Board of Pharmacy

Proposed Permanent Rules for Pharmacy Practice

6800.0100 DEFINITIONS.

[For text of subps 1 to 1b, see M.R.]

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 ~~product to~~ for another pharmacy ~~for the purpose of filling a prescription~~.

Subp. 2. ~~**Community/retail**~~ **Community/outpatient pharmacy.** ~~"Community/retail~~ "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. [See repealer.]

[For text of subps 2b to 3a, see M.R.]

Subp. 4. **Long-term care pharmacy.** "Long-term care pharmacy" means an established place, whether or not in conjunction with a hospital pharmacy or a ~~community/retail~~ 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.

[For text of subps 4a and 5, see M.R.]

Subp. 6. ~~**Parenteral-enteral/home**~~ **Home health care pharmacy.** ~~"Parenteral-enteral/home~~ "Home health care pharmacy" means an established place, whether or not in conjunction with a hospital pharmacy, long-term care pharmacy, or a ~~community/retail~~ 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.

[For text of subps 7 to 10, see M.R.]

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, 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.

[For text of subps 12 and 13, see M.R.]

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

Subp. 15. **Sterile product compounding.** "Sterile product compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug product 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.

6800.0300 PHARMACY LICENSE AND FEE REQUIRED.

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

6800.0350 LICENSE CATEGORIES.

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

A. ~~community/retail~~ community/outpatient;

B. hospital;

C. ~~parenteral-enteral/home~~ home health care;

D. long-term care;

E. nuclear; ~~and~~

F. central service~~.~~;

G. nonsterile product compounding;

H. sterile product 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 January 3, 2012, the 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. The board shall issue a revised license 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. No additional fee shall be required for issuance of a revised license.

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.

6800.0400 ANNUAL LICENSE RENEWAL DATE AND FEES.

Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application for license renewal, on or before June 1 of each year, together with a fee ~~of $165~~ 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.

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:

[For text of items A and B, see M.R.]

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~~; or~~.

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

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.

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:

[For text of items A to D, see M.R.]

E. in the case of a ~~community/retail~~ community/outpatient pharmacy, contains an area where consultation between the patient and the pharmacist may be conducted with ~~an~~ a reasonable assurance of privacy. ~~Community/retail pharmacies in existence on February 1, 1999, have until February 1, 2001, to comply with this item; and~~ All new and remodeled community/outpatient pharmacies must meet the standards of this subpart. 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 is deemed by the board to provide a reasonable assurance of privacy. For pharmacies using 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 step into 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. An accessible computer terminal for patient profile review and clinical documentation must be available.

Consultation areas must be accessible to the patient outside of the prescription dispensing area and open at all times when the pharmacy is open; and

[For text of item F, see M.R.]

[For text of subp 2, see M.R.]

6800.0910 PATIENT ACCESS TO PHARMACIST.

[For text of subp 1, see M.R.]

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 ~~medication~~ drug according to this part.

A. Upon receipt of a new prescription ~~or a new prescription drug order~~, 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:

[For text of subitems (1) to (10), see M.R.]

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.

6800.0950 ~~SALE RESTRICTED TO LIMITED AREA UNDER SUPERVISION~~REQUIREMENT FOR A SUPERVISED PHARMACY AREA.

The Board of Pharmacy shall refuse to grant a pharmacy license to any ~~pharmacy or proposed pharmacy~~ existing or proposed facility or place of business unless ~~there is provided in~~ the ~~pharmacy a prescription department and a drug area which is used exclusively for the display, sale, compounding, and dispensing of drugs, medicines, chemicals, and poisons, and for the display and sale of other items used in the cure, mitigation, treatment, or prevention of disease in humans or other animals.~~ 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.

6800.1010 CLOSING A PHARMACY.

[For text of subp 1, see M.R.]

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

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

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

[For text of items C to F, see M.R.]

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.

6800.1050 REQUIRED REFERENCE BOOKS AND EQUIPMENT.

Subpart 1. **Reference books.** Except as indicated, the references in this subpart may be in electronic or hard copy form. In addition to the most recent editions of the laws relating to the practice of pharmacy, the rules of the Board of Pharmacy, and the current copy of the Drug Enforcement Agency regulations, Code of Federal Regulations, title 21, parts 1300 to 1316, each pharmacy in Minnesota must have on file at least one

current reference from each of the categories in items A to C. At least one dosage and toxicology reference must be in hard copy form that is appropriate to the majority of the patient base of the pharmacy. An equivalent reference approved by the board in writing may be used in an appropriate category.

A. Examples of pharmacotherapy references are:

~~(1) Pharmacology in Medicine;~~

~~(2)~~ (1) Goodman and Gilman's The Pharmacological Basis of Therapeutics;

~~(3)~~ (2) Applied Therapeutics: The Clinical Use of Drugs;

~~(4)~~ (3) Pharmacotherapy: A Pathophysiologic Approach; and

~~(5) United States Pharmacopeia - Dispensing Information; and~~

~~(6)~~ (4) Conn's Current Therapy.

[For text of item B, see M.R.]

C. Examples of general references are:

[For text of subitems (1) and (2), see M.R.]

(3) ~~Remington's Pharmaceutical Sciences~~ Remington: The Science and Practice of Pharmacy;

[For text of subitems (4) and (5), see M.R.]

(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:

[For text of items A to D, see M.R.]

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

[For text of items F and G, see M.R.]

[For text of subp 3, see M.R.]

6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. ~~**Submitting**~~ **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 ~~for examination including~~, affidavits of internship, a copy of the applicant's official and certified birth record, and a recent photograph. An applicant shall ~~show evidence of graduation~~ 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~~, from a college of pharmacy or a department of pharmacy of a university approved by the board~~. ~~The college or department of pharmacy must meet at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual or, for Canadian graduates, must meet at least~~

~~the minimum standards set by the Canadian Council for Accreditation of Pharmacy Programs and must conduct its instruction in English. The evidence shall be shown by submitting an official final transcript showing the date on which a degree was conferred.~~ The documents in this subpart, together with a check for ~~$125~~ 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 participating in the North American Pharmacy Licensing Exam (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE) must complete a separate application for these exams and submit the applications to the board. A certified check or money order for these exams made payable to the National Association of Boards of Pharmacy (NABP) must be submitted to NABP after the applications for examination have been approved by the board. An applicant who is a graduate of a school or college of pharmacy located outside the United States or Canada, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, is considered to have satisfied the requirements of graduation if the applicant verifies to the board the applicant's academic record and the applicant's graduation. Before taking the licensing examination, a foreign graduate applicant shall pass the Foreign Pharmacy Graduate Equivalency Examination, which is recognized and approved by the board, given by the Foreign Pharmacy Graduate Examination Commission and demonstrate proficiency in the English language by passing the Test of English as a Foreign Language, which is recognized and approved by the board, given by the Educational Testing Service as a prerequisite to taking the licensure examination. The board shall consider an application for licensure by examination or a NAPLEX or MPJE registration to be invalid 18 months after the date that the board determines an application or registration form is complete. An applicant whose application or registration form is invalid, and who wishes to continue licensure procedures, shall submit a new application or registration form and fee.~~ 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. ~~1a~~ 1d. **Authorization to practice.** An applicant who obtains a passing score on the ~~examination~~ required examinations is authorized to practice pharmacy only after paying an original licensure fee ~~of $105~~ under Minnesota Statutes, chapter 151, to the board.

Subp. 2. **Retaking exam.** Any applicant who has failed to pass ~~the~~ an examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake the examination within the next ensuing ~~14~~ 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 applicant shall, at least 45 days before an examination, notify the board in writing of the intention to retake the examination, certifying that information furnished on the original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee, as described in subpart 1.~~ 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.** ~~Examination or license~~ Fees paid to the board ~~shall~~ according to this part will not be returned or refunded.

6800.1300 LICENSURE TRANSFER (RECIPROCITY).

Subpart 1. **Applications.** An application for ~~reciprocal~~ licensure transfer (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with ~~a~~ an application fee ~~of $205~~ under Minnesota Statutes, chapter 151, shall be filed with the director of the board ~~at least 30 days before the date the application is to be considered by the board~~. 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 must have practiced in the profession for at least one year after licensure in another state which is an active member of the National Association of Boards of Pharmacy before the applicant will be considered eligible to reciprocate to Minnesota;~~

~~B~~ 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;

~~C~~ B. an applicant, if examined and licensed ~~after~~ 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 ~~third~~ 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.

[For text of subps 3 and 4, see M.R.]

Subp. 5. **Examination.** Applicants for ~~reciprocal~~ licensure transfer shall be required to display their familiarity with the laws regulating the practice of pharmacy in Minnesota by ~~submitting to an examination on the Minnesota laws and rules and the federal laws and regulations governing the practice of pharmacy~~ passing the Minnesota version of the Multistate Pharmacy Jurisprudence Exam that is offered by the National Association of Boards of Pharmacy.

Subp. 6. [See repealer.]

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 ~~of $180 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $180 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $155 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $130 for manufacturing or wholesale distribution of prescription medical gases only; and $105 for licensed pharmacies engaged in wholesale distribution~~ 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.

[For text of subp 2, see M.R.]

Subp. 3. **Separate licenses required.** A separate license is required for each separate location ~~where drugs are stored~~ involved in wholesale drug distribution within this state~~. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license~~

~~each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.~~ 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.

6800.1430 PERSONNEL.

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

6800.1440 REQUIREMENTS FOR WHOLESALE DRUG DISTRIBUTORS.

[For text of subp 1, see M.R.]

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. ~~(Rockville, Maryland, 1990)~~, which is incorporated by reference. A wholesale drug distributor must follow the standards set forth in the most recent edition of the United States Pharmacopeia/National Formulary. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

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

[For text of items A and B, see M.R.]

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

[For text of items D and E, see M.R.]

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:

[For text of subitems (1) and (2), see M.R.]

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

[For text of items B and C, see M.R.]

[For text of subp 5, see M.R.]

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

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

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

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

[For text of item A, see M.R.]

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

[For text of items C and D, see M.R.]

[For text of subp 8, see M.R.]

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.

[For text of items A to C, see M.R.]

D. A procedure to ensure that any outdated ~~prescription~~ drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

[For text of subps 10 to 12, see M.R.]

6800.1500 CONTINUING ~~PHARMACY~~ EDUCATION.

Subpart 1. **Definitions.** ~~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.

[For text of item B, see M.R.]

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 ~~practitioners~~ pharmacist and shall include but is not limited to professional postgraduate education in any of the following subjects:

[For text of subitems (1) to (4), see M.R.]

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 ~~on October 1~~ 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.

[For text of subps 3 to 4, see M.R.]

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 ~~45~~ 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.

[For text of subp 5, see M.R.]

Subp. 6. **Credit for presentation of professional lectures.** Pharmacists may apply for credit for presentation of in-service training programs or lectures consisting of subjects included in the definition of Continuing ~~Pharmaceutical~~ 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 ~~the Board of Pharmacy's~~ any instructional program for pharmacist preceptors that is developed or approved by the board.

[For text of subps 7 to 9, see M.R.]

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:

[For text of items A and B, see M.R.]

C. Refusing to compound and dispense ~~prescriptions~~ 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.

[For text of item D, see M.R.]

E. Discriminating in any manner between patients or groups of patients, for reasons of ~~religion,~~ race, ~~creed,~~ color, ~~sex, age,~~ creed, religion, disability, national origin, marital status, sexual orientation, sex, or ~~disease~~ 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 ~~prescription~~ legend or ~~nonprescription~~ nonlegend drugs, chemicals, or poisons.

[For text of items G to J, see M.R.]

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.** ~~Prescription~~ 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:

[For text of items A to C, see M.R.]

[For text of subps 3 and 4, see M.R.]

6800.2400 PHARMACIST-IN-CHARGE.

[For text of subps 1 to 3, see M.R.]

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.

6800.2600 ~~VENDING MACHINES~~ AUTOMATED COUNTING AND DISTRIBUTION.

Subpart 1. **Generally.** It is unlawful to count, distribute, dispense, or vend any legend drug ~~by automatic~~ through the use of an automated counting device or automated drug distribution system, or a vending machine ~~without first providing the board with~~ except as provided in this part.

A. **Notification.** The board must be provided with written notification of the location of the automated ~~medication management~~ 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 ~~and patient safety~~ of the device or system, and the name of the pharmacist-in-charge of the pharmacy. ~~Nothing in this part prohibits a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises from utilizing such a device in an emergency, after regular pharmacy hours, when the hospital's pharmacist has complete control over the monitoring of drug therapy, packaging, labeling, filling, record keeping, and security of~~

~~the drugs involved and of the device, and when the device is utilized in compliance with all other state and federal laws and regulations regarding the distribution of legend drugs. In addition, nothing in this part prevents a licensed hospital, receiving pharmaceutical service from a licensed pharmacy on the premises, from using an automated medication management system as its primary drug distribution system if the system requires that drug orders are reviewed and released by a pharmacist before hospital nursing staff are allowed access to the drug.~~ 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.

~~Use of automated medication management systems at sites remote from the location of the pharmacy responsible for the system must be approved by the board before installation and implementation. Requests for approval must be submitted in writing and must include a copy of the policies and procedures which will govern the operation of the system. The board shall grant approval if it determines that:~~

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

~~B. the measures to be taken in the use of the automated system are equivalent or superior to those of a more traditional unit dose or other dispensing system; and~~

~~C. the system requires that drug orders are reviewed and released by a pharmacist before facility staff are allowed access to the drug.~~

~~The board shall deny approval if it determines that item A, B, or C has not been met.~~

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 considered to be prepackaging subject to the requirements of part 6800.3200, subpart 1. Only one cell or cassette may be filled at a time. Drugs previously removed from a manufacturer's stock container may not be used to fill a cell or cassette. No drug may be distributed from an automated counting device unless a pharmacist certifies the accuracy of the filling of each cell or cassette. All manufacturer stock containers used to fill a cell or cassette must be available for the pharmacist to check during the certification process.

B. The labeling of cells and cassettes is subject to the requirements of part 6800.3200, subpart 2.

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 equivalent committee shall develop and regularly review a list of drugs 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 equivalent 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 segregated;

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

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

F. Whenever possible, removal of high alert drugs from the system should be double-checked by a second licensed health care professional to ensure that the prescription drug order is being correctly interpreted and followed.

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. A monthly inspection 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.

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 should be developed that addresses possible system failures, process failures, high-risk drugs, medication errors, and controlled substance discrepancies.

6800.3000 PRESCRIPTIONS AND DISTRIBUTION OF ~~MEDICATION~~ DRUGS.

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

A. No licensed pharmacist shall participate in any arrangement or agreement whereby ~~prescriptions~~ 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. ~~This applies to the prescription order blank and to the completed prescription medication container.~~ Provided, however, that nothing in this part prohibits a licensed pharmacist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up ~~prescriptions~~ 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 ~~medical~~ 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 maintains the written 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, the caregiver, or an authorized agent identified in the written authorization; 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 and 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, unless the patient refuses the consultation. Refusal of consultation by patients must be documented. 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.** ~~Prescriptions and~~ 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 ~~or~~ drug order. Unless the fax transmission is received on a machine generating a copy that is readily readable for at least five years, all fax transmissions of 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. ~~Orders~~ 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, chapter 325L, Minnesota Statutes, section 62J.497, 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. ~~This requirement shall not apply to orders for the medications to be administered in an acute care hospital.~~

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.

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 ~~personal~~ direct supervision of a pharmacist:

A. determination of brands and suppliers;

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

C. ~~verifying~~ verification of the prescription drug order;

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

E. ~~extemporaneous compounding on an individual basis~~ establishment and validation of the initial formulation record of all compounded preparations according to part 6800.3300;

F. ~~certifying~~ certification of the ~~completed~~ filled prescription drug order;

G. ~~assuring~~ ensuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized ~~prescribers or their agents~~ 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 ~~initials~~ the unique identifier of the pharmacist refilling the prescription;

H. supervising clerical personnel in limited nonprofessional duties such as ~~looking up prescription refills, filing prescriptions, record keeping, nonprofessional aspects of presenting completed medications to patients, and completing the transaction~~ 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~~, rewritten, verbal, or electronically produced,~~ 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 ~~completed~~ filled prescription drug order under subpart 1, item F, ~~the~~ an individual pharmacist, practitioner, or pharmacist-intern shall ~~include~~:

A. ~~checking of~~ check the original labeled container from which the medication was withdrawn, except as provided in part 6800.2600;

B. ~~checking of~~ check the labeling on the ~~prescription~~ medication container that will be dispensed;

C. ~~checking~~ check the contents of the ~~prescription~~ medication container that will be dispensed and the appearance of the total product;

D. ~~reviewing~~ 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. ~~initialing of~~ place the pharmacist's, practitioner's, or pharmacist-intern's unique identifier on the prescription drug order or other permanently maintained record ~~by the individual performing the certification~~. 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 ~~distributed~~ dispensed to the patient. These policies and procedures must be made available for inspection by the board upon request.

Subp. 3a. **Accountability.** ~~The prescription filling process must provide documentation to identify the names, initials, or identification codes of each pharmacist, pharmacist intern, or pharmacy technician who performed any portion of the prescription filling process.~~ 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 ~~product~~, or other services must notify the pharmacy's patients of that fact.

[For text of subp 4, see M.R.]

6800.3110 PATIENT MEDICATION PROFILES.

Subpart 1. **System required.** A patient profile record system must be maintained in all pharmacies for persons for whom ~~prescriptions~~ 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.

[For text of subps 2 and 2a, see M.R.]

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~~, preseription~~ 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:

[For text of items A to F, see M.R.]

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 review must scan all prescriptions received by the patient at the pharmacy during the previous six months and conduct the prospective review required in this subpart.~~ The pharmacist-in-charge must develop procedures ~~restricting "override" decision making regarding computer-identified drug problems at the pharmacy~~ 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.

[For text of subp 5, see M.R.]

Subp. 6. [See repealer.]

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 ~~prescriptions~~ prescription drug orders may not be transferred. Schedules III-V ~~prescriptions~~ 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 ~~the prescription~~ 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 ~~and~~, 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 ~~provide~~ obtain from the transferring pharmacist or intern all information required by law to be on a prescription, ~~including~~ plus:

[For text of items A to E, see M.R.]

F. the transferring pharmacy's name ~~and~~, address, and telephone number and~~, in the case of a controlled substance in Schedules III-V, parts 6800.4230 to 6800.4250, the transferring pharmacy's Drug Enforcement Administration registration number and~~ 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 ~~pharmacist~~ pharmacy shall keep the original prescription drug order on file for at least two years from the date of last filling. The receiving ~~pharmacist~~ pharmacy shall keep the transferred prescription drug order on file for at least two years from the date of last filling.

[For text of subp 6, see M.R.]

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 ~~prescriptions~~ 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 ~~pharmacy~~ pharmacist or a pharmacist intern may~~, however,~~ provide informational copies of a prescription drug order to another ~~pharmacy~~ 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 ~~to~~ for whom the prescription drug order was issued ~~as provided in this part~~. A pharmacist may also provide drug therapy information to a physician ~~for~~ 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. ~~A new written prescription personally signed by the prescribing practitioner is required prior to dispensing 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.

6800.3200 PREPACKAGING AND LABELING.

Subpart 1. **Prepackaging.** Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing 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, ~~manufacturer's~~ lot number assigned by manufacturer or distributor, strength, and ~~manufacturer's~~ expiration date assigned by manufacturer or distributor, if any;

C. container specification;

D. copy of the label;

E. ~~initials~~ unique identifier of the packager;

F. ~~initials~~ 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:

[For text of items A to D, see M.R.]

E. internal control number or date; ~~and~~

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.

6800.3300 COMPOUNDING STANDARDS.

[For text of subps 1 to 5, see M.R.]

Subp. 6. **Certifying compounding procedure.** A pharmacist shall certify that each component used in the compounding of a drug product 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.

6800.3350 PHARMACEUTICALS BEYOND-USE DATES.

[For text of subps 1 to 3, see M.R.]

Subp. 4. **Prescription vials.** ~~Prescription~~ 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 ~~and~~ 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.

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 ~~shall~~ 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 ~~distributing~~ dispensing the medication to the patient;

[For text of items B to H, see M.R.]

I. generic or trade name of drug and strength, except when specified by prescriber to the contrary. In the case of combining premanufactured drug products, the

names of the products, or a category of use name shall suffice. In the case of compounding basic pharmaceutical ingredients, the common pharmaceutical name, if such exists, the names and strengths of the principle active ingredients or a category of use ~~label~~ name shall suffice;

J. ~~prescriptions~~ prescription drug orders filled as part of a central service operation ~~shall~~ must bear ~~a unique~~ an identifier ~~to indicate that the prescription was filled at a~~ that indicates the central service pharmacy at which they were filled; and

K. after July 1, 2008, any dispensed ~~prescription medication shall~~ 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.

[For text of subps 2 and 3, see M.R.]

Subp. 4. **Veterinary prescription drug label.** ~~A veterinary prescription drug label must include~~ 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;

[For text of items B to G, see M.R.]

H. cautionary statements if appropriate for the drug; ~~and~~

I. ~~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.~~ 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.

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

[For text of subp 1, see M.R.]

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

[For text of subp 3, see M.R.]

6800.3510 REFILL LIMITATIONS.

No prescription drug order may be filled or refilled more than 12 months after the date on which ~~the prescription~~ 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.

6800.3750 UNIT DOSE DISPENSING.

[For text of subps 1 and 2, see M.R.]

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:

[For text of items A to C, see M.R.]

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, ~~in the prescriber's~~ made to the prescription drug order;

[For text of items E and F, see M.R.]

G. a means for the pharmacist to verify the original ~~prescriber's~~ prescription drug order; and

[For text of item H, see M.R.]

[For text of subps 4 to 8, see M.R.]

Subp. 9. **Storage of medications.**

A. ~~All medication shall be stored in a locked area or locked cart.~~ 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.

[For text of subp 10, see M.R.]

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. ~~Registration is established for the purpose of identification, tracking, and disciplinary action.~~

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. For the purposes of implementing this subpart, beginning January 1, 1999, a pharmacy technician must register with the board pursuant to the requirements of this part.~~

~~C~~ B. Initial registration shall not be prorated.

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

A. The fee for an initial registration ~~is $15. Effective July 1, 2000, the initial registration is $20~~ is the amount established in Minnesota Statutes, chapter 151.

B. The fee for each annual renewal ~~is $15. Effective July 1, 2000, the annual renewal is $20~~ 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 ~~at~~ on which it is due, must pay a late fee of 50 percent of the renewal fee in addition to the renewal fee.

[For text of subp 1d, see M.R.]

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.

[For text of subp 1f, see M.R.]

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, 2013, the board shall not renew the registration of a pharmacy technician who was initially registered after January 1, 2012, 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 480 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. The board may renew the registration of a pharmacy technician who has not completed this training requirement 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 ~~technician functions which~~ pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist or pharmacist-intern and that do not involve the use of professional ~~pharmaceutical~~ 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 ~~shall~~ 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 document that each technician reviews the procedures when the technician is first employed by the pharmacy as a technician, when any substantial changes to the procedures have been made, and at least annually.

Subp. 5. **Supervision.** Pharmacy technicians shall be supervised by a licensed pharmacist~~, practitioner, or pharmacist-intern~~ stationed within the same work area who has the ability to control and is responsible for the action of the 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:

[For text of items A to C, see M.R.]

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

The most restrictive ratio shall apply in a pharmacy in which multiple functions are being performed.

Subp. 7. **Persons not included.** Personnel used solely for clerical duties such as typing~~, other than prescription~~ or keyboarding that does not involve prescription data entry, ~~and~~ record keeping, filing, billing, and completing sales transactions need not be included ~~in the ratios of the functions performed by pharmacy technicians~~ 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 ~~1,500-hour~~ 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. **~~Penalty~~ Unprofessional conduct.** The use of pharmacy technicians in the performance of delegated tasks not included in written procedures may be considered ~~to be~~ 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.

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE.

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

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

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

[For text of items C and D, see M.R.]

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 ~~identity~~ 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:

[For text of items A and B, see M.R.]

C. guarantee the confidentiality of the information contained in the ~~data bank~~ 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 ~~initials~~ the unique identifier of the pharmacist ~~which shall act in lieu of the requirements of part 6800.3100, subpart 1, item G (initials)~~;

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

[For text of subitems (1) and (2), see M.R.]

G. be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the ~~data bank~~ 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 ~~identification code~~ 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.

[For text of subp 3, see M.R.]

Subp. 4. **New prescriptions.**

A. A pharmacy must develop and implement a written quality assurance plan that includes ~~the~~ 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 ~~initials~~ 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.

[For text of item B, see M.R.]

[For text of subps 5 and 6, see M.R.]

6800.4075 CENTRALIZED PRESCRIPTION PROCESSING AND FILLING.

[For text of subp 1, see M.R.]

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:

[For text of subitems (1) to (3), see M.R.]

(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:

[For text of subitems (1) to (6), see M.R.]

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 ~~product~~ drug order, or other services must notify its patients of that fact.

6800.4200 INCLUSIONS AND EXCEPTIONS.

[For text of subp 1, see M.R.]

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

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

Subpart 1. **Authorization.** ~~Prescriptions~~ 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 ~~identification~~ 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."

[For text of subp 3, see M.R.]

Subp. 4. **Validity of prescription.** Schedule II ~~prescriptions~~ 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 ~~prescriptions~~ 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.

6800.5100 DEFINITIONS.

Subpart 1. [See repealer.]

Subp. 2. ~~**Approved externship**~~ **Experiential education program.** ~~"Approved externship program" means an undergraduate program of practical experience administered by a college of pharmacy approved by the board.~~ "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 ~~fourth, fifth, and sixth academic~~ 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.

[For text of subp 4, see M.R.]

Subp. 5. **Pharmacist-intern; intern.** "Pharmacist-intern" and "intern" mean:

[For text of items A to C, see M.R.]

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. [See repealer.]

Subp. 8. [See repealer.]

Subp. 9. [See repealer.]

Subp. 10. [See repealer.]

6800.5300 REGISTRATION AND REPORTING.

Subpart 1. **Registration.** Every person shall register with the board before beginning ~~an~~ a pharmacy internship~~, residency, or fellowship~~ 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 ~~of~~ ~~$20~~ established in Minnesota Statutes, chapter 151. Registration remains in effect ~~during successive quarters of internship training~~ if notices of employment, progress ~~reports, examinations, and~~ report affidavits ~~of experience~~, or similar forms are submitted as required by the board ~~are submitted promptly upon beginning or terminating employment~~, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy, 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 ~~time~~ hours will not be granted unless registration forms and materials, notices of employment, and progress ~~reports, and~~ report affidavits ~~of experience for preceding time are completed and received~~ 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 ~~role as an intern, and the card shall be surrendered to the director of the board on termination of the internship program~~ registration.

[For text of subp 3, see M.R.]

Subp. 4. [See repealer.]

Subp. 5. **Manual.** Interns completing ~~240~~ 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.

[For text of subp 7, see M.R.]

6800.5350 PRECEPTORS.

Subpart 1. **Certificates.** Pharmacists intending to act as preceptors for pharmacist-interns ~~in licensed pharmacies shall first obtain preceptor certificates from~~

must register as preceptors with the board by submitting an application and any supporting documentation required by the board. ~~Certificates~~ A preceptor registration shall ~~be renewed~~ expire every other year on the anniversary of ~~their~~ its issuance. The board shall grant ~~certificates~~ 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 ~~college-based externship~~ 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 ~~pharmacy~~ practice ~~after licensure~~ as a licensed pharmacist, with at least 2,000 hours of that ~~pharmacy~~ practice ~~after licensure as a pharmacist in~~ 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:

[For text of items A and B, see M.R.]

C. they will provide time on at least a weekly basis for the purpose of helping ~~the intern~~ their interns meet the competencies of the internship requirement; and

D. for renewal of a ~~certificate~~ 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.

6800.5400 TRAINING.

Subpart 1. **Intent.** The intent of this rule is to ~~provide~~ establish minimum standards for the training of interns so that they are provided with a proper preceptor-intern (teacher-student) relationship ~~within the context of the employer-employee relationship, provide~~ and a broad base of ~~internship~~ practical experience~~, and supplement~~ that

supplements didactic academic training in a manner which prepares ~~the intern~~ them for all aspects of the practice of pharmacy.

[For text of subp 2, see M.R.]

Subp. 3. **Training in other state.** When an intern desires to obtain credit for training received in a state other than Minnesota, the intern shall abide by the internship rules in that state, and shall provide evidence from that state's Board of Pharmacy ~~that the intern's internship training has been completed in compliance with the internship standards of the National Association of Boards of Pharmacy and with the standards herein provided. Where a possible conflict may exist between the provisions of this part and the requirements of the state in which the intern is training, the intern shall contact the director of the Board of Pharmacy in Minnesota and outline any possible problem~~ 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 ~~trainees~~ number of interns.** ~~No more than one intern shall be trained by a preceptor at one time.~~ 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. A licensed pharmacist may not supervise more than one intern who is 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 must be reviewed and approved by a licensed pharmacist before they are made. An intern's preceptor 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 ~~for~~ 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 ~~credit may be acquired by any combination of the following: internship experience gained concurrent with~~

~~attendance at a college of pharmacy during the fourth, fifth, and sixth year; participation in approved clinical pharmacy programs; or participation in approved internship demonstration projects such as industrial or research experiences~~ will be granted to an intern;

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

~~C~~ B. ~~860 hours of internship credit may be acquired through Pharm D clinical rotations on condition that the remaining 640 hours of the 1,500-hour total requirement is of a traditional compounding, patient counseling, and dispensing nature. Effective May 1, 2003,~~ 800 hours of internship credit may be acquired through ~~Pharm D clinical rotations on condition that~~ 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 ~~is of a~~ must focus on traditional compounding, ~~patient counseling, and~~ dispensing ~~nature~~, and related patient counseling activities.

6800.5500 ~~RECIPROCITY~~ LICENSURE TRANSFER STANDARDS.

The board may accept internship credit from applicants for licensure ~~by reciprocity~~ 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~~, and provided, further, that the applicant has practiced pharmacy for one year prior to being examined for licensure in this state pursuant to the requirements of part 6800.1300~~.

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 ~~prescription order as documented in the patient's~~ 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, ~~whether a chart order or a prescription,~~ 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, ~~subpart~~ 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:

[For text of items A and B, see M.R.]

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.

6800.6500 CONSULTING SERVICES TO LICENSED NURSING HOMES.

[For text of subp 1, see M.R.]

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

[For text of items A to F, see M.R.]

G. providing in-service training to nursing personnel; ~~and~~

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

6800.6700 DRUGS FOR USE IN EMERGENCY KITS.

[For text of subp 1, see M.R.]

Subp. 2. **Emergency drug supplies.** Only emergency drug supplies determined by the quality assurance and assessment committee necessary for patient care in life threatening emergencies may be made available. The drugs in the emergency kit are the responsibility of the pharmacist and, therefore, shall not be used or altered in any way

except as outlined in this subpart. The emergency drug supplies shall comply with the following:

A. The drugs shall be limited to the extent possible to a 72-hour supply of any one emergency drug in either sealed ampules, vials, or prefilled syringes. If an emergency drug is not available in parenteral form, a supply in an alternate dosage form may be provided. Notwithstanding these restrictions, if the quality assurance and assessment committee considers it necessary, up to a 72-hour supply of each of a maximum of 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 ~~expiration~~ beyond-use dates and lot numbers.

[For text of items B and C, see M.R.]

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.

[For text of items E and F, see M.R.]

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

[For text of items A to F, see M.R.]

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:

[For text of subitems (1) and (2), see M.R.]

(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 ~~sedatives and~~ stimulants in oral dosage forms may not be included in emergency kits.

[For text of subp 5, see M.R.]

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:

[For text of items A to O, see M.R.]

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~~,~~ ~~subpart 4,~~ and must be prepared ~~in a laminar or vertical flow hood whenever possible. Chemotherapy admixtures shall be prepared in a vertical flow hood whenever possible~~ as required in part 6800.3300, subpart 2.

[For text of items Q and R, see M.R.]

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

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

(a) a "proof-of-use" sign-out sheet where each dose given is accounted for by the ~~nurse administering~~ 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 ~~nurse~~ licensed health care professional at the time the drug is procured from the ~~nursing station~~ stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed ~~nurse's~~ health care professional's signature; ~~or~~

(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;

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) ~~Wasted~~ Wasting of doses must be ~~documented and witnessed~~ carried out by ~~the signature of~~ two licensed individuals who are ~~nurses or pharmacists.~~ 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.

[For text of subitems (5) to (7), see M.R.]

T. Developing policies for the issuance of medications to patients who are going on leave from the facility. These policies may allow the preparation, by ~~facility personnel~~ 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.

[For text of subp 2, see M.R.]

6800.7900 PRESCRIPTION LABELING.

Subpart 1. **Outpatient prescriptions.** Labels for filled outpatient ~~prescriptions~~ 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 ~~prescriptions~~ chart orders.** The containers of all ~~prescriptions~~ 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:

[For text of items A to G, see M.R.]

[For text of subps 3 and 4, see M.R.]

Subp. 5. **Intravenous admixtures.** Intravenous admixtures must be labeled with the following information:

A. name of solution~~, lot number,~~ and volume of solution;

[For text of items B to F, see M.R.]

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

~~H~~ G. date and time of administration if appropriate;

~~I~~ H. ~~expiration~~ beyond-use date ~~and date and time of compounding~~; and

~~J~~ I. ancillary precaution labels.

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

6800.8000 SCOPE AND PURPOSE.

The purpose of parts 6800.8000 to 6800.8008 is to provide standards for the preparation, labeling, and distribution of sterile products by licensed ~~parenteral-enteral/home~~ home health care pharmacies pursuant to ~~an order or~~ 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.

6800.8004 DRUG DISTRIBUTION AND CONTROL.

Subpart 1. **General.** This part governs the mechanism by which a ~~physician's~~ 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 ~~written or oral~~ prescription drug order from a ~~physician~~ 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 ~~assure~~ ensure the environmental control of all products shipped as follows:

A. compounded, sterile pharmaceuticals must be shipped or delivered ~~to a patient in appropriate temperature-controlled delivery containers, as defined by United States Pharmacopeia standards,~~ 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.

6800.8007 PATIENT CARE GUIDELINES.

Subpart 1. **Primary provider.** The pharmacist who assumes the responsibilities under this part must ensure that there is a designated ~~physician~~ practitioner primarily responsible for the patient's medical care and that there is a clear understanding between the ~~physician~~ 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.

[For text of subp 2, see M.R.]

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 ~~physician~~ 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.

[For text of item A, see M.R.]

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:

[For text of subitems (1) to (4), see M.R.]

(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

[For text of subitem (6), see M.R.]

[For text of item C, see M.R.]

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 worlds "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 worlds "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 worlds "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 worlds "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.

6800.9900 VARIANCES.

[For text of subps 1 to 4, see M.R.]

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.

[For text of subp 6, see M.R.]

6800.9921 REGISTRATION.

[For text of subp 1, see M.R.]

Subp. 2. **Issuance.** Upon the filing of an application for registration, and upon the payment of ~~a~~ the applicable fee ~~of $50~~ in 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.

[For text of subps 3 and 4, see M.R.]

REPEALER. Minnesota Rules, parts 6800.0100, subpart 2a; 6800.1300, subpart 6; 6800.3110, subpart 6; 6800.5100, subparts 1, 7, 8, 9, and 10; 6800.5300, subpart 4; and 6800.6500, subpart 3, are repealed.