CHAPTER 6800
BOARD OF PHARMACY
PHARMACIES AND PHARMACISTS

6800.0700 PHARMACY, SPACE, AND SECURITY.

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

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

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

E in the case of a community/retail pharmacy, contains an area where consultation between the patient and the pharmacist may be conducted with an assurance of privacy Community/retail pharmacies in existence on February 1, 1999, have until February 1, 2001, to comply with this item, and

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

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

Statutory Authority: *MS s 151.06; 152 02*

History: *27 SR 260*

6800.0910 PATIENT ACCESS TO PHARMACIST.

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

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

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

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

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

If a prescription drug has been previously dispensed to a patient, the pharmacist or the pharmacist's designee shall attempt to determine if the patient has experienced any unexpected or unusual reactions or changes in health, whether the patient has experienced the expected outcome, whether the patient is using the medication as prescribed, and whether the patient has been using any over-the-counter or prescription drugs not in the patient's record since the last visit to the pharmacy. If the pharmacist's review of the patient's record or discussions with the patient reveal any of the conditions listed in part 6800 3110, subpart 4, the pharmacist or the pharmacist's

designee must offer counseling by the pharmacist to the patient or the patient's agent or caregiver regarding those conditions or problems The consultation must be in person whenever practicable

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

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

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

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

6800.1300 RECIPROCITY.

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

Subp. 5. **Examination.** Applicants for reciprocal licensure shall be required to display their familiarity with the laws regulating the practice of pharmacy in Minnesota by submitting to an examination on the Minnesota laws and rules and the federal laws and regulations governing the practice of pharmacy

[For text of subp 6, see M R]

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

6800.2150 PHARMACIST ON DUTY.

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

B When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800 7530 In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

6800.3110 PATIENT MEDICATION PROFILES.

[For text of subpart 1, see M R]

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

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

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

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

(1) the pharmaceutical care needs of the patient,

(2) the services rendered by the pharmacist, and

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

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

Subp 2a. [Repealed, 27 SR 260]

[For text of subp 3, see M R]

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

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

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

Statutory Authority: *MS s 151.06; 152 02*

History: *27 SR 260*

6800.3350 EXPIRATION DATES.

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

Subp 3 **Unit-of-use and blister card packages.** An expiration 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

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

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

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

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

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

(1) Flunitrazepam,

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

(3) Mecloqualone,

(4) Methaqualone;

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

Statutory Authority: *MS s 151.06, 152 02*

History: *27 SR 260*

6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

The following items are listed in Schedule II

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

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

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(a) Raw opium	
(b) Opium extracts	
(c) Opium fluidextracts	
(d) Powdered opium	
(e) Granulated opium	
(f) Tincture of opium	Laudanum
(g) Codeine	Methylmorphine
(h) Dihydroetorphine	
(i) Ethylmorphine	Dionin
(j) Etorphine hydrochloride	
(k) Hydrocodone	Dihydrocodeinone
(l) Hydromorphone	Dihydromorphinone, Dilaudid
(m) Metopon	
(n) Morphine	Chlor-Anodyne
(o) Oxycodone	Dihydrohydroxycodeinone, Percodan, Nucodan
(p) Oxymorphone	Dihydrohydroxymorphinone, Numorphan
(q) Thebaine	

[For text of subitems (2) to (5), see M R]

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance

[For text of subitems (1) to (26), see M R]

(27)	Remifentaml	
(28)	Sufentanil	Sufenta

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

G Hallucinogenic substances Nabilone [another name for Nabilone. (±)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1- hydroxy-6,6-dimethyl-9H-dibenzo [b,d] pyran-9-one]

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

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

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

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

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*

6800.4240 SCHEDULE IV CONTROLLED SUBSTANCES.

The following items are listed m Schedule IV

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

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.

[For text of subitems (1) to (14), see M R]

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

[For text of subitems (21) to (47), see M R]

(48) Zaleplon	
(49) Zolpidem	

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

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Cathine ((+)-Norpseudoephedrine)	
(2) Diethylpropion	Tenuate, Tepanil
(3) Fencamfamine	
(4) Fenproporex	
(5) Mazindol	Sanorex
(6) Mefenorex	
(7) Modafinil	
(8) Pemoline (including organometallic complexes and chelates thereof	Cylert
(9) Phentermine	Wilpo, Fastin, Ionamin
(10) Pipradrol	
(11) Sibutramine	
(12) SPA ((-)-1-dimethylamino-1, 2-diphenylethane)	

F. Other substances Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Pentazocine	Talwin
(2) Butorphanol (including its optical isomers)	

Statutory Authority: *MS s 151 06, 152 02*
History: *27 SR 260*

6800.5100 DEFINITIONS.

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

Subp 3 **Concurrent time.** "Concurrent time" means internship experience gained during the fourth, fifth, and sixth academic years only, while a person is a full-time student carrying, in any given school term, 12 or more credits

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

Statutory Authority: *MS s 151 06, 152 02*
History: *27 SR 260*

6800.5300 REGISTRATION AND REPORTING.

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

Subp 5 **Manual.** Interns completing 240 hours or more of their internship requirement in Minnesota must complete an internship manual, provided by the board, before the board will recognize the completed hours as acceptable for use in meeting the board's internship requirement.

[For text of subps 6 and 7, see M R]

Statutory Authority: *MS s 151 06, 152 02*
History: *27 SR 260*

6800.5400 TRAINING.

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

Subp 6 **Evidence of completion.** Applicants for licensure as pharmacists who are examined and licensed after September 17, 1973, shall submit evidence that they have successfully completed not less than 1,500 hours of internship under the instruction and supervision of a preceptor. Effective May 1, 2003, candidates for licensure shall submit evidence that they have successfully completed not less than 1,600 hours of internship under the direction and supervision of a preceptor Credit for internship shall be granted only to registered interns who have completed the third year of the five-year or six-year pharmacy curriculum, provided, however, that·

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

C 860 hours of internship credit may be acquired through Pharm D clinical rotations on condition that the remaining 640 hours of the 1,500-hour total requirement is of a traditional compounding, patient counseling, and dispensmg nature Effective May 1, 2003, 800 hours of internship credit may be acquired through Pharm D clinical rotations on condition that the remaimng 800 hours of the 1,600 hour total requirement is of a traditional compounding, patient counseling, and dispensmg nature

Statutory Authority: *MS s 151 06, 152 02*
History: *27 SR 260*

6800.7520 ADMINISTRATION.

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

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

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

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

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

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

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

L. Providing for a system of accountability for inpatient dispensing meeting the intent of the certification requirement of part 6800 3100

M. 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.

N 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

O 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

P 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)

Q 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

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

[For text of subitems (1) to (7), see M R]

S 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]

Statutory Authority: *MS s 151 06, 152 02*

History: *27 SR 260*