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ADMINISTRATIVE HEARINGS

Minnesota Board of Pharmacy

Adopted Permanent Rules Relating to Pharmacy Regulations

6800.0100 DEFINITIONS.

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

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

Subp. 1c. **Central service pharmacy.** "Central service pharmacy" means a pharmacy ~~located in Minnesota~~ that may provide dispensing functions, drug utilization review (DUR), packaging, labeling, or delivery of a prescription product to another pharmacy ~~in the state~~ for the purpose of filling a prescription.

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

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

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

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

Subp. 3a. **Hospital satellite.** "Hospital satellite" means a site in a licensed hospital, which is not physically connected

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with the centrally licensed pharmacy, but is within the same facility or building and is dependent on the centrally licensed pharmacy for administrative control, staffing, and drug procurement. A hospital satellite must be under the direction of a licensed pharmacist, comply with the requirements of part 6800.0800, subpart 3, and provide pharmacy services to hospital patients only.

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

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

[For text of subps 5 to 12, see M.R.]

Subp. 13. [See repealer.]

6800.0350 LICENSE CATEGORIES.

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

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A. community/retail;

B. hospital;

C. parenteral-enteral/home health care;

D. long-term care;

E. nuclear; and

F. central service.

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

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

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES.

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

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

6800.0910 PATIENT ACCESS TO PHARMACIST.

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

Subp. 2. **Description of procedure.** When dispensing a prescription for a patient, a pharmacist must consult with the patient or the patient's agent or caregiver and inquire about the patient's understanding of the use of the medication according to this part.

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

(1) the name and description of the drug;

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

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

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

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

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

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(7) proper storage;

(8) prescription refill information;

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

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

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

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

Personal communication by the pharmacist is not required for inpatients of a hospital or other institution, such as a licensed nursing home, where other licensed health care professionals are authorized to administer the drugs, or where a patient or patient's agent or caregiver has expressed a desire not to receive the consultation. When a new prescription or a refilled prescription for which counseling is required is being

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mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions, and through the provision of a toll-free phone number for long distance calls.

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

6800.1010 CLOSING A PHARMACY.

Subpart 1. **Before closing.** At least 14 days before a licensed pharmacy closes and ceases operation it shall notify the board of the intended closing.

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

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

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

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

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regional administrator.

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

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

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

(4) If the Drug Enforcement Administration does not approve of the transfer, instructions must be given to the pharmacy that is closing to dispose of the drugs according to the written instructions provided by the regional director.

6800.1050 REQUIRED REFERENCE BOOKS AND MINIMUM EQUIPMENT FOR PHARMACIES.

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

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base of the pharmacy. An equivalent reference approved by the board in writing may be used in an appropriate category.

A. Examples of pharmacotherapy references are:

(1) Pharmacology in Medicine;

(2) Pharmacological Basis of Therapeutics;

(3) Applied Therapeutics;

(4) Pharmacotherapy: A Pathophysiologic Approach;

(5) United States Pharmacopeia - Dispensing Information; and

(6) Conn's Current Therapy.

B. Examples of dosage and toxicology references are:

(1) American Hospital Formulary Service;

(2) Facts and Comparisons; and

(3) Drug Information Handbook.

C. Examples of general references are:

(1) Handbook of Nonprescription Drugs;

(2) Physician's Desk Reference;

(3) Remington's Pharmaceutical Sciences;

(4) United States Pharmacopeia - National Formulary;

(5) United States Pharmacopeia - Pharmacists' Pharmacopeia;

(6) Orange Book; and

(7) Merck Manual.

In addition to items A to C, long-term care pharmacies must have on file the most recent edition of Minnesota Department of

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

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

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

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

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

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

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

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

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

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

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

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

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

6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. **Submitting.** An applicant for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicant's birth record, and a recent photograph. An applicant shall show evidence of graduation with a bachelor of science degree or doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy, from a college of pharmacy or a department of pharmacy of a university approved by the board. The college or department of pharmacy must meet at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual or, for Canadian graduates, must meet at least the minimum standards set by the Canadian Council for Accreditation of Pharmacy Programs and must conduct its instruction in English. The evidence shall be shown by submitting an official final transcript showing the date on which a degree was conferred.

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The documents in this subpart together with a check for $125 payable to the Minnesota Board of Pharmacy must be received by the board prior to approval being granted to sit for the examinations. Applicants participating in the North American Pharmacy Licensing Exam (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE) must complete a separate application for these exams and submit the applications to the board. A certified check or money order for these exams made payable to the National Association of Boards of Pharmacy (NABP) must be submitted to NABP after the applications for examination have been approved by the board. An applicant who is a graduate of a school or college of pharmacy located outside the United States or Canada, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, is considered to have satisfied the requirements of graduation if the applicant verifies to the board the applicant's academic record and the applicant's graduation. Before taking the licensing examination, a foreign graduate applicant shall pass the Foreign Pharmacy Graduate Equivalency Examination, which is recognized and approved by the board, given by the Foreign Pharmacy Graduate Examination Commission and demonstrate proficiency in the English language by passing the Test of English as a Foreign Language, which is recognized and approved by the board, given by the Educational Testing Service as a prerequisite to taking the licensure examination. The board shall consider an application for licensure by examination or a NAPLEX or MPJE registration to be

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invalid 18 months after the date that the board determines an application or registration form is complete. An applicant whose application or registration form is invalid, and who wishes to continue licensure procedures, shall submit a new application or registration form and fee.

Subp. 1a. **Authorization to practice.** An applicant who obtains a passing score on the examination is authorized to practice pharmacy only after paying an original licensure fee of $105 to the board.

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

6800.1300 RECIPROCITY.

Subpart 1. **Applications.** An application for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of $205 shall be filed with the director of the board at least 30 days before the date the application is to be considered by the board.

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

Subp. 4. **NAPLEX examination.** The board may compel applicants who have not engaged in practice as a licensed pharmacist for the two years immediately preceding the time of filing of their application for reciprocity to take the NAPLEX examination.

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

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs,

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medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient, except as allowed under part 6800.9921, shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee of $180 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $180 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $155 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $130 for manufacturing or wholesale distribution of prescription medical gases only; and $105 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of one-half of the renewal fee in addition to the amount of the renewal fee.

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

6800.1500 CONTINUING PHARMACY EDUCATION.

Subpart 1. **Definitions.** Definitions:

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

B. "Approved provider" means any association,

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corporation, educational institution, organization, group, or person who has been recognized by the Board of Pharmacy, in accordance with subpart 3, as having met its criteria indicative of the ability to provide quality continuing education programs or who has been recognized by the board as being approved by the Accreditation Council for Pharmacy Education (ACPE) for the provision of quality continuing education programs.

C. "Continuing pharmacy education" is a planned learning experience beyond a formal undergraduate degree program designed to promote the continual development of professional knowledge, professional skills, and professional attitudes on the part of the practitioners and shall include but is not limited to professional postgraduate education in any of the following subjects:

(1) properties and actions of drugs and drug dosage forms;

(2) etiology, characteristics, and therapeutics of the disease state;

(3) pharmacy practice; or

(4) legal, psychological, and socioeconomic aspects of health care delivery.

Subp. 2. **Minimum hours required; reporting.** Beginning March 4, 1975, no annual license renewal shall be issued to a pharmacist under Minnesota Statutes, section 151.13, until the pharmacist has submitted to the board satisfactory evidence that the pharmacist has completed at least 30 hours of approved continuing education during the previous two-year period.

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Thereafter, a pharmacist shall submit the evidence every two years. Pharmacists exempted from the payment of all renewal fees and from the filing of any application for renewal under Minnesota Statutes, section 326.56, subdivision 2, shall also be exempted from the requirements of this subpart for a concurrent period of time. Beginning with the 1981-1983 reporting period, participation in continuing education shall be reported on October 1 of each even-numbered year. The board may grant a pharmacist, on application, an extension of time not to exceed one year to comply with the requirements of this subpart. The extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period. ~~The requested extension requires a payment of $100 and will require the pharmacist to show documentation of the completed 30 credits.~~ Each pharmacist is responsible for maintaining a complete record of the pharmacist's continuing education participation during each continuing education reporting cycle.

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

Subp. 4. **Revocation or suspension of approval.** The board may deny, refuse to renew, revoke, or suspend authorization, recognition, or approval previously furnished to programs or providers if the program or provider fails to conform to its application approved by the board, fails to furnish program content as publicized, or if the program or provider violates any provision of Minnesota Statutes, section 214.12, or this chapter.

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[For text of subps 4a to 7, see M.R.]

Subp. 9. **Program promotion.** No reference shall be made by a program provider in publicizing a program that it is an "approved program provider" unless the provider is so approved by the board or the Accreditation Council for Pharmacy Education (ACPE). No other reference indicating endorsement by the board may be made except as follows: "This program is approved by the Minnesota Board of Pharmacy for ____ hours of continuing education credit."

6800.2350 PHARMACEUTICAL WASTE.

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

6800.2600 VENDING MACHINES.

It is unlawful to distribute, dispense, or vend any legend drug by automatic or vending machine without first providing the board with written notification of the location of the automated medication management system, the name and address of the pharmacy responsible for control of the system, written policies and procedures that govern the operation and patient safety of the system, and the name of the pharmacist-in-charge of the pharmacy. Nothing in this part prohibits a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises from utilizing such a device in an emergency, after regular pharmacy hours, when the hospital's pharmacist has complete control over the monitoring of drug therapy, packaging,

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

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

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

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

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

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

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6800.2700 RETURN OF DRUGS AND DEVICES.

Subpart 1. **Reuse.** Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any drugs, prescribed medications, chemicals, poisons, or medical devices; except that in a hospital with a licensed pharmacy, drugs, devices, or other items dispensed for hospital inpatient use only, which have not left the span of control of the pharmacy, may be returned to the pharmacy for reuse or disposal in accordance with good professional practice.

Subp. 2. **Drugs from nursing homes and assisted living facilities.** Drugs from nursing homes and assisted living facilities may be returned to the dispensing pharmacy ~~and~~. The returned drugs may be redispensed if:

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

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

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

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

E. the drugs are received by the pharmacy in the

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

~~F.--the-pharmacy-ensures-that-patients-who-may-receive returned-drugs,-are-notified-that-the-pharmacy-accepts-and redispenses-drugs-returned-from-approved-facilities.~~

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

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

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

Subp. 3. **Electronic prescriptions.** Any electronic prescription transmitted from the prescriber to the pharmacy must comply with Minnesota Statutes, chapter 325L, and conform to the rules of the federal Drug Enforcement Administration. An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for the medications to be administered

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in an acute care hospital.

6800.3100 COMPOUNDING AND DISPENSING.

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

A. determination of brands and suppliers;

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

C. verifying the prescription order;

D. selecting the drug to be used in filling the prescription;

E. extemporaneous compounding on an individual basis;

F. certifying the completed prescription;

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

H. supervising clerical personnel in limited

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nonprofessional duties such as looking up prescription refills, filing prescriptions, record keeping, nonprofessional aspects of presenting completed medications to patients, and completing the transaction; and

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

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

Subp. 3a. **Accountability.** The prescription filling process must provide documentation to identify the names, initials, or identification codes of each pharmacist, pharmacist intern, or pharmacy technician who performed any portion of the prescription filling process.

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

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

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

[For text of subps 1 to 10, see M.R.]

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

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this part.

6800.3200 PREPACKAGING AND LABELING.

Subpart 1. **Prepackaging.** Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing according to United States Pharmacopeia, chapter 1146. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall cause to be prepared and kept a packaging control record containing the following information:

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

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

A. name of drug;

B. strength;

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

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

E. internal control number or date; and

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

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unit-doses.

6800.3300 COMPOUNDING STANDARDS.

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

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

Subp. 3. [See repealer.]

Subp. 4. [See repealer.]

Subp. 5. [See repealer.]

6800.3350 BEYOND-USE DATES.

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

Subp. 2. [See repealer.]

Subp. 3. **Unit-of-use and blister card packages.** A beyond-use date of not more than one year from the packaging date or the time remaining to the manufacturer's expiration date, whichever is less, shall be placed on all unit-of-use and blister card packaging whether prepared by the pharmacist at the time of dispensing or prepared earlier in anticipation of the

dispensing.

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

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

6800.3400 PRESCRIPTION LABELING.

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

A. name, address, and telephone number of pharmacy, central service pharmacies shall use the name, address, and telephone number of the pharmacy distributing the medication to the patient;

B. patient's name;

C. prescription number;

D. name of prescribing practitioner;

E. directions for use;

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

G. auxiliary labels as needed;

H. date of original issue or renewal;

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

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

J. prescriptions filled as part of a central service operation shall bear a unique identifier to indicate that the prescription was filled at a central service pharmacy; and

K. after July 1, 2008, any dispensed prescription medication shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

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

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

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

A. ~~the name and address of the prescribing veterinarian;~~

~~B.~~ the name of the client;

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

~~D.~~ C. the name, strength, and quantity of the drug,

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

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

~~F.~~ E. the date of issue;

~~G.~~ F. directions for use;

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

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

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

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

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

A. date of compounding;

B. beyond-use date;

C. storage requirements if other than room temperature;

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D. infusion or administration rate;

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

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

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

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE.

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

Subp. 1a. **Entering orders.** When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed by a prescriber or a pharmacist. If orders are entered by other personnel, the pharmacist or the prescriber, must certify the accuracy of the information entered and verify the prescription order prior to the dispensing of the medication. The identity of the person entering the order must be retained in the computer record.

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

Subp. 3. **Original prescription retained.** In all cases where electronic data processing equipment is used the original prescription must be retained on file according to law to assure access to the information contained thereon in the event of a computer breakdown. Original prescriptions or any other patient specific records stored outside the licensed pharmacy area must be stored in a secure area accessible only to registered or licensed pharmacy staff, or others delegated by the pharmacist-in-charge and trained on the policies and procedures

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relating to protected health information.

Subp. 4. **New prescriptions.**

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

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

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

6800.4075 CENTRALIZED PRESCRIPTION PROCESSING AND FILLING.

Subpart 1. **Licensure.**

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

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Statutes, section 151.19, subdivision 2.

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

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

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

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

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

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

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

B. The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that operations

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are occurring in a manner consistent with the manual. The manual shall be made available to the board for review upon request and shall include, at a minimum, the following:

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

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

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

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

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

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

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

A. A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription to the patient is responsible for certifying the completed prescription.

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

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

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

The following items are listed in Schedule III:

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

C. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Any compound, mixture, or preparation containing: (a) Amobarbital; (b) Secobarbital; (c) Pentobarbital, or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule	
(2) Any suppository dosage form containing: (a) Amobarbital; (b) Secobarbital;	

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(c) Pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository	
(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically excepted or listed in other schedules	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital
(4) Chlorhexadol	
(5) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug, and Cosmetic Act.	
(6) Ketamine, its salts, isomers, salts of isomers	
(7) Lysergic acid	
(8) Lysergic acid amide	
(9) Methyprylon	Noludar
(10) Sulfondiethylmethane	
(11) Sulfonethylmethane	
(12) Sulfonmethane	
(13) Tiletamine and zolazepam and any salt thereof	
(14) Embutramide	

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

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

6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The following items are listed in Schedule V:

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

B. Narcotic drugs containing nonnarcotic active

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medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

Statutory Names	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.	
(2) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.	
(3) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.	Lomotil
(4) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.	Parapectolin, Donnagel P.G.
(5) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.	

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

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isomers: Pyrovalerone.

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

6800.4400 REGISTRATION OF CONTROLLED SUBSTANCE RESEARCHERS.

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

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

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

Subpart 1. **Verbal or telephone orders.** Notwithstanding

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any other provisions of parts 6800.0100 to 6800.9700, a licensed pharmacist, registered nurse, or licensed practical nurse who is employed by a licensed facility and who is authorized by the facility's administrator and is acting on the behalf of the prescriber, may communicate to the pharmacy provider a prescription order lawfully ordered by a practitioner authorized to prescribe drugs or devices pursuant to Minnesota Statutes, section 151.37. Whenever possible, these prescription orders shall be transmitted via facsimile or secure electronic format, to the pharmacy in an order format which produces a direct copy of the prescription order as documented in the patient's chart, which the prescriber will sign at a later date. The pharmacy provider shall record on the prescription the name of the person who transmits the order in addition to the other required information. This subpart does not apply to orders for Schedule II controlled substances as defined by part 6800.4220.

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

Subp. 3. **Schedule II orders.** Except as provided in part 6800.3000, subpart 2, Schedule II controlled substances shall be dispensed only upon receipt of an original written order signed by the prescribing individual practitioner or upon an oral order reduced to writing given in emergency situations as allowed by these criteria:

A. immediate administration of the controlled

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substance is necessary for the proper treatment of the intended ultimate user;

B. no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of Minnesota Statutes, chapter 152 and parts 6800.4200 to 6800.4250; and

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

6800.7400 HOSPITAL PHARMACIST-IN-CHARGE.

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

Subp. 5. **Span of control.** The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than every month inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the required emergency drug supply.

6800.7510 PATIENT CARE.

Pharmaceutical service policies shall cover at least the following:

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

B. the limiting of drug administration;

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

D. the immediate reporting of adverse drug reactions;

E. the self-administration of drugs by patients;

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

G. the use of investigational drugs;

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

I. the preparation of compounded sterile products; and

J. the preparation of compounded nonsterile products.

6800.7520 PHARMACEUTICAL SERVICE POLICIES.

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

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

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

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

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

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

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

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

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

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the pharmacy).

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

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

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

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

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

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

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

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

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

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

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

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

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

6800.8001 POLICY AND PROCEDURES MANUAL.

To obtain a pharmacy license as a parenteral-enteral home

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

A. compliance with the official compendium United States Pharmacopeia, chapter 797;

B. clinical services;

C. cytotoxics handling, storage, and disposal;

D. disposal of unused supplies and medications;

E. drug destruction and returns;

F. drug dispensing;

G. drug labeling and relabeling;

H. drug storage;

I. duties and qualifications for professional and nonprofessional staff;

J. equipment;

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

L. infusion devices and drug delivery systems;

M. investigational drugs;

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

O. public safety;

P. quality assurance procedures, including:

(1) recall procedures;

(2) storage and dating;

(3) educational procedures for professional

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staff, nonprofessional staff, and patients;

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

(5) sterility testing of the product;

Q. record keeping;

R. reference materials;

S. sanitation;

T. security;

U. sterile product preparation procedures; and

V. transportation.

6800.8002 PHYSICAL REQUIREMENTS.

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

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

Subp. 3. [See repealer.]

6800.9700 SERVICE AND FILING OF PAPERS.

Unless otherwise provided by law, all orders, notices, and other papers may be served by the director of the board by first class, certified, or registered mail addressed to the party at the last known post office address, or to the attorney of record. Papers required to be filed with the board may be mailed to the following address: 2829 University Avenue SE, No. 530, Minneapolis, MN 55414.

6800.9900 VARIANCES.

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Subpart 1. **Right to request variance.** The pharmacist-in-charge of a pharmacy requesting a variance, or in the case of manufacturers, wholesalers, or gas distributors, a person responsible for the operation, may request that the board grant a variance from any rule of the Board of Pharmacy.

[For text of subps 2 to 6, see M.R.]

6800.9921 REGISTRATION.

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

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

REPEALER. Minnesota Rules, parts 6800.0100, subpart 13; 6800.2810; 6800.3300, subparts 3, 4, and 5; 6800.3350, subpart 2; 6800.4500; and 6800.8002, subpart 3, are repealed.

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