

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. 829

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 7-2-82
DATE FOR REVIEW 7-12-82
DATE DUE 7-16-82

Adopted w/a hearing ____
Adopted w/o hearing ✓
Temporary rule ____

Approved ____ Disapproved 7-16-82 Returned to Agency ____

Resubmitted 8-4-82 Due 8-13-82
Approved 8-4-82 Disapproved ____ Returned to Agency 8-5-82

Date filed w/Secretary of State 8-5-82 Revisor approved 7/9/82 disapproved ____

✓✓ Rule as Adopted

✓ Rule as Proposed

✓ Order Adopting 6.9.82 Date

____ Notice of Intent to Solicit Outside Opinion

✓ Order for rulemaking Revised Order 7/29/82
N/A date of Hearing

✓ Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency but does contain incorrect statutory citation

✓ Affidavit of Mailing Notice or rulemaking
4.23.82 At least 30 days prior to ~~hearing~~/adoption

✓ Mailing list Certificate

✓ Publication in State Register
✓ At least 30/20 days prior to ~~hearing~~/adoption. contains same citation error as in Notice

N/A Hearing Examiner's Report

____ Chief Hearing Examiner's Report(s)
____ Approving H.E.'s Report
____ Approving agency action

✓ Agency's Findings of Fact

N/A LCRAR Report or agency Affidavit

✓ Certificate of Board's Resolution Adopting Rules FOR Revised Order

N/A Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

✓ Record (includes transcript or tape, exhibits, comments received by agency, requests for a hearing, and other relevant materials)

✓ Certificate of Compliance w/Rulemaking Procedures

✓ Affidavit of Mailing Notice of Submission to Attorney General

? Notice of Submission to the Attorney General
Mistakes no. of days this office will allow for comment.

ADMIN. 1000
3

STATE OF MINNESOTA

DEPARTMENT BOARD OF PHARMACY

Office Memorandum

TO : Judith Wehrwein
Administration Bldg. 2nd Floor
Attorney General's Office

DATE: August 4, 1982

FROM : David E. Holmstrom
Executive Secretary

SUBJECT: Non-Controversial Rules

Attached are the Certificate of Board's Resolution Adopting Rules and Order Adopting Rules for the resubmission of our non-controversial rules. I understand you have already received a revised copy from the revisors office.

DEH:pe

Enc. (2)

SF-00006-02

DEPARTMENT ATTORNEY GENERAL

STATE OF MINNESOTA
Office Memorandum

TO : DAVID E. HOLMSTROM
Executive Secretary of Board of Pharmacy

DATE: 8/4/82

ATTN : ROBERT T. HOLLEY, Spec. Ass't. Atty. Gen.

FROM : LARRY D. STARNS
Special Assistant
Attorney General

PHONE: 297-3493

SUBJECT: In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

Enclosed herewith are the rules you have submitted for approval. These rules have been approved by this office and filed with the Secretary of State. Please note that they have not been filed with the State Register. This must be done promptly by your agency.

Upon receipt and before transmittal to your agency, however, it is important that you recheck these rules as to:

1. Affixation of stamps of the Attorney General and Secretary of State;

2. Coverage by these stamps of all rules submitted; and

3. Inclusion of all pages to the rules in the approved set.

If you have any questions in this regard, please contact me.

LDS:drw

Encs.

cc: Ms. Kathy Burek
Mr. Duane Harves

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Board of Pharmacy

Adopted Amendments to Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

Rules as Adopted

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 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 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.

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.-D. [Unchanged.]

7 MCAR S 8.027 Continuing education requirements.

A. [Unchanged.]

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.-J. [Unchanged.]

7 MCAR S 8.032 Return of drugs and devices.

A. [Unchanged.]

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.

C. [Unchanged.]

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.-I. [Unchanged.]

~~7 MCAR S 8.049 Transfer of prescriptions between pharmacies.~~

~~A. Authorization to dispense a transferred prescription. A prescription label, a written copy of the prescription, or a telephone report of a prescription shall be used for information purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription shall contact the prescribing practitioner for authorization to dispense the prescription.~~

~~B. Conditions of transfer. Pharmacies may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.~~

~~C. Duties of transferring pharmacist. The transferring pharmacist shall:~~

~~1. Write the word "VOID" on the face of the original prescription to make the prescription invalid;~~

~~2. Record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and~~

~~3. Record the date of the transfer.~~

~~For controlled substances in Schedules III-V, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.~~

~~D. Duties of receiving pharmacist. The pharmacist receiving the transferred prescription information shall:~~

~~1. Write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription; and~~

~~2. Provide all information required to be on a prescription pursuant to the law and include:~~

~~a. The date of issuance and of filling of the original~~

prescription;

b. The original number of refills authorized;

c. The number of valid refills remaining;

d. The date of last refill from original prescription;

e. The original prescription number from which the prescription information was transferred; and

f. The transferring pharmacy's name and address and, in the case of controlled substances in Schedules III-V, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

E. Retention of prescription. The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

F. Notice to patient of prescription invalidation. The transferring pharmacist shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

G. Computerized prescription record keeping systems. Computerized prescription record keeping systems must satisfy all the requirements of C.-E. including invalidation of the original prescription even when the prescription is transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership.

H. Transfer of prescription by presentation of container. When the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by C.-E. shall be exchanged.

I. Unprofessional conduct. It is grounds for a charge of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is

~~making a legal request for such information under this rule.~~

~~J. Schedule II controlled substances. Nothing in this rule authorizes the transfer of prescriptions for Schedule II controlled substances. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.~~

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.

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 ~~impossible~~ impractical. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

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. [Unchanged.]

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.-5. [Unchanged.]

B. The following items are listed in Schedule II:

1. [Unchanged.]

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:

Some examples of common names, trade names, or names of products which contain a

Statutory Name	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. [Unchanged.]

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.-2. [Unchanged.]

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:

	Some examples of common names, trade names, or names of products which contain a

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.-5. [Unchanged.]

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:	Equanil, Miltown, Equagesic, Equalysen

conjugated estrogens 0.4 mg
tridihexethyl chloride 25 mg
pentaerythritol tetranitrate 20 mg

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 (/1/-1-Dimethylamino-1, 2-diphenylethane)	
32.	Temazepam	Restoril

E.-F. [Unchanged.]

7 MCAR S 8.052 Partial ~~filling~~ 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 ~~filled~~ dispensed in partial quantities, including individual dosage units.

B. Records. For each partial ~~filling~~ 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 ~~filling~~ 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 ~~fillings~~

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 ~~fillings~~ 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 ~~filling~~ dispensing of the prescription is conducted; and

3. Retrieval of partially ~~filled~~ 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; ~~license~~ 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 ~~license~~ 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.

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. [Unchanged.]

B. Registration and reporting.

1.-3. [Unchanged.]

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. [Unchanged.]

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.-E. [Unchanged.]

7 MCAR S 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.-C. [Unchanged.]

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.

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 S 8.088 Labeling.

A.-C. [Unchanged.]

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, ~~than~~ 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.

Renumbering. Renumber 7 MCAR S 8.041 as 7 MCAR S 8.042.

APPROVED AS TO LEGALITY

August 4, 1982

WARREN SPANNAUS, ATTORNEY GENERAL

BY Jerry D. Jones

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
AUG 5 1982
Joan Anderson Growe
Secretary of State

10:45 AM

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Board of Pharmacy

Adopted Amendments to Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

Rules as Adopted

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 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 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.

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.-D. [Unchanged.]

7 MCAR S 8.027 Continuing education requirements.

A. [Unchanged.]

B. Minimum hours required and reporting. Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minn. Stat. S 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.-J. [Unchanged.]

7 MCAR S 8.032 Return of drugs and devices.

A. [Unchanged.]

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.

C. [Unchanged.]

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.-I. [Unchanged.]

~~7 MCAR S 8.049 Transfer of prescriptions between pharmacies.~~

~~A. Authorization to dispense a transferred prescription. A prescription label, a written copy of the prescription, or a telephone report of a prescription shall be used for information purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription shall contact the prescribing practitioner for authorization to dispense the prescription.~~

~~B. Conditions of transfer. Pharmacies may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.~~

~~C. Duties of transferring pharmacist. The transferring pharmacist shall:~~

~~1. Write the word "VOID" on the face of the original prescription to make the prescription invalid;~~

~~2. Record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and~~

~~3. Record the date of the transfer.~~

~~For controlled substances in Schedules III-V, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.~~

~~D. Duties of receiving pharmacist. The pharmacist receiving the transferred prescription information shall:~~

~~1. Write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription; and~~

~~2. Provide all information required to be on a prescription pursuant to the law and include:~~

~~a. The date of issuance and of filling of the original~~

prescription;

b. The original number of refills authorized;

c. The number of valid refills remaining;

d. The date of last refill from original prescription;

e. The original prescription number from which the prescription information was transferred; and

f. The transferring pharmacy's name and address and, in the case of controlled substances in Schedules III-V, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

E. Retention of prescription. The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

F. Notice to patient of prescription invalidation. The transferring pharmacist shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

G. Computerized prescription record keeping systems. Computerized prescription record keeping systems must satisfy all the requirements of C.-E. including invalidation of the original prescription even when the prescription is transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership.

H. Transfer of prescription by presentation of container. When the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by C.-E. shall be exchanged.

I. Unprofessional conduct. It is grounds for a charge of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is

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~~making a legal request for such information under this rule.~~

~~J. Schedule II controlled substances. Nothing in this rule authorizes the transfer of prescriptions for Schedule II controlled substances. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.~~

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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.

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 Minn. Stat. S 151.361, subd. 2 impossible. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

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 Minn. Stat. ch. 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. [Unchanged.]

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.-5. [Unchanged.]

B. The following items are listed in Schedule II:

1. [Unchanged.]

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, Isonipecaine, Mepadin, Mepergan
q. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine		
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:

Some examples of common names, trade names, or names of products which contain a

Statutory Name	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. [Unchanged.]

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.-2. [Unchanged.]

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:

	Some examples of common names, trade names, or names of products which contain a

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.-5. [Unchanged.]

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:	Equanil, Miltown, Equagesic, Equalysen

conjugated estrogens 0.4 mg
tridihexethyl chloride 25 mg
pentaerythritol tetranitrate 20 mg

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.-F. [Unchanged.]

7 MCAR S 8.052 Partial ~~filling~~ 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 ~~filled~~ dispensed in partial quantities, including individual dosage units.

B. Records. For each partial ~~filling~~ 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 ~~filling~~ 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 ~~fillings~~

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 ~~fillings~~ 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 ~~filling~~ dispensing of the prescription is conducted; and

3. Retrieval of partially ~~filled~~ 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; ~~license~~ 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 ~~license~~ 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.

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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 Minn. Stat. S 152.01, subd. 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.

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 Minn. Stat. SS 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. [Unchanged.]

B. Registration and reporting.

1.-3. [Unchanged.]

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. [Unchanged.]

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

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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.-E. [Unchanged.]

7 MCAR S 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 Minn. Stat. S 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.-C. [Unchanged.]

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.

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 S 8.088 Labeling.

A.-C. [Unchanged.]

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, ~~than~~ 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 S 8.118 Variances and waivers.

A. Right to request variance or waiver. A person subject to the rules of the Board of Pharmacy may request that the board

grant a variance or waiver from any rule of the Board of Pharmacy.

B. Submission and contents of request. A request for a variance or waiver shall be submitted to the board in writing. Each request shall contain the following information:

1. The specific rule for which the variance or waiver is requested;

2. The reason for the request;

3. The alternative measures that will be taken if a variance or waiver is granted;

4. The length of time for which a variance or waiver is requested; and

5. Other relevant information necessary to properly evaluate the request for the variance or waiver.

C. Decision on the variance or waiver. The board shall grant a variance or waiver if it determines that:

1. The variance or waiver will not adversely affect, directly or indirectly, the health, safety, or well-being of the public;

2. The alternative measures to be taken, if any, are equivalent or superior to those prescribed in the rule for which the variance or waiver is requested; and

3. Compliance with the rule for which the variance or waiver is requested would not impose an undue burden upon the applicant.

The board shall deny, revoke, or refuse to renew a variance or waiver if the board determines that 1., 2., or 3. have not been met.

D. Notification. The applicant shall be notified in writing of the board's decision. If a variance or waiver is granted, the notification shall specify the period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

E. Renewal. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified

in B. A variance or waiver shall be renewed by the board if the applicant continues to satisfy the criteria contained in C.1.-3. and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

F. Appeal procedure. An applicant may contest the denial, revocation, or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedure Act, Minn. Stat. SS 15.0418-15.0426. The applicant shall submit, within 15 days of the receipt of the board's decision, a written request for a hearing. The request for hearing shall set forth in detail the reasons for a reversal or modification of the board's decision. At the hearing, the applicant shall have the burden of proving that he or she satisfied the criteria specified in C.1., 2., and 3.

Renumbering. Renumber 7 MCAR S 8.041 as 7 MCAR S 8.042.

Rules as Proposed

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 ~~$40~~ $75. ~~(Beginning January 1, 1978 said fee shall be $50.)~~ 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 S 8.010 ~~Minimum equipment required in~~ Required reference books and minimum equipment for pharmacies.

A. ~~Each pharmacy must have on file~~ 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 ~~(available through Documents Section, Department of Administration), the latest edition or revision of the U.S. Pharmacopeia -- National Formulary and~~, each pharmacy must have on file at least one current reference from each ~~category~~ of the following categories:

~~A.~~ 1. Pharmacology. Examples:

~~1.~~ a. Pharmacology in Medicine;

~~2.~~ b. Pharmacological Basis of Therapeutics;

~~3.~~ c. Merck Manual;

~~4.~~ d. Pharmindex;

~~5.~~ e. United States Dispensatory; and

f. United States Pharmacopeia - Dispensing Information.

~~B.~~ 2. Dosage and toxicology. Examples:

~~1.~~ a. Hazards of Medications;

~~2.~~ b. American Hospital Formulary Service;

~~3.~~ c. Facts and Comparisons;

~~4.~~ d. Pediatric Dosage Handbook; and

~~5.~~ e. Evaluation of Drug Interactions ~~(APhA)~~.

~~C.~~ 3. Miscellaneous. Examples:

~~1.~~ a. Handbook of Non-Prescription Drugs;

~~2.~~ b. Modern Drug Encyclopedia;

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~~3.~~ c. Physician's Desk Reference;

~~4.~~ 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. In addition,~~ B. Equipment. Each pharmacy must ~~also~~ have the following minimum equipment, clean and in good working order:

1. One prescription balance, as specified in ~~regulations~~ rules of the Department of ~~Weights and Measures,~~ 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. ~~Suitable refrigerator for drug storage with a thermometer,~~ 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 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 ~~$50~~ $100, the board may issue a license in such form as it may prescribe to ~~such~~ the manufacturer or wholesaler. ~~(Beginning January 1, 1978 said fee shall be $75.)~~ ~~Such~~ 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 ~~the 1st day of~~ June 1 of each year, and shall be renewed annually upon the filing of an application

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therefor, on or before May 1 of each year together with a fee of ~~$50~~ $100. ~~(Beginning January 1, 1978 said fee shall be $75.)~~ Renewal applications received after June 1 shall be subject to a late filing fee of $25 in addition to the renewal fee.

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. ~~Applicants not citizens of the United States must have filed and proved their intention of becoming citizens.~~ 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.-D. [Unchanged.]

7 MCAR S 8.027 Continuing education requirements.

A. [Unchanged.]

B. ~~Requirements for Continuing Pharmaceutical Education~~ Minimum hours required and reporting. Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minn. Stat. S 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he or she has completed ~~an accredited program~~ 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

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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 ~~this rule~~ B. Such extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period.

C.-J. [Unchanged.]

7 MCAR S 8.032 Return of drugs and devices.

A. [Unchanged.]

B. Drugs ~~and prescribed medications~~ from nursing homes may be returned to the dispensing pharmacy ~~provided that~~ if:

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

2. The drugs ~~and prescribed medicines~~ are returned to the pharmacy which dispensed the ~~drug or prescribed medicine,~~ drugs;

3. The drugs ~~and prescribed medications~~ are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's ~~single~~ unit-dose, ~~single~~ unit-of-use, or strip packaging ~~indicating~~ with each tablet or capsule individually wrapped and labeled, or in blister-cards, which indicate the drug name and strength, the ~~manufacturer's or~~ 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~~,~~ ~~and~~.

~~5.~~ No reconstituted drugs, drugs requiring refrigeration, or controlled substances may be so returned.

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C. [Unchanged.]

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. ~~Identification~~ Name, address, and telephone number of pharmacy.

B.-I. [Unchanged.]

7 MCAR S 8.049 Tranfer of prescriptions between pharmacies.

A. Authorization to dispense a transferred prescription. A prescription label, a written copy of the prescription, or a telephone report of a prescription shall be used for information purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription shall contact the prescribing practitioner for authorization to dispense the prescription.

B. Conditions of transfer. Pharmacies may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.

C. Duties of transferring pharmacist. The transferring pharmacist shall:

1. Write the word "VOID" on the face of the original prescription to make the prescription invalid;

2. Record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and

3. Record the date of the transfer.

For controlled substances in Schedules III-V, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.

D. Duties of receiving pharmacist. The pharmacist receiving the transferred prescription information shall:

1. Write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription; and

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2. Provide all information required to be on a prescription pursuant to the law and include:

a. The date of issuance and of filling of the original prescription;

b. The original number of refills authorized;

c. The number of valid refills remaining;

d. The date of last refill from original prescription;

e. The original prescription number from which the prescription information was transferred; and

f. The transferring pharmacy's name and address and, in the case of controlled substances in Schedules III-V, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

E. Retention of prescription. The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

F. Notice to patient of prescription invalidation. The transferring pharmacist shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

G. Computerized prescription record keeping systems. Computerized prescription record keeping systems must satisfy all the requirements of C.-E. including invalidation of the original prescription even when the prescription is transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership.

H. Transfer of prescription by presentation of container. When the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by C.-E. shall be exchanged.

I. Unprofessional conduct. It is grounds for a charge of

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unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is making a legal request for such information under this rule.

J. Schedule II controlled substances. Nothing in this rule authorizes the transfer of prescriptions for Schedule II controlled substances. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.

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.

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 Minn. Stat. S 151.361, subd. 2 impossible. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

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

A. The following items are listed in Schedule I:

1. Any of the following substances, including their

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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, ~~Dextrorphan,~~ Diampromide, Diethyliambutene, Difenoxin, Dimenoxadol, Dimepheptanol, Dimethyliambutene, Dioxaphetyl butyrate, Dipipanone, Ethylmethylthiambutene, Etonitazene, Etoxeridine, Furethidine, Hydroxypethidine, Ketobemidone, Levomoramide, Levophenacylmorphan, Methyl substituted isomers of Fentanyl, Morpheridine, ~~Noracymethadol~~ 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. [Unchanged.]

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	MMDA

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	Amphetamine	
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-ethlylamphetamine	
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.-5. [Unchanged.]

B. The following items are listed in Schedule II:

1. [Unchanged.]

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	

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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

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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. [Unchanged.]

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.-2. [Unchanged.]

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

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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
~~Mazindol~~	~~Sanorex (Sandoz)~~
d. Phendimetrazine	Plegine, Stim-35, Melfiant, Bacarate

4.-5. [Unchanged.]

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
~~1.~~ 2. Barbital	Barbitone
~~2.~~ 3. Chloral betaine	Beta-Chlor
~~3.~~ 4. Chloral hydrate	Noctec, Somnos
~~4.~~ 5. Chlordiazepoxide	Librium, Libritabs
~~5.~~ 6. Clonazepam	Clonopin
~~6.~~ 7. Clorazepate	Tranxene
~~7.~~ 8. Diazepam	Valium
~~8.~~ 9. Diethylpropion	Tenuate, Tepanil
~~9.~~ 10. Ethchlorvynol	Placidyl
~~10.~~ 11. Ethinamate	Valmid
~~11.~~ 12. Fenfluramine	Pondamin
~~12.~~ 13. Flurazepam	Dalmane
14. Halazepam	Paxipam
~~13.~~ 15. Lorazepam	Ativan
16. Mazindol	Sanorex

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~~14.~~ 17. Mebutamate		
~~15.~~ 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	
~~16.~~ 19. Methohexital	Brevital	
~~17.~~ 20. Methylphenobarbital	Mebral, Mephobarbital	
~~18.~~ 21. Oxazepam	Serax	
~~19.~~ 22. Paraldehyde	Paral	
~~20.~~ 23. Pemoline	Cylert	
~~21.~~ 24. Pentazocine	Talwin	
~~22.~~ 25. Petrichloral	Periclor	
~~23.~~ 26. Phenobarbital	Luminal, Phenobarbitone, Eskabarb	
~~24.~~ 27. Phentermine	Wilpo, Fastin, Ionamin	
28. Pipradrol		
~~25.~~ 29. Prazepam	Centrax	
~~26.~~ 30. Propoxyphene	Darvon	
31. SPA (/1/-1-Dimethylamino-1, 2-diphenylethane)		
32. Temazepam	Restoril	

E.-F. [Unchanged.]

7 MCAR S 8.052 Partial filling 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 filled in partial quantities, including individual dosage units.

B. Records. For each partial filling, 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 filling, the quantity

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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 fillings 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 fillings 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 filling of the prescription is conducted; and

3. Retrieval of partially filled 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; license. 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 license.

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

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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 Minn. Stat. S 152.01, subd. 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.

7 MCAR S 8.061 Internship. A ~~regulation for~~ The purpose of ~~defining~~ this rule is to define and ~~regulating~~ regulate the internship experience of prospective pharmacists as required by Minn. Stat. SS 151.10 and 151.101. This ~~regulation~~ 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. [Unchanged.]

B. Registration and reporting.

1.-3. [Unchanged.]

4. The intern may be required to maintain additional records of his professional activities. ~~Such~~ 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. ~~Such~~ The examinations shall be administered approximately quarterly at ~~such~~ 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

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deems appropriate. ~~Interns completing the first quarter of their internship experience will be required to attain a score of 65% on the post test examination before credit will be granted by the board for that experience. Interns participating in subsequent quarters will be required to attain a score of 75% on the post-test examination before credit will be granted by the board for that experience.~~ 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. [Unchanged.]

C. Training requirements. The intent of this ~~regulation~~ 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 ~~regulation~~ 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 ~~regulations~~ 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 ~~regulation~~ 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

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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 ~~insure~~ 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 ~~begun the fourth year~~ 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. At least 520 hours of the required internship time shall be completed after graduation from a college of pharmacy approved by the board and shall consist of advanced internship training involving the compounding and dispensing of drugs and drug consultation with patients.~~

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

D.-E. [Unchanged.]

7 MCAR S 8.071 Prescription order communication.

~~A. Pharmacists and pharmacies shall accept orders for dispensing and refilling only if such orders are communicated directly from the prescriber or transmitted through his designated agent. Such an agent shall be an employee of the physician or a nurse employed by the facility and designated in~~

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~~writing by the prescriber as authorized to communicate, either orally or in writing, the prescriber's medication orders to a pharmacy.~~ 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 Minn. Stat. S 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.-C. [Unchanged.]

7 MCAR S 8.074 Drugs for use in emergency kits.

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

B. Emergency drug supplies. Only emergency drug supplies, ~~as~~ 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. ~~Such~~ The emergency drug supplies shall comply with the following:

~~A.~~ ~~such~~ 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 ~~to the extent possible, of any one emergency drug~~. 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 ~~to be~~ discouraged. All drugs in this supply shall be

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properly labeled;

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

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

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

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

~~F.~~ 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;

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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 substance.

D. Excluded controlled substances. Controlled substance sedatives and stimulants 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 S 8.088 Labeling.

A.-C. [Unchanged.]

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;

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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 read.

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

7 MCAR S 8.118 Variances and waivers.

A. Right to request variance or waiver. A person subject to the rules of the Board of Pharmacy may request that the board grant a variance or waiver from any rule of the Board of Pharmacy.

B. Submission and contents of request. A request for a variance or waiver shall be submitted to the board in writing. Each request shall contain the following information:

1. The specific rule for which the variance or waiver is requested;

2. The reason for the request;

3. The alternative measures that will be taken if a variance or waiver is granted;

4. The length of time for which a variance or waiver is requested; and

5. Other relevant information necessary to properly evaluate the request for the variance or waiver.

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C. Decision on the variance or waiver. The board shall grant a variance or waiver if it determines that:

1. The variance or waiver will not adversely affect, directly or indirectly, the health, safety, or well-being of the public;

2. The alternative measures to be taken, if any, are equivalent or superior to those prescribed in the rule for which the variance or waiver is requested; and

3. Compliance with the rule for which the variance or waiver is requested would not impose an undue burden upon the applicant.

The board shall deny, revoke, or refuse to renew a variance or waiver if the board determines that 1., 2., or 3. have not been met.

D. Notification. The applicant shall be notified in writing of the board's decision. If a variance or waiver is granted, the notification shall specify the period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

E. Renewal. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified in B. A variance or waiver shall be renewed by the board if the applicant continues to satisfy the criteria contained in C.1.-3. and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

F. Appeal procedure. An applicant may contest the denial, revocation, or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedure Act, Minn. Stat. SS 15.0418-15.0426. The applicant shall submit, within 15 days of the receipt of the board's decision, a written request for a hearing. The request for hearing shall set forth in detail the reasons for a reversal or modification of the board's decision. At the hearing, the applicant shall have the burden of proving that he or she

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satisfied the criteria specified in C.1., 2., and 3.

Renumbering. Renumber 7 MCAR S 8.041 as 7 MCAR S 8.042.

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OFFICE BY:

_____

3/24/82
RD170

OFFICE OF THE REVISOR OF STATUTES
PROPOSED RULES

Agency Board of Pharmacy

Division

Agency Contact David E. Holmstrom, R.Ph. Phone Number 296-5411

Title: Proposed Rules Amending the Board of Pharmacy Rules

Type of Rules: Permanent X Temporary

Incorporations by References:

Rule Number	Material Incorporated
	~~Author~~
7 MCAR S 8.032	~~Title~~ United States Pharmacopeia
	~~Place~~
	~~Publisher~~
	~~Date~~
	~~Cost~~
	~~Places Available~~

See Additional references on back Yes No X

Duplication of Statutory Language.

Rule Number	Statutory Section Duplicated

The attached rules are approved as to form.

Steven C. Cross
Revisor of Statutes

Name: Maryanne V. Hruby
Maryanne V. Hruby

Title: Assistant Revisor

Phone: 297-2957

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

CERTIFICATE OF BOARD'S RESOLUTION ADOPTING RULES

I, Michael Hart, do hereby certify that I am a member and the President of the Board of Pharmacy, a board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete, and correct copy of a resolution adopted at a meeting of the Board of Pharmacy, duly and properly called and held on the 9th day of June, 1982, that a quorum was present at said meeting, that a majority of those present voted for the resolution, and that said resolution is set forth in the minutes of said meeting and has not been rescinded or modified.

"RESOLVED, that the rules relating to licensure fees, internship, pharmacy equipment, licensure requirements, continuing education, return of drugs, prescription labeling, controlled substance samples, transfer of prescriptions, controlled substances, registration of researchers, prescription order communication, emergency kits, labeling of large volume parenterals, waivers of board requirements, and reorganization of existing rules be and they hereby are approved and adopted, pursuant to authority vested in us by Minnesota Statutes 151.06 and that David

E. Holmstrom, the Executive Secretary of the Board of Pharmacy, be and hereby is authorized to sign an order adopting these rules and further is authorized to perform the necessary acts to provide that these rules shall have the force and effect of law."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 29th day of June, 1982.

Michael E. Hart Jr

MICHAEL E. HART, JR.
PRESIDENT, MN BOARD OF PHARMACY

Lester C. Haakner

BOARD MEMBER

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, and Reorganization of Existing Rules

ORDER ADOPTING RULES

Notice of the Board's intent to adopt the above-entitled rules without a public hearing was published in the State Register on April 26, 1982 and was sent by the United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes section 15.0412, subdivision 4 on April 23, 1982. After affording interested and affected persons an opportunity to submit comments for 30 days after Notice, receiving fewer than seven written requests for a public hearing within the 30-day comment period, reviewing and considering the comments, and determining the need for and reasonableness of the above-captioned rules,

NOW, THEREFORE, IT IS ORDERED that these rules identified as licensure fees, internship, pharmacy equipment, licensure requirements, continuing education, return of drugs, prescription labeling, controlled substance samples, transfer of prescriptions, controlled substances, registration of researchers, prescription order communication, emergency kits, labeling of large volume parenterals, and reorganization of existing rules are adopted this 29th day of July, 1982 pursuant to authority vested in the Board by Minnesota Statutes section 151.06.

STATE OF MINNESOTA

DAVID E. HOLMSTROM
Executive Secretary of
Minnesota Board of Pharmacy

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

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NOW, THEREFORE, IT IS ORDERED that these rules identified as licensure fees, internship, pharmacy equipment, licensure requirements, continuing education, return of drugs, prescription labeling, controlled substance samples, transfer of prescriptions, controlled substances, registration of researchers, prescription order communication, emergency kits, labeling of large volume parenterals, waivers of board requirements, and reorganization of existing rules are adopted this 9th day of June, 1982 pursuant to authority vested in the Board by Minnesota Statutes section 151.06.

STATE OF MINNESOTA

David E. Holmstrom

DAVID E. HOLMSTROM
EXECUTIVE SECRETARY OF
MINNESOTA BOARD OF PHARMACY

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

ORDER FOR NOTICE OF INTENT TO ADOPT RULES WITHOUT PUBLIC HEARING

IT IS ORDERED this 10th day of March, 1982 that Notice of Intent to Adopt Rules Without Public Hearing in the above-entitled matter be given to all persons who have registered their names with the State Board of Pharmacy for that purpose and be published in the State Register.

STATE OF MINNESOTA

David E. Holmstrom

EXECUTIVE SECRETARY
BOARD OF PHARMACY

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, and Reorganization of Existing Rules

CERTIFICATE OF BOARD'S RESOLUTION ADOPTING RULES

I, Michael Hart, do hereby certify that I am a member and the President of the Board of Pharmacy, a board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete, and correct copy of a resolution adopted at a meeting of the Board of Pharmacy, duly and properly called and held on the 28th day of July, 1982, that a quorum was present at said meeting, that a majority of those present voted for the resolution, and that said resolution is set forth in the minutes of said meeting and has not been rescinded or modified.

"RESOLVED, that the rules relating to licensure fees, internship, pharmacy equipment, licensure requirements, continuing education, return of drugs, prescription labeling, controlled substance samples, transfer of prescriptions, controlled substances, registration of researchers, prescription order communication, emergency kits, labeling

of large volume parenterals, and reorganization of existing rules be and they hereby are approved and adopted, pursuant to authority vested in us by Minnesota Statutes 151.06 and that David E. Holmstrom, the Executive Secretary of the Board of Pharmacy, be and hereby is authorized to sign an order adopting these rules and further is authorized to perform the necessary acts to provide that these rules shall have the force and effect of law."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 3rd day of August, 1982.

Michael E. Hart

MICHAEL E. HART, JR.
President, MN Board of Pharmacy

Lester Hoaksmo

BOARD MEMBER

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments to Pharmacy Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy proposes to amend the above-entitled rules without a public hearing. A copy of the proposed amendments is attached to this Notice.

The Board has determined that the proposed adoption of these rules will be noncontroversial in nature. Therefore, this proceeding is being made under the provisions of Minn. Stat. § 15.0412, subd. 4h (1980) which provides for an expedited process for the adoption of noncontroversial administrative rule changes without the holding of a public hearing.

THE PUBLIC IS HEREBY ADVISED THAT:

1. There is a period of 30 days in which to submit comment on the proposed rules with the exception of the changes in 7 MCAR 8.004 and 8.013 which have been approved and implemented pursuant to Minn. Stat. § 16A.028 and are included here for information purposes only.

2. No public hearing will be held on this matter unless seven or more persons make a written request for a hearing within the 30-day comment period;

3. All comments and any written requests for a public hearing may be submitted to David E. Holmstrom, Executive Secretary, Minnesota Board of Pharmacy, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414. If a person desires to request a public hearing, the Board requests that the person identify the particular provisions objected to, the suggested modifications to the proposed language, and the reasons and data relied on to support the suggested modifications.

4. The proposed amendments may be modified if modifications are supported by the data and views submitted, and do not result in a substantial change in the proposed language;

5. Authority to amend these rules is contained in Minn. Stat. § § 151.06, subd. 1 and 152.02, subd. 7, 8, 9 and 12 (1980). Additionally, a Statement of Need and Reasonableness which describes the need for and reasonableness of each provision of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above-listed address;

6. Under this expedited procedure, the agency must submit its rules to the Attorney General for review of the form and legality of the rule change. Notice of the submission of this matter to the Attorney General will be made to all persons who request to be informed of the submission. Requests to be informed must be submitted to Mr. Holmstrom at the above-listed address;

7. If seven or more persons request a public hearing on this matter, notice of any such hearing will be given in the same manner as has this Notice, and the agency will then proceed pursuant to Minn. Stat. § 15.0412, subds. 4-4g (1980);

8. Any rule change made pursuant to this proceeding shall be effective five days after publication in the State Register of notice of the adoption of the change.

Dated: April 12, 1982

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments to Pharmacy Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

AFFIDAVIT OF MAILING

David E. Holmstrom, being first duly sworn, deposes and says:

That on the 23rd day of April, 1982, at the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Intent to Adopt Rules Without Public Hearing by depositing in the United States mail at said City of Minneapolis a copy thereof, properly enveloped, with postage prepaid, on all persons and associations who have requested that their names be placed on file with the Minnesota Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by this agency.

David E. Holmstrom

Subscribed and sworn to before me

this 23rd day of April, 1982.

Alice D. Hummer

ALICE D. HUMMER
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSION EXPIRES NOVEMBER 18, 1988

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

CERTIFICATE

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minn. Stat. § 15.0412, subd. 4, that their names be placed on file with and maintained by the State Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by this Board is accurate and complete as of 4:00 p.m., this 22nd day of April, 1982.

Alice D. Hummel

Donald A. Dee, Exec. Dir.
MN State Pharmaceutical Ass'n
2469 University Ave.
St. Paul, MN 55114

Phillips Legis. Svc., Inc.
459 Rice St.
St. Paul, MN 55103

Robert Gale
Twin City Geriatric Drug
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Vangard Labs., Div. MWM Corp
PO Drawer K, 101-107 Samson
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Mark A. Kalkis
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Richfield, MN 55423

Joanne Schneider
Methodist Hosp.
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R. J. Lavell, Dep. Comm.
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Blue Earth, MN 56013

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Patrick B. Donoho
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1911 Jefferson Davis Hwy.
Arlington, VA 22202

Natl. Pharm. Council, Inc.
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Washington, DC 20005

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Inver Grove Hgts., MN 55075

Michael J. Frakes
2151 Fairmount Ave.
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PROPOSED RULES

Pursuant to Minn. Laws of 1980, § 15.0412, subd. 4h, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. The notice must advise the public:

1. that they have 30 days in which to submit comment on the proposed rules;
2. that no public hearing will be held unless seven or more persons make a written request for a hearing within the 30-day comment period;
3. of the manner in which persons shall request a hearing on the proposed rules;

and

4. that the rule may be modified if modifications are supported by the data and views submitted.

If, during the 30-day comment period, seven or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of § 15.0412, subds. 4 through 4g, which state that if an agency decides to hold a public hearing, it must publish in the *State Register* a notice of its intent to do so. This notice must appear at least 30 days prior to the date set for the hearing, along with the full text of the proposed rules. (If the agency has followed the provisions of subd. 4h and has already published the proposed rules, a citation to the prior publication may be substituted for republication.)

Pursuant to Minn. Stat. § 15.0412, subd. 5, when a statute, federal law or court order to adopt, suspend or repeal a rule does not allow time for the usual rulemaking process, temporary rules may be proposed. Proposed temporary rules are published in the *State Register*, and for at least 20 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Board of Pharmacy

Proposed Amendments to Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

Notice of Intent to Adopt Rules without a Public Hearing

Notice is hereby given that the Minnesota Board of Pharmacy proposes to amend the above-entitled rules without a public hearing. A copy of the proposed amendments is attached to this Notice.

The board has determined that the proposed adoption of these rules will be noncontroversial in nature. Therefore, this proceeding is being made under the provisions of Minn. Stat. § 15.0412, subd. 4h (1980) which provides for an expedited process for the adoption of noncontroversial administrative rule changes without the holding of a public hearing.

The public is hereby advised that:

1. There is a period of 30 days in which to submit comment on the proposed rules with the exception of the changes in 7 MCAR §§ 8.004 and 8.013 which have been approved and implemented pursuant to Minn. Stat. § 16A.028 and are included here for information purposes only.

2. No public hearing will be held on this matter unless seven or more persons make a written request for a hearing within the 30-day comment period;

3. All comments and any written requests for a public hearing may be submitted to David E. Holmstrom, Executive Secretary, Minnesota Board of Pharmacy, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414;

4. The proposed amendments may be modified if modifications are supported by the data and views submitted, and do not result in a substantial change in the proposed language;

5. Authority to amend these rules is contained in Minn. Stat. §§ 151.06, subd. 1 and 152.02, subd. 7, 8, 9 and 12 (1980). Additionally, a statement of need and reasonableness which describes the need for and reasonableness of each provision of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above-listed address;

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6. Under this expedited procedure, the agency must submit its rules to the Attorney General for review of the form and legality of the rule change. Notice of the submission of this matter to the Attorney General will be made to all persons who request to be informed of the submission. Requests to be informed must be submitted to Mr. Holmstrom at the above-listed address;

7. If seven or more persons request a public hearing on this matter, notice of any such hearing will be given in the same manner as has this notice, and the agency will then proceed pursuant to Minn. Stat. § 15.0412, subds. 4-4g (1980);

8. Any rule change made pursuant to this proceeding shall be effective five days after publication in the *State Register* of notice of the adoption of the change.

April 7, 1982

David E. Holmstrom, Executive Secretary
Board of Pharmacy

Rules as Proposed

7 MCAR § 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 ~~$40~~ $75. ~~(Beginning January 1, 1978 said fee shall be $50.)~~ 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 § 8.010 ~~Minimum equipment required in~~ Required reference books and minimum equipment for pharmacies.

A. ~~Each pharmacy must have on file~~ 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 ~~(available through Documents Section, Department of Administration), the latest edition or revision of the U.S. Pharmacopeia—National Formulary and~~, each pharmacy must have on file at least one current reference from each ~~category~~ of the following categories:

~~A.~~ 1. Pharmacology. Examples:

~~1.~~ a. Pharmacology in Medicine;

~~2.~~ b. Pharmacological Basis of Therapeutics;

~~3.~~ c. Merck Manual;

~~4.~~ d. Pharmindex;

~~5.~~ e. United States Dispensatory; and

f. United States Pharmacopeia—Dispensing Information.

~~B.~~ 2. Dosage and toxicology. Examples:

~~1.~~ a. Hazards of Medications;

~~2.~~ b. American Hospital Formulary Service;

~~3.~~ c. Facts and Comparisons;

~~4.~~ d. Pediatric Dosage Handbook; and

~~5.~~ e. Evaluation of Drug Interactions ~~(APhA)~~.

~~C.~~ 3. Miscellaneous. Examples:

~~1.~~ a. Handbook of Non-Prescription Drugs;

~~2.~~ b. Modern Drug Encyclopedia;

~~3.~~ c. Physician's Desk Reference;

~~4.~~ 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.

~~D. In addition,~~ B. Equipment. Each pharmacy must ~~also~~ have the following minimum equipment, clean and in good working order:

1. One prescription balance, as specified in ~~regulations~~ rules of the Department of ~~Weights and Measures,~~ 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. ~~Suitable refrigerator for drug storage with a thermometer,~~ 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 § 8.013 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 ~~$50~~ $100, the board may issue a license in such form as it may prescribe to ~~such~~ the manufacturer or wholesaler. ~~(Beginning January 1, 1978 said fee shall be $75.) Such~~ 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 ~~the 1st day of~~ 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 ~~$50~~ $100. ~~(Beginning January 1, 1978 said fee shall be $75.)~~ Renewal applications received after June 1 shall be subject to a late filing fee of $25 in addition to the renewal fee.

7 MCAR § 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. ~~Applicants not citizens of the United States must have filed and proved their intention of becoming citizens.~~ 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.-D. [Unchanged.]

7 MCAR § 8.027 Continuing education requirements.

A. [Unchanged.]

B. ~~Requirements for Continuing Pharmaceutical Education~~ Minimum hours required and reporting. Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minn. Stat. § 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he or she has completed ~~an accredited program~~ 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 ~~this rule~~ B. Such extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period.

C.-J. [Unchanged.]

7 MCAR § 8.032 Return of drugs and devices.

A. [Unchanged.]

B. Drugs ~~and prescribed medications~~ from nursing homes may be returned to the dispensing pharmacy ~~provided that~~ if:

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

2. The drugs ~~and prescribed medicines~~ are returned to the pharmacy which dispensed the ~~drug or prescribed medicine,~~ drugs;

3. The drugs ~~and prescribed medications~~ are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's ~~single~~ unit-dose, ~~single~~ unit-of-use, or strip packaging ~~indicating~~ with each tablet or capsule individually

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wrapped and labeled, or in blister-cards, which indicate the drug name and strength, the ~~manufacturer's or~~ 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~~;~~ ~~and~~.

~~5.~~ No reconstituted drugs, drugs requiring refrigeration, or controlled substances may be so returned.

C. [Unchanged.]

7 MCAR § 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. ~~Identification~~ Name, address, and telephone number of pharmacy.

B.-I. [Unchanged.]

7 MCAR § 8.049 Transfer of prescriptions between pharmacies.

A. Authorization to dispense a transferred prescription. A prescription label, a written copy of the prescription, or a telephone report of a prescription shall be used for information purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription shall contact the prescribing practitioner for authorization to dispense the prescription.

B. Conditions of transfer. Pharmacies may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.

C. Duties of transferring pharmacist. The transferring pharmacist shall:

1. Write the word "VOID" on the face of the original prescription to make the prescription invalid;

2. Record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and

3. Record the date of the transfer.

For controlled substances in Schedules III-V, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.

D. Duties of receiving pharmacist. The pharmacist receiving the transferred prescription information shall:

1. Write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription; and

2. Provide all information required to be on a prescription pursuant to the law and include:

a. The date of issuance and of filling of the original prescription;

b. The original number of refills authorized;

c. The number of valid refills remaining;

d. The date of last refill from original prescription;

e. The original prescription number from which the prescription information was transferred; and

f. The transferring pharmacy's name and address and, in the case of controlled substances in Schedules III-V, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

E. Retention of prescription. The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

F. Notice to patient of prescription invalidation. The transferring pharmacist shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

G. Computerized prescription record keeping systems. Computerized prescription record keeping systems must satisfy all

the requirements of C.-E. including invalidation of the original prescription even when the prescription is transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership.

H. Transfer of prescription by presentation of container. When the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by C.-E. shall be exchanged.

I. Unprofessional conduct. It is grounds for a charge of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is making a legal request for such information under this rule.

J. Schedule II controlled substances. Nothing in this rule authorizes the transfer of prescriptions for Schedule II controlled substances. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.

7 MCAR § 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.

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 Minn. Stat. § 151.361, subd. 2 impossible. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

7 MCAR § 8.051 Controlled substances. The following substances are, because of their ~~abuse~~ potential for abuse, defined and controlled in the following schedules and are, therefore, subject to the provisions of Minn. Stat. ~~§~~ ch. 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, ~~Dextrorphan,~~ Diampromide, Diethyliambutene, Difenoxin, Dimenoxadol, Dimepheptanol, Dimethyliambutene, Dioxaphetyl butyrate, Dipipanone, Ethylmethylthiambutene, Etonitazene, Etoxeridine, Furethidine, Hydroxypethidine, Ketobemidone, Levomoramide, Levophenacylmorphan, Methyl substituted isomers of Fentanyl, Morpheridine, ~~Noracymethadol~~ 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. [Unchanged.]

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

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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-ethlylamphetamine	
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.-5. [Unchanged.]

B. The following items are listed in Schedule II:

1. [Unchanged.]

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. [Unchanged.]

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.-2. [Unchanged.]

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:

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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
~~Mazindol~~	~~Sanorex (Sandoz)~~
d. Phendimetrazine	Plegine, Stim-35, Melfiant, Bacarate

4.-5. [Unchanged.]

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
~~1.~~ 2. Barbital	Barbitone
~~2.~~ 3. Chloral betaine	Beta-Chlor
~~3.~~ 4. Chloral hydrate	Noctec, Somnos
~~4.~~ 5. Chlordiazepoxide	Librium, Libritabs
~~5.~~ 6. Clonazepam	Clonopin
~~6.~~ 7. Clorazepate	Tranxene
~~7.~~ 8. Diazepam	Valium
~~8.~~ 9. Diethylpropion	Tenuate, Tepanil
~~9.~~ 10. Ethchlorvynol	Placidyl
~~10.~~ 11. Ethinamate	Valmid
~~11.~~ 12. Fenfluramine	Pondamin
~~12.~~ 13. Flurazepam	Dalmane
14. Halazepam	Paxipam
~~13.~~ 15. Lorazepam	Ativan
16. Mazindol	Sanorex
~~14.~~ 17. Mebutamate	
~~15.~~ 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
~~16.~~ 19. Methohexital	Brevital
~~17.~~ 20. Methylphenobarbital	Mebral, Mephobarbital
~~18.~~ 21. Oxazepam	Serax
~~19.~~ 22. Paraldehyde	Paral
~~20.~~ 23. Pemoline	Cylert
~~21.~~ 24. Pentazocine	Talwin
~~22.~~ 25. Petrichloral	Periclor
~~23.~~ 26. Phenobarbital	Luminal, Phenobarbitone, Eskabarb
~~24.~~ 27. Phentermine	Wilpo, Fastin, Ionamin
28. Pipradrol	
~~25.~~ 29. Prazepam	Centrax
~~26.~~ 30. Propoxyphene	Darvon

31. SPA (/1/-1-Dimethylamino-1, 2-diphenylethane)
32. Temazepam Restoril

E.-F. [Unchanged.]

7 MCAR § 8.052 Partial filling 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 filled in partial quantities, including individual dosage units.

B. Records. For each partial filling, 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 filling, 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 fillings 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 fillings 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 filling of the prescription is conducted; and

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

7 MCAR § 8.053 Registration of controlled substance researchers.

A. Application; fee; license. 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 license.

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 § 8.054 Controlled substance samples. A manufacturer, distributor, or agent of a manufacturer or distributor of a controlled substance as defined in Minn. Stat. § 152.01, subd. 4 or 7 MCAR § 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.

7 MCAR § 8.061 Internship. ~~A regulation for~~ The purpose of ~~defining~~ this rule is to define and ~~regulating~~ regulate the internship experience of prospective pharmacists as required by Minn. Stat. §§ 151.10 and 151.101. This ~~regulation~~ 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. [Unchanged.]

B. Registration and reporting.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

1.-3. [Unchanged.]

4. The intern may be required to maintain additional records of his professional activities. ~~Such~~ 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. ~~Such~~ The examinations shall be administered approximately quarterly at ~~such~~ 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 completing the first quarter of their internship experience will be required to attain a score of 65% on the post test examination before credit will be granted by the board for that experience. Interns participating in subsequent quarters will be required to attain a score of 75% on the post-test examination before credit will be granted by the board for that experience.~~ 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. [Unchanged.]

C. Training requirements. The intent of this ~~regulation~~ 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 ~~regulation~~ 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 ~~regulations~~ 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 ~~regulation~~ 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 ~~insure~~ 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 ~~begun the fourth year~~ 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. ~~At least 520 hours of the required internship time shall be completed after graduation from a college of pharmacy approved by the board and shall consist of advanced internship training involving the compounding and dispensing of drugs and drug consultation with patients.~~

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

D.-E. [Unchanged.]

7 MCAR § 8.071 Prescription order communciation.

A. ~~Pharmacists and pharmacies shall accept orders for dispensing and refilling only if such orders are communicated directly from the prescriber or transmitted through his designated agent. Such an agent shall be an employee of the physician or a nurse employed by the facility and designated in writing by the prescriber as authorized to communicate, either orally or in writing, the prescriber's medication orders to a pharmacy.~~ Notwithstanding any other provisions of 7 MCAR §§ 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 Minn. Stat. § 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 § 8.051 B.

B.-C. [Unchanged.]

7 MCAR § 8.074 Drugs for use in emergency kits.

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

B. Emergency drug supplies. Only emergency drug supplies~~,~~ ~~as~~ 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. ~~Such~~ The emergency drug supplies shall comply with the following:

~~A.~~ ~~such~~ 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 ~~to the extent possible, of any one emergency drug~~. 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 ~~to be~~ discouraged. All drugs in this supply shall be properly labeled;

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

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

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

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

~~F.~~ 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;

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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 substance.

D. Excluded controlled substances. Controlled substance sedatives and stimulants 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 § 8.088 Labeling.

A.-C. [Unchanged.]

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, than 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 read.

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

7 MCAR § 8.118 Variances and waivers.

A. Right to request variance or waiver. A person subject to the rules of the Board of Pharmacy may request that the board grant a variance or waiver from any rule of the Board of Pharmacy.

B. Submission and contents of request. A request for a variance or waiver shall be submitted to the board in writing. Each request shall contain the following information:

1. The specific rule for which the variance or waiver is requested;

2. The reason for the request;

3. The alternative measures that will be taken if a variance or waiver is granted;

4. The length of time for which a variance or waiver is requested; and

5. Other relevant information necessary to properly evaluate the request for the variance or waiver.

C. Decision on the variance or waiver. The board shall grant a variance or waiver if it determines that:

1. The variance or waiver will not adversely affect, directly or indirectly, the health, safety, or well-being of the public;

2. The alternative measures to be taken, if any, are equivalent or superior to those prescribed in the rule for which the variance or waiver is requested; and

3. Compliance with the rule for which the variance or waiver is requested would not impose an undue burden upon the applicant.

The board shall deny, revoke, or refuse to renew a variance or waiver if the board determines that 1., 2., or 3. have not been met.

D. Notification. The applicant shall be notified in writing of the board's decision. If a variance or waiver is granted, the notification shall specify the period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

E. Renewal. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified in B. A variance or waiver shall be renewed by the board if the applicant continues to satisfy the criteria contained in C.1.-3. and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

F. Appeal procedure. An applicant may contest the denial, revocation, or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedure Act, Minn. Stat. §§ 15.0418-15.0426. The applicant shall submit, within 15 days of the receipt of the board's decision, a written request for a hearing. The request for hearing shall set forth in detail the reasons for a reversal or modification of the board's decision. At the hearing, the applicant shall have the burden of proving that he or she satisfied the criteria specified in C.1., 2. and 3.

Renumbering. Renumber 7 MCAR § 8.041 as 7 MCAR § 8.042.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

FINDINGS OF FACT AND CONCLUSIONS

The above-entitled matter was opened for public comment on the 26th day of April, 1982 after proper notice required by Minnesota Statutes § 15.0412 was served upon all persons, associations, and other interested groups registered with the Board for that purpose.

After affording interested persons an opportunity to present written data, statements and arguments, having considered all the evidence submitted the Board finds the following:

a) The position taken by the Minnesota State Pharmaceutical Association relative to the deletion of proposed 7 MCAR 8.049 from the non-controversial rules is reasonable. This rule will thus be deleted from the package of rule changes.

b) The Minnesota State Pharmaceutical Assocation's position relative to changing the term "filling" to the more professional "dispensing" is reasonable. The terms "filling", "fillings" or "filled" in 7 MCAR 8.052 will be replaced with the proper tense of "dispensing".

c) The various typographical errors found in 7 MCAR 8.051, 8.052, 8.053, 8.071, 8.074 and 8.088 are reasonable.

what they mean is correction of . . .

d) That the changes in a) through c) above are not substantial changes which would require a hearing on these proposals.

STATE OF MINNESOTA

David E. Holmstrom

DAVID E. HOLMSTROM
EXECUTIVE SECRETARY
MINNESOTA BOARD OF PHARMACY

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments to Pharmacy Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

STATEMENT OF NEED FOR AND FACTS ESTABLISHING REASONABLENESS OF AMENDMENTS

The Minnesota Board of Pharmacy (hereinafter "Board"), pursuant to Minn. Stat. § 15.0412, subd. 4 (1980), hereby affirmatively presents the need for and facts establishing the reasonableness of adopting the above-captioned amendments to the Board rules. The statutory authority for the proposed amendments is set forth in Minn. Stat. § 151.06 and Minn. Stat. § 152.02 subd. 7-9. The approval of the Commissioner of Finance of Provisions relating to fee adjustments is contained in a separate document.

The need to adopt these proposed amendments to the Board's existing rules arises: out of the necessity that licensure fees be set at a level which, over the biennium, will, as nearly as possible, match the appropriation which has been granted the Board by the legislature; from changes in the curriculum at the College of Pharmacy; from changes in the Federal Controlled Substances Act; from studies and recommendations done by the Board's Continuing Education Advisory Committee and because of advances and changes in the profession of pharmacy which must be addressed. Some of the proposed changes are for clarification only and do not change the substance of existing rules. Other proposed rule changes reflect changes in the profession and may, in a few instances, involve substantive changes in existing rules. Each of the proposed changes will be more fully explained below.

7 MCAR § 8.004 and § 8.013

The intent of the proposed changes in 7 MCAR 8.004 is to allow the Board to meet its statutory requirement of adjusting its fees to meet the expenditures over each biennium. Minn. Stat. § 16A.028 already allows the Commissioner of

Finance to approve the adjustment of fees without the necessity of a public hearing as long as the amount of fee requested equals anticipated expenditures. The Board, however, believes that it is to the advantage of its licensees and the public to have information regarding fees in the rule document itself. The figures contained in exhibit one, attached hereto, provide the basis upon which the Board based its need for increased revenue from fees.

In that individual pharmacist licensees bore the brunt of the last required fee increase the Board is proposing that its facility license fees be the focal point for this next required fee increase.

7 MCAR § 8.010

The Board proposes to eliminate the current edition or revision of United States Pharmacopeia-National Formulary as a required reference in each pharmacy and instead placed the United States Pharmacopeia-National Formulary and the United States Pharmacopeia-Dispensing Information among those references that are optional. This change is being proposed because, while the United States Pharmacopeia-National Formulary is still the official compendium for the United States, recent editions of this reference have been revised to the point where they have lost a good deal of their usefulness to the dispensing pharmacist. The reference is quite expensive and the Board is of the opinion that to require this reference of every pharmacy is unreasonable.

7 MCAR § 8.026

There are two changes being proposed to this section, which deals with the qualifications for licensure.

The first proposed change deletes from the licensure requirement the necessity of the candidate having filed and proved their intention of becoming citizens of the United States. The Board is acting to eliminate this requirement due to a lack of proof that citizenship in the United States or the filing of intention to become a citizen of the United States bears any relationship to competency in the practice of pharmacy.

The second change being proposed recognizes a trend in education at the colleges of pharmacy in the United States, which provides for either a B.S. degree or a Pharm D degree as the first professional undergraduate degree. This change makes it clear that the Board will recognize either a B.S. Degree or a Pharm D Degree as meeting the educational requirement for licensure.

7 MCAR 8.027

The Board's authority to require continuing professional education is found in Minn. Stat. § 214.12. Prior to the enactment of that statutory section a legislatively mandated continuing education provision was found in Minn. Stat. ch. 151.

Currently pharmacists are required to report continuing education participation at the time of their license renewals in every other year. The timing of the continuing education reporting makes it administratively impossible to determine non-compliance prior to the time of expiration of current registration for pharmacists. This means that pharmacists who find themselves short of continuing education hours have no time to acquire additional hours before their current registration expires.

By separating the reporting of continuing education participation from license renewal the Board has more time to determine compliance by licensees and licensees notified of shortages of acceptable hours have some time to participate in additional programs prior to the expiration of their existing license.

License renewal is March 1. By requiring continuing education reporting on October 1 of the preceeding year pharmacists will have approximately six months to obtain additional continuing education hours before their current license expires.

During the year of the reporting date change only the Board will pro-rate the hours required to be reported on October 1 on a basis of 1½ hours per month from the last reporting date. Thus only 24 hours of continuing education must be reported on October 1, 1982. Further, this time only, the Board will allow pharmacists who have more than 24 hours accumulated by October 1, 1982 to carry those hours in excess of 24 over to the next reporting period.

This reporting date change should serve to benefit both the Board and the pharmacist licensee.

7 MCAR § 8.032

For a number of years the Board had a blanket prohibition against the return of dispensed medications for reuse or reissuance. This requirement was justifiable as part of the Board's rules in order that pharmacists would not be found to be in violation of FDA regulations concerning adulteration and misbranding. Developments in the drug packaging industry over the past several

years have brought about the subsequent wide spread use of unit of use packaging and unit dose distribution systems which allowed a reconsideration of the previously existing position. In 1978 the Board revised the total prohibition on returns allowing medications, where each individual tablet or capsule was wrapped and labeled, to be returned for reuse or reissuance if certain essential criteria were met.

The Board has now been approached by the users of a blister pack card type of packaging system requesting that they too be allowed to accept dispensed drugs for reuse or reissuance. The Board acted on this request by establishing an adhoc committee to review the issue and incorporated the essential parts of the committee's recommendations in its proposal to revise 7 MCAR 8.032.

As it is proposed, the pharmacist dispensing medications where each tablet and capsule has been individually wrapped and labeled will continue to be able to accept returns under the same essential criteria as has been the case since 1978. The proposed amendments would expand the return allowance to those pharmacists using blister pack card systems if the user can demonstrate that their 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 and that procedures have been developed in the pharmacy that will prevent the co-mingling of dosage units from different lot numbers once they are returned. Meeting these criteria will enable the pharmacist involved to avoid violation of FDA regulations as well.

7 MCAR § 8.040

The small change proposed for this section is made simply to clarify what is meant by the previously existing phrase "Identification of Pharmacy". It has been the experience of the Board that pharmacists have interpreted that phrase differently. The new wording will make it clear that "identification of pharmacy" means more than just the name, it also means the address and telephone number.

7 MCAR § 8.042

This is simply a renumbering change, old rule 7 MCAR § 8.041 has now been renumbered as 8.042.

7 MCAR § 8.047

This change simply reflects the correction of a typographical error.

7 MCAR § 8.049

The Food and Drug Administration and the Minnesota Board of Pharmacy have long held that a copy of a prescription transferred from one pharmacy to another is not a valid prescription order and pharmacists receiving such a copy must contact the prescribing practitioner for verification. No system of uniformity has ever been established relative to the transferring of prescriptions from one pharmacy to another and as a result the records maintained in both the receiving pharmacy and the providing pharmacy have often been incomplete. This has posed significant problems in patient compliance and has resulted in patients often obtaining the same prescription from more than one pharmacy at the same time. The National Association of Boards of Pharmacy, in conjunction with the Federal Drug Enforcement Administration, has developed a model regulation for the transfer of prescription information between pharmacies. DEA, in addition, is proposing a formal rule on the transfer of prescription information for Schedule III, IV and V controlled substance prescriptions between pharmacies. The Board's proposal takes into account both the proposals for formal rule by DEA and the NABP model regulation.

7 MCAR § 8.050

The Minnesota Legislature, in the 1981 session, passed a bill requiring all drug manufacturers to identify all solid oral dosage forms of their products being distributed in Minnesota by placing an identifying mark or symbol on the product. The companies are further required to supply the Board with a list of their products showing or describing the identifying mark. This rule serves to clarify the statutory requirements, particularly in the area of petitioning for exemption from the requirements.

7 MCAR § 8.051

The changes proposed by the Board in this rule are made primarily to bring state law on the use of controlled substances into conformity with the Federal law.

The provisions of the Federal Controlled Substances Act are applicable to all pharmacists in Minnesota. The changes proposed by the Board thus will not have any effect on pharmacy practice as such.

Under the provisions of Minn. Stat. § 152.02 subd. 7, 8 and 9 rescheduling done by the Board through its rules will affect prosecutions of drug related felonies in the state court system. The changes being proposed by the Board in 7 MCAR § 8.051 will serve the people of Minnesota by allowing state law enforcement agencies the same latitudes in pursuing drug related felonies in the state courts as is now available to the federal authorities in federal court.

7 MCAR § 8.052

As a result of the Federal Controlled Substances Act, pharmacists have not been allowed to partially fill a Schedule II controlled substance prescription and provide the remaining amount at a later time. According to the Federal Controlled Substances Act a pharmacist had 72 hours in which to fill and dispense the entire amount indicated on a prescription for a Schedule II controlled substance. This posed a significant problem for pharmacists dispensing medications to patients in long term care facilities via unit dose dispensing systems.

Unit dose dispensing systems offer significant advantages in the areas of patient safety and drug accountability in long term care facilities. The unit dose dispensing system, however, provides that only a limited number of dosage units of each drug are dispensed to the home at any one time. The amounts dispensed ordinarily range from a one to five day supply. For prescriptions written for Schedule II controlled substances this posed a problem in that the federal law required that the entire amount of the prescription be dispensed within 72 hours while the unit dose dispensing system would allow only a three day supply to be dispensed during that same time period.

The Federal Drug Enforcement Administration has recognized this problem and has adopted a regulation that will allow the partial filling of prescriptions for Schedule II controlled substances if the state develops similar provisions. The proposed rule 7 MCAR § 8.052 is designed to meet, at the state level, the federal requirement and allowances.

7 MCAR § 8.053

The registration of researchers involved in the use of controlled substances has not been previously done in Minnesota. There are several statutory sections which indicate that it is not only appropriate but expected that the Board of Pharmacy will perform this function.

Minnesota Statutes 151.37 subd. 4 clearly seems to require that someone is to determine what is meant by "bonafide" research. In that Minn. Stat. § 151.37

is part of the Pharmacy Practice Act it seems entirely logical that that responsibility fall to the Board. Minn. Stat. § 152.101 also refers to "bonafide" research.

Minn. Stat. § 152.12 subd. 3 is more specific in that it very clearly requires that researchers register with the Board. For its part, the Federal Drug Enforcement Administration seems to expect that states will register researchers in controlled substances. Their procedure for registration at the Federal level requires the applicant to indicate on the application form what his state registration number is. Minnesota has for years confused DEA in that we do not have a system for state registration. The vast majority of other states do have a registration requirement not only for researchers in controlled substances but for anyone who is going to handle controlled substances, including pharmacies, hospitals, physicians, and others.

Judging by the number of contacts we receive from reseachers who are perplexed at the questions asked on their federal registration application it is anticipated that somewhere between ten and fifteen researchers would be registered each year.

7 MCAR § 8.054

Controlled substances as defined in Minn. Stat. § 152.01 subd. 4 are subject to state and federal control in all aspects of their manufacture and distribution except where they are distributed as manufacturer "samples" by manufacturer's sales representatives. There have been several instances of careless distribution by drug company representatives in recent months. It is hoped that this rule will eliminate the haphazard approach to controlled substance sample distribution that has occurred while still allowing access to these drugs by physicians and pharmacists.

7 MCAR § 8.061

As a result of a competency study done in 1973 the Minnesota Board of Pharmacy instituted an internship requirement that limited internship to a time subsequent to the third year of the standard five year pharmacy curriculum and required 520 hours of post-graduate experience. The competency study showed that a significant amount of learning took place during this post-graduate period.

Since 1973 the College of Pharmacy at the University of Minnesota implemented first a one quarter college directed internship and now has expanded to a two quarter community and hospital based college directed internship.

It is the belief of the Board that the structured and supervised internship experiences now obtained by University of Minnesota graduates will provide a level of competency equal to or greater than that provided by a relatively unstructured post-graduate experience.

The Board will continue to require students to demonstrate a minimal level of competency obtained through their internship experience by continuing to require participation in the Board's Internship Competency Exam.

7 MCAR § 8.071

The method by which prescription orders can be communicated from the prescribing practitioner to the dispensing pharmacist in the case of patients housed in long term care facilities continues to be a problem. Ideally the prescription order would be communicated directly from the prescriber to the pharmacist personally but in the case of long term care facilities this is seldom actually the case. In long term care facilities the usual situation is that the physician will write an order in the patient's chart or phone an order to the staff at the long term care facility. That order then is redirected to the pharmacist by someone on the staff of the facility. In order to achieve a legally defensible chain of authority in responsibility between the prescriber and the pharmacist a couple of different systems have been tried. All systems tried have been found wanting in one way or another.

The Board's proposal for change in 7 MCAR § 8.071 comes through the recognition that the existing system is too cumbersome to operate efficiently. Representatives from the Minnesota Medical Association and the Minnesota Pharmaceutical Association have met, discussed the issue and have requested that the Board consider revising this section. The proposal submitted here by the Board was found to be acceptable by both the Pharmaceutical and Medical Associations.

7 MCAR § 8.074

In the Board rule changes that were made in 1978 the pharmacists became responsible for the contents of the emergency kit at long term care facilities. The rule that was promulgated at that time also delineated certain restrictions applicable to the use of the emergency kit. Previously the primary physician at the facility was responsible, on paper, for the kit but it was the pharmacist, in reality, who saw to it that it remained properly stocked and that proper records of use were kept.

The stocking of controlled substance drugs in the emergency kit has always posed a problem from a recordkeeping and accountability aspect. Under previously existing federal law the physician who wished to have controlled substances kept in the emergency kit was required to obtain a federal registration in his name at the address of the long term care facility. This then would give him the authority to use controlled substances at that address. The problem was that under a strict interpretation of the federal law no other physician could use the controlled substances in the emergency kit that were placed there by the registration of the primary physician. This posed a significant problem for patients at the home.

The Federal Drug Enforcement Administration has recognized the problem that is posed by their current regulations in the area of controlled substances in emergency kits and has taken action to change their rules. The Drug Enforcement Administration will allow controlled substances to be placed in the emergency kits of nursing homes if the state develops regulations to control the drugs in conformity with guidelines established by the DEA. The Board's proposal in 7 MCAR § 8.074 is designed to meet these federal requirements.

7 MCAR § 8.088

This addition to the labeling requirements found in the hospital pharmacy section comes about as a result of recommendations made by the Committee on Institutional Pharmacy of the National Association of Boards of Pharmacy. The Chairman of the Committee on Institutional Pharmacy served as a member on the National Coordinating Committee on Large Volume Parenterals and brought back to the Committee on Institutional Pharmacy recommendations from the NCCLVP regarding the proper labeling of large volume parenterals in a hospital setting. These recommendations were adopted by the Committee on Institutional Pharmacy and recommended to the individual Boards of Pharmacy by the National Association of Boards of Pharmacy. The Board's proposal in 7 MCAR § 8.088 will implement these recommendations.

7 MCAR § 8.118

Recent legislative changes in Minn. Stat. § 15.0412 subd. 1A indicates that before an agency may grant a variance to an existing rule it shall have promulgated rules setting forth procedures and standards by which variances shall be granted and denied. The Board's proposal in 7 MCAR § 8.118 represents the procedures that the Board will follow in addressing requests for variances to its currently existing rules.

ADMIN. 10(3

STATE OF MINNESOTA

DEPARTMENT BOARD OF PHARMACY

Office Memorandum

TO : Allen A. Yozamp, Director
Budget Planning & Control Division
Dept. of Finance

DATE: January 22, 1982

FROM : David E. Holmstrom
Executive Secretary
717 Delaware St. SE #351

SUBJECT: Adjustment in Board of Pharmacy Fees

On December 30, 1981 I sent you a memo requesting approval of some proposed fee increases for the Board of Pharmacy. Enclosed please find an amended request.

Re-evaluation of our budget situation subsequent to the enactment of the budget bill finally produced by the legislative special session has indicated that our fee increases will need to be made in accordance with the enclosed updated proposal.

Thank you for your cooperation.

DEH:pe

cc: Tom Rice, Controller

Approved by: Allen A. Yozamp 2/1/82

Allen A. Yozamp, Assistant
State Budget Director

BOARD OF PHARMACY
PROPOSED FEES
TO COVER
F.Y. 1982 ANTICIPATED EXPENDITURES

SOURCE	NUMBER	UNIT COST	AMOUNT
Pharmacist	4,037	35.	141,295
Pharmacist-Intern	200	20.	4,000
Pharmacies	1,075	75. (now 50)	80,625
Drug Wholesalers	150	100. (now 75)	15,000
Drug Manufacturers	90	100. (now 75)	9,000
Drug Researchers	15	25. (now -0-)	375
Continuing Education Provider Approval	10	100. (now -0-)	1,000
Continuing Education Program Approval	250	20. (now -0-)	5,000
Continuing Education Program Approval for Individuals	120	5. (now -0-)	600
Board Exam Fees	175	75.	13,125
Reciprocity Fees	100	150.	15,000
Original Licensure Fees	150	35.	5,250
Certificate of Rating	52	10.	520
Duplicate Certificate	9	15.	135
Pharmacist Late Fees	312	15.	4,680
Pharmacist Fees in Arrears	6	50.	300
Pharmacy Late Fees	13	20.	260
Pharmacy Fees in Arrears	4	50.	200
Wholesalers Late Fees	7	25.	175
Manufacturers Fees in Arrears	1	25.	25
		TOTAL REVENUE	$296,565

BUDGET - F.Y. 1982

Current	271,764	
Anticipated transfer in for Salary Supplement Based on 8% Increase	14,321	
	286,085	
Anticipated indirect cost for statewide services based on cost allocation plan from Department of Finance	4,509	
		$290,594
MDH general support 1% of revenue costs	2,966	
		$293,560
		$ 3,005

SF-00006-02

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : DAVID E. HOLMSTROM
Executive Secretary of Pharmacy Board

DATE: 7/16/82

ATTN : ROBERT R. HOLLEY, Spec. Ass't. Atty. Gen.

FROM : LARRY D. STARNS
Special Assistant
Attorney General

PHONE: 297-3493

SUBJECT: In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

The rules in the above-entitled matter have not been approved by this office for the following reasons:

1. 7 MCAR § 8.050.C states that in order for an applicant to obtain an exemption from the drug identification requirements stated in the rule, it must establish that compliance with those requirements is "impossible." The statutory authority for this exemption is found within Minn. Stat. § 151.361, Subd. 2(b). Said provision states that such exemption may be granted when an applicant establishes that the specific characteristics of a given drug render it "impractical" for the application of the drug identification requirements. Because "impossible" is a more stringent standard than "impractical," the rule is beyond the authority provided by Minn. Stat. § 151.361, Subd. 2(b) and so that standard cannot be required of an applicant.

2. 7 MCAR § 8.118.C.3 provides that as a condition of obtaining a variance or waiver from the rules an applicant must establish that compliance with the rule "would not impose an undue burden upon the applicant (emphasis added). Clearly, there is no need for a variance from a rule when compliance with that rule is not an undue burden. By inserting the word "not" in the condition for variance or waiver (which appears to be an error), the Board of Pharmacy is effectively precluded from exercising its power to grant a variance. As such, the variance rule is rendered nugatory and, because non-rules cannot be promulgated, must be disapproved.

3. The portion of the Statement of Need and Reasonableness relating to 7 MCAR § 8.118 is deficient in that, while it sets forth the proposition that the rule provides standards by which variances and waivers are to be granted, it nevertheless fails to establish why the rule is needed and what makes the standards adopted for granting the variance reasonable.

7 MCAR § 8.118 may not be re-adopted and resubmitted to this office until Notice of the availability of the amended Statement of Need and Reasonableness has been made available to the public as provided in Minn. Stat. § 15.0412, Subd. 4h.

After consideration of the above comments and agency action, if any, these rules may be resubmitted for our review. Upon resubmission, please include a new or supplemental Order Adopting and two copies of the new Rule as Adopted. Also, please include a memorandum specifying that the rules are being resubmitted so that we may obtain our initial file in this matter.

Additionally, at the time when you resubmit the new rule to this office, you must submit two copies of the same to the Revisor of Statutes.

If you have any questions concerning the issues raised in this memorandum, please do not hesitate to call me.

LDS:drw

cc: Ms. Kathy Burek
Ms. Theresa Lauterbach

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

STATEMENT OF COMPLIANCE WITH RULEMAKING PROCEDURES

I, Special Assistant Attorney General Robert T. Holley, do hereby declare that I have examined the proposed rules and all related documents and that, based on my examination and my personal familiarity with the applicable procedures, the Administrative Procedure Act, the rules of the Office of Administrative Hearings, and the rules of the Attorney General have been followed. Any exceptions are noted below.

Robert T. Holley

ROBERT T. HOLLEY
SPECIAL ASSISTANT
ATTORNEY GENERAL

Dated: July 2, 1982

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

AFFIDAVIT OF MAILING NOTICE OF SUBMISSION TO THE ATTORNEY GENERAL

David E. Holmstrom, being first duly sworn, deposes and says:

That on the 2nd day of July, 1982, in the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Submission to the Attorney General by depositing in the State of Minnesota Central Mail System for first class mailing (or) in the United States mail at said City of Minneapolis, a copy thereof, properly enveloped, with postage prepaid, to all persons and associations who requested notice that the rules in the above-entitled matter have been submitted to the Attorney General.

David E. Holmstrom

DAVID E. HOLMSTROM
EXECUTIVE SECRETARY
MINNESOTA BOARD OF PHARMACY

Subscribed and sworn to before me this 2nd day of July, 1982.

Alice D. Hummer

ALICE D. HUMMER
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSION EXPIRES NOVEMBER 18, 1988

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy Governing Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

NOTICE OF SUBMISSION TO THE ATTORNEY GENERAL

Pursuant to your request and in accordance with Minnesota Statutes, section 15.0412:

PLEASE TAKE NOTICE that the above-captioned rules have been submitted to the Office of the Attorney General on this date, July 2, 1982, for review as to form and legality. Pursuant to 1 MCAR § 1.206 B., the Attorney General will not approve the rules for at least five calendar days after receipt to allow any person or association time to comment on the legality of the rules, after which that Office will complete its review. If you desire to comment on the legality of the above-captioned rules, you should direct your comments to the Office of the Attorney General, G-25 State Administration Building, 50 Sherburne Avenue, St. Paul, Minnesota 55155, telephone (612) 296-7030. Please note that the above-cited rule of the Attorney General also provides that a copy of any written comments submitted to the Attorney General must be submitted simultaneously to this agency.

If you are interested in determining what changes, if any, were made in the proposed rules after publication in the State Register and before submission to the Attorney General, you may contact David E. Holmstrom.

David E. Holmstrom

DAVID E. HOLMSTROM
EXECUTIVE SECRETARY
MINNESOTA BOARD OF PHARMACY