36 SR 237*

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 [Repealed, 23 SR 1597]

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*

6800.7800 PHARMACEUTICAL SERVICE SPACE.

Subpart 1. **Pharmacy security.** 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.

Subp. 2. **Nursing service units.** 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*

6800.7900 PRESCRIPTION LABELING.

Subpart 1. **Outpatient prescriptions.** Labels for filled outpatient prescription drug orders 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 chart orders.** The containers of all drugs dispensed to inpatients on the basis of chart orders, 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 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. date and time of administration if appropriate;

H. beyond-use date; and

I. ancillary precaution labels.

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

Statutory Authority: *MS s 151.06; 151.212*

History: *9 SR 1656; 18 SR 1145; 36 SR 237*

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 home health care pharmacies pursuant to a prescription drug order. 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; 36 SR 237*

6800.8001 POLICY AND PROCEDURES MANUAL.

To obtain a pharmacy license as a parenteral-enteral home health care pharmacy, a policy and procedures manual 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. compliance with the official compendium United States Pharmacopeia, chapter 797;

B. clinical services;

C. cytotoxics handling, storage, and disposal;

D. disposal of unused supplies and medications;

E. drug destruction and returns;

F. drug dispensing;

G. drug labeling and relabeling;

H. drug storage;

I. duties and qualifications for professional and nonprofessional staff;

J. equipment;

K. handling of infectious waste, pharmaceutical waste, and hazardous waste;

L. infusion devices and drug delivery systems;

M. investigational drugs;

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

O. public safety;

P. 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;

Q. record keeping;

R. reference materials;

S. sanitation;

T. security;

U. sterile product preparation procedures; and

V. transportation.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673*

6800.8002 PHYSICAL REQUIREMENTS.

Subpart 1. **Space.** The pharmacy shall meet United States Pharmacopeia, chapter 797, compendium requirements.

Subp. 2. **Equipment.** The licensed pharmacy shall meet United States Pharmacopeia, chapter 797, compendium requirements.

Subp. 3. [Repealed, 31 SR 1673]

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673*

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 practitioner's prescription drug order 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 prescription drug order from a practitioner 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 ensure the environmental control of all products shipped as follows:

A. compounded, sterile pharmaceuticals must be shipped or delivered as required in part 6800.3000 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; 36 SR 237*

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 practitioner primarily responsible for the patient's medical care and that there is a clear understanding between the practitioner, 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 response to drug therapy. Any unexpected or untoward response shall be reported to the prescribing practitioner. 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.

Subp. 4. **Emergency kit.** The pharmacy may provide emergency medications and supplies to be used by designated, registered nurses, employed in the hospice or home health care setting.

The minimum requirements relating to the establishment of an emergency kit are described in items A to C.

A. The pharmacy must have ownership of and assume the responsibility for the emergency supply.

B. Appropriate and agreed-to policies and procedures for the use of the kit must be developed by hospice and home health agencies in conjunction with the supplying pharmacy. Copies of the policies and procedures must be kept at the supplying pharmacy and a copy submitted to the board. The policies and procedures must address the following:

(1) the signed prescriber's protocols stating the drugs to be used, under what medical circumstances they are to be used, who can administer these drugs, how the prescriber is notified of the use of drugs from the kit, and how the prescription covering the drugs that were used is transmitted to the pharmacy;

(2) the storage, temperature, stability, humidity, and proper transportation of the portable container of drugs;

(3) security and who has access to the drugs. An acceptable method is assigning responsibility by a numbering system for each separate box, designated to each separate registered nurse;

(4) replacement of the medications used from the container within 72 hours and the application of tamperproof seals;

(5) the method by which a pharmacy would be furnished with a copy of each prescriber's prescription drug order or approved protocol reference which will be used as a hard copy prescription drug order and will trigger drug replacement; and

(6) a system whereby the supplying pharmacy inspects the contents of the emergency box at least every 60 days for expiration dates of the medications, the tamperproof seal, and the correctness of the contents list; and documents and retains records of the inspection.

C. The pharmacy having ownership and responsibility shall ensure that each portable emergency supply is:

(1) sealed with a tamperproof seal to ascertain entry into the kit;

(2) delivered to and kept under the control of a registered nurse;

(3) labeled on the outside of the container with a list of drugs and quantities contained in the kit; and

(4) limited to drugs that are not controlled substances.

Statutory Authority: *MS s 151.06; 151.102*

History: *18 SR 1145; 23 SR 1597; 36 SR 237*

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*

6800.8550 LABELING OF RADIOPHARMACEUTICALS.

Subpart 1. **Immediate container of bulk radiopharmaceutical product.** Each compounded container must bear a label containing the following information:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation; and

C. radiopharmaceutical lot number.

Subp. 2. **Outer container of bulk radiopharmaceutical product.** Each individual prepared dose must bear a label containing the following information:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. amount of radioactivity;

D. calibration date and time;

E. expiration date and time;

F. volume - if liquid, weight - if solid, number of vials or ampoules - if gas, number of capsules - if capsules;

G. added substances, such as stabilizers and preservatives;

H. radiopharmaceutical lot number;

I. name, address, and telephone number of nuclear pharmacy, if it is to be transferred for commercial distribution; and

J. initials of preparing nuclear pharmacist, if it is to be transferred for commercial distribution.

Subp. 3. **Immediate container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. radiopharmaceutical prescription or lot number; and

D. patient name.

Subp. 4. **Outer container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. amount of radioactivity;

D. calibration date and time;

E. expiration date and time;

F. volume - if liquid, or weight - if solid, and number of vials or ampoules - if gas;

G. added substances, such as stabilizers and preservatives;

H. radiopharmaceutical prescription or lot number;

I. name, address, and telephone number of nuclear pharmacy;

J. patient name; and

K. initials of dispensing nuclear pharmacist.

Statutory Authority: *MS s 151.06*

History: *36 SR 237*

6800.8600 ACQUISITION, STORAGE, AND DISTRIBUTION.

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*

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*

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*

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*

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*

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: 2829 University Avenue SE, No. 530, Minneapolis, MN 55414.

Statutory Authority: *MS s 151.06; 152.02*

History: *17 SR 1279; 18 SR 1145; 31 SR 1673*

VARIANCES

6800.9900 VARIANCES.

Subpart 1. **Right to request variance.** The pharmacist-in-charge of a pharmacy requesting a variance, or in the case of manufacturers, wholesalers, or gas distributors, a person responsible for the operation, 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 of variance.** 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. 5a. **Successor pharmacist-in-charge duties for active variances.** After termination of the services of a pharmacist-in-charge, the successor pharmacist-in-charge shall submit, on the approved form, an acknowledgment of an awareness and understanding of any active variances that the pharmacy has been granted according to this part. The successor pharmacist-in-charge shall be responsible for ensuring that any conditions imposed by the board on any active variances continue to be met. Existing active variances shall remain in effect until the successor pharmacist-in-charge successfully submits the forms required in this subpart, for 90 days from the naming of a successor pharmacist-in-charge, or until the expiration date of the existing variance, whichever is sooner.

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; 152.02*

History: *10 SR 2007; 18 SR 1145; 31 SR 1673; 36 SR 237*

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; 151.19*

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, medical gas manufacturer, medical gas wholesaler, 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 the applicable fee in Minnesota Statutes, chapter 151, the board shall issue a registration certificate in a form it prescribes. An application for a medical gas distributor registration which has not been completed within 12 months of the date on which the board received the application is no longer valid.

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; 151.19; 152.02*

History: *14 SR 617; 31 SR 1673; 36 SR 237*

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; 151.19*

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*