

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. 1124

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 12-24-84
DATE FOR REVIEW 1-2-85
DATE DUE 1-7-85

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

Approved 1/2/85 (CDS) Disapproved _____ Returned to Agency _____

Resubmitted _____ Due _____
Approved _____ Disapproved _____ Returned to Agency _____

Date filed w/Secretary of State 1-2-85 Revisor approved 12/26/84 disapproved _____

✓ Rule as Adopted

✓ Rule as Proposed see SR

✓ Order Adopting 12.18.84 Date

N/A Notice of Intent to Solicit Outside Opinion

✓ Order for rulemaking
N/A date of Hearing

✓ Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency contains minimal small biz statement

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

✓ Mailing list Certificate

✓ Publication in State Register
11.12.84 At least 30/~~20~~ days prior to ~~hearing~~/adoption

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

LCRAR Report or agency Affidavit

✓ Certificate of Board's Resolution Adopting Rules

N/A Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

N/A 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

N/A Notice of Submission to the Attorney General

✓ Dept. of Finance approval of fees.

BOARD OF PHARMACY

An Equal Opportunity Employer

Office of the Secretary • 717 Delaware St., SE, Room 351 • Telephone 612/296-5411
MINNEAPOLIS, MINNESOTA 55414

December 18, 1984

Office of the Minnesota Attorney General
204 State Administration Building
50 Sherburne Ave.
St. Paul, MN 55155

Attention Judith Wehrwein

RE: In the Matter of the Proposed Amendment of Rules Concerning Licensure Fees and Controlled Substances

Dear Ms. Wehrwein:

Herewith submitted for your review under Minnesota Statutes 14.26 and Minnesota Rules Part 2000.0400, subparts 1-6 are the following non-controversial rulemaking documents of the Minnesota Board of Pharmacy in the above subject matter:

1-2. Certificate of Board's authorizing resolution, with order for notice of intent to amend rules without a public hearing;
3-4. Notice of intent to amend rules without a public hearing, with affidavit of mailing;
5. Mailing list certificate;
6. Relevant pages of the State Register;
7. Statement of need and reasonableness;
8. Certificate regarding comments received;
9. Approval of fee increases by Department of Finance;
10. Certificate of Board's resolution adopting rules;
11. Order adopting rules (two copies);
12. Rule changes as adopted (original and three copies), and;
13. Statement of compliance with rulemaking procedures.

In connection with the foregoing please note that there were no written comments received at all and that the Board adopted the rule changes in precisely the same form as proposed.

If there are any questions about this submission, please notify me as soon as possible.

Very truly yours,

David E. Holmstrom
Executive Secretary

DEH:pe

Enc.

RECEIVED
DEC 24 1984
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

SF-00006-02

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : David E. Holmstrom, Executive Secretary
Minnesota Board of Pharmacy

DATE: 1-2-85

ATTN: Robert T. Holley
Special Assistant Attorney General

FROM : Larry D. Starns LDS
Special Assistant Attorney General

PHONE: 297-3493

SUBJECT: In the Matter of the Proposed Amendment of Rules Concerning Controlled Substances and License Fees.

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:sz
Encs.

cc: Ms. Kathy Burek
Mr. Duane Harves

AG copy

Board of Pharmacy

Adopted Rules Relating to the Board of Pharmacy

Rules as Adopted

6800.0400 ANNUAL LICENSE RENEWAL DATE AND FEES.

Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application for license renewal, on or before June 1 of each year, together with a fee of $90. Renewal applications received on or after July 1 are subject to a late filing fee of $25 in addition to the renewal fee.

6800.1000 ANNUAL RENEWAL, FEES, AND POSTING.

Each pharmacist license shall expire on March 1 of each year and shall be renewed annually by filing an application for license renewal on or before February 1 of each year, together with a fee of $50. Any pharmacist license renewal application submitted after March 1 shall be subject to a late filing fee of $25 in addition to the renewal fee.

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

6800.1100 APPLICATIONS FOR LICENSURE.

Subpart 1. **Submitting.** 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 $90 must be submitted to the board at least 30 days prior to the examination.

Subp. 2. **Retaking exam.** Any applicant who has failed to pass the examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake such examination within the next ensuing 14 months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the board. The applicant shall, at least 30 days before an examination, notify the board in writing of his intentions to retake the examination, certifying that information furnished on his original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of $90 payable to the Minnesota Board of Pharmacy. The board reserves the right to request a full and complete application.

Subp. 3. [Unchanged.]

CONTROLLED SUBSTANCES

6800.3500 LABELING OF CONTROLLED SUBSTANCES AND CERTAIN OTHER DRUGS.

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

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

6800.4200 INCLUSIONS AND EXCEPTIONS.

Subpart 1. and 2. [Unchanged.]

6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

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

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

(1) Acetylmethadol;

(2) Alfentanil;

(3) Allylprodine;

(4) Alphacetylmethadol;

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Benzethidine;

(9) Betacetylmethadol;

(10) Betameprodine;

(11) Betamethadol;

(12) Betaprodine;

(13) Clonitazene;

(14) Dextromoramide;

(15) Diampromide;

(16) Diethylthiambutene;

(17) Difenoxin;

(18) Dimenoxadol;

(19) Dimepheptanol;

(20) Dimethylthiambutene;

(21) Dioxaphetyl butyrate;

(22) Dipipanone;

(23) Ethylmethylthiambutene;

(24) Etonitazene;

(25) Etoxeridine;

(26) Furethidine;

(27) Hydroxypethidine;

(28) Ketobemidone;

(29) Levomoramide;

(30) Levophenacylmorphan;

(31) Methyl substituted isomers of Fentanyl;

(32) Morpheridine;

(33) Noracymethadol;

(34) Norlevorphanol;

(35) Normethadone;

(36) Norpipanone;

(37) Phenadoxone;

(38) Phenampromide;

(39) Phenomorphan;

(40) Phenoperidine;

(41) Piritramide;

(42) Proheptazine;

(43) Properidine;

(44) Propiram;

(45) Racemoramide;

(46) Tilidine; and

(47) Trimeperidine.

B. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Acetylcodone;

(4) Benzylmorphine;

(5) Codeine methylbromide;

(6) Codeine-N-Oxide;

(7) Cyprenorphine;

(8) Desomorphine;

(9) Dihydromorphine;

(10) Drotebanol;

(11) Etorphine (except hydrochloride salt);

(12) Heroin;

(13) Hydromorphinol;

(14) Methyldesorphine;

(15) Methylhydromorphine/Methyldihydromorphine;

(16) Morphine Methylbromide;

(17) Morphine Methylsulfonate;

(18) Morphine-N-Oxide;

(19) Myrophine;

(20) Nicocodeine;

(21) Nicomorphine;

(22) Normorphine;

(23) Pholcodine; and

(24) Thebacon.

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

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1)	4-Bromo-2,5-Dimethoxyamphetamine	4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA
(2)	2,5-Dimethoxyamphetamine	2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA
(3)	4-Methoxyamphetamine	4-methoxy-a-Methylphenethylamine; paramethoxyamphetamine, PMA
(4)	5-Methoxy-3,4-Methylenedioxyamphetamine	MMDA
(5)	4-Methyl-2,5-Dimethoxyamphetamine	4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP"
(6)	3,4-Methylenedioxy Amphetamine	MDA
(7)	3,4-Methylenedioxymeth-amphetamine	MDMA

(8)	3,4,5-Trimethoxy Amphetamine	TMA
(9)	Bufotenine	3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(10)	Diethyltryptamine	N,N-Diethyltryptamine; DET
(11)	Dimethyltryptamine	DMT
(12)	Ibogaine	7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga
(13)	Lysergic acid diethylamide	LSD
(14)	Marijuana	
(15)	Mescaline	
(16)	Parahexyl	3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl
(17)	Peyote Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or extracts	
(18)	N-ethyl-3-piperidyl Benzilate	JB-318
(19)	N-methyl-3-piperidyl Benzilate	JB-336
(20)	Psilocybin	
(21)	Psilocyn	
(22)	Tetrahydrocannabinols Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activities such as the following: 1 cis or trans tetrahydrocannabinol, and their optic isomers; 6 cis or trans tetrahydrocannabinol, and their optical isomers; 3,4 cis or trans tetrahydrocannabinol, and its optic isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic	THC

	positions covered.)	
(23)	Ethylamine analog of phencyclidine	N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(24)	Pyrrolidine analog of phencyclidine	1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(25)	Thiophene analog of phencyclidine	1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP

D. Peyote. The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church; and members of the Native American Church, however, are required to obtain federal registration annually and to comply with all other requirements of law.

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

(1) Mecloqualone;

(2) Methaqualone.

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

(1) Fenethylline;

(2) N-ethylamphetamine.

6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

The following items are listed in schedule II:

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

B. Substances, vegetable origin, or chemical synthesis. Unless specifically excepted or unless listed in

another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

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

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

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subitem (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

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

(5) Concentrate of poppy straw (the crude extract

of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

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

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

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

Statutory Name	Some examples of common

		names, trade names, or names of products which contain a controlled substance.
(1)	Amphetamine, its salts, optical isomers, and salts of its optical isomers;	Dexedrine, Dexamyl, Benzedrine, Raphetamine, Biphetamine,
(2)	Methamphetamine, its salts, isomers, and salts of its isomers;	Desoxyn, Methedrine, Drinalfa, Desoxyephedrine Hydrochloride, Syndrox, Efroxine, Norodin, Obedrin, Ambar
(3)	Phenmetrazine and its salts;	Preludin
(4)	Methylphenidate	Ritalin, Plimasin, Ritonic

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

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	Amobarbital	Amytal
(2)	Pentobarbital	Nembutal, Tuinal
(3)	Phencyclidine	Sernyl, Sernylar
(4)	Secobarbital	Seconal

F. 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:

(1) Immediate precursor to amphetamine and methamphetamine:

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

(2) Immediate precursor to phencyclidine (PCP):

(a) 1-phenylcyclohexylamine

(b) 1-piperidinocyclohexane carbonitrile (PCC)

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

The following items are listed in schedule III:

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

B. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Amphetamine, Methamphetamine, Methylphenidate and Phenmetrazine, when required by federal law to be labeled with either of the following symbols: C-III or III	
(2) Benzphetamine	Didrex
(3) Chlorphentermine	Pre-Sate
(4) Clortermine	Voranil
(5) Phendimetrazine	Plegine, Stim-35, Melfiant, Barcarate

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

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

any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.	
(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically excepted or listed in other schedules:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital
(4) Chlorhexadol	
(5) Glutethimide	Doriden
(6) Lysergic acid	
(7) Lysergic acid amide	
(8) Methyprylon	Noludar
(9) Sulfondiethylmethane	
(10) Sulfonethylmethane	
(11) Sulfonmethane	
D. Nalorphine	Nalline

E. Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium: Copavin.

(2) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cheracol, Elixir, Terpin Hydrate and Codeine, Cosadein, Prunicodeine, Robitussin A.C.

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

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Ambenyl, Tussend, Hycomine, Tussionex.

(5) Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cidicol.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Paregoric, Camphorated Opium Tincture.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6800.4240 SCHEDULE IV CONTROLLED SUBSTANCES.

The following items are listed in schedule IV:

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

B. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) Not more than one milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane), for example, Darvon, Darvocet.

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

of isomers is possible within the specific chemical designation:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Alprazolam	Xanax
(2) Barbital	Barbitone
(3) Bromazepam	
(4) Camazepam	
(5) Chloral betaine	Beta-Chlor
(6) Chloral hydrate	Noctec, Somnos
(7) Chlordiazepoxide	Librium, Libritabs
(8) Clobazam	
(9) Clonazepam	Clonopin
(10) Clorazepate	Tranxene
(11) Clotiazepam	
(12) Cloxazolam	
(13) Delorazepam	
(14) Diazepam	Valium
(15) Estazolam	
(16) Ethchlorvynol	Placidyl
(17) Ethinamate	Valmid
(18) Ethyl Loflazepate	
(19) Fludiazepam	
(20) Flunitrazepam	
(21) Flurazepam	Dalmane
(22) Halazepam	Paxipam
(23) Haloxazolam	
(24) Ketazolam	
(25) Loprazolam	
(26) Lorazepam	Ativan
(27) Lormetazepam	
(28) Mebutamate	
(29) Medazepam	
(30) Meprobamate, except when in combination with the following drugs in the following or lower concentrations: conjugated estrogens 0.4 mg tridihexethyl chloride 25 mg pentaerythritol tetranitrate 20 mg	Equanil, Miltown, Equagesic, Equalysen
(31) Methohexital	Brevital
(32) Methylphenobarbital	Mebral, Mephobarbital
(33) Nimetazepam	
(34) Nitrazepam	
(35) Nordiazepam	
(36) Oxazepam	Serax
(37) Oxazolam	
(38) Paraldehyde	Paral
(39) Petrichloral	Periclor
(40) Phenobarbital	Luminal, Phenobarbitone, Eskabarb
(41) Pinazepam	
(42) Prazepam	Centrax
(43) Temazepam	Restoril
(44) Tetrazepam	
(45) Triazolam	Halcion

D. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

Statutory Name	Some examples of common

	names, trade names, or names of products which contain a controlled substance
(1) Fenfluramine	Pondamin

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Diethylpropion	Tenuate, Tepanil
(2) Mazindol	Sanorex
(3) Pemoline (including organometallic complexes and chelates thereof	Cylert
(4) Phentermine	Wilpo, Fastin, Ionamin
(5) Pipradrol	
(6) SPA ((-)-1-dimethylamino-1, 2-diphenylethane)	

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Pentazocine	Talwin

6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The following items are listed in schedule V:

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

B. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one or more nonnarcotic active medicinal ingredients in sufficient

proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

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

RENUMBERING. Renumber the Minnesota Rules parts in column A as the Minnesota Rules parts in column B.

A	B
6800.0900	6800.2250
6800.1000	6800.1150
6800.1100	6800.1250
6800.1200	6800.1300
6800.2000	6800.2150
6800.2100	6800.1050
6800.2200	6800.0950
6800.3500	6800.4150
6800.3600	6800.3550
6800.3700	6800.3650
6800.3800	6800.3750
6800.3900	6800.3850
6800.4000	6800.3950
6800.4100	6800.4050

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JAN – 2 1985
Joan Anderson Growe
Secretary of State
2:20 PM

APPROVED AS TO LEGALITY
January 2, 1985
HUBERT H. HUMPHREY, III
ATTORNEY GENERAL
BY Jerry D. James
SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendment of Rules Concerning Controlled Substances and License Fees

ORDER ADOPTING RULES

Notice of the Board's intent to adopt the above entitled rules changes without a public hearing was published in the State Register on November 19, 1984 and was sent by United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes, section 14.14, subdivision 1 on November 9, 1984. After affording interested and affected persons an opportunity to submit comments for 30 days after Notice, receiving fewer than twenty-five (25) 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 changes,

NOW, THEREFORE, IT IS ORDERED that these rules changes identified as Minn. Rules pt. 6800.0400, 6800.1000, 6800.1100, 6800.3500, 6800.4200, 6800.4210, 6800.4220, 6800.4230, 6800.4240 and 6800.4250 are adopted this 18th day of December, 1984 pursuant to authority vested in the Board of Minnesota Statutes, section 151.06, subd. 1(9).

Dated: December 18, 1984

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 the proposed Amendment and Repeal of Rules Concerning Controlled Substances and License Fees

ORDER FOR NOTICE OF INTENT TO AMEND AND REPEAL RULES WITHOUT A PUBLIC HEARING

IT IS HEREBY ORDERED that Notice of Intent to Adopt Rules Without a Public Hearing in the above-entitled matter be given to all persons who have registered their names with the Minnesota Board of Pharmacy for that purpose and that said notice be published in the State Register.

IT IS FURTHER ORDERED that if less than twenty-five persons request a hearing pursuant to the aforesaid Notice of Intent to Adopt rules Without a Public Hearing, all remaining procedures for the adopting of rules without a public hearing shall be followed.

Dated: Oct 26 1984

STATE OF MINNESOTA

BOARD OF PHARMACY

David Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

CERTIFICATE OF BOARD OF PHARMACY

AUTHORIZING RESOLUTION

I, David E. Holmstrom, do hereby certify that I am the Executive Secretary of the Minnesota 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 duly and properly called and held on the 8th day of August, 1984, that a quorum was present at the meeting, that a majority of those present voted for the resolution and that the resolution is set forth in the minutes of the meeting and has not been rescinded or modified:

> RESOLVED, that David E. Holmstrom, Executive Secretary of the Minnesota Board of Pharmacy, be and hereby is granted the authority and is directed to sign and publish an order and a notice of intent to adopt rules without a public hearing for the purpose of amending existing Board rules relating to controlled substances and license fees; and to proceed with noncontroversial rulemaking if less than the statutorily required number of persons request a hearing. Mr. Holmstrom is also granted the authority and is directed to perform any and all acts incidental thereto, including complying with all applicable provisions of the Minnesota Administrative Procedures Act and the rules of the office of Administrative Hearings.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 26th day of October, 1984.

Alice D. Hummer

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

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 the Proposed Amendment and Adoption of Rules Concerning Controlled Substances and License Fees

NOTICE OF INTENT TO AMEND AND ADOPT RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy proposes to adopt the above-entitled rules' changes without a public hearing unless twenty-five or more persons submit written requests for a public hearing. The Board has determined that the proposed changes will be noncontroversial in nature and has elected to follow the procedures set forth in Minn. Stat. sections 14.21-14.28.

Interested persons shall have 30 days to submit comments in support of or in opposition to the proposed rules' changes. Comment is encouraged. Each comment should identify the portion of the proposed rule change being addressed, the reason for the comment, and any change proposed. The proposed changes may be modified if the modifications are supported by the data and views submitted to the agency and do not result in a substantial change in the proposed language.

Persons who wish to submit comments or a written request for a public hearing should submit such comments or requests to:

David E. Holmstrom
Executive Secretary
Minnesota Board of Pharmacy
717 Delaware St. SE #351
Minneapolis, MN 55414
Telephone (612) 623-5411

Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed.

The statutory authority of the Board to make the proposed rules' changes is contained in Minn. Stat. section 151.06, subd. 1(9).

If adopted, the proposed changes would clarify existing rules, set license fees for pharmacists and pharmacies and would make several changes in the states list of controlled substance drugs. A copy of the proposed changes is attached to this Notice. One additional, free copy is available from the Board upon request.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed changes and identifies the data and information relied upon to support the proposed changes has been prepared and is also available from the Board upon request.

Promulgation of the proposed rules' changes will not result in the expenditure of public monies by local public bodies. In accordance with Minn. Stat. section 14.115, the Board's consideration of any effect on small business will be addressed in the Statement of Need and Reasonableness. Persons representing small businesses are invited to participate in the rulemaking process.

Upon adoption of the final rules' changes without a public hearing, the proposed changes, this Notice, the Statement of Need and Reasonableness, all written comments received, and the final rules' changes as adopted will be delivered to the Attorney General for review as to form and legality, including the issue of substantial change. Persons who wish to be advised of the submission of this material to the Attorney General, or who wish to receive a copy of the final rules' changes as proposed for adoption, should submit a written statement of such request to David E. Holmstrom.

Dated: Nov 9 1984

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary
Minnesota Board of Pharmacy

In the Matter of the Proposed Adoption of Rules of the Board of Pharmacy

AFFIDAVIT OF MAILING

STATE OF MINNESOTA)
)ss.
COUNTY OF HENNEPIN)

Patricia Eggers, being first duly sworn deposes and says:

That on the 9th day of November, 1984, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Intent to Adopt Rules Without Public Hearing by depositing in the (State of Minnesota Central Mail System for United States mailing [or] 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 Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by this agency. The attached notice was also mailed to persons who had requested that their names be placed on file with the Minnesota Board of Pharmacy and who were determined by the Board of Pharmacy to be interested in the above captioned rules.

Patricia Eggers

Subscribed and sworn to before me
this 19th day of December, 1984.

Alice D. Hummer

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

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Pharmacy

CERTIFICATE OF MAILING LIST

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, section 14.14, subdivision 1a, that their names be placed on file with and be maintained by the Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by this agency is accurate and complete as of 9:00 A.M., this 9th day of November, 1984.

Patricia Eggers

Board of Pharmacy

Proposed Rules Relating to the Board of Pharmacy

Notice of Intent to Amend and Adopt Rules without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy proposes to adopt the above-entitled rules changes without a public hearing unless twenty-five or more persons submit written requests for a public hearing. The Board has determined that the proposed changes will be noncontroversial in nature and has elected to follow the procedures set forth in Minn. Stat. section 14.21-14.28.

Persons interested in these rules have thirty (30) days to submit comments in support of or in opposition to the proposed rules. Comment is encouraged. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed. If twenty-five or more persons submit a written request for a public hearing within the thirty day comment period, a public hearing will be held. If a public hearing is required, the agency will proceed according to the provisions of Minnesota Statutes, section 14.14 to 14.18 and Laws 1984, Chapter 640, Sections 7, 8, 9, 10 and 11. The proposed rule may be modified if the modifications are supported by the data and views submitted to the agency and do not result in a substantial change in the proposed language.

Persons who wish to submit comments or a written request for a public hearing should submit such comments or requests to:

David E. Holmstrom
Executive Secretary
Minnesota Board of Pharmacy
717 Delaware St. SE #351
Minneapolis, MN 55414
Telephone (612) 623-5411

The statutory authority of the Board to make the proposed rules changes is contained in Minn. Stat. section 151.06, subd. 1(9).

If adopted, the proposed changes would clarify existing rules relating to controlled substances, would bring state controlled substance schedules into conformity with the federal schedules, and would implement license fee increases required to comply with Minn. Stat. 214.06. A copy of the proposed changes is attached to this notice. One additional, free copy is available from the Board upon request.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed changes and identifies the data and information relied upon to support the proposed changes has been prepared and is also available from the Board upon request.

Promulgation of the proposed rules changes will not result in the expenditure of public monies by local public bodies. The proposed changes will not affect small businesses.

Upon adoption of the final rules changes without a public hearing, the proposed changes, the notice, the Statement of Need and Reasonableness, all written comments received, and the final rules changes as adopted will be delivered to the Attorney General for review as to form and legality, including the issue of substantial change. Persons who wish to be advised of the

submission of this material to the Attorney General, or who wish to receive a copy of the final rules changes as proposed for adoption, should submit a written statement of such request to David E. Holmstrom.

August 20, 1984

Board of Pharmacy
David E. Holmstrom
Executive Secretary

Rules as Proposed

6800.0400 ANNUAL LICENSE 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~~ for license renewal, on or before June 1 of each year, together with a fee of ~~$75~~ $90. Renewal applications received on or after July 1 ~~shall be~~ are subject to a late filing fee of ~~$20~~ $25 in addition to the renewal fee.

6800.1000 ANNUAL RENEWAL, FEES, AND POSTING.

Each pharmacist license shall expire on March 1 of each year and shall be renewed annually by filing an application ~~therefor~~ for license renewal on or before February 1 of each year, together with a fee of ~~$25~~ $50. ~~Beginning January 1, 1978, said fee shall be $35.~~ Any pharmacist license renewal application submitted after March 1 shall be subject to a late filing fee of ~~$15~~ $25 in addition to the renewal fee.

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

6800.1100 APPLICATIONS FOR LICENSURE.

Subpart 1. Submitting. 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~~ $90 must be submitted to the board at least 30 days prior to the examination.

Subp. 2. Retaking exam. Any applicant who has failed to pass the examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake such examination within the next ensuing 14 months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the board. The applicant shall, at least 30 days before an examination, notify the board in writing of his intentions to retake the examination, certifying that information furnished on his original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of ~~$75~~ $90 payable to the ~~state treasurer~~ Minnesota Board of Pharmacy. The board reserves the right to request a full and complete application.

Subp. 3. [Unchanged.]

CONTROLLED SUBSTANCES

6800.3500 LABELING OF CONTROLLED SUBSTANCES AND CERTAIN OTHER DRUGS.

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

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

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.

6800.4200 ~~CONTROLLED SUBSTANCES~~ INCLUSIONS AND EXCEPTIONS.

Subpart 1. and 2. [Unchanged.]

6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

~~The following items are listed in schedule I:~~

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

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

(1) Acetylmethadol~~,~~;

(2) Alfentanil;

(3) Allylprodine~~,~~;

(4) Alphacetylmethadol~~,~~;

(5) Alphameprodine~~,~~;

(6) Alphamethadol~~,~~;

(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Benzethidine~~,~~;

(9) Betacetylmethadol~~,~~;

(10) Betameprodine~~,~~;

(11) Betamethadol~~,~~;

(12) Betaprodine~~,~~;

(13) Clonitazene~~,~~;

(14) Dextromoramide~~,~~;

(15) Diampromide~~,~~;

~~Diethyliambutene,~~ (16) Diethylthiambutene;

(17) Difenoxin~~,~~;

(18) Dimenoxadol~~,~~;

(19) Dimepheptanol~~,~~;

~~Dimethyliambutene,~~ (20) Dimethylthiambutene;

(21) Dioxaphetyl butyrate~~,~~;

(22) Dipipanone~~,~~;

(23) Ethylmethylthiambutene~~,~~;

(24) Etonitazene~~,~~;

(25) Etoxeridine~~,~~;

(26) Furethidine~~,~~;

(27) Hydroxypethidine~~,~~;

(28) Ketobemidone~~,~~;

(29) Levomoramide~~,~~;

(30) Levophenacylmorphan~~,~~;

(31) Methyl substituted isomers of Fentanyl~~,~~;

(32) Morpheridine~~,~~;

(33) ~~Noracetylmethadol,~~ Noracymethadol;

(34) Norlevorphanol~~,~~;

(35) Normethadone~~,~~;

(36) Norpipanone~~,~~;

(37) Phenadoxone~~,~~;

(38) Phenampromide~~,~~;

(39) Phenomorphan~~,~~;

(40) Phenoperdine~~,~~;

(41) Piritramide~~,~~;

(42) Proheptazine~~,~~;

(43) Properidine~~,~~;

(44) Propiram~~,~~;

(45) Racemoramide~~,~~;

~~Sufentanil,~~

(46) Tilidine~~,~~; and

(47) Trimeperidine.

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

B. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, ~~their~~ its 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:

(1) Acetorphine~~,~~;

(2) Acetyldihydrocodeine~~,~~;

(3) Acetylcodone~~,~~;

(4) Benzylmorphine~~,~~;

(5) Codeine methylbromide~~,~~;

(6) Codeine-N-Oxide~~,~~;

(7) Cyprenorphine~~,~~;

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.

(8) Desomorphine~~,~~;

(9) Dihydromorphine~~,~~;

(10) Drotebanol;

(11) Etorphine~~,~~ (except hydrochloride salt);

(12) Heroin~~,~~;

(13) Hydromorphinol~~,~~;

(14) Methyldesorphine~~,~~;

(15) Methylhydromorphine~~,~~/Methyldihydromorphine;

(16) Morphine Methylbromide~~,~~;

(17) Morphine Methylsulfonate~~,~~;

(18) Morphine-N-Oxide~~,~~;

(19) Myrophine~~,~~;

(20) Nicocodeine~~,~~;

(21) Nicomorphine~~,~~;

(22) Normorphine~~,~~;

(23) Pholcodine~~,~~; and

(24) Thebacon.

C. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, ~~their~~ or which contains any of its salts, isomers (whether optical, positional, or geometric), 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
~~(1) 3, 4 Methylenedioxy Amphetamine~~	~~MDA~~
~~(2) 4 Bromo 2, 5 Dimethoxyamphetamine~~	
~~(3) 2, 5 Dimethoxyamphetamine~~	
~~(4) 4 Methoxyamphetamine~~	
~~(5) 5 Methoxy 3, 4 Methylenedioxy Amphetamine~~	~~MMDA~~
~~(6) Bufotenine~~	
~~(7) Diethyltryptamine~~	~~DET~~
~~(8) Dimethyltryptamine~~	~~DMT~~
~~(9) 3, 4, 5 Trimethoxy Amphetamine~~	~~TMA~~
~~(10) 4 Methyl 2, 5 Dimethoxyamphetamine~~	~~DOM,STP~~
~~(11) Ibogaine~~	
~~(12) Lysergic Acid Diethylamide~~	~~LSD~~
~~(13) Marijuana~~	
~~(14) Mescaline~~	
~~(15) N-ethylamphetamine~~	
~~(16) N-ethyl-1-phenyl-cyclohexylamine~~	
~~(17) N-ethyl-3-Piperidyl Benzilate~~	~~JB318~~
~~(18) N-methyl-3-Piperidyl Benzilate~~	~~JB336~~
~~(19) Psilocybin~~	
~~(20) Psilocyn~~	
~~(21) Tetrahydrocannabinols~~	~~THC~~

~~(22) 1 [1(2Thienyl) Cyclohexy]Piperidine~~
~~(23) 1 (1 phenylcyclohexyl) pyrrolidine~~

(1) 4-Bromo-2,5-Dimethoxyamphetamine	4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA
(2) 2,5-Dimethoxyamphetamine	2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA
(3) 4-Methoxyamphetamine	4-methoxy-a-Methylphenethylamine; paramethoxyamphetamine, PMA
(4) 5-Methoxy-3,4-Methylenedioxyamphetamine	MMDA
(5) 4-Methyl-2,5-Dimethoxyamphetamine	4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP"
(6) 3,4-Methylenedioxy Amphetamine	MDA
(7) 3,4-Methylenedioxymeth-amphetamine	MDMA
(8) 3, 4, 5-Trimethoxy Amphetamine	TMA
(9) Bufotenine	3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(10) Diethyltryptamine	N,N-Diethyltryptamine; DET DMT
(12) Ibogaine	7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga
(13) Lysergic acid diethylamide	LSD
(14) Marijuana	
(15) Mescaline	
(16) Parahexyl	3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]py Synhexyl
(17) Peyote Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or extracts	
(18) N-ethyl-3-piperidyl Benzilate	JB-318
(19) N-methyl-3-piperidyl Benzilate	JB-336
(20) Psilocybin	
(21) Psilocyn	
(22) Tetrahydrocannabinols Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activities such as the following: 1 cis or trans tetrahydrocannabinol, and their optic isomers; 6 cis or trans tetrahydrocannabinol, and their optical isomers; 3,4 cis or trans tetra hydrocannabinol, and its optic isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)	THC

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.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subitem (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

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

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

~~B.~~ C. Opiates. Unless specifically excepted or unless listed in another schedule any of the following opiates, including ~~their~~ its 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, dextrorphan and levopropoxyphene excepted:

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

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

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(23) Ethylamine analog of phencyclidine	N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE
(24) Pyrrolidine analog of phencyclidine	1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(25) Thiophene analog of phencyclidine	1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP

D. Peyote~~, providing~~. The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church; and members of the Native American Church, however, are required to obtain federal registration annually and to comply with all other requirements of law.

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

(1) Mecloqualone;

(2) Methaqualone.

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

(1) Fenethylline;

(2) N-ethylamphetamine.

6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

The following items are listed in schedule II:

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

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

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

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;	Dexedrine, Dexamyl, Benzedrine, Raphetamine, Biphetamine,
(2) Methamphetamine, its salts, ~~optical~~ isomers, and salts of its ~~optical~~ isomers;	Desoxyn, Methedrine, Drinalfa, Desoxyephedrine Hydrochloride, Syndrox, Efroxine, Norodin, Obedrin, Ambar
(3) Phenmatrazine and its salts;	Preludin
(4) Methylphenidate	Ritalin, Plimasin, Ritonic

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

~~(1) Methaqualone: Sopor, Quaalude, Parest;~~

~~(2) Amobarbital: Amytal;~~

~~(3) Secobarbital: Seconal;~~

~~(4) Pentobarbital: Nembutal, Tuinal;~~

~~(5) Phencyclidine: Sernyl, Sernylar.~~

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Amobarbital	Amytal
(2) Pentobarbital	Nembutal, Tuinal
(3) Phencyclidine	Sernyl, Sernylar
(4) Secobarbital	Seconal

~~E.~~ F. 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:

(1) Immediate precursor to amphetamine and methamphetamine:

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

(2) Immediate precursor to phencyclidine (PCP):

(a) 1-phenylcyclohexylamine

(b) 1-piperidinocyclohexane carbonitrile (PCC)

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

The following items are listed in schedule III:

A. ~~Any material, compound, mixture, or preparation which contains any quantity of Amphetamine, its salts, optical isomers, and salts of its optical isomers; Phenmetrazine and its salts; Methamphetamine, its salts, isomers, and salts of isomers; Methylphenidate; and which is required by federal law to be labeled with either of the following symbols; C III or III:~~ Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this part.

B. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Amphetamine, Methamphetamine, Methylphenidate and Phenmetrazine, when required by federal law to be labeled with either of the following symbols: C-III or III	
(2) Benzphetamine	Didrex
(3) Chlorphentermine	Pre-Sate
(4) Clortermine	Voranil
(5) Phendimetrazine	Plegine, Stim-35, Melfiant, Barcarate

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Any compound, mixture, or preparation containing: (a) Amobarbital~~,~~; (b) Secobarbital~~,~~; (c) Pentobarbital, or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.	
(2) Any suppository dosage form containing: (a) Amobarbital~~,~~; (b) Secobarbital~~,~~; (c) Pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.	
~~Statutory~~ ~~Name~~	~~Some examples of common names, trade names, or names of products which contain a controlled substance~~
(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically excepted or listed in other schedules:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital
(4) Chlorhexadol	
(5) Glutethimide	Doriden
(6) Lysergic acid	
(7) Lysergic acid amide	
(8) Methyprylon	Noludar
(9) Sulfondiethylmethane	
(10) Sulfonethylmethane	
(11) Sulfonmethane	

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

~~Statutory Name~~	~~Some examples of common names, trade names, or names of products which contain a controlled substance~~
~~(1) Benzphetamine~~	~~Didrex~~
~~(2) Chlorphentermine~~	~~Pre-Sate~~
~~(3) Clortermine~~	~~Voranil~~
~~(4) Phendimetrazine~~	~~Plegine, Stim-35, Melfiant, Bacarate~~
D. Nalorphine	Nalline

E. Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities ~~of any of the following narcotic drugs, or any salts thereof~~ as follows:

(1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium: Copavin.

(2) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cheracol, Elixir, Terpin Hydrate and Codeine, Cosadein, Prunicodeine, Robitussin A.C.

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

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Ambenyl, Tussend, Hycomine, Tussionex.

(5) Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Cidicol.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: Paregoric, Camphorated Opium Tincture.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6800.4240 SCHEDULE IV CONTROLLED SUBSTANCES.

The following items are listed in schedule IV:

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

B. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) Not more than one milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane), for example, Darvon, Darvocet.

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
~~A.~~ (1) Alprazolam	Xanax
~~B.~~ (2) Barbital	Barbitone
(3) Bromazepam	
(4) Camazepam	
~~C.~~ (5) Chloral betaine	Beta-Chlor
~~D.~~ (6) Chloral hydrate	Noctec, Somnos
~~E.~~ (7) Chlordiazepoxide	Librium, Libritabs
(8) Clobazam	
~~F.~~ (9) Clonazepam	Clonopin
~~G.~~ (10) Clorazepate	Tranxene
(11) Clotiazepam	
(12) Cloxazolam	
(13) Delorazepam	
~~H.~~ (14) Diazepam	Valium
~~I. Diethylpropion~~	~~Tenuate, Tepanil~~
(15) Estazolam	
~~J.~~ (16) Ethchlorvynol	Placidyl
~~K.~~ (17) Ethinamate	Valmid
~~L. Fenfluramine~~	~~Pondamin~~
(18) Ethyl Loflazepate	
(19) Fludiazepam	
(20) Flunitrazepam	
~~M.~~ (21) Flurazepam	Dalmane
~~N.~~ (22) Halazepam	Paxipam
(23) Haloxazolam	
(24) Ketazolam	
(25) Loprazolam	
~~O.~~ (26) Lorazepam	Ativan
~~P. Mazindol~~	~~Sanorex~~
(27) Lormetazepam	
~~Q.~~ (28) Mebutamate	
(29) Medazepam	
~~R.~~ (30) Meprobamate, except when in combination with the following drugs in the following or lower concentrations: conjugated estrogens 0.4 mg tridihexethyl chloride 25 mg pentaerythritol tetranitrate 20 mg	Equanil, Miltown, Equagesic, Equalysen
~~S.~~ (31) Methohexital	Brevital
~~T.~~ (32) Methylphenobarbital	Mebral, Mephobarbital
(33) Nimetazepam	
(34) Nitrazepam	
(35) Nordiazepam	
~~U.~~ (36) Oxazepam	Serax

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(37) Oxazolam	
~~V.~~ (38) Paraldehyde	Paral
~~W. Pemoline~~	~~Cylert~~
~~X. Pentazocine~~	~~Talwin~~
~~Y.~~ (39) Petrichloral	Periclor
~~Z.~~ (40) Phenobarbital	Luminal, Phenobarbitone, Eskabarb
~~AA. Phentermine~~	~~Wilpo, Fastin, Ionamin~~
~~BB. Pipradrol~~	
(41) Pinazepam	
~~CC.~~ (42) Prazepam	Centrax
~~DD. Propoxyphene~~	~~Darvon~~
~~EE. SPA (/1/-1 Dimethylamino-1, 2-diphenylethane)~~	
~~FF.~~ (43) Temazepam	Restoril
(44) Tetrazepam	
(45) Triazolam	Halcion

D. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, (whether optical, positional, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Fenfluramine	Pondamin

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Diethylpropion	Tenuate, Tepanil
(2) Mazindol	Sanorex
(3) Pemoline (including organometallic complexes and chelates thereof	
(4) Phentermine	Wilpo, Fastin, Ionamin
(6) Pipradrol	
(6) SPA ((-)-1-dimethylamino-1, 2-diphenylethane)	

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

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance
(1) Pentazocine	Talwin

6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The following items are listed in schedule V:

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

B. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following ~~limited quantities of~~ narcotic drugs, or their salts calculated as the free anhydrous base or

alkaloid, in limited quantities as follows, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by ~~the~~ narcotic ~~drug~~ drugs alone:

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

RENUMBERING. Renumber the Minnesota Rules parts in column A as the Minnesota Rules parts in column B.

A	B
6800.0900	6800.2250
6800.1000	6800.1150
6800.1100	6800.1250
6800.1200	6800.1300
6800.2000	6800.2150
6800.2100	6800.1050
6800.2200	6800.0950
6800.3500	6800.4150
6800.3600	6800.3550
6800.3700	6800.3650
6800.3800	6800.3750
6800.3900	6800.3850
6800.4000	6800.3950
6800.4100	6800.4050

Pollution Control Agency

Proposed Rules Governing Hazardous Waste Fees

Notice of Intent to Adopt Amendments to Rules without a Public Hearing

Notice is hereby given that the Minnesota Pollution Control Agency (Agency) intends to adopt without a public hearing, in accordance with the provisions of Minn. Stat. § 16A.128 (Supp. 1983), amendments to 6 MCAR §§ 4.9701-4.9706 (Minnesota Rules Parts 7046.0010-7046.0070, Hazardous Waste Facility and Generator Fee Rules. In accordance with Minn. Stat. § 16A.128 (Supp. 1983), the Agency will follow the procedure for non-controversial rules set out in Minn. Stat. §§ 14.22 to 14.28 (Supp. 1983), with the exception that no public hearing will be held in the event that twenty-five or more requests for hearing are received.

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CERTIFICATE OF BOARD'S

RESOLUTION ADOPTING RULES

I, Arnold D. Delger, do hereby certify that I am a member and the President of the Minnesota 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 18th day of December, 1984, 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 changes relating to Amendment and Repeal of rules concerning Controlled Substances and license fees and they hereby are approved and adopted, pursuant to authority vested in us by Minn. Stat. section 151.06, subd. 1(9) and that David E. Holmstrom, Executive Secretary of the Board of Pharmacy, be and hereby is authorized to sign an order adopting these rules changes and further is authorized to perform the necessary acts to provide that these rules changes shall have the force and effect of law."

IN WITNESS WHEREOF, I have hereunto subscribed me name this 18th day of December, 1984.

STATE OF MINNESOTA

BOARD OF PHARMACY

Arnold D. Delger

ARNOLD D. DELGER
President

Attest:

Board Member

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendment of Rules Concerning Licensure Fees and Controlled Substances

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. section 14.14, subd. 2, and 14.23 and Minn. Rules part 1400.0500 hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendment of Board rules. The statutory authority for these proposed rule changes is contained in Minn. Stat. section 151.06, subd. 1 (9), which authorizes the Board to make and publish uniform rules and regulations to enforce the provisions of the statute, Minn. Stat. section 152.02 subd. 7, 8 and 9, which authorize the Board to schedule and reschedule controlled substances, and laws of Minnesota 1984, Chapter 628, article 2 which authorizes the Board to adjust its fees without a public hearing. Minnesota Rules part 6800.4200 through part 6800.4500 are the Board's current rules on controlled substances. The Board is proposing to amend all of those subparts to provide easier understanding and reading and amend various parts by scheduling, rescheduling, or deleting various substances from the schedules. Most of the proposed changes involving controlled substances are for clarification only and do not change the substance of existing rules.

FEE CHANGES.

The need to adopt these proposed fee change 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. This requirement is found in Minn. Stat. section 214.06.

MINN. RULE PART 6800.0400 AND 6800.1000.

The intent of the proposed changes in Minn. Rules 6800.0400 and 6800.1000 is to allow the Board to meet its statutory requirement of adjusting its fees to meet the legislatively authorized expenditures over each biennium. Minn. Stat. section 16A.128 allows agencies to use the non-controversial rules promulgation process and eliminates the public hearing process as long as the amount of fee requested approximates the sum of all direct appropriations, statewide indirect costs, general support costs, transfers in, and salary supplements for each biennium. Attached hereto as Exhibit 1 is the approval of the Commissioner of Finance of the proposed fee increases.

It should be noted that both individual pharmacist license fees, which have been increased only once since 1978, and pharmacy license fees, which have been increased only once since 1977, are being proposed for increase at this time. Even with these increases the fees proposed are in line with those of neighboring states and are, in fact, lower than the corresponding fees found in some neighboring states.

MINN. RULE PART 6800.1100.

While it would appear that two changes are being made to this section the change regarding the examination fee was made in 1982 pursuant to the procedures provided for at that time in Minn. Stat. section 16A.128 and Minn. Stat. section 214.06 subd. 1. The $90 examination fee thus established, however, does not appear in the printed editions of the Board's rules. The examination fee amount is included herein solely for the purpose of providing for its inclusion in the printed versions of the Board's rules.

The other change proposed in this section involves the time for submission of applications to participate in the Board's licensure examination. The Board has found that the 30 day lead time currently included in the Board's rule does not provide sufficient time for Board staff to adequately review the submitted applications and other documents. The additional lead time provided by this change should not involve any substantial inconvenience to the potential applicants in that students at the College of Pharmacy at the University of Minnesota and students from other schools who are completing their required internship in Minnesota receive their applications to sit for the Board exam from the Board office several months, and in some cases up to two or three years, in advance of the examination date.

CONTROLLED SUBSTANCES.

The need to adopt these proposed changes to the Board's existing rules relating to controlled substances arises primarily because of the

difficulty in reading the existing rule the way it is set up and because of changes in the Federal Controlled Substances Act and the regulations thereunder that have taken place over the past few years. The proposed scheduling changes reflect findings on the state and federal level that certain drug entities are potentially subject to abuse and thus deserve more stringent controls over the recordkeeping and security associated with their use. In one instance a drug which had no previously legitimate known medical use was found to have legitimate uses in the practice of medicine and is being rescheduled accordingly. In one other instance a drug previously thought to show abuse potential was found not to have the abuse potential originally thought and is thus being removed from control.

MINN. RULE PART 6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

Schedule I controlled substances are those substances found to have a very high potential for abuse and which, at the same time, have no legitimate use in medical practice.

Items listed as A (2) and (7) are new additions to the list of Schedule I substances which will bring state law into conformity with federal law in this area. In placing Alfentanil and Alpha-methylfentanyl in Schedule I the Federal Drug Enforcement Administration found that they had a high potential for abuse, they did not currently have accepted medical use in treatment in the United States and that there is a lack of accepted safety in their use even under medical supervision.

In the cases of items A (16) and A (20) the change is simply one of correcting a previous misspelling.

The final change in section A of part 6800.4210 is the transferring of the drug Sufentanil from Schedule I into Schedule II. As previously indicated, Schedule I substances are those substances that do not have a recognized medical use in the United States. Until recently this was the case for Sufentanil. A medical usefulness of the drug has now been established and the drug has been reclassified into Schedule II on the Federal level. The drug is being marketed under the trade name Sufenta by Janssen Pharmaceutica for use in managing patients under anesthesia. The drug is said to provide a more comfortable recovery following surgery for patients who have had this drug administered to them.

The Board has been contacted both by hospitals in the Twin Cities metropolitan area and by hospitals associated with the Mayo Clinic in Rochester urging rapid rescheduling of this product so that hospital use could begin.

In section B, item 10 involves a new substance being added to the list of Schedule I substances on the state level. Again this simply brings the State Controlled Substances Act into conformity with the Federal Act. The changes in items B (11) and B (15) are included simply for clarification purposes.

In section C, item 7 is a new item being added to the controlled substances list at the state level. In discussing this item at the federal level it was indicated that the World Health Organization is recommending control of this substance on a world wide level in that the substance is a hallucinatory substance that produces behavior effects similar to those

produced by LSD although some affects appear to be amphetamine like. The substance has a very high potential for abuse and does not have an accepted medical use in treatment in the United States.

Item C (16) is also a change designed to bring state law into conformity with the federal law. Parahexyl has a high potential for abuse and does not have a recognized medical use in treatment in the United States.

The remaining changes in section C represent restructuring of the layout of the entire rule rather than new items being added to the schedules or items being deleted from the schedules.

The change in section E, the placing of Methaqualone in Schedule I brings state statutes into conformity with federal. On June 29, 1984, President Reagan signed PL 98.329 which placed Methaqualone into Schedule I of the Federal Controlled Substances Act effective September 26, 1984. This law follow the November 14, 1983 announcement by Lemmon Company, the nations sole manufacturer of Methaqualone, that it is discontinuing production of the drug.

MINN. RULE PART 6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

Most of the changes in this part represent a rewriting and restructuring of the various sections and subparts to make them easier to read and to better provide uniformity with the Federal Act.

Items B (1) (g) and E (e), which was discused previously, is being deleted in conformity with deletions in the Federal Act. Items B (1) (i) and C (24) are being added in conformity with Federal changes. Item B(1)

(i) has been a Schedule II controlled substance on the federal level for some time and it was simply through oversight that it was not included previously in the state schedules. Item C (24), Sufentanil, has been discussed previously. All of the remaining changes in part 6800.4220 are simply rewrites and clarification making the sections easier to read and placing them in closer conformity to the layout of the Federal Act.

The importance of laying out the State Controlled Substances Act in a manner identical to or nearly identical to that of the Federal Act comes into play during rescheduling activities at the Federal level. It is much easier to accomodate similar scheduling changes at the state level if the item being changed at the federal level can be "plugged in" to the same spot at the state level.

MINN. RULE PART 6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

All of the changes in this part are of a clarification and categorization nature only. No new substances are being added to Schedule III and no existing substances are being deleted from Schedule III.

MINN. RULE PART 6800.4240 SCHEUDLE IV CONTROLLED SUBSTANCES.

In this section the changes represent not only clarification and categorization of the substances listed but also the addition of a number of substances in conformity with changes being made at the federal level.

In the Federal Register of Wednesday, August 1, 1984 the Drug Enforcement Administration announced its intention to place twenty-one different Benzodiazapine substances in Schedule IV of the Controlled Substances Act. This action is required in order for the United States to

discharge its obligations under the Convention on Psychotropic Substances, 1971. On March 29, 1984 the Secretary General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs has decided that thirty-three Benzodiazapines be added to Schedule IV of the 1971 Convention on Psychotropic Substances. Of the thirty-three Benzodiazapines twelve have already been controlled in Schedule IV.

By a letter dated May 1, 1984 the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services, recommended to the Administrator of DEA that the remaining twenty-one Benzodiazapines also be controlled in the Controlled Substances Act Schedule IV. The changes being proposed here in section C accomplish the rescheduling of these same substances at the state level. All of the other changes in 6800.4240 are of a clarification and categorization nature.

MINN. RULE PART 6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The only substantive change proposed by the Board in this part involves the drug Loperamide.

When the drug Loperamide, commonly known as Imodium, first came on the market the Federal Drug Enforcement Administration and the Food and Drug Administration placed the drug in the category of Schedule V controlled substance at the federal level. Likewise, the Board placed Loperamide in Schedule V at the state level.

Subsequent to its marketing, additional studies were completed which demonstrated that the drug does not have the abuse potential that was

originally ascribed to it. As a result of that finding the Drug Enforcement Administration deleted Loperamide from its list of controlled substances. The Board is now proposing to do likewise.

SMALL BUSINESS IMPACT.

Whenever an agency proposes a new rule or seeks to amend an existing rule, Minn. Stat. section 14.115 requires the agency to consider whether the rule changes will have an impact on small businesses. If the agency determines that they will, the agency must consider whether certain methods, set forth in subd. 2 of the statute, could be adopted to reduce the impact of the rule changes on small businesses. The statute requires the agency to document in its Statement of Need and Reasonableness how it considered these methods and the feasibility of adopting any of the specified methods.

In addition to the licensure of pharmacists, the Board licenses pharmacies, drug manufacturers, and drug wholesalers. The Board has reviewed the impact, if any, its proposed rule changes would have on such businesses. The increase in license fees does not, at this time, affect drug wholesalers or drug manufacturers at all and the effect on licensed pharmacies is insignificant.

The effect of the rescheduling of the various controlled substances at the state level is also negligible. All pharmacies, drug wholesalers and drug manufacturers licensed by the Board are already required to comply with whatever standards are adopted at the federal level. Changing state law to conform with the federal law will not have any additional impact on the Board's licensees.

Minn. Stat. section 14.115, subd. 2 enumerates the following five methods an agency must consider to reduce the impact of the rules on small businesses:

(a) The establishment of less stringent compliance or reporting requirements for small businesses;

(b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) The consolidation or simplification of compliance or reporting requirements for small businesses;

(d) The establishment or performance standards for small businesses to replace design or operational standards required in the rule; and

(e) The exemption of small businesses from any or all requirements of the rule.

The Board's proposed rule changes do not contain any reporting requirements, deadlines for compliance or performance standards. Therefore parts (a) to (d) are not applicable to the Board's proposed rules. The Board finds it impossible to exempt small businesses from either the fee increase or from the changes in the controlled substance rules. To exempt small businesses from the fee increase would amount to not being able to implement the fee increase at all. To exempt small businesses from the effect of the Controlled Substances Act would serve no logical purpose in that small businesses are already subject to the Act from the federal level.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendment of Rules Concerning Controlled Substances and License Fees

STATEMENT OF COMPLIANCE WITH RULEMAKING PROCEDURES

I, Special Assistant Attorney General Robert T. Holley, do hereby declare that I have examined the above-captioned 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 without any exceptions.

Dated: December 20, 1984

Robert T. Holley

ROBERT T. HOLLEY
Special Assistant
Attorney General

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Pharmacy

CERTIFICATE

I hereby certify that no written comments were received during the comment period regarding the Board's proposed non-controversial rules.

David E. Holmstrom