

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

PHONE (612) 296-5411

MINNESOTA STATE BOARD
OF PHARMACY

DAVID E. HOLMSTROM, R.PH.
SECRETARY

717 DELAWARE ST., SE, RM 351
MINNEAPOLIS, MN. 55414

MINNESOTA STATE REGULATIONS

Notice of filing by the Commissioner of Administration

We have received on this date, stamped and filed 2 copies of Rules and Regulations pertaining to

the Pharmacy
(Agency or Board)

Regulation No. Pharm Reg 51(d) amended

Subject: Stantory Name of Drugs

Department of Administration
Publication, Central Services Division
Documents Section
140 Centennial Office Building
St. Paul, Minnesota 55155
Telephone: (612) 296-2874

FILED
RICHARD L. BRUBACHER
Commissioner of Administration

JAN 22 1976

BY Edw Staudemann
AUTH. SIGNATURE 3:55 pm

Stamped and filed with the Secretary of State Jan 22, 1976 3:15 pm

Rev. 9-72

Office of the Secretary ROOM 351 Telephone 612/296-5411

BOARD OF PHARMACY

An Equal Opportunity Employer

717 Delaware Street, Southeast
MINNEAPOLIS, MINNESOTA 55414

Adopted 11/20/75

PROPOSED REVISION OF PHARM REG. 51

Pharm Reg 51 (d) is hereby Amended to Read:

(d) The following items are listed in Schedule IV:

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	Barbital	Barbitone
(2)	Chloral Betaine	Beta-chlor
(3)	Chloral Hydrate	Noctec, Somnos
(4)	Chlordiazepoxide	Librium, Libritabs
(5)	Clonazepam	Clonopin
(6)	Clorazepate	Tranxene
(7)	Diazepam	Valium
(8)	Diethylpropion	Tenuate Tepanil
(9)	Ethehlorvynol	Placidyl
(10)	Ethinamate	Valmid
(11)	Fenfluramine	Pondamin
(12)	Flurazepam	Dalmane
(13)	Mebutamate	
(14)	Meprobamate, except	Equanil, Miltown, Equagesic, Equalysen
	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.	
(15)	Methohexital	Brevital
(16)	Methylphenobarbital	Mebaral
(17)	Oxazepam	Serax
(18)	Paraldehyde	Paral
(19)	Pemoline	Cylert
(20)	Petrichloral	Periclor
(21)	Phenobarbital	Luminal, Phenobarbitone, Eskabarb,
(22)	Phentermine	Wilpo, Fastin, Ionamin

DH:mw
8/25/75

FILED
RICHARD L. BRUBACHER
Commissioner of Administration

JAN 22 1976

BY Edna Staudenmaier
AUTH. SIGNATURE

3:55 PM.

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JAN 22 1976
3:15 PM
Joan Anderson Growe
Secretary of State

RECEIVED
JAN 22 1976
SECRETARY OF STATE
CORPORATION DIVISION

RECEIVED
JAN 22 1976
SECRETARY OF STATE
CORPORATION DIVISION

APPROVED AS TO FORM AND LEGALITY
JAN 22 1976 19
WARREN SPANNAUS, ATTORNEY GENERAL
BY /s/ Michael B. Miller
SPECIAL ASSISTANT ATTORNEY GENERAL

Office of the Secretary ROOM 351 Telephone 612/296-5411

BOARD OF PHARMACY

An Equal Opportunity Employer

717 Delaware Street, Southeast
MINNEAPOLIS, MINNESOTA 55414

Adopted 11/20/75

PROPOSED REVISION OF PHARM REG. 51

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(10)	Ethinamate	Valmid
(11)	Fenfluramine	Pondamin
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(17)	Oxazepam	Serax
(18)	Paraldehyde	Paral
(19)	Pemoline	Cylert
(20)	Petrichloral	Periclor
(21)	Phenobarbital	Luminal, Phenobarbitone, Eskabarb, Wilpo, Fastin, Ionamin
(22)	Phentermine	

DH:mw
8/25/75

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the matter of the proposed Revision of Rules of Board of Pharmacy Governing the Scheduling and Labeling of Controlled Substances.

RESOLUTION

I, David E. Holmstrom, do hereby certify that I am secretary of the Board of Pharmacy, a board duly authorized under the laws of the state of Minnesota, and that the following is 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 20th day of November. That a quorum was present at said meeting; that a majority of those present voted for the resolution; that said resolution is set forth in the minutes of said meeting and not been rescinded or modified.

WHEREAS, the public hearing was held on September 23, 1975 in room 116-A in the State Administration Building, Capitol Complex, St. Paul, Minnesota, concerning the adoption of the proposed amendment for board regulation number 51 and proposed new Regulation 41.

WHEREAS, said public hearing was held after proper notice required by Minnesota statutes 1974, Section 15.0412, was served upon all persons, associations and other interested groups registered with the Secretary of State for that purpose, and

WHEREAS, all interested persons were afforded opportunity at said public hearing to present written and oral data, statements, and arguments, and

WHEREAS, all interested persons were afforded an opportunity to present further written materials, data, arguments, and briefs through October 13, 1975.

WHEREAS, five members of the Minnesota State Board of Pharmacy were in attendance at said public hearing, and

WHEREAS, all members of the State Board of Pharmacy have considered all of the evidence introduced at the public hearing and the members attending this meeting have considered all of the written material, data, statements, arguments, and briefs submitted at said public hearing, and

WHEREAS, all the members of the State Board of Pharmacy have determined the need for each of the rules contained in Exhibit "A" attached hereto and made a part hereof, and

WHEREAS, such need has been set forth in document marked Exhibit "B" attached hereto and made a part hereof.

NOW THEREFORE, BE IT RESOLVED that the rules and regulations marked Exhibit "A" attached hereto, and made a part hereof be and hereby are approved and adopted pursuant to authority vested in us by MS 151.06, and MS 152.02 Subdivision 7 Laws of 1974.

BE IT FURTHER RESOLVED that David E. Holmstrom be and hereby is authorized to execute a certificate certifying the passage of this resolution and he is further directed to submit to the office of the Attorney General of the State of Minnesota all of the necessary papers, documents and transcripts for his approval.

Motion unanimously passed.

STATE OF MINNESOTA
BOARD OF PHARMACY

David E. Holmstrom
Secretary

STATEMENT OF COMPLIANCE WITH

MANUAL OF RULE MAKING PROCEDURES

I, Robert T. Stich, Special Counsel to Minnesota State Board of Pharmacy do hereby declare that I have examined the proposed rules and all related documents and that, based on them and my personal familiarity with the applicable procedures, the Manual of Rule Making Procedures has been followed. Any exceptions are noted below.

Robert T. Stich

Special Counsel to Minnesota
State Board of Pharmacy

Dated: 12-4-75

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA STATE BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Regulations of the State Board of Pharmacy

ORDER FOR HEARING

To effectively implement the powers and duties of the State Board of Pharmacy, the said Board deems it necessary to consider adoption of proposed Revision to Regulation 41 and 51, a copy of which is attached hereto, marked Exhibit "A" and made a part hereof, pursuant to the authority vested in the said Board by MS 151.06 and MS 152.02, Subdivision 7, Laws of 1974, and Chapter 356, Subdivision 2, Laws of 1975.

NOW THEREFORE, IT IS ORDERED this 16th day of July 1975, that a public hearing on the proposed rules set forth in said Exhibit "A" be held in Room 115-A of the State Administration Building, Capitol Complex, St. Paul, Minnesota on September 23, 1975, commencing at 9:00 o'clock a.m. and continuing thereafter until all representatives of associations of other interested groups or persons have had an opportunity to be heard.

IT IS FURTHER ORDERED that notice of the said hearing be given to all of the current members of the legislature of the State of Minnesota and to all representatives of associations or other interested groups or persons who have registered their names with the Secretary of State for that purpose.

MINNESOTA STATE BOARD OF PHARMACY

By David Holmstrom
David E. Holmstrom
Secretary

CERTIFICATE OF RESOLUTION

OF STATE BOARD OF PHARMACY

I, DAVID E. HOLMSTROM, do hereby certify that I am the Secretary of the Board of Pharmacy, a Board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete and correct copy of a Resolution adopted at a meeting of the Board of Pharmacy duly and properly called and held on the 16th day of July, 1975 and that a quorum of the said Board was present at said meeting and that the said Resolution set forth below was passed by a majority vote of the members of the Board, and that the said Resolution set forth below are also set forth in the Minute Book of the State Board of Pharmacy and has not been rescinded or modified:

July 16, 1975

The Board first turned it's attention to the recent federal changes in the Controlled Substances Act of 1970. Secretary Holmstrom described to the Board changes made in the lists of drugs to be found in the various schedules of the Controlled Substances Act and described the changes in Pharm Reg 51 that would be needed to bring the State Controlled Substances Act into conformity with the federal requirements. Mrs. Kitty Alcott then moved and Mr. Tom Berg seconded that it be resolved that David E. Holmstrom, Secretary of the Minnesota State Board of Pharmacy, be and hereby is granted the authority to call a hearing for the purpose of promulgating proposed revisions to Pharm Reg 51 as well as to perform any and all acts incidental thereto, including that not being limited to, signing an order for hearing and notice of hearing as well as appointing a hearing examiner. The motion passed.

The Board next turned it's attention to the possible need for a clarifying regulation to the newly enacted legislation which adds a subdivision 2 to MS 151.212. This new section, dealing with controlled substances, requires that "in addition to the requirements of subdivision 1, (of MS 151.212) when the use of any drug containing a controlled substances as defined in Chapter 152, either alone or in conjunction with alcoholic beverages, may impair the ability of the user to operate a motor vehicle, that fact shall be permanently set forth on the label or container."

David E. Holmstrom

Secretary

Exhibit 2

STATE OF MINNESOTA

COUNTY OF HENNEPIN

Exhibit "B"

In the matter of the proposed Revision of Rules of Board of Pharmacy Governing the scheduling and Labeling of Controlled Substances

STATEMENT OF NEED

The need to adopt these rules arises out of two distinct areas.

The need to adopt Proposed Regulation 51 arises pursuant to Minnesota Statutes 152.02, Subdivision 7 at et seq. In the interest of the speedy administration of justice on the state and county level, a prosecution of drug related offenses must be done on a state level. The Legislature foresaw the problem of crowded federal court calandars when it passed the State Controlled Substances Act. The State Controlled Substances Act is virtually identical with the Federal Controlled Substances Act but allows prosecution of drug related offenses in the state court system. In passing Minnesota Statutes 152 the Legislature also foresaw the possibility of rescheduling of Controlled Substances on the federal level at times when the Legislature was not in session. In order that the state requirements might remain in close conformity with the federal requirements, the Legislature created the Controlled Substances Advisory Council and directed that they study the drug abuse problems in the state and recommend to the State Board of Pharmacy the rescheduling of the various drugs of abuse. The Legislature at the same time placed upon the Board of Pharmacy the responsibility for scheduling and rescheduling the various drugs of abuse.

Under this mandate, the Controlled Substances Advisory Council has met and reviewed the drugs that were the subject of the latest revisions of the Federal Controlled Substances Act. It was the determination of the Controlled Substances Advisory Council that Pharmacy Board Regulation 51 should be modified to reflect on the state level the changes that have taken place in the Federal Controlled Substances Act.

These proposed rescheduling changes will aid the various law enforcement agencies of the state in the enforcement of the drug laws in that the offenders can be brought before the state judiciary at the earliest opportunity rather than being placed on the crowded federal court calendars.

The need for the proposed Regulation 41 comes about as a result of legislation passed as part of the 1975 Legislative Session.

During the 1975 Session the Legislature at the urging of the Department of Public Safety, passed House File Number 470 which can be found in Chapter 356 of the laws of 1975. House File 470 calls for the amendment of Minnesota Statutes 151.212 by adding a subdivision 2 which reads "in addition to the requirements of subdivision 1, when the use of any drug containing a controlled substance, as defined in Chapter 152, either alone or in conjunction with alcoholic beverages, may impair the ability of the user to operate a motor vehicle, that fact shall be prominently set forth on the label or container."

In order that the pharmacists of the state might more easily comply with the intent of this legislation, the Board of Pharmacy tried to determine whether specific wording should be developed for inclusion on the label or container of all dispensed controlled substances. While the adoption of specific wording regarding the controlled substances warning would aid the pharmacist in complying with the new statute and would allow the manufacturers of labels and other pharmaceutical specialty items to prepare highly visible supplementary labels which would aid in bringing the attention of the consumer to this important warning, the Board has determined that there is an even greater need to have the entire statutory enactment revised to take into consideration some of the obvious exemptions that should have been included in the original Act. In light

of this the Board is delaying any further action on proposed Regulation 41 until after the 1976 Legislative Session wherein it is hoped the necessary changes will be made.

The Board feels that proposed change to Regulation 51 is a positive step in meeting the needs of the citizens of the state and should be adopted.

David Kalmbach

Secretary

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

STATE BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Regulation 51 and Regulation 40 Relating to the Scheduling and Labeling of Controlled Substances.

NOTICE OF HEARING

Notice is hereby given that a public hearing will be held pursuant to M.S. 1974, Section 15.0412, Subdivision 4, in the above entitled matter in Room 116-A, Administration Building, 50 Sherburne Ave., St. Paul, Minnesota on Tuesday, September 23, 1975, commencing at 9:00 a.m., and continuing until all representatives of associations or other interested groups have had an opportunity to be heard concerning the adoption of the proposed regulations by submitting either oral or written data, statements or arguments. Statements or briefs may be submitted without appearing at the hearing.

Copies of the proposed revised Regulations 51 and 40 are now available and may be obtained by writing to David E. Holmstrom, Secretary, Minnesota State Board of Pharmacy, Room 351, 717 Delaware St. SE, Minneapolis, MN 55414. Additional copies will be available at the door on the date of the hearing.

MINNESOTA STATE BOARD OF PHARMACY

By David Holmstrom
David E. Holmstrom, Secretary

DEH:sl
8-20-75

MINNESOTA STATE BOARD OF PHARMACY

PROCEDURAL RULES FOR HEARING

The purpose of the hearing is to allow interested parties to express their views and present facts bearing upon the proposed regulations. So as to provide for an orderly presentation of evidence, the following rules will be in effect during the hearing specified in the attached Notice of Hearing:

1. Anyone wishing to be heard should indicate by signing the speaking sheet, listing his name, address, and the group which he represents. The speaking sheet will be available at the main entrance to the hearing room. It is requested that each group select one speaker only to present its views.

2. The first time the witness makes a statement he should spell his name and identify the group he is representing. Prior to making any subsequent statements he should state his name and the group which he represents. He may be sworn upon his request but it is not required. If he elects not to be sworn, that may be considered in determining the weight to be given to his testimony.

3. By giving testimony, a witness, including one who may also be a member of the panel, subjects himself to questioning by the panel. However, he is subject to cross-examination by non-members of the panel only if he affirmatively consents to being so examined. A refusal to be cross-examined may be considered in determining the weight to be given to his testimony.

4. All parties interested in introducing any written matter may do so by having it marked as an exhibit and then introduced for the record. Unsworn written matter may be received, but the fact that it is unsworn may be considered in determining the weight to be given it.

Office of the Secretary ROOM 351 Telephone 612/296-5411

BOARD OF PHARMACY

An Equal Opportunity Employer

717 Delaware Street, Southeast
MINNEAPOLIS, MINNESOTA 55414

PROPOSED REVISION OF PHARM REG. 51

Pharm Reg 51 (d) is hereby Amended to Read:

(d) The following items are listed in Schedule IV:

	Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1)	Barbital	Barbitone
(2)	Chloral Betaine	Beta-chlor
(3)	Chloral Hydrate	Noctec, Somnos
(4)	Chlordiazepoxide	Librium, Libritabs
(5)	Clonazepam	Clonopin
(6)	Clorazepate	Tranxene
(7)	Diazepam	Valium
(8)	Diethylpropion	Tenuate Tepanil
(9)	Ethehlorvynol	Placidyl
(10)	Ethinamate	Valmid
(11)	Fenfluramine	Pondamin
(12)	Flurazepam	Dalmane
(13)	Mebutamate	
(14)	Meprobamate, except	Equanil, Miltown, Equagesic, Equalysen
	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.	
(15)	Methohexital	Brevital
(16)	Methylphenobarbital	Mebaral
(17)	Oxazepam	Serax
(18)	Paraldehyde	Paral
(19)	Pemoline	Cylert
(20)	Petrichloral	Periclor
(21)	Phenobarbital	Luminal, Phenobarbitone, Eskabarb, Wilpo, Fastin, Ionamin
(22)	Phentermine	

DH:mw
8/25/75

STATE OF MINNESOTA

COUNTY OF RAMSEY

In the matter of the proposed Adoption of Revised Rules of the Minnesota State Board of Pharmacy Governing the Scheduling and Labeling of Controlled Substances.

I hereby certify that the attached 436 labels and sheet constitute the complete list of persons, associations, and other interested groups who as of 2:30 o'clock p.m., this 18th day of Aug., 1975, have requested pursuant to M.S. 74, 15.0412, that their names be placed on file with the Secretary of State for the purpose of receiving notice of public hearing on proposed rules on the subject captioned above.

SECRETARY OF STATE

Joan Anderson Growe

BY Virginia Daniels

AFFIDAVIT

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

(1) That he is the secretary of the Minnesota State Board of Pharmacy

(2) That on the 15th day of August 1975, he contacted the Secretary of State's Office for the State of Minnesota and requested a current list of all representatives of associations or other interested groups or persons who have registered their names with the Secretary of State for the purpose of obtaining notices of public hearings relating to the promulgation of rules pursuant to MS 15.0412.

(3) That on the 18th day of August 1975, in response to the above request, the Secretary of State provided this affiant with such a list, composed of mailing labels and a list of recent additions thereto, a copy of which is attached hereto, marked Exhibit A and made a part hereof..

(4) That on the 21st day of August 1975, at the City of Minneapolis, county of Hennepin, State of Minnesota, he served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis a true and correct copy there of together with a copy of the proposed regulations, properly addressed and postage prepaid to all persons and associations set forth in said Exhibit A and also to all of the current members of the Minnesota Legislature.

David E. Holmstrom
Secretary

Subscribed and sworn to before
me this 16th day of December, 1975

Alice D. Hummer
Notary Public

ALICE D. HUMMER
Notary Public, Ramsey Co. Minn.
My Commission Expires
Nov. 18, 1981

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

STATE BOARD OF PHARMACY

In the matter of the Proposed Adoption of Rules of the State Board of Pharmacy governing the Scheduling and Labeling of Controlled Substances

FINDINGS OF FACT

The above-entitled matter came on for hearing before the Minnesota State Board of Pharmacy on the 23rd day of September, 1975, at 9:00 o'clock a.m. in Room 116-B, State Administration Building after proper notice required by MS 1974, Section 15.0412 was served upon all persons, associations and other interested groups registered with the Secretary of State for that purpose.

After affording interested persons an opportunity to present written and oral data, statements and arguments, having heard all of the testimony, having considered all of the evidence adduced and upon the records, files and proceedings herein, I find the following:

1) in relation to the proposed revision of Pharm. Reg. 51:

a) based on information now available, Chlordiaxepoxide, Diazepam, Oxazepam, Clorazepate, Flurazepam and Clonazepam have a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

b) Chlordiaxepoxide, Diazepam, Oxazepam, Clorazepate, Flurazepam have a currently accepted medical use in treatment in the United States.

c) Clonazepam will, upon the approval of a new drug application by the Food and Drug Administration, have a currently accepted medical use in treatment in the United States.

d) abuse of these drugs may lead to limited physical dependence or psychological dependence relative to drugs or other substances in Schedule III.

e) the Federal Government pursuant to the authority vested in it by the comprehensive Drug Abuse Provention and Control Act of 1970 has placed these drugs in Schedule IV on the federal level.

f) the abovementioned changes in the Federal Act subsequent to the last revision of this section have caused significant differences to appear between the State and Federal Acts causing much confusion and difficulty in the enforcement of the State Act.

g) the revisions proposed are in the best interest of the state as they put the State Controlled Substances Act on equal footing with the Federal Act.

h) no opposition of any kind was forthcoming from any source whatsoever regarding the proposed rescheduling.

i) all of the evidence submitted relative to this issue upholds the position taken by the board as set forth in its proposed regulations.

2) in relation to the proposed revision of Pharm Reg. 41:

a) Chapter 357 Laws of Minnesota for 1975 amended Minnesota Statutes 151.212 to require the notation on the label or container of a prescription for controlled substances whenever the use of that drug alone or in conjunction with alcoholic beverages might impair the ability of the user to operate a motor vehicle.

b) While the proposed regulation may be in the best interest of the pharmacy profession in Minnesota in that it would make uniform the wording to be placed on controlled substance prescriptions and allow label manufacturers to produce small, readily available, stick-on warning labels bearing the appropriate wording, it is not in the best interest of the State to adopt it at this time. The statute requiring the above mentioned notification contains no allowances for exemptions of any kind, exemptions which good pharmacy practice and common sense would tend to indicate. It is the finding of the Board that passing this regulation at this time would only serve to confuse still further those who should have been exempted from the required labeling of the bill.

c) opposition to the bill was expressed by the Minnesota State Pharmaceutical Association subsequent to the public hearing and not within the allowed period of time for submission of such documents but was accepted by the Board none-the-less.

d) in light of the evidence submitted by the MSPhA and discussions within the Board, proposed Regulation 41 will not be filed at this time.

MINNESOTA STATE BOARD OF PHARMACY

David Holmstrom

DAVID E. HOLMSTROM
SECRETARY

STATE OF MINNESOTA

COUNTY OF RAMSEY

In the matter of the Proposed Revision of Rules of the State Board of Pharmacy Governing the Scheduling of Controlled Substances.

ORDER ADOPTING RULES

The above entitled matter came on for hearing before the Minnesota Board of Pharmacy on the 23rd day of September, 1975, at 9:00 a.m. in the State Administration Building, St. Paul, Minnesota, after proper notice required by M.S. 1974, Section 15.0412 was served upon all persons, associations and other interested groups, registered with the Secretary of State for that purpose.

After affording interested parties an opportunity to present written and oral data, statements and arguments, having heard all of the testimony, having considered all of the evidence adduced and upon the records, files and proceedings herein, and applicable statutory standards or criteria, and having confirmed the need for the above captioned rules;

NOW, THEREFORE, IT IS ORDERED that these rules identified as Pharm Reg 51 are adopted this 20th day of November, 1975 pursuant to authority vested in me by the Minnesota State Board of Pharmacy.

STATE OF MINNESOTA
BOARD OF PHARMACY

David E. Holmstrom
Executive Secretary