Board of Pharmacy

Adopted Permanent Rules Relating to Pharmacists' Licensing and Operation

Rules as Adopted

6800.0100 DEFINITIONS.

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

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

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

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

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Subp. 5. **Nuclear pharmacy.** "Nuclear pharmacy" is an area, place, or premises described in a license issued by the board with reference to plans approved by the board where radioactive drugs are stored, prepared, manufactured, derived, manipulated, compounded, or dispensed and from which related clinical services are provided.

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

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

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

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

Subp. 10. **Poisons.** "Poisons" means any substance except drugs or medicines which has the inherent capability to produce bodily harm, injury, or morbidity to humans or animals through ingestion, inhalation, or absorption through or from any body organ or surface and shall include, but not be limited to, substances that are toxic, caustic, corrosive, sensitizing, extremely flammable or explosive, alone or in mixtures, and whose label bears the signal word "Poison" or cautionary words such as "Caution," "Warning," or "Danger," intended to signal a use alert.

Subp. 11. **Prescription drug order.** "Prescription drug

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order" means a lawful written or oral order of a practitioner for a drug for a specific patient.

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

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

LICENSING PHARMACIES

6800.0300 PHARMACY LICENSE AND FEE REQUIRED.

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

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

6800.0350 LICENSE CATEGORIES.

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

A. community/retail;

B. hospital;

C. parenteral-enteral/home health care;

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D. ~~nursing-home~~ long-term care; and

E. nuclear.

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

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

6800.0500 SEPARATE LICENSE REQUIRED.

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

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

B. the addition or deletion of one or more partners in a partnership to which a pharmacy license has been issued;

C. the change of ownership of 20 percent or more of the issued voting stock of a corporation pharmacy since the issuance of the license or the last renewal; this does not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market;

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

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

6800.0700 PHARMACY, SPACE, AND SECURITY.

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

A. contains more than 400 square feet;

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

C. in the case of a community/retail pharmacy, contains an area where consultation between the patient and the

pharmacist may be conducted with a reasonable expectation of privacy. Community/retail pharmacies in existence on the effective date of this subpart have until January 1, 1994, to comply with this item.

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

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES.

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

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

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

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13, and 6800.0700. Failure of the board to respond in writing within 60 days shall be considered to be approval of the proposed satellite.

6800.0910 PATIENT ACCESS TO PHARMACIST.

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

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

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

A. the name and description of the drug;

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

C. intended use of the drug and expected action;

D. special directions and precautions for

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preparation, administration, and use by the patient;

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

F. techniques for self-monitoring of drug therapy;

G. proper storage;

H. prescription refill information;

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

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

~~For refill prescriptions~~ If a prescription drug has been previously dispensed to a patient, the pharmacist or the pharmacist's designee shall attempt to determine if the patient has experienced any unexpected or unusual reactions or changes in health, whether the patient has experienced the expected outcome, whether the patient is using the medication as prescribed, and whether the patient has been using any over-the-counter or prescription drugs not in the patient's record since the last visit to the pharmacy~~, and advise the patient accordingly~~. If the pharmacist's review of the patient's record or discussions with the patient reveal any of the conditions listed in part 6800.3110, subpart 4, the pharmacist or the pharmacist's designee must offer counseling by the pharmacist to the patient or the patient's agent or caregiver regarding those conditions or problems. The consultation must be in person whenever practicable.

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

A pharmacist may vary or omit the patient information if,

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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 ~~both~~ a specially developed log.

Personal communication by the pharmacist is not required for hospitals dispensing Medicaid-covered outpatient drugs, using the hospital's drug formulary system and billed at no more than the hospital's purchasing costs, for inpatients of a hospital or other institution, such as a licensed nursing home, where other licensed health care professionals are authorized to administer the drugs, or where a patient or patient's agent or caregiver has expressed a desire not to receive the consultation. When ~~the~~ a new prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by ~~telephone or in writing.~~ 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.

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

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other animals.

6800.1010 CLOSING A PHARMACY.

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

A. notify the board of the intended closing; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6800.1050 REQUIRED REFERENCE BOOKS AND MINIMUM EQUIPMENT FOR PHARMACIES.

Subpart 1. **Reference books.** In addition to the most

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

A. Examples of pharmacotherapy references are:

(1) Pharmacology in Medicine;

(2) Pharmacological Basis of Therapeutics;

(3) ~~Merck Manual;~~

~~(4)~~ Applied Therapeutics;

~~(5)~~ (4) Pharmacotherapy: A Pathophysiologic Approach;

~~(6)~~ (5) United States Pharmacopeia - Dispensing Information; and

~~(7)~~ (6) Conn's Current Therapy.

B. Examples of dosage and toxicology references are:

(1) Hazards of Medications;

(2) American Hospital Formulary Service;

(3) Facts and Comparisons;

(4) Pediatric Dosage Handbook;

(5) Evaluation of Drug Interactions; and

(6) American Medical Association Drug Evaluations.

C. Examples of general references are:

(1) Handbook of Nonprescription Drugs;

(2) Handbook on Injectable Drugs;

(3) Physician's Desk Reference;

(4) Remington's Pharmaceutical Sciences; ~~and~~

(5) United States Pharmacopeia - National Formulary; and

(6) Merck Manual.

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

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

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

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

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

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

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

D. cleaning equipment;

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

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

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LICENSING PHARMACISTS

6800.1150 ANNUAL RENEWAL, FEES, AND POSTING.

A pharmacist license expires on March 1 of each year and shall be renewed annually by filing an application for license renewal on or before February 1 of each year, together with a fee of $75. A pharmacist license renewal application received after March 1 is subject to a late filing fee of an amount equal to 50 percent of the renewal fee in addition to the renewal fee.

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

6800.1210 INACTIVE STATUS AND EMERITUS LICENSE.

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

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

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

If an individual's license is on inactive status and that individual maintains an active status license in good standing in another state that requires continuing education, the individual may reactivate the Minnesota license by showing compliance with the continuing education requirements of the other state. If an individual in this category has been on

inactive status in Minnesota for longer than five years, the individual must also take and pass the jurisprudence examination described in part 6800.1300, subpart 5, offered to candidates for licensure by reciprocity.

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

An individual whose license has lapsed before the effective date of this part and who wishes to be relicensed must apply under Minnesota Statutes, section 151.14.

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

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

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

6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. **Submitting.** An applicant for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicant's birth certificate, and a recent photograph. An applicant shall show evidence of graduation with a bachelor of science degree or

doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy, from a college of pharmacy or a department of pharmacy of a university approved by the board and meeting at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual. The evidence shall be shown by submitting an official final transcript showing the date on which degree was conferred. The above listed documents together with a check for $250 must be received by the board at least 45 days prior to the examination. An applicant who is a graduate of a school or college of pharmacy located outside the United States, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, is considered to have satisfied the requirements of graduation if the applicant verifies to the board the applicant's academic record and the applicant's graduation. Before taking the licensing examination, a foreign graduate applicant shall pass the Foreign Pharmacy Graduate Equivalency Examination, which is recognized and approved by the board, given by the Foreign Pharmacy Graduate Examination Commission and demonstrate proficiency in the English language by passing the Test of English as a Foreign Language, which is recognized and approved by the board, given by the Educational Testing Service as a prerequisite to taking the licensure examination.

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

6800.1300 RECIPROCITY.

Subpart 1. **Applications.** An application for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of $175 shall be filed with the director of the board at least 30 days before the date the application is to be considered by the board. The board will consider applications for reciprocity in at least January and June of each calendar year.

Subp. 2. **Eligibility.** To be found eligible for

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consideration by the board:

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

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

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

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

[For text of subps 4 to 6, see M.R.]

LICENSING MANUFACTURERS AND WHOLESALERS

6800.1460 MANUFACTURING PROCEDURES.

A person engaged in the manufacturing of drugs, medicines,

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

CONTINUING EDUCATION

6800.1500 CONTINUING PHARMACEUTICAL EDUCATION.

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

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

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

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

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

H. The provider has developed and will employ evaluation techniques that assess the effectiveness of the

continuing education activities, and the level of fulfillment of the stated objectives for the purpose of provider and activity improvement if indicated.

Applications for program approval must be submitted not less than 45 days prior to the commencement of the program. The board shall assign the number of credit hours to each program and shall grant approval or deny approval of such application within 60 days of receiving the application.

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

Subp. 4a. **Programs not previously submitted for approval.** A pharmacist may apply for credit for attendance at programs not previously submitted to the board for approval provided that the pharmacist completes a continuing education program approval form, obtainable from the board, and submits it to the board within 45 days after completing the program. The applicant shall provide, at a minimum, the title, site, date, type, and length of the program being proposed for approval, a program outline, and a description of the type of evaluation mechanism used at the program. Approval of the program is subject to all the standards of Minnesota Statutes, section 214.12, and subparts 1, item C, and 3a, items B to G.

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

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

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

OPERATION OF PHARMACY

6800.2150 PHARMACIST ON DUTY.

A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except that brief absences of the pharmacist arising out of and in the course of pharmacy practice are allowable.

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

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 to D, see M.R.]

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

F. Refusing to consult with patrons or patients, attempting to circumvent the consulting requirements, or discouraging the patient from receiving consultation concerning contents, therapeutic values, uses, and prices of prescription or nonprescription drugs, chemicals, or poisons.

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

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

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

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

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

Subp. 4. **Drug diversion.** It is unprofessional conduct for

a pharmacist to sell, purchase, or trade, or offer to sell, purchase, or trade, any drug that was purchased by a public or private hospital or other health care entity or that was donated or supplied at a reduced price to a charitable organization. This subpart does not apply to:

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

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

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

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

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

6800.2300 SANITATION.

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

6800.2400 PHARMACIST-IN-CHARGE.

Subpart 1. **Responsibilities and duties.** No person shall conduct a pharmacy without a pharmacist-in-charge, who shall be a pharmacist regularly employed in the pharmacy department and shall be designated in the application for license, each renewal thereof or pursuant to subpart 4. It is the pharmacist-in-charge's duty and responsibility, consistent with

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the accepted standards of professional conduct and practice and in compliance with all applicable laws:

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

C. to assure that all persons participating in an internship, residency, or fellowship program at the pharmacy are appropriately licensed or registered with the board;

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

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

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

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

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

I. to respond to deficiency reports.

[For text of subps 2 to 4, see M.R.]

6800.2500 NOTIFICATION OF CHANGE OF BUSINESS OR RESIDENCE ADDRESS.

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

6800.2700 RETURN OF DRUGS AND DEVICES.

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

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

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

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

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

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

6800.2810 PRESCRIPTION NUMBERS.

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

6800.3000 ACCEPTANCE OF ORDER AND DISTRIBUTION OF MEDICATION; FAX TRANSMISSION OF PRESCRIPTIONS.

Subpart 1. **Acceptance of order.** No licensed pharmacist shall participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. This applies to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this part prohibits a licensed pharmacist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or medical care facility in which a patient is confined.

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

6800.3100 COMPOUNDING AND DISPENSING.

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

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

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

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

I. supervising supportive personnel utilized in the performance of certain pharmacy tasks not requiring professional judgment in accordance with part 6800.3850.

Subp. 2. **Verification.** Verification of validity and propriety under subpart 1, item C, must be of the original prescription order. A copy, rewritten, verbal, or electronically produced, is not acceptable except as provided in parts 6800.3000, subpart 2, and 6800.3120, subpart 7.

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

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

D. reviewing the patient's medication profile for purposes of conducting a prospective drug review and checking the accuracy of the addition to the profile of the medication dispensed; and

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

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

6800.3110 PATIENT MEDICATION PROFILES.

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

Subp. 2. **Minimum information required; generally.** A reasonable effort must be made by the ~~pharmacist~~ pharmacy to obtain, record, and maintain at least the following information regarding individuals obtaining prescription services at the pharmacy:

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

B. individual history where significant, including disease state or states, known allergies and drug reactions, and

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a comprehensive list of medications and relevant devices being used~~;--and~~

~~c.--pharmacist-comments-relevant-to-the-individual's drug-therapy~~ showing the prescription number, the name and strength of the drug or device, the quantity and date received by the patient, and the name of the prescriber; if this information is obtained by someone other than the pharmacist, the pharmacist must review the information with the patient.

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

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

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

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

(1) the pharmaceutical care needs of the patient;

(2) the services rendered by the pharmacist; and

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

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

Subp. 3. ~~**Documentation**~~ **Drug interactions, generally.** ~~In meeting-the-requirements-of-subpart-2,-item-C,-the-pharmacist shall-document:~~

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~~A.---the-pharmaceutical-care-needs-of-the-patient;~~

~~B.---the-services-rendered-by-the-pharmacist;-and~~

~~C.---the-outcome-experienced-by-the-patient.~~ Upon receiving a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction.

Upon recognizing a potentially harmful interaction or reaction, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

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

A. overutilization or underutilization;

B. therapeutic duplication;

C. drug-disease contraindications;

D. drug-drug interactions;

E. incorrect drug dosage or duration of drug treatment;

F. drug-allergy interactions; or

G. clinical abuse or misuse.

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

For the purpose of meeting the requirements of this subpart, a pharmacist may rely on computerized medication profile review. The review must scan all prescriptions received by the patient at the pharmacy during the previous six months~~,~~ ~~check-for-drug-and-allergy-interactions,-over-utilization,-and under-utilization~~ and conduct the prospective review required in this subpart. The pharmacist-in-charge must ~~also~~ develop procedures restricting "override" decision-making regarding

computer-identified drug problems at the pharmacy and include these procedures in the written procedures required under part 6800.3950.

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

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

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

Subp. 2. **Conditions of transfer.** A pharmacy may transfer prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another. Schedule II prescriptions may not be transferred. Schedule III-V prescriptions may only be transferred once.

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

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

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

[For text of subps 4 to 10, see M.R.]

6800.3200 PREPACKAGING AND LABELING.

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

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

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

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

D. except as provided in part 6800.3350, subpart 1, an expiration date of not more than one-fourth of the period of time from the prepackaging date to the manufacturer's expiration date, up to a maximum of six months, or any earlier date which, in the pharmacist's professional judgment, is preferable; and

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

6800.3300 BULK COMPOUNDING.

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

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

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

B. records of each step in the compounding process including: dates; identification of ingredients, including lot numbers; quantities of ingredients used; initials of person preparing each process; and initials of pharmacist supervising each process;

C. a batch number; and

D. total yield.

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

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

Subp. 5. **Supply.** The size of batches of bulk compounded

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drugs must not exceed a three-month average supply, based on historical dispensing records, of the prescription formula that serves as the impetus for the compounding.

6800.3350 EXPIRATION DATES.

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

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

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

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

6800.3400 PRESCRIPTION LABELING.

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

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

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

[For text of items G and 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 shall suffice.

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

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

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

A. date ~~and time~~ of compounding;

B. expiration date and time of product;

C. storage requirements if other than room temperature;

D. infusion or administration rate;

E. sequential number of unit, if appropriate;

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

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

Subp. 2. **Additions to admixtures.** When an additional drug is added to intravenous admixtures, the admixtures shall be labeled on the original label or with a distinctive

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supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and initials of person adding the drug.

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

6800.3510 REFILL LIMITATIONS.

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

6800.3850 SUPPORTIVE PERSONNEL.

Subpart 1. **Nonspecified tasks.** Supportive personnel, commonly known as pharmacy technicians, may be used in performing pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist, practitioner, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

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

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

Subp. 4. **Written procedures.** Written procedures for the use of supportive personnel in a pharmacy shall be prepared by the pharmacist-in-charge, shall be submitted to the board, and a copy shall be kept on file in the pharmacy. These procedures must comply with the standards in this chapter and will be

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approved on that basis. Approval must be obtained prior to implementation of the procedures.

These procedures shall indicate in detail the tasks performed by the supportive person; the name, address, and social security number of the supportive person; that the supportive person will be identified to the public by the use of a name tag giving both the supportive person's name and title; and the certification steps performed by the licensed pharmacist. New procedures or changes in procedures shall be submitted to the board for approval as specified in this subpart. Procedures shall be updated and resubmitted every five years.

The submitted procedures shall be automatically approved 90 days after receipt by the board unless the pharmacist-in-charge is notified by the board of the specific reasons the procedures are unacceptable. A change in personnel filling the approved position does not require resubmission of procedures but does require notification of the board of the names, addresses, and social security numbers of the individuals involved.

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

Subp. 6. **Ratios.** The basic ratio of supportive personnel to pharmacists in a pharmacy is ~~2:1~~ 1:1. Specific functions are excepted from the ~~2:1~~ 1:1 ratio as follows:

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

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

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

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

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

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

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entry, and record keeping need not be included in the ratios of the functions performed by supportive personnel.

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

[For text of subps 8 and 9, see M.R.]

~~Subp. 10. Pharmacist-in-charge to report. The pharmacist-in-charge of a pharmacy where a supportive person, or technician, is found to have diverted or misappropriated drugs shall immediately report that fact and the identity of the individual involved to the board.~~

~~Subp. 11. Registration of technicians. The board shall maintain a record of individuals employed as pharmacy supportive personnel, or pharmacy technicians, and of individuals reported to the board in accordance with subpart 10. The board shall provide to pharmacists who inquire any information in its possession regarding specific supportive personnel.~~

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE.

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

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

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

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

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

Subp. 1a. **Entering orders.** When electronic data processing equipment is employed by any pharmacy, input of drug

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information may be performed by a physician or a pharmacist. If orders are entered by other personnel the pharmacist must certify the accuracy of the information entered and verify the prescription order prior to the dispensing of the medication. The identity of the person entering the order must be retained in the computer record.

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

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

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

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

D. be capable of producing a patient profile indicating all drugs being taken and the dates and quantities of refills of these prescriptions and:

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

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

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

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

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

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

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

Subp. 4. **Prescription refills.**

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

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

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

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

CONTROLLED SUBSTANCES

6800.4150 LABELING OF CONTROLLED SUBSTANCES AND CERTAIN OTHER DRUGS.

Drugs administered systemically as controlled substances

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

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

Controlled substances shall also be labeled:

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

6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

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

A. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers (whether optical, positional, or geometric), esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, or salts is possible within the specific chemical designation:

[For text of subitems (1) to (29), see M.R.]

(30) MPPP;

1-Methyl-4-Phenyl-4-Propionoxypiperidine;

[For text of subitems (31) to (48), see M.R.]

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

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

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	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	4-Bromo-2,5-Dimethoxyamphetamine	4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA
(2)	2,5-Dimethoxyamphetamine	2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA
(3)	4-Methoxyamphetamine	4-methoxy-a-Methylphenethylamine; paramethoxyamphetamine, PMA
(4)	5-Methoxy-3,4-Methylenedioxyamphetamine	MMDA
(5)	4-Methyl-2,5-Dimethoxyamphetamine	4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP"
(6)	3,4-Methylenedioxy Amphetamine	MDA
(7)	3,4-Methylenedioxymeth-amphetamine	MDMA
(8)	3,4-Methylenedioxy-N-ethylamphetamine	N-ethyl-alpha-methyl-3,4(Methylenedioxy) phenethylamine; N-ethyl MDA; MDE; MDEA
(9)	N-hydroxy-3, 4-Methylenedioxy-amphetamine	N-hydroxy-alpha-methyl-3, 4(Methylenedioxy) phenethylamine; N-hydroxy MDA
(10)	3,4,5-Trimethoxy Amphetamine	TMA
(11)	Bufotenine	3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(12)	Diethyltryptamine	N,N-Diethyltryptamine; DET
(13)	Dimethyltryptamine	DMT
(14)	Ibogaine	7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga
(15)	Lysergic acid diethylamide	LSD
(16)	Marijuana	
(17)	Mescaline	
(18)	Parahexyl	3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl
(19)	Peyote Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or extracts	
(20)	N-ethyl-3-piperidyl Benzilate	JB-318
(21)	N-methyl-3-piperidyl Benzilate	JB-336
(22)	Psilocybin	

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(23)	Psilocyn	
(24)	Tetrahydrocannabinols Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activities such as the following: 1 cis or trans tetrahydrocannabinol, and their optical isomers, excluding dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration. 6 cis or trans tetrahydrocannabinol, and their optical isomers; 3,4 cis or trans tetrahydrocannabinol, and its optical isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)	THC
(25)	Ethylamine analog of phencyclidine	N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(26)	Pyrrolidine analog of phencyclidine	1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(27)	Thiophene analog of phencyclidine	1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP
(28)	2-thienyl Pyrrolidine analog of Phencyclidine	1-[1-(2-thienyl)cyclohexyl]-pyrrolidine, TCPy

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

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

(1) Fenethylline;

(2) 4-Methylaminorex

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(2-Amino-4-methyl-5-phenyl-2-oxazoline);

(3) N-ethylamphetamine.

6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

The following items are listed in Schedule II:

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

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

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	Alfentanil	Alfenta
(2)	Alphaprodine	Nisentil
(3)	Anileridine	Leritine
(4)	Bezitramide	
(5)	Bulk Dextropropoxyphene (nondosage forms)	
(6)	Carfentanil	
(7)	Dihydrocodeine	Paracodin
(8)	Dihydromorphinone	Dilaudid
(9)	Diphenoxylate	
(10)	Fentanyl	Sublimaze, Innovar
(11)	Isomethadone	
(12)	Levomethorphan	
(13)	Levorphanol	Levo-Dromoran
(14)	Metazocine	
(15)	Methadone	Dolophine, Amidone, Adanon
(16)	Methadone-Intermediate 4-cyano-2-dimethylamino-4, 4-diphenylbutane	
(17)	Moramide-Intermediate 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid	
(18)	Pethidine (meperidine)	Meperidine, Demerol, Isonipecaine, Mepadin, Mepergan
(19)	Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	
(20)	Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	
(21)	Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	
(22)	Phenazocine	Prinadol
(23)	Piminodine	Alvodine
(24)	Racemethorphan	
(25)	Racemorphan	Dromoran
(26)	Sufentanil	Sufenta

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

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6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

The following items are listed in Schedule III:

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

F. Anabolic Steroids.

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

6800.4240 SCHEDULE IV CONTROLLED SUBSTANCES.

The following items are listed in Schedule IV:

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

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Alprazolam	Xanax
(2) Barbital	Barbitone
(3) Bromazepam	
(4) Camazepam	
(5) Chloral betaine	Beta-Chlor
(6) Chloral hydrate	Noctec, Somnos
(7) Chlordiazepoxide	Librium, Libritabs
(8) Clobazam	
(9) Clonazepam	Clonopin
(10) Clorazepate	Tranxene
(11) Clotiazepam	
(12) Cloxazolam	
(13) Delorazepam	
(14) Diazepam	Valium
(15) Estazolam	
(16) Ethclorvynol	Placidyl
(17) Ethinamate	Valmid
(18) Ethyl Loflazepate	
(19) Fludiazepam	
(20) Flunitrazepam	

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

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

6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The following items are listed in Schedule V:

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

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

6800.4400 REGISTRATION OF CONTROLLED SUBSTANCE RESEARCHERS.

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

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board shall issue a permit.

Subp. 2. [See repealer.]

6800.4500 CONTROLLED SUBSTANCE SAMPLES.

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

6800.4600 PERPETUAL INVENTORY.

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

6800.4700 CONTROLLED SUBSTANCE VERIFICATION.

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

INTERNSHIP

6800.5100 DEFINITIONS.

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

Subp. 3. **Concurrent time.** "Concurrent time" means internship experience gained during the fourth, fifth, and sixth

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

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

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

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

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

C. a qualified applicant awaiting examination for licensure; or

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

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

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

Subp. 8. **Supervision.** Except as provided in subpart 9, "supervision," as used in connection with parts 6800.5100 to 6800.5600, means that in the pharmacy where the intern is being trained, a registered pharmacist designated as preceptor or another registered pharmacist shall be in continuous personal contact with and actually giving instructions to the intern during all professional activities of the entire period of the intern's internship.

Subp. 9. **Supervision in approved clinical programs.** Direct supervision for interns is not required for drug information gathering for the purpose of patient assessment. Direct supervision is required when making drug therapy

recommendations to other health professionals when the recommendations may affect patient therapy.

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

6800.5200 INTERNSHIP.

The purpose of parts 6800.5100 to 6800.5600 is to define and regulate the internship experience of prospective pharmacists as required by Minnesota Statutes, sections 151.10 and 151.101. These parts take effect immediately but do not nullify any period of internship service by any individual previous to their adoption if the period of internship is filed in a proper manner with the director of the Board of Pharmacy.

6800.5300 REGISTRATION AND REPORTING.

Subpart 1. **Registration.** Every person shall register with the board before beginning an internship, residency, or fellowship in Minnesota. Applications for the registration of a pharmacist-intern shall be on a form or forms the Board of Pharmacy prescribes and shall be accompanied by a fee of $20. Registration remains in effect during successive quarters of internship training if progress reports, examinations, and affidavits of experience as required by the board are submitted promptly upon beginning or terminating employment, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy. Registration for purposes of participating in a residency or fellowship program remains in effect until the individual obtains licensure as a pharmacist, for two years, or until the completion of the residency or fellowship program, whichever occurs first. Credit for internship time will not be granted unless registration, progress reports, and affidavits of experience for preceding time are completed and received.

Subp. 2. **Identification.** The pharmacist-intern shall be

so designated in professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall on proper registration issue to the intern a pocket registration card for purposes of identification and verification of the intern's role as an intern, and the card shall be surrendered to the director of the board on termination of the internship program.

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

Subp. 5. **Examinations.** Examinations shall be administered approximately quarterly at times and locations that the board designates. These examinations shall be of a pretest and posttest nature bracketing the segments of the intern's experience as the board deems appropriate. Interns will be required to attain a score of 75 percent on the posttest examination as verification of having met the minimum objectives of an internship before qualifying to sit for the examination for licensure as a pharmacist. Candidates for licensure by examination who are licensed as pharmacists in another state are exempt from this requirement.

[For text of subps 6 and 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 the board. Certificates shall be renewed every other year on the anniversary of their issuance. The board shall grant certificates or renewals to applicants who fulfill the requirements of subparts 2 and 3.

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

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

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

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Minnesota~~;~~.

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

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

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

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

~~E.--the-pharmacy-has-a-reference-library-that-meets-or exceeds-the-requirements-of-part-6800.1050-at-the-location-at which-the-internship-training-will-take-place;~~

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

~~G.--they-are-participating-in-the-college-based externship-program-of-the-University-of-Minnesota-College-of Pharmacy-as-an-approved-preceptor~~

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

6800.5400 TRAINING.

[For text of subps 1 and 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

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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.

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

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

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

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

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

6800.5600 ADVISORY COMMITTEE.

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

OPERATIONS IN LONG-TERM CARE FACILITIES

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

Subpart 1. **Transmitting orders.** Notwithstanding any other provisions of parts 6800.0100 to 6800.9700, except that part

6800.3000, subpart 2, shall continue to apply, a licensed pharmacist, registered nurse, or licensed practical nurse who is employed by a ~~duly~~ licensed ~~skilled~~ nursing home, boarding care home, ~~intermediate care, or other licensed health care facility~~ or supervised living facility, and who is authorized by the facility's administrator, may transmit to the pharmacy provider a prescription lawfully ordered by a practitioner authorized to prescribe drugs or devices pursuant to Minnesota Statutes, section 151.37. The pharmacy provider shall record on the prescription the name of the person who transmits the order in addition to the other required information. This subpart does not apply to orders for Schedule II controlled substances as defined by part 6800.4220.

Subp. 2. **Written orders.** Orders in subpart 1 may be in writing or, except for Schedule II controlled substances, an oral order reduced to writing by the pharmacist, and may include authorization for multiple refills consistent with good practice and legal limitations. A facsimile copy of the prescriber's medication order may be accepted and filed as a prescription by the pharmacy in accordance with part 6800.3000, subpart 2.

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

6800.6300 PRESCRIPTION LABELING.

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

Subp. 2. **Directions for use.** Directions for use on labels of medications shall be changed only by a pharmacist acting on the instructions of the prescriber or the prescriber's agent. ~~The medications shall be returned to the pharmacist provider to be relabeled or a pharmacist shall relabel the medications at the facility.~~ Personnel of the facility may affix supplemental

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labels alerting staff to a change in the directions for use when a corresponding change is made on the appropriate medication administration record, in accordance with procedures approved by the facility's quality assurance and assessment committee. Subsequent refills of the medication shall be appropriately labeled with the directions for use in effect at the time of dispensing.

6800.6500 ~~CONSULTATIVE~~ CONSULTING SERVICES TO ~~LONG-TERM-CARE FACILITIES~~ LICENSED NURSING HOMES.

Subpart 1. **Written agreement.** A pharmacist providing pharmacy consultative services to a ~~long-term-care-facility~~ licensed nursing home shall devote a sufficient number of hours during regularly scheduled visits to the ~~long-term-care~~ facility for the purpose of reviewing the quality of the pharmaceutical services provided to the ~~long-term-care~~ facility residents. There shall be a written agreement, separate and apart from that provided to pharmacists supplying prescription drug services to residents, for the pharmaceutical consultative services between the facility and the consulting services provider which shall be available for review by the board.

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

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

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

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

E. preparing, at least quarterly, a written report on the status of the pharmaceutical service and staff performance and submitting this report to the administrator and the quality assurance and assessment committee;

F. developing policies for destroying, in the

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

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

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

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

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

~~The drugs shall be destroyed in an environmentally acceptable manner.~~

6800.6700 DRUGS FOR USE IN EMERGENCY KITS.

Subpart 1. **Authorization upon request.** A ~~pharmacist~~

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

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

A. The drugs shall be limited to the extent possible to a ~~maximum of six single doses~~ 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 ~~of the drug in inhalation, buccal, dermal, or sublingual form may be obtained in the smallest sealed manufacturer's package~~ in an alternate dosage form may be provided. Notwithstanding these restrictions, if the quality assurance and assessment committee considers it necessary, up to ~~six doses of four different oral antibiotics~~ a 72-hour supply of each of a maximum of ten different oral pharmaceuticals restricted to therapeutic categories related to symptomatic patient distress or emergencies may be stocked. Inclusion of other oral legend drugs is permissible only through the granting of a variance by the board. Drugs in the supply shall be properly labeled, including expiration dates and lot numbers.

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

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

D. Drugs used from the kit shall be replaced by submitting a prescription for the used item to the pharmacist

within 72 hours and the supply shall be resealed by the pharmacist or the pharmacist's agent.

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

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

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

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

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

Subp. 5. **Penalty.** If any of the provisions of this part are violated, the board may suspend or revoke a pharmacy's privilege to maintain an emergency kit of drug supplies <u>at the noncompliant facility</u>.

OPERATIONS IN HOSPITALS

6800.7100 DEFINITIONS.

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

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

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

HOSPITAL SERVICE POLICIES

6800.7510 PATIENT CARE.

Pharmaceutical service policies shall cover at least the following:

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

E. the self-administration of drugs by patients;

F. the use of drugs brought into the hospital by or with the patient. If the drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored, and returned to the patient at the time of discharge~~.---If not returned to the patient, the drugs shall be destroyed in an environmentally acceptable manner~~;

G. the use of investigational drugs; and

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

6800.7520 ADMINISTRATION.

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

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

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

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

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

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

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

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

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

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

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

P. Assuring that precautionary measures, including quality control documentation, for the safe admixture of parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, pharmacist-interns, supportive personnel under the supervision of a pharmacist, licensed practitioners, and licensed nurses. Furthermore, admixtures shall be labeled as in part 6800.7900, subpart 4, and must be prepared in a laminar or vertical flow hood whenever possible. Chemotherapy admixtures shall be prepared ~~only~~ in a vertical flow hood whenever possible.

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

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

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

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

(a) a "proof-of-use" sign-out sheet where each dose given is accounted for by the nurse administering the drug. No controlled substance may be kept on floor stock unless it is accompanied by the sign-out sheet and each dose is documented by the nurse at the time the drug is procured from the nursing station stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the ~~registered~~ licensed nurse's signature; or

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

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

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

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

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

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

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

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

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of a supply of medications, not to exceed a 72-hour supply, in paper envelopes or other more suitable containers for use by a patient temporarily leaving the facility at times when the facility's pharmacy is closed or cannot supply the needed medication in a timely manner. A container may hold only one medication. A label on the container shall include the date, the patient's name, the facility, the name of the medication, its strength, dose, and time of administration, and the initials of the person preparing the medication and label.

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

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

[For text of subitems (1) to (9), see M.R.]

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room, as permitted under subpart 1, item D and part 6800.7530, for two years.

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

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

(4) copies of current staffing patterns and weekly work schedules for two years;

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

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

6800.7530 MAINTAINING SECURITY AND EMERGENCY ACCESS.

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

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

emergency access.

The person withdrawing from a bulk stock container the limited doses for administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing the patient's name, the name of the drug and dose prescribed, drug strength, the amount taken, the time and date, and the signature of nurse withdrawing drug.

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

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

6800.7900 LABELING.

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

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

A. name ~~and location~~ of patient;

B. name of drug;

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

D. strength of drug;

E. auxiliary labels as needed;

F. expiration date, if applicable; and

G. date dispensed.

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

Subp. 4. **Supplemental label.** Whenever a drug is added to a parenteral solution, a distinctive supplemental label shall be firmly affixed to the container. The supplemental label should be placed to permit visual inspection of the infusion contents and to allow the name, type of solution, and lot number on the manufacturer's label to be read.

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

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

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C. bottle sequence number or other control number system, if appropriate;

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

E. infusion or administration rate, if appropriate;

F. storage requirements if other than room temperature;

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

H. date and time of administration;

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

J. ancillary precaution labels.

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

6800.7950 EXTENSION OF PHARMACY SERVICES UNDER LICENSE.

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

OPERATION OF PARENTERAL-ENTERAL/HOME HEALTH CARE PHARMACIES

6800.8000 SCOPE AND PURPOSE.

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

6800.8001 POLICY AND PROCEDURES MANUAL.

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health care pharmacy a policy and procedures manual relating to sterile products shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis. The manual shall include the policy and procedures for:

A. clinical services;

B. cytotoxics handling, storage, and disposal;

C. disposal of unused supplies and medications;

D. drug destruction and returns;

E. drug dispensing;

F. drug labeling and relabeling;

G. drug storage;

H. duties and qualifications for professional and nonprofessional staff;

I. equipment;

J. handling of infectious wastes;

K. infusion devices and drug delivery systems;

L. investigational drugs;

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

N. public safety;

O. quality assurance procedures, including:

(1) recall procedures;

(2) storage and dating;

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

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

(5) sterility testing of the product;

P. record keeping;

Q. reference materials;

R. sanitation;

S. security;

T. sterile product preparation procedures; and

U. transportation.

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6800.8002 PHYSICAL REQUIREMENTS.

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

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

Subp. 3. **Time for compliance.** Licensed pharmacies providing services to parenteral-enteral home health care patients on the effective date of this part shall have 90 days to comply with subparts 1 and 2.

6800.8003 PERSONNEL.

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

review of policies and procedures, training manuals, and quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.

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

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

6800.8004 DRUG DISTRIBUTION AND CONTROL.

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

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

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

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

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

patient's home; and

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

6800.8005 CYTOTOXIC AGENTS.

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

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

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

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

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

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

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

6800.8006 DRUG USE REVIEW.

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

6800.8007 PATIENT CARE GUIDELINES.

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

the pharmacist of the responsibilities of each in the areas of the delivery of care and the monitoring of the patient. Compliance with this subpart shall be documented in the patient's profile.

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

Subp. 3. **Patient monitoring.** The pharmacist shall request access to clinical and laboratory data concerning each patient and, if the data is obtained, monitor each patient's response to drug therapy. Any unexpected or untoward response shall be reported to the prescribing physician. If the data is not obtained and the pharmacist is not doing the monitoring, the identity of the health care provider who has assumed the responsibility shall be documented in the patient's profile.

6800.8008 QUALITY ASSURANCE.

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

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

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

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

testing for sterility and pyrogens.

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

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

RADIOACTIVE DRUGS

6800.8100 DEFINITIONS.

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

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

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

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

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

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

radiopharmaceuticals and other drugs.

6800.8200 SCOPE.

Parts 6800.8100 to 6800.8700 are applicable to pharmacies and manufacturers dealing with radiopharmaceuticals; provided, however, that parts 6800.0100 to 6800.5600 shall also be applicable to such pharmacies, unless specifically exempted by parts 6800.8100 to 6800.8700 or are in direct conflict with them, in which case parts 6800.8100 to 6800.8700 apply.

6800.8300 MINIMUM STANDARDS.

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

Compliance with all laws and regulations of the U.S. Nuclear Regulatory Commission and other applicable federal and state agencies shall be deemed minimal compliance with this part. Further requirements, as the board in its opinion finds necessary and proper for health and safety in the production, compounding, dispensing, and use of radiopharmaceuticals, may be imposed as a condition of licensure. A pharmacy exclusively handling radioactive materials may be exempt from the building and equipment standards of parts 6800.0700, 6800.0800, 6800.0910, 6800.0950, 6800.1050, and 6800.2150 if the board finds it is in the public interest.

6800.8400 PHARMACISTS HANDLING RADIOPHARMACEUTICALS.

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

approved programs.

6800.8500 PHARMACIST-IN-CHARGE.

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

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

(1) radiation physics and instrumentation;

(2) radiation protection;

(3) mathematics of radioactivity;

(4) radiation biology; and

(5) radiopharmaceutical chemistry;

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

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

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

6800.8600 ACQUISITION, STORAGE, AND DISTRIBUTION OF RADIOPHARMACEUTICALS.

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

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

Radiopharmaceuticals shall not be transferred, distributed,

or dispensed to any person or firm not licensed or authorized to receive or possess the drugs.

6800.8700 RECORD KEEPING.

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

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

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

DISCIPLINARY PROCEEDINGS

6800.9200 INITIATING PROCEEDINGS.

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

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

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

6800.9700 SERVICE AND FILING OF PAPERS.

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

WAIVERS AND VARIANCES

6800.9900 VARIANCES.

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

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

DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES

6800.9923 LABELING.

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

6800.9924 RECORDS.

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

DISPENSING BY PRACTITIONERS.

6800.9950 DISPENSING BY PRACTITIONERS.

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

6800.9951 DRUG STORAGE.

Practitioners engaged in dispensing drugs shall have a separate locked drug storage area for the safe storage of drugs.

Access to the drug supply shall be limited to persons who have legal authority to dispense and to those under their direct supervision.

6800.9952 DISPENSING.

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

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

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

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

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

6800.9953 LABELING.

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

6800.9954 RECORDS.

A practitioner engaged in dispensing drugs shall keep on

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file at each location from which dispensing is taking place a record of drugs received, administered, dispensed, sold, or distributed. The records shall be readily retrievable, shall be maintained for at least two years, and shall include:

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

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

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

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

REPEALER. Minnesota Rules, parts 6800.4400, subpart 2; and 6800.7400, subpart 6, are repealed.

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