MINNESOTA CODE OF AGENCY RULES

RULES OF THE MINNESOTA BOARD OF PHARMACY

1982 Reprint

All rules as in effect on September 15, 1982

Prepared by

THE OFFICE OF REVISOR OF STATUTES
Room 3, State Capitol, St. Paul, Minnesota 55155

Distributed by

STATE REGISTER AND PUBLIC DOCUMENTS DIVISION
DEPARTMENT OF ADMINISTRATION
117 University Avenue, St. Paul, Minnesota 55155

MINNESOTA BOARD OF PHARMACY

Chapter One: Pharmacies, Wholesalers, Manufacturers

Chapter Two: Pharmacists

Chapter Three: Professional Practice

7 MCAR S 8.031	Vending machines.
7 MCAR S 8.032	Return of drugs and devices.
7 MCAR S 8.033	Mail order sale.
7 MCAR S 8.034	Prescription blanks.
7 MCAR S 8.035	Acceptance of prescription order and distribution of prescription medication.
7 MCAR S 8.036	Compounding and dispensing.
7 MCAR S 8.037	Unprofessional conduct.
7 MCAR S 8.038	Prepackaging.
7 MCAR S 8.039	Bulk compounding.
7 MCAR S 8.040	Prescription labeling.
7 MCAR S 8.042	Labeling of controlled substances and certain other drugs.
7 MCAR S 8.043	Electronic data processing.
7 MCAR S 8.044	Poisons.
7 MCAR S 8.045	Sale of poisons.
7 MCAR S 8.046	Labeling of poisons.
7 MCAR S 8.047	Supportive personnel.
7 MCAR S 8.048	Unit Dose dispensing.

Chapter Four: Prohibited Drugs

7 MCAR S 8.050	Drug Identification.
7 MCAR S 8.051	Controlled substances.
7 MCAR S 8.052	Partial dispensing of prescriptions for Schedule II controlled substances.
7 MCAR S 8.053	Registration of controlled substance researchers.
7 MCAR S 8.054	Controlled substance samples.

Chapter Five: Internship

7 MCAR S 8.061	Internship.

Chapter Six: Pharmaceutical Services to Patients in Nursing Homes and Residents of Boarding Care Homes

7 MCAR S 8.071	Prescription order communication.
7 MCAR S 8.072	Prescription labeling.
7 MCAR S 8.073	Labeling of insulin.
7 MCAR S 8.074	Drugs for use in emergency kits.
7 MCAR S 8.075	Pharmacist consultative services to long term care facilities.
7 MCAR S 8.076	Freedom of choice.

Chapter Seven: Pharmaceutical Services to Patients in Hospitals

7 MCAR S 8.081	Pharmaceutical service definitions.
7 MCAR S 8.082	Pharmaceutical service general requirements.
7 MCAR S 8.083	Pharmaceutical service staff.
7 MCAR S 8.084	Pharmaceutical service policies.
7 MCAR S 8.085	Pharmaceutical service equipment and supplies.
7 MCAR S 8.086	Drug handling and storage.
7 MCAR S 8.087	Pharmaceutical service space.
7 MCAR S 8.088	Labeling.
7 MCAR S 8.089	Extension of pharmacy services under license.
7 MCAR S 8.090	Use of supportive personnel.

Chapter Eight: Nuclear Pharmacy

7 MCAR S 8.101	Definitions.
7 MCAR S 8.102	Minimum standards.
7 MCAR S 8.103	Pharmacists handling radioactive drugs.
7 MCAR S 8.104	Pharmacist-in-charge.
7 MCAR S 8.105	Acquisition, storage and distribution of radioactive drugs.
7 MCAR S 8.106	Recordkeeping.

Chapter Nine: Pleading, Practice and Procedure

7 MCAR S 8.111	Definitions as used in these rules.
7 MCAR S 8.112	How proceedings initiated.
7 MCAR S 8.113	Procedure upon filing of complaint.
7 MCAR S 8.114	Style of pleadings.
7 MCAR S 8.115	Form of charges.
7 MCAR S 8.116	Order for and notice of hearing.
7 MCAR S 8.117	Service and filing of papers.

BOARD OF PHARMACY

Chapter One: Pharmacies, Wholesalers, Manufacturers.

7 MCAR § 8.001 Pharmacy defined. The term "pharmacy" means an established place regularly licensed by the Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded, dispensed, vended or sold to the consuming public. Whenever an applicable rule or regulation requires or prohibits action by a "pharmacy," responsibility for said action shall be that of the owner and pharmacist-in-charge thereof, whether said owner is a sole proprietor, partnership, association, corporation or otherwise.

7 MCAR § 8.002 License required. No person or persons shall conduct a pharmacy in the State of Minnesota unless such pharmacy is licensed by the Board of Pharmacy. A fee set by the Board and indicated in 7 MCAR § 8.004 shall be charged for each license.

7 MCAR § 8.003 Form of application and license. Applications for the licensing of a pharmacy and renewal thereof shall be on such form or forms as the Board of Pharmacy may from time to time prescribe and the license of such pharmacy shall be issued by the Board of Pharmacy in such form as it may from time to time prescribe.

R01705T

7 MCAR S 8.004 Pharmacy license; annual renewal date and fees. Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application therefor, on or before June 1 of each year, together with a fee of $75. Renewal applications received on or after July 1 shall be subject to a late filing fee of $20 in addition to the renewal fee.

7 MCAR § 8.005 Posting of license. Each pharmacy license shall be posted in a conspicuous place in the pharmacy for which the license has been issued.

7 MCAR § 8.006 Separate license required. A separate license shall be required for each pharmacy and is not transferable. The following shall be deemed a transfer requiring relicensure.

A. The sale of all or substantially all of the assets of the pharmacy.

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

C. The change of ownership of 20% or more of the issued voting stock of a corporation pharmacy since the issuance of the license or the last renewal thereof. This shall not apply to any corporation, the voting stock of which is actively traded on any securities exchange or in any over the counter market.

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

7 MCAR § 8.007 Access, space and security requirements. No person shall be issued a license to conduct a pharmacy unless such pharmacy:

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

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

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

In the interest of public health the Board may waive any of these provisions for pharmacies located in hospitals.

7 MCAR § 8.008 Change in location, dimension, or security.

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

B. No duly licensed pharmacy shall change its physical dimensions or elements of physical security until it has submitted documents and plans of the proposed changes to the Board of Pharmacy. Such documents and plans shall be submitted at least 60 days prior to the proposed changes. The Board shall within 30 days after receipt of the proposed changes notify the licensee that the proposed changes either comply or do not comply with 7 MCAR § 8.007. The failure of the Board to respond in writing within said 30 days shall be deemed to be approval of the proposed changes.

7 MCAR § 8.009 Pharmacist on duty. Each pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business.

7 MCAR S 8.010 Required reference books and minimum equipment for pharmacies.

A. Reference books. In addition to the most recent editions of the laws relating to the practice of pharmacy and the rules of the Board of Pharmacy, each pharmacy must have on file at least one current reference from each of the following categories:

1. Pharmacology. Examples:

   a. Pharmacology in Medicine;

   b. Pharmacological Basis of Therapeutics;

   c. Merck Manual;

   d. Pharmindex;

   e. United States Dispensatory; and

   f. United States Pharmacopeia - Dispensing Information.

2. Dosage and toxicology. Examples:

   a. Hazards of Medications;

   b. American Hospital Formulary Service;

   c. Facts and Comparisons;

   d. Pediatric Dosage Handbook; and

   e. Evaluation of Drug Interactions.

3. Miscellaneous. Examples:

   a. Handbook of Non-Prescription Drugs;

   b. Modern Drug Encyclopedia;

   c. Physician's Desk Reference;

   d. Remington's Pharmaceutical Sciences; and

   e. United States Pharmacopeia - National Formulary.

An equivalent reference approved by the board in writing may be utilized in an appropriate category.

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

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

2. One set of accurate metric weights from 50 mg. to 100g.;

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

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

5. Refrigerator with a thermometer suitable for drug storage;

6. Sink with hot and cold running water; and

7. Toilet with a handwashing lavatory and disposable towels in a location which is reasonably accessible.

7 MCAR § 8.011 Sale of drugs restricted to limited area under supervision. Hereafter the Board of Pharmacy shall refuse to grant a license to any pharmacy or proprosed pharmacy unless there is provided in such pharmacy a prescription department and a drug area which shall be used exclusively for the display, sale, compounding and dispensing of drugs, medicines, chemicals and poisons, and for the display and sale of other items used in the cure, mitigation, treatment, or prevention of disease in man or other animals.

7 MCAR § 8.012 Each pharmacy shall maintain clean and sanitary conditions at all times.

7 MCAR S 8.013 Drug manufacturer or wholesaler license. Every person engaged in manufacturing or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public shall annually be licensed by the board. Upon the filing of an application therefor, and upon payment of a fee of $100, the board may issue a license in such form as it may prescribe to the manufacturer or wholesaler. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with a fee of $100. Renewal applications received after June 1 shall be subject to a late filing fee of $25 in addition to the renewal fee.

ARD 1057

Chapter Two: Pharmacists.

7 MCAR § 8.021 Pharmacist-in-charge, requirements, definitions 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 7 MCAR § 8.023. The term "pharmacist-in-charge" means a duly licensed pharmacist in the State of Minnesota who has been so designated, and it shall be his duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations:

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

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

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

D. To develop appropriate detailed written procedures directing activities of supportive personnel and to submit these procedures to the Board in accordance with 7 MCAR § 8.047;

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

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

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

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

7 MCAR § 8.022 Pharmacist-in-charge, more than one location. No pharmacist shall be designated pharmacist-in-charge of more than one pharmacy. In the interest of public health, this requirement may be waived in the case of a pharmacist serving a hospital pharmacy on a part-time basis.

7 MCAR § 8.023 Pharmacist-in-charge, termination of service. Each pharmacy shall notify the Board of Pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the Board of Pharmacy of such designation. The Board of Pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the Board of Pharmacy within 10 days after receipt thereof.

7 MCAR § 8.024 Notification of change of business or residence address. Each pharmacist, assistant pharmacist, and registered pharmacist-intern shall notify the Board of Pharmacy immediately of any change in location of his employment or any change of his residence address.

7 MCAR § 8.025 Pharmacist licenses, annual renewal, fees, posting. Each pharmacist license shall expire on March 1 of each year and shall be renewed annually by filing an application therefor on or before February 1 of each year, together with a fee of $25. (Beginning January 1, 1978 said fee shall be $35.) Any pharmacist license renewal application submitted after March 1 shall be subject to a late filing fee of $15 in addition to the renewal fee.

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

7 MCAR S 8.026 Licensure.

A. Applicants for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicant's birth certificate and a recent photograph. All applicants shall show evidence of graduation with a bachelor of science degree or doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy, from a college of pharmacy or a department of pharmacy of a university approved by the board and meeting at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual.

Such evidence shall be shown by submitting a final transcript showing the date on which degree was conferred. The above listed documents together with a check for $75 must be submitted to the board at least 30 days prior to the examination.

B. Any applicant who has failed to pass the examination required by Minn. Stat. §§ 151.06, 151.07, 151.10 or 151.12, may retake such examination within the next ensuing fourteen months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the Board. The applicant shall, at least 30 days before an examination, notify the Board in writing of his intentions to retake the examination, certifying that information furnished on his original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of $75 payable to the State Treasurer. The Board reserves the right to request a full and complete application.

C. Examination or license fees paid to the Board shall not be returned or refunded.

D. An applicant who has failed to successfully pass the Minnesota Board of Pharmacy licensure examination shall not be eligible for licensure by reciprocity.

7 MCAR § 8.027 Continuing education requirements.

A. Definitions.

1. Continuing pharmaceutical education shall include but is not limited to professional post graduate education in any of the following subjects:

a. Properties and actions of drugs and drug dosage forms;

b. Etiology, characteristics and therapeutics and the disease state;

c. Pharmacy practice;

d. Legal, psychological and socio-economic aspects of health care delivery.

2. Accredited program of Continuing Pharmaceutical Education means that a pharmacist must complete at least 30 hours of credit in programs which are accredited by the Board of Pharmacy.

3. Accredited program means those classes, conferences, correspondence study courses, institutes, lectures, professional meetings, programmed learning courses, journal readings, seminars, study groups, or comparable educational activities in Continuing Pharmaceutical Education which are accredited by the Board of Pharmacy.

R0170ST

B. Minimum hours required and reporting. Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to ' Minnesota Statutes, ' section 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he or she has completed at least 30 hours of approved continuing education during the previous two-year period. Thereafter, each pharmacist shall submit such evidence every two years. Beginning with the 1981-1983 reporting period, participation in continuing education shall be reported on October 1 of each even-numbered year. The 1981-1983 reporting requirement will be prorated from March 1, 1981 to October 1, 1982 to require 24 hours of participation reportable October 1, 1982. The board may grant a pharmacist, upon application, an extension of time not to exceed one year to comply with the requirements of B. Such extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period.

C. Accreditation of programs. Application may be made by an association, corporation, educational institution, organization, or person to have a program designated as an accredited program and shall be made on forms provided by the Board. The applicant shall show evidence of an ability to conduct the program and must maintain records of program content and attendance for not less than three years following completion of such program. Applications shall be submitted not less than 60 days prior to the commencement of the program. The Board shall assign the number of credit hours to each program and shall accredit or deny accreditation of such application within 30 days of receipt of the application.

D. Revocation or suspension of an accredited program. The Board may deny, refuse to renew, revoke, or suspend authorization or accreditation previously furnished to sponsors of an accredited program if the program fails to conform to its application accredited by the Board, fails to furnish program content as publicized, or if the sponsor or program violates any provision of Laws of 1973, ch. 655, or this rule.

E. Hours of credit.

1. Credit shall be earned on the basis of attendance or, in the case of correspondence courses, completion of a program. Failure to attend or complete an accredited program shall be the only reason for rejecting program credit hours.

2. Credit for an identical program may be given only once to any individual during any reporting period.

F. Credit for a presentation of professional lectures. Pharmacists may

apply for credit for presentation of in-service training programs or lectures consisting of subjects included in the definition of Continuing Pharmaceutical Education, however, credit shall not be allowed for the preparation or presentation of programs or lectures for which academic credit may be granted to the pharmacy student. Such pharmacists need not apply for accreditation of the program provided that hours of credit applied for do not exceed the number of hours required to present the in-service training program or lecture, and, further provided that information, such as a syllabus or lecture manuscript, be made available upon request to document the presentation of the in-service training. Credit for presentation of the in-service programs or other lectures will be granted only once for any given program or lecture.

G. Advisory Task Force on Continuing Education. The Advisory Task Force shall consist of not more than ten members. Five members of the Advisory Task Force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the College of Pharmacy of the University of Minnesota and two members shall be designated by the Board. The Advisory Task Force on Continuing Education shall meet at least quarterly and shall annually elect a chairman and vice chairman from its membership. The secretary of the Board of Pharmacy shall act as secretariat to the Advisory Task Force.

H. List of accredited programs. The Board shall maintain a record of accredited programs including the hours of credit assigned to each program. Such records may be made available to any registrant upon request.

I. Non-accredited programs. Pharmacists may apply for credit for inclusion of programs not previously accredited by the Board, provided that the name and address of the program sponsor and all of the information required by the Board in compliance with Section C is submitted to the Board within 45 days after completing the program. Such programs shall be subject to all of the standards herein provided.

J. Program promotion. No reference shall be made by a program sponsor in publicizing a program that it is an "accredited program sponsor" unless he is so accredited by the American Council on Pharmaceutical Education or other reference indicating endorsement by the Board except as follows: "This program is accredited by the Minnesota Board of Pharmacy for _____ hours of Continuing Education credit."

7 MCAR § 8.028 Reciprocity.

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

B. To be found eligible for consideration by the Board;

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

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

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

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

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

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

7 MCAR §§ 8.029 and 8.030 Reserved for future use.

Chapter Three: Professional Practice.

7 MCAR § 8.031 Vending machines. It shall be deemed unlawful to distribute, dispense or vend any legend drug by automatic or vending machine. Provided, however, that nothing in this rule shall prohibit a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises, from utilizing such a device in an emergency, after regular pharmacy hours, when the hospital's pharmacist shall have complete control over the monitoring of drug therapy, packaging, labeling, filling, recordkeeping and security of the drugs involved and of the device, and when such device is utilized in

compliance with all other state and federal laws and regulations regarding the distribution of legend drugs.

7 MCAR § 8.032 Return of drugs and devices.

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

B. Drugs from nursing homes may be returned to the dispensing pharmacy if:

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

2. The drugs are returned to the pharmacy which dispensed the drugs;

3. 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,' (Rockville, Maryland: United States Pharmacopeial Convention, Inc.), and that procedures have been developed and implemented to prevent the commingling of dosage units of different lot numbers; and

4. The integrity of such packaging remains intact. No reconstituted drugs, drugs requiring refrigeration, or controlled substances may be so returned.

AR0170ST

C. Commingling of returned medication or mixing of lot numbers of returned medication, upon or prior to repackaging, shall result in such medication being deemed misbranded and subject to embargo under Minn. Stat. § 151.38. This prohibition shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale or rerent thereof.

7 MCAR § 8.033 Mail order sale. Hereafter no pharmacist or pharmacy shall solicit or participate in the solicitation, by advertising of any kind the sale or distribution of drugs requiring a prescription by any mail order plan of any form. The mail order sale or distribution of drugs requiring a prescription is prohibited whenever such sale has been solicited by advertising of any kind by any person or persons. No pharmacist or pharmacy shall accept or fill a prescription which has been received by mail and that has been written by a practitioner not licensed to practice his profession in this state.

7 MCAR § 8.034 *Prescription blanks.* No licensed pharmacy, or pharmacist, shall accept, furnish, or cause to be furnished to any practitioner authorized

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

7 MCAR § 8.035 Acceptance of prescription order and distribution of prescription medication. No licensed pharmacist shall participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. This shall apply to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this section shall prohibit 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.

7 MCAR § 8.036 Compounding and dispensing. The practice of compounding and dispensing a prescription includes, but is not limited to, the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Determination of brands and suppliers.

B. Receipt of verbal prescriptions.

C. Verifying the prescription order. Verification of validity and propriety must be of the original prescription order. A copy, rewritten or verbal, is not acceptable.

D. Selecting the drug to be used in filling the prescription.

E. Extemporaneous compounding on an individual basis.

F. Certifying the completed prescription. In certifying and documenting the completed prescription order, the pharmacist shall include:

1. Checking of the original labeled container from which the medication was withdrawn;

2. Checking of the labeling on the prescription medication container;

3. Checking the contents of the prescription medication container and the appearance of the total product;

4. Checking the patient's medication profile, when utilized, for possible therapeutic incompatibilities and the accuracy of the addition to the profile of the medication dispensed;

5. Initialing of the prescription by the pharmacist performing the certification.

G. Assuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized prescribers or their agents, and then noting on the reverse side of the prescription the following data:

1. Date refilled;

2. Name of practitioner authorizing refill (if different from original prescriber);

3. Quantity of drug dispensed (if different from the original prescription);

4. Initials of the pharmacist refilling the prescription.

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

I. Supervising nonpharmacist supportive personnel utilized in the performance of certain pharmacy tasks. The use of such supportive personnel shall be in accordance with the provisions of 7 MCAR § 8.047.

The provisions of this rule shall apply to all pharmacies provided, however, that nothing in this rule shall prevent pharmacists in hospitals from dispensing to hospital inpatients according to the provisions of 7 MCAR §§ 8.081-8.100.

7 MCAR § 8.037 Unprofessional conduct. Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. The assertion or inference in a public manner of professional superiority in the practice of pharmacy,

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

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

D. Participation in agreements or arrangements, with any person, corporation, partnership, association, firm, or others involving rebates, "kickbacks", fee-splitting, or special charges in exchange for professional pharmaceutical services,

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

F. Refusing to consult with patrons or patients concerning contents, therapeutic values and uses of prescription or non-prescription drugs, chemicals or poisons,

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

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

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

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

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

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

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

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

The public promotion, direct or indirect, of drugs requiring a prescription, narcotics, depressants, or stimulants is hereby declared to be an act of unprofessional conduct. The reference in any advertisement in any media or other means of the term "cut rate", "discount", "bargain", or terms of similar connotation in connection with drugs requiring a prescription or for pharmaceutical services related thereto shall be included within the meaning of public promotion.

L. The selling, giving away, or otherwise disposing of acccessories (i.e., glassine papers, empty capsules, quinine, lactose, or similar products found in illegal drug traffic), chemicals, or drugs by a pharmacist when he knows or should have known of their intended use in illegal activities.

7 MCAR § 8.038 Prepackaging.

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

1. Date.
2. Identification of drug.
   a. Name.
   b. Dosage form.
   c. Manufacturer.
   d. Manufacturer's lot number.
   e. Strength.
   f. Manufacturer's expiration date (if any).
3. Container specification.
4. Copy of the label.
5. Initials of the packager.
6. Initials of the supervising pharmacist.
7. Quantity per container.
8. Internal control number or date.

B. Each prepackaged container shall bear a label containing the following information:

1. Name of drug.
2. Strength.
3. Name of the manufacturer of the finished dosage form of the drug.

4. Manufacturer's expiration date (if any), or any earlier date which, in the pharmacist's professional judgment, is preferable.

5. Internal control number or date.

7 MCAR § 8.039 Bulk compounding. Pharmacies may compound drugs in bulk quantities. Such drugs shall be compounded by or under the direct supervision of a pharmacist. For each drug product compounded in bulk quantities, a master formula record shall be prepared containing the following information:

A. Name of the product.

B. Specimen or copy of label.

C. List of ingredients and quantities.

D. Description of container used.

E. Compounding instructions, procedures and specifications.

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

A. A copy of the information on the master formula record.

B. Records of each step in the compounding process including:

1. Dates.

2. Identification of ingredients (including lot numbers).

3. Quantities of ingredients used.

4. Initials of person preparing each process.

5. Initials of pharmacist supervising each process.

C. A batch number.

D. Total yield.

For each batch of drug product compounded, labels shall be prepared and affixed to each container containing the following information:

A. Identifying name or formula.

B. Dosage form.

C. Strength.

D. Quantity per container.

E. Internal control number or date.

F. Expiration date (if any).

G. Auxiliary labels, as needed.

7 MCAR S 8.040 Prescription labeling. All drugs dispensed to or for a patient other than an in-patient of a hospital shall be labeled with the following information:

A. Name, address, and telephone number of pharmacy.

B. Patient's name.

C. Prescription number.

D. Name of prescribing practitioner.

E. Directions for use.

F. Generic or trade name of drug and strength (except when specified by prescriber to the contrary).

1. In the case of combining premanufactured drug products, the names of the products, or a category of use name shall suffice.

2. 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.

G. Name of the manufacturer of the finished dosage form of the drug.

H. Auxiliary labels, as needed.

I. Date of original issue or renewal.

7 MCAR § 8.042 Labeling of controlled substances and certain other drugs. All drugs administered systemically as controlled substances under Minn. Stat. § 152 and 7 MCAR § 8.051, antihistamines, psycho-therapeutic agents, and other drugs deemed appropriate in the professional judgment of the pharmacist and dispensed to or for an adult patient (other than an in-patient of a hospital or nursing home) shall be labeled according to the requirements of 7 MCAR § 8.040 and in addition shall contain the following:

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

7 MCAR § 8.043 Electronic data processing.

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

B. Electronic data processing equipment, when used to store prescription information must:

1. Guarantee the confidentiality of the information contained in the data bank.

2. Be capable of producing a hard copy daily summary of controlled substance transactions.

3. Be capable of recording and carrying in the record all dates of refills of any prescription and initials of the pharmacist which shall act in lieu of the requirements of Pharm 36 (g) (4). (7 MCAR § 8.036 G. 4.)

4. Be capable of producing a patient profile indicating all drugs being taken and the dates of refills of these prescriptions.

5. Be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank.

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

7 MCAR § 8.044 Poisons. For the purpose of this regulation, poisons shall be deemed to mean any substance except drugs or medicines which has the inherent capability to produce bodily harm, injury, or morbidity to man or beast through ingestion, inhalation, or absorption through or from any body organ or surface and shall include, but not be limited to substances that are toxic, caustic, corrosive, sensitizing, extremely flammable or explosive alone or in mixtures and whose label bears the signal word "Poison" or cautionary words such as "Caution", "Warning", "Danger", etc., intended to signal a use alert.

7 MCAR § 8.045 Sale of poisons. Sales of poisons or hazardous substances shall be made only by a licensed pharmacist or by a pharmacist-intern under the direct supervision of a pharmacist. Each such transaction shall be entered into a poison register with pen and each entry shall show the date and time of day, the name and quantity of substance, the proposed use, the name, address, and signature of the purchaser, and signature of the seller. No such substance shall be sold without the pharmacist first determining the proprietv

of the purported use and satisfying himself that such purchaser has produced proof of identity and legal age.

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

7 MCAR § 8.046 Labeling of poisons. All poisons sold, except when in the original manufacturer's container or on the written prescription of a licensed practitioner, shall bear a label containing the word "Poison", the name and quantity of the substance, and the name and business address of the seller. In addition the package labeling shall contain the following information in accordance with the Hazardous Substance Labeling Act.

A. Name of substance.

B. The name and business address of the manufacturer or repackager.

C. The word "POISON" in letters no smaller than the largest point on the label accompanied by the "Mr. Yuk" symbol. For extremely dangerous substances this must be accompanied by the "skull and crossbones."

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

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

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

7 MCAR § 8.047 Supportive personnel. Supportive personnel may be used in performing pharmacy tasks not specifically reserved in these rules to a licensed pharmacist, assistant pharmacist or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Supportive personnel may perform functions which do not involve professional pharmaceutical judgment.

B. Pharmaceutical products prepared by supportive personnel must be certified for accuracy by a licensed pharmacist (as provided for in 7 MCAR § 8.036 F.) prior to release for patient use.

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

1. These procedures shall indicate in detail the tasks performed by the supportive person and the certification steps performed by the licensed pharmacist.

2. New procedures or changes in procedures shall be submitted to the Board for approval as specified above.

3. 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. (This paragraph shall become effective one year after final promulgation of this rule.)

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

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

a. Intravenous admixture preparation (7 MCAR § 8.084), 3:1;

b. Unit Dose dispensing (7 MCAR § 8.048), 3:1;

c. Prepackaging (7 MCAR § 8.038), 3:1;

d. Bulk compounding (7 MCAR § 8.039), 3:1.

2. Personnel used solely for clerical duties such as typing, looking up refills, filing prescriptions, recordkeeping, etc. need not be included in the ratios of the functions performed by supportive personnel.

3. A pharmacist-intern submitting hours toward completion of the 1500-hour requirement is not considered a supportive person for the purpose of determining the number of supportive persons supervised by a licensed pharmacist.

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

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

7 MCAR § 8.048 Unit Dose dispensing. A Unit-Dose system shall be under the control of the pharmacist-in-charge. The act of drug dispensing is reserved for licensed pharmacists and registered pharmacist-interns acting under the supervision of licensed pharmacists, as set forth in 7 MCAR § 8.036. A Unit Dose system may be used as an alternative to 7 MCAR § 8.036 D., F., and G., according to the following paragraphs:

A. Definitions.

1. Unit Dose packaging. Unit Dose packaging is the packaging of individual doses of medication in containers which will preserve the identity and integrity of the drug from the point of packaging to the point of administration to the patient. Packaging may be accomplished by a manufacturer or by a pharmacy in accordance with 7 MCAR § 8.038.

a. Individual doses of medication shall be properly labeled from the manufacturer with the name of the drug, dosage form and strength, manufacturer's name and lot number and expiration date of all time dated drugs or labeled in accordance with 7 MCAR § 8.038 if prepackaged by the pharmacy.

b. Unit Dose packaging may provide individual doses of medication attached to each other by placement in a card or other container. Such packaging shall be labeled in accordance with 7 MCAR § 8.038 in such a manner as to provide continuous identification of the contents and, when dispensed, the name and location of the patient, name of the prescribing practitioner, prescription number, date, the directions for use and identification of the pharmacy.

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

The system must provide and the pharmacist must utilize:

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

b. A means of separating medications by day of administration;

c. A means of identifying individual doses dispensed, doses administered and doses returned;

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

e. A means of identifying the total dosage regimen of each patient;

f. A means of identifying the time of administration of each drug;

g. A means for the pharmacist to verify the original prescriber's order;

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

B. Each pharmacy utilizing a Unit Dose dispensing system shall establish written policies specifying the categories of drugs which will or categories of drugs which will not be dispensed under the Unit Dose distribution system. Such policies shall be available in the pharmacy for inspection by the Board.

1. Proper utilization of the Unit Dose system requires that in as far as is practicable all medications be in Unit Dose packaging when dispensed.

2. Schedule II, III, and IV controlled substances may be included in the Unit Dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

3. Legend drugs not dispensed under the Unit Dose dispensing system must be dispensed in accordance with 7 MCAR § 8.036 and labeled in accordance with 7 MCAR §§ 8.040 and 8.041.

C. Selection of individual Unit Dose packaging for placement in individual patient containers, bins, compartments or drawers is not dispensing under 7 MCAR § 8.036 and may be performed by supportive personnel. Dispensing occurs upon the certification of the accuracy of the selected Unit Dose packages which shall be done by the pharmacist before the dose is delivered for administration to the patient.

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

E. Unit Dose system shall comply with existing law with respect to provisions of pharmaceutical services to hospitals and nursing homes and as set forth in 7 MCAR §§ 8.071-8.100.

7 MCAR S 8.050 Drug identification.

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

AR01705T

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

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

Chapter Four: Prohibited Drugs.

7 MCAR S 8.051 Controlled substances. The following substances are, because of their potential for abuse, defined and controlled in the following schedules and are, therefore, subject to the provisions of ' Minnesota Statutes, ' chapter 152.

A. The following items are listed in Schedule I:

1. Any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation: Acetylmethadol, Allylprodine, Alphacetylmethadol, Alphameprodine, Alphamethadol, Benzethidine, Betacetylmethadol, Betameprodine, Betamethadol, Betaprodine, Clonitazene, Dextromoramide, Diampromide, Diethyliambutene, Difenoxin, Dimenoxadol, Dimepheptanol, Dimethyliambutene, Dioxaphetyl butyrate, Dipipanone, Ethylmethylthiambutene, Etonitazene, Etoxeridine, Furethidine, Hydroxypethidine, Ketobemidone, Levomoramide, Levophenacylmorphan, Methyl substituted isomers of Fentanyl, Morpheridine, Noracetylmethadol, Norlevorphanol, Normethadone, Norpipanone, Phenadoxone, Phenampromide, Phenomorphan, Phenoperidine, Piritramide, Proheptazine, Properidine, Propiram, Racemoramide, Sufentanil, Tilidine, Trimeperidine.

For the purposes of this paragraph only, the term "isomer" includes the optical, positional, and geometric isomers.

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation: Acetorphine, Acetyldihydrocodeine, Acetylcodone, Benzylmorphine, Codeine methylbromide, Codeine-N-Oxide, Cyprenorphine, Desomorphine, Dihydromorphine, Etorphine, Heroin, Hydromorphinol, Methyldesorphine, Methylhydromorphine, Morphine Methylbromide, Morphine Methylsulfonate, Morphine-N-Oxide, Myrophine, Nicocodeine, Nicomorphine, Normorphine, Pholcodine, Thebacon.

3. Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted, 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.
a. 3, 4-Methylenedioxy Amphetamine	MDA
b. 4-Bromo-2, 5-Dimethoxyamphetamine	
c. 2, 5-Dimethoxyamphetamine	
d. 4-Methoxyamphetamine	
e. 5-Methoxy-3, 4-Methylenedioxy Amphetamine	MMDA

f.	Bufotenine	
g.	Diethyltryptamine	DET
h.	Dimethyltryptamine	DMT
i.	3, 4, 5-Trimethoxy Amphetamine	TMA
j.	4-Methyl-2, 5-Dimethoxyamphetamine	DOM, STP
k.	Ibogaine	
l.	Lysergic Acid Diethylamide	LSD
m.	Marijuana	
n.	Mescaline	
o.	N-ethylamphetamine	
p.	N-ethyl-1-phenyl-cyclohexylamine	
q.	N-ethyl-3-Piperidyl Benzilate	JB-318
r.	N-methyl-3-Piperidyl Benzilate	JB-336
s.	Psilocybin	
t.	Psilocyn	
u.	Tetrahydrocannabinols	THC
v.	1-[1(2Thienyl) Cyclohexy] Piperidine	
w.	1-(1-phenylcyclohexyl) pyrrolidine	

4. Peyote, providing the listing of peyote as a controlled substance in Schedule I does not apply to the non-drug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church, however, are required to obtain federal registration annually and to comply with all other requirements of law.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation: Mecloqualone.

B. The following items are listed in Schedule II:

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

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, including the following:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
raw opium	
opium extracts	
opium fluidextracts	
powdered opium	
granulated opium	
tincture of opium	Laudanum
apomorphine	

codeine	Methylmorphine
ethylmorphine	Dionin
hydrocodone	Dihydrocodeinone, Dicodid, Hycodan
hydromorphone	Dihydromorphinone, Dilaudid
metopon	
morphine	Chlor-Anodyne
oxycodone	Dihydrohydroxycodeinone, Percodan, Nucodan
oxymorphone	Dihydrohydroxymorphinone, Numorphan
thebaine	

b. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause a., except that these substances shall not include the isoquinoline alkaloids of opium.

c. Opium poppy and poppy straw.

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

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, or unless listed in another schedule, whenever the existence of such isomers, esters, ethers and salts 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.
a. Alphaprodine	Nisentil
b. Anileridine	Leritine
c. Bezitramide	
d. Bulk Dextropropoxyphene	
e. Dihydrocodeine	Paracodin
f. Dihydromorphinone	Dilaudid
g. Diphenoxylate	
h. Fentanyl	Sublimaze, Innovar
i. Isomethadone	
j. Levomethorphan	
k. Levorphanol	Levo-Dromoran
l. Metazocine	
m. Methadone	Dolophine, Amidone, Adanon
n. Methadone-Intermediate 4-cyano-2-dimethylamino-4, 4-diphenylbutane	
o. Moramide-Intermediate 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid	

p.	Pethidine	Meperidine, Demerol,
q.	Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	Isonipecaine, Mepadin, Mepergan
r.	Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	
s.	Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	
t.	Phenazocine	Prinadol
u.	Piminodine	Alvodine
v.	Racemethorphan	
w.	Racemorphan	Dromoran

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

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

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

a. Methaqualone	Sopor, Quaalude, Parest
b. Amobarbital	Amytal
c. Secobarbital	Seconal
d. Pentobarbital	Nembutal Tuinal
e. Phencyclidine	Sernyl, Sernylar

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

a. Immediate precursor to amphetamine and methamphetamine:

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

b. Immediate precursor to phencyclidine (PCP):

(1) 1-phenylcyclohexylamine
(2) 1-piperidinocyclohexane carbonitrile (PCC)

C. The following items are listed in Schedule III:

1. Any material, compound, mixture, or preparation which contains any quantity of Amphetamine, its salts, optical isomers, and salts of its optical isomers; Phenmetrazine and its salts; Methamphetamine, its salts, isomers, and salts of isomers; Methylphenidate; and which is required by federal law to be labeled with either of the following symbols; C-III or III.

2. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

a. Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

b. Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
c. Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital.
d. Chlorhexadol	
e. Glutethimide	Doriden
f. Lysergic acid	

g. Lysergic acid amide

h. Methyprylon — Noludar

i. Sulfondiethylmethane

j. Sulfonethylmethane

k. Sulfonmethane

3. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
a. Benzphetamine	Didrex
b. Chlorphentermine	Pre-Sate
c. Clortermine	Voranil
d. Phendimetrazine	Plegine, Stim-35, Melfiant, Bacarate

4. Nalorphine — Nalline

5. Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

a. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.	Copavin
b. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.	Cheracol, Elixir, Terpin Hydrate and Codeine, Cosadein, Prunicodeine, Robitussin A.C.

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

d. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.	Ambenyl, Tussend, Hycomine, Tussionex

e. Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

f. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.	Cidicol
g. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.	Paregoric, Camphorated Opium Tincture

h. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

ARCHIVE

D. The following items are listed in Schedule IV:

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. Chloral betaine	Beta-Chlor
4. Chloral hydrate	Noctec, Somnos
5. Chlordiazepoxide	Librium, Libritabs
6. Clonazepam	Clonopin
7. Clorazepate	Tranxene
8. Diazepam	Valium
9. Diethylpropion	Tenuate, Tepanil
10. Ethchlorvynol	Placidyl
11. Ethinamate	Valmid
12. Fenfluramine	Pondamin
13. Flurazepam	Dalmane
14. Halazepam	Paxipam
15. Lorazepam	Ativan
16. Mazindol	Sanorex

17. Mebutamate	
18. 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
19. Methohexital	Brevital
20. Methylphenobarbital	Mebral, Mephobarbital
21. Oxazepam	Serax
22. Paraldehyde	Paral
23. Pemoline	Cylert
24. Pentazocine	Talwin
25. Petrichloral	Periclor
26. Phenobarbital	Luminal, Phenobarbitone, Eskabarb
27. Phentermine	Wilpo, Fastin, Ionamin
28. Pipradrol	
29. Prazepam	Centrax
30. Propoxyphene	Darvon
31. SPA (/l/-1-Dimethylamino-1, 2-diphenylethane)	
32. Temazepam	Restoril

E. The following items are listed in Schedule V:

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone;

Statutory Names	Some examples of common names, trade names, or names of products which contain a controlled substance.
1. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.	
2. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.	
3. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.	Lomotil
4. Not more than 15 milligrams of anhydrous morphine per 100 milliliters or per 100 grams.	Parapectolin, Donnagel P.G.
5. Loperamide	Imodium

F. Exceptions.

Drugs which are not required by federal law to bear any one of the following symbols, C-I, C-II, C-III, C-IV, or C-V, I, II, III, IV, or V are exempt from the provisions of Minn. Stat. § 152, provided, however, that drugs containing any quantity of phenobarbital shall be dispensed only on prescription.

7 MCAR S 8.052 Partial dispensing of prescriptions for Schedule II controlled substances.

A. Authorization. Prescriptions for Schedule II controlled substances written for patients in long term care facilities may be dispensed in partial quantities, including individual dosage units.

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

C. Quantity dispensed. The total quantity of Schedule II controlled substances dispensed in all partial dispensings must not exceed the total quantity prescribed.

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

E. Computerization of information. Information pertaining to current Schedule II prescriptions for patients in a long term care facility may be maintained in a computerized record keeping system if the system has the capability to permit:

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

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

3. Retrieval of partially dispensed Schedule II prescription information, the same as required by federal law for Schedule III and IV prescription refill information.

7 MCAR S 8.053 Registration of controlled substance researchers.

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

B. Exemption. Registration under A. shall not be required of any physician conducting research involving controlled substances who is otherwise licensed by the state and who has complied with federal laws covering research projects of controlled substances.

7 MCAR S 8.054 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 7 MCAR S 8.051, may not distribute controlled substance samples directly or by other means without charge or at a charge below fair market value unless a practitioner signs a written request for a designated quantity of the controlled substance. The request must also indicate that the controlled substance is to be distributed to the practitioner by the manufacturer, distributor, or agent or distributed to a pharmacist for dispensing to a patient.

Chapter Five: Internship

7 MCAR S 8.061 Internship. The purpose of this rule is to define and regulate the internship experience of prospective pharmacists as required by ' Minnesota Statutes, ' sections 151.10 and 151.101. This rule shall take effect immediately but the provisions contained herein shall not nullify any period of internship service by any individual previous to its adoption provided such period of internship is filed in a proper manner with the secretary of the Board of Pharmacy.

A. Definitions.

1. "Pharmacist intern" and "intern" means:

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

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

c. a qualified applicant awaiting examination for licensure.

2. "Preceptor" means a natural person licensed as a pharmacist by the Board of Pharmacy, and who participates in instructional programs approved by the board.

3. "Hour" means the standard 60 minute division of time.

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

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

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

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

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

B. Registration and reporting.

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

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

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

4. The intern may be required to maintain additional records of his professional activities. The records, which shall be submitted after the completion of each quarter of internship, are to be prescribed by the board for the purpose of recording details of the scope of internship experience and may include examinations to test the competency of interns. The examinations shall be administered approximately quarterly at times and locations as the board may designate. These examinations shall be of a pre-test and post-test nature bracketing such segments of the intern's experience as the board deems appropriate. Interns will be required to attain a score of 75 percent on the post-test examination as verification of having met the minimum objectives of an internship before qualifying to sit for the examination for licensure as a pharmacist.

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

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

AR01705T

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

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

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

3. No more than one intern shall be trained by a preceptor at one time.

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

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

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

b. Not more than 700 hours of internship credit may be given during any internship quarter.

D. Reciprocity standards. The board may accept internship credit from applicants for licensure by reciprocity who have submitted evidence of completion of internship training in another state, provided that the training is, in the opinion of the board, substantially equivalent to the standards herein provided, and is in compliance with the internship standards of the National Association of Boards of Pharmacy, and provided, further, that the applicant has practiced pharmacy for one year prior to being examined for licensure in this state pursuant to the requirements of 7 MCAR § 8.028.

E. Advisory committee. The board shall appoint an Advisory Committee on Internship to advise the board on the administration of this regulation. The committee shall include practicing pharmacists, pharmacist-educators, pharmacy-interns and representatives of the board.

7 MCAR §§ 8.062-8.070 Reserved for future use.

Chapter Six: Pharmaceutical Services to Patients in Nursing Homes and Residents of Boarding Care Homes. The provisions of 7 MCAR §§ 8.071 through 8.080 are applicable to pharmaceutical services provided to patients in long term care facilities, provided, however, that 7 MCAR §§ 8.001 through 8.070 shall also be applicable to such pharmaceutical services, unless specifically exempted by 7 MCAR §§ 8.071 through 8.080 or are in direct conflict therewith, in which case 7 MCAR §§ 8.071 through 8.080 shall apply.

7 MCAR § 8.071 Prescription order communication.

A. Notwithstanding any other provisions of 7 MCAR SS 8.001-8.117, a licensed pharmacist, registered nurse, or licensed practical nurse who is employed by a duly licensed skilled care, intermediate care, or other licensed health care facility, and who is authorized by the facility's administrator, may transmit to the pharmacy provider a prescription lawfully ordered by a practitioner authorized to prescribe drugs or devices pursuant to ' Minnesota Statutes, ' section 151.37. The pharmacy provider shall record on the prescription the name of the person who transmits the order in addition to the other required information. This paragraph shall not apply to orders for Schedule II controlled substances as defined by 7 MCAR S 8.051 B.

B. Such orders 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.

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

1. Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user; and,

2. No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of Minn. Stat. § 152 and Pharmacy Rule 7 MCAR § 8.051; and,

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

7 MCAR § 8.072 Prescription labeling. All prescription containers, other than those dispensed pursuant to 7 MCAR § 8.048, shall be properly labeled in accordance with 7 MCAR § 8.040 and shall also contain at least the following information:

A. Quantity of drug dispensed.

B. Date of original issue, or in the case of a refill, the most recent date thereof.

C. Expiration date of all time dated drugs.

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

7 MCAR § 8.073 Labeling of insulin. Insulin shall be dispensed with a label affixed to the vial showing at least the patient's full name and location.

7 MCAR S 8.074 Drugs for use in emergency kits.

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

AR01705T

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

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

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

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

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

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

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

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

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

2. The emergency kit is kept in a locked medicine room or medicine cabinet;

3. Access to the emergency kit is limited to the following individuals:

a. A licensed professional nurse who is employed by the facility and who has been directed by a physician to administer a drug from the kit, or

b. A consultant pharmacist or other licensed pharmacist designated by the facility's pharmaceutical services committee, or

c. A licensed medical practitioner;

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

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

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

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

a. Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;

b. No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance; and

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

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

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

7 MCAR § 8.075 Pharmacist consultative services to long term care facilities.

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

B. The pharmacist shall be responsible for but not limited to the following:

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

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

3. review of the drug regimen of each resident and preparation of appropriate reports and recommendations. This shall include at least a review of:

a. all drugs currently ordered;

b. information concerning the patient's condition as it relates to drug therapy;

c. medication administration records and, where appropriate, physician progress notes, nurses' notes, and laboratory test results.

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

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

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

a. 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;

b. any other unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued shall be destroyed by the facility in the presence of a pharmacist or registered nurse who shall witness such destruction or shall be handled in accordance with 7 MCAR § 8.032;

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

7. providing in-service training to nursing personnel.

7 MCAR § 8.076 Freedom of choice. No pharmacist shall participate in any agreement or plan which infringes on any patient's right to freedom of choice as to the provider of prescription services.

7 MCAR §§ 8.077-8.080 Reserved for future use.

Chapter Seven: Pharmaceutical Services to Patients in Hospitals. The provisions of 7 MCAR §§ 8.081 through 8.100 are applicable to pharmaceutical services provided to patients in hospitals, including state hospitals, provided, however, that 7 MCAR §§ 8.001 through 8.070 and 8.100 through 8.120 shall also be applicable to such pharmaceutical services, unless specifically exempted by 7 MCAR §§ 8.081 through 8.100 or unless in direct conflict therewith, in which case 7 MCAR §§ 8.081 through 8.100 shall apply.

7 MCAR § 8.081 Pharmaceutical service definitions.

A. 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 section. The provision of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

B. "Credentialed" means registered with, certified by, or similarly recognized by a health-related agency or department of the State of Minnesota.

C. "Supervision," as used in connection with this rule, means stationed within the same work area, coupled with the ability to control and responsibility for an action.

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

1. preparing the individual dose from a previously dispensed, properly labeled container;

2. verifying the dose as prescribed;

3. giving the individual dose by the proper route to the correct patient at the proper time;

4. assuring that the dose is taken; and,

5. promptly recording the time and dose given.

E. "Drug dispensing" means to deliver one or more doses of a drug for subsequent administration to, or use by a patient or human research subject. Such drug dispensing shall be performed by the pharmacist in compliance with 7 MCAR §§ 8.036 A.-I. or 8.048 A.-E. with delivery being made in a suitable container properly labeled.

7 MCAR § 8.082 Pharmaceutical service general requirements. Pharmaceutical services in hospitals shall be organized and directed by a pharmacist.

7 MCAR § 8.083 Pharmaceutical service staff.

A. Pharmacist-in-charge.

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

2. Availability.

a. On-site pharmacies. A pharmacist providing pharmaceutical services to a hospital maintaining an on-site pharmacy shall be engaged by the hospital and shall provide at least part-time, 5 day/week services.

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

3. Responsibilities. The responsibilities and duties of the hospital pharmacist-in-charge include at least the following specific duties in addition to the duties of the pharmacist-in-charge found in 7 MCAR § 8.021:

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

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

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

d. the supervision of bulk compounding of pharmaceuticals;

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

f. the development of a hospital formulary system;

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

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

i. the maintaining of pharmaceutical service records; and

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

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

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

B. Other staff.

1. Generally. Pharmaceutical services shall be provided only by pharmacists and other personnel under a pharmacist's supervision.

7 MCAR § 8.084 Pharmaceutical service policies.

A. Patient care. Pharmaceutical service policies shall cover at least the following:

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

2. the limiting of drug administration;

3. the immediate reporting of drug related errors;

4. the immediate reporting of adverse drug reactions;

5. the self administration of drugs by patients;

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

B. Administration. Pharmaceutical service policies shall cover at least:

1. the following measures related to the control, accessibility, dispensing and administration of drugs:

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

b. dispensing of legend drugs;

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

d. maintaining security and emergency access in accordance with the following:

(1) Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth below:

(a) In the case of disaster the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.

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

The person withdrawing from a bulk stock container the limited doses for administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing:

(i) the patient's name;

(ii) the name of the drug and dose prescribed;

(iii) drug strength;

(iv) the amount taken;

(v) the time and date;

(vi) 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.

(2) The pharmacist-in-charge shall develop an emergency access procedure and may make provisions for pre-packaged drugs for emergency withdrawal provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.

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

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

g. specifying the maintenance of permissible supplies of non-prescription drugs in nursing service units;

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

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

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

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

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

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

n. assuring that precautionary measures for the safe admixture of

parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, supportive personnel under the supervision of a pharmacist, licensed practitioners and licensed nurses. Furthermore, admixtures shall be labeled as in 7 MCAR § 8.088 D.;

o. assuring that investigational drug use is in accordance with state and federal law. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs shall be available in the pharmacy. Investigational drugs shall be distributed only from the pharmacy;

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

2. The following measures related to the maintenance of documents:

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

(1) a statement of service philosophy and objectives;

(2) a job description for each classification of personnel;

(3) a list of pharmaceutical service committees, and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;

(4) procurement records for controlled substances for two years or as required by law;

(5) prescriptions or other forms initiated by the prescriber, for two years or as required by law;

(6) records of packaging, bulk compounding or manufacturing for two years or as required by law;

(7) records of action taken pursuant to drug recalls for two years or as required by law;

(8) special reports concerning narcotics and other drugs for two years or as required by law;

(9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room as permitted under 7 MCAR § 8.084 B.1.e. and f. for two years;

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room as permitted under 7 MCAR § 8.084 B.1.d. for one month;

b. other necessary documents. The following documents relative to pharmaceutical services shall also be maintained:

(1) a current organization chart delineating intra-service structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff and other relevant hospital services;

(2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;

(3) a record of the number of persons, by job description, employed full time and part time in the pharmaceutical services;

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

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

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

7 MCAR § 8.085 Pharmaceutical service equipment and supplies. In addition to the requirements of 7 MCAR § 8.010, equipment and supplies shall be maintained by the pharmacy as necessary to fulfill the further needs of patients and the scope of services offered.

7 MCAR § 8.086 Drug handling and storage. At least the following provisions for the safe handling and secure storing of drugs shall be observed:

A. storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security;

B. drugs shall be protected from contamination; and

C. drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

7 MCAR § 8.087 Pharmaceutical service space.

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

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

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

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

7 MCAR § 8.088 Labeling.

A. Out-patient prescriptions. Labels for out-patient prescriptions shall comply with 7 MCAR §§ 8.040 and 8.041. Labels for out-patient nonprescription drugs shall comply with the federal regulations. Drugs originally dispensed to an in-patient shall be returned to the pharmacy for proper labeling before leaving the hospital premises.

B. In-patient prescriptions. All prescriptions dispensed to in-patients, other than those dispensed pursuant to 7 MCAR § 8.048, shall be labeled with the following information:

1. identification of pharmacy;

2. name of patient;

3. name of drug;

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

5. strength of drug;

6. auxiliary labels as needed;

7. expiration date, if applicable;

8. date dispensed.

C. Drugs prepackaged for emergency use. All drugs dispensed under 7 MCAR § 8.084 B.1.e. shall be labeled with the following information:

1. identification of pharmacy or other source;

2. name of drug or list of ingredients;

3. strength of drug or amount of ingredients;

4. auxiliary labels as needed;

5. expiration date, if any;

6. usual dose;

7. control number or date of issue;

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

1. It is recommended that all intravenous admixtures be labeled with the following information:

a. Name of solution, lot number, and volume of solution;

b. Patient's name;

c. Bottle sequence number or other control number system;

d. Name and quantity of each additive;

e. Date of preparation;

f. Beyond-use time and date of intravenous admixture; and

g. Ancillary precaution labels.

2. The information in D.1., except for lot number, should be recorded on a supplemental label. If the large volume parenteral contains no additives, the same label may be used, omitting those items which do not apply. If, at some later time an additive might be added, then a suitable space should be available for recording the additive.

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

4. The hospital pharmacy service is responsible for labeling all medications.

7 MCAR § 8.089 Extension of pharmacy services under license. A licensed pharmacy in a hospital may utilize additional locations within the hospital without the necessity of securing additional licenses provided, however, that the pharmacist-in-charge of any such hospital pharmacy shall designate another licensed pharmacist to assume professional responsibility, in accordance with 7 MCAR §§ 8.021-8.023, for the practice of pharmacy in each such additional location.

7 MCAR § 8.090 Use of supportive personnel. The use of supportive personnel shall be in accordance with the provisions of 7 MCAR § 8.047.

7 MCAR §§ 8.091-8.100 Reserved for future use.

Chapter Eight: Nuclear Pharmacy. The provisions of 7 MCAR §§ 8.101-8.110 are applicable to pharmacies and manufacturers dealing with radioactive pharmaceuticals, provided, however, that 7 MCAR §§ 8.001-8.070 shall also be applicable to such pharmacies, unless specifically exempted by 7 MCAR §§ 8.101-8.110 or are in direct conflict therewith, in which case 7 MCAR §§ 8.101-8.110 shall apply.

7 MCAR § 8.101 Definitions.

A. Radioactive drug. A radioactive drug is any substance defined as a drug in Section 201 (g) (1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any non-radioactive 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 which contain trace quantities of naturally occurring radionuclides.

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

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

7 MCAR § 8.102 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 section and further requirements, as the Board in its opinion finds necessary and proper for health and safety in the production, compounding, dispensing and use of radioactive drugs, may be imposed as a condition of licensure. A pharmacy exclusively handling radioactive materials may be exempt from the building and equipment standards of 7 MCAR §§ 8.007-8.011 if the Board finds it is in the public interest.

7 MCAR § 8.103 Pharmacists handling radioactive drugs. A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be accepted if, in the opinion of the Board, such programs provide a level of competence substantially the same as approved programs.

7 MCAR § 8.104 Pharmacist-in-charge. A pharmacy handling radioactive drugs shall not function without having a pharmacist who is competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs in charge of the licensed premises. All personnel performing tasks within such pharmacy shall be under the immediate and direct supervision of the pharmacist competent in handling radioactive drugs.

7 MCAR § 8.105 Acquisition, storage and distribution of radioactive drugs. Only radioactive drugs which are approved by the U.S. Food and Drug Administration or which are investigational drugs having IND or NDA status may be dispensed by a nuclear pharmacy.

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

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

7 MCAR § 8.106 Recordkeeping. Pharmacists handling radioactive drugs shall maintain records of acquisition and disposition of all radioactive drugs for a period of not less than two (2) years.

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

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

7 MCAR § § 8.107-8.110 Reserved for future use.

Chapter Nine: Pleading, Practice and Procedure.

7 MCAR § 8.111 Definitions as used in these rules:

A. "Board" means the Minnesota Board of Pharmacy;

B. "Hearing" includes a joint hearing of the Board and any other administrative agency;

C. "License" means any license, permit, certificates of registration or other grant of authority, issued or subject to suspension or revocation by the Board;

D. "Revocation or Suspension" of license includes refusal to renew the same.

7 MCAR § 8.112 How proceedings initiated. Proceedings to revoke or suspend licenses may be initiated in one of two ways, except insofar as any order of suspension or revocation which may be issued pursuant to a statute not requiring hearing.

A. On a verified complaint by an individual or an agency required by law to enforce the law in question, filed with the Board of Pharmacy;

B. By the Board on its own motion whenever its investigation discloses probable grounds for disciplinary action. The Board president or secretary may act for the Board in initiating proceedings under this section.

7 MCAR § 8.113 Procedure upon filing of complaint. All complaints received pursuant to the provisions of 7 MCAR § 8.112 shall be dealt with in accordance with the requirements of Minn. Stat. § 214.10.

7 MCAR § 8.114 Style of pleadings. All pleadings, notices, orders, and other papers filed in such proceedings shall be captioned "BEFORE THE MINNESOTA BOARD OF PHARMACY", and shall be entitled "IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE_____OF _____ RESPONDENT." The party whose license is involved shall be known and designated as the "Respondent".

7 MCAR § 8.115 Form of charges. If the alleged offense is a continuing one, its general nature and the approximate time covered shall be stated in the complaint or notice of hearing, if a specific incident is relied on, it shall be alleged with such particularity as to time, place and circumstances, as may be necessary to enable the respondent to prepare his defense; and in either case

the offense may be alleged in the language of the statute or rule claimed to have been violated. Separate charges shall be stated in separate paragraphs and numbered consecutively.

7 MCAR § 8.116 Order for and notice of hearing. Notices of hearing shall be addressed to the respondent at his last known post office address. All hearings shall be conducted pursuant to Minn. Stat. ch. 15 and the Rules for Contested Cases of the Office of Hearing Examiners.

7 MCAR § 8.117 Service and filing of papers. Unless otherwise provided by law, all orders, notices and other papers may be served by the secretary or the Board by first class, certified, or registered mail addressed to the party at his last known post office address, or to his attorney of record. Papers required to be filed with the Board may be mailed to the following address: 717 Delaware Street, SE, #351, Minneapolis, Minnesota 55414.