

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. 1043

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 6-29-84
DATE FOR REVIEW 7-9-84
DATE DUE 7-13-84

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

Approved 7-13-84 mjc Disapproved ____ Returned to Agency ____

Resubmitted ____ Due ____
Approved ____ Disapproved ____ Returned to Agency ____

Date filed w/Secretary of State 7/13/84 Revisor approved 7.3.84 disapproved ____

✓ Rule as Adopted

____ Rule as Proposed

✓ Order Adopting 6.28.84 Date

____ Notice of Intent to Solicit Outside Opinion

✓ Order for rulemaking w/o and w/ a Hearing – No hearing was held.
____ date of Hearing

✓ Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking w/o and w/ a Hearing - No hearing was held.
✓ Sufficiency

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

✓ Mailing list Certificate

✓ Publication in State Register
5.14.84 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

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

✓ Certificate of Compliance w/Rulemaking Procedures

✓ Affidavit of Mailing Notice of Submission to Attorney General

✓ Notice of Submission to the Attorney General

SF-00006-02

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : ARNOLD D. DELGER
President
Board of Pharmacy
Attn: ROBERT T. HOLLEY/Special Assist. Att. General

DATE: 7/13/84

FROM : MARTHA J. CASSERLY
Special Assistant
Attorney General

MJC

PHONE: 296-4692

SUBJECT: In the Matter of the Proposed Amendment and Repeal of Rules Concerning Prohibited Conduct and the Public Promotion of Drugs.

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.

Encs.

cc: Ms. Kathy Burek
Mr. Duane Harves

MJC:sa

AG copy

Rules as Adopted

6800.0900 UNPROFESSIONAL CONDUCT.

Subpart 1. **Prohibited conduct.** Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. the assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated;

B. to J. [Unchanged.]

Subpart 2. [Unchanged.]

Subpart 3. [See repealer.]

Subpart 4. [Unchanged.]

REPEALER. Minnesota Rules, part 6800.0900, subpart 3 is repealed.

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JUL 13 1984 3:33 P.M.
Joan Anderson Growe
Secretary of State

APPROVED AS TO FORM AND LEGALITY
July 13 1984
HUBERT H. HUMPHREY, III
ATTORNEY GENERAL
BY Martha J. Casserly
SPECIAL ASSISTANT ATTORNEY GENERAL

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

STATE OF MINNESOTA

OFFICE OF THE ATTORNEY GENERAL

ST. PAUL 55155

ADDRESS REPLY TO:
136 UNIVERSITY PARK PLAZA BLDG.
2829 UNIVERSITY AVENUE S.E.
MINNEAPOLIS, MN 55414
TELEPHONE: (612) 341-7272

June 29, 1984

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

Attention: Judith Wehrwein

Re: In the Matter of the Proposed Amendment and Repeal of Rules Concerning Prohibited Conduct and the Public Promotion of Drugs

Dear Ms. Wehrwein:

Herewith submitted for your review under Minn. Stat. § 14.26 and Minn. Rules pt. 2000.0400, subps. 1-6 are the following noncontroversial 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 and repeal rules without a public hearing;

3-4. notice of intent to amend and repeal 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;

8-9. all written comments received on the rule changes, including a portion of a letter from the Federal Trade Commission which otherwise relates to a potential adjudicatory matter;

10. certificate of Board's resolution adopting rules;

11. order adopting rules (two copies);

12. rule changes as adopted (original and three copies);

13-14. affidavit of mailing notice of submission to the Attorney General, and the accompanying notice; and

15. statement of compliance with rulemaking procedures.

In connection with the foregoing, please note that Minn. Rules pts. 1.B, F and H are not applicable to this proceeding. Also, there were no requests for a public hearing, and the Board adopted the rule changes in precisely the form published in the State Register.

Finally, due to a certain urgency relating to the previously referenced potential action by the Federal Trade Commission, it is requested that your review of the instant rule changes be completed at the earliest permissible date. Likewise, if there are any questions about this submission, please notify me or the Board's Executive Secretary, David E. Holmstrom (623-5411), as soon as possible.

Very truly yours,

Robert T. Holley

ROBERT T. HOLLEY
Special Assistant
Attorney General

RTH:cm

Enclosures

cc: David E. Holmstrom

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed
Amendment and Repeal of
Rules Concerning Prohibited Conduct
and the Public Promotion of Drugs

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 May 14, 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 May 10, 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. 6800.0900, subps. 1.A and 3 (formerly 7 MCAR § 8.037A and K (last paragraph)) are adopted this 28th day of June, 1984 pursuant to authority vested in the Board by Minnesota Statutes, section 151.06, subd. 1(9).

Dated: June 28, 1984

STATE OF MINNESOTA

BOARD OF PHARMACY

Arnold D. Delger

ARNOLD D. DELGER
President

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendment and Repeal of Rules Concerning Prohibited Conduct and the Public Promotion of Drugs

ORDER FOR NOTICE OF INTENT TO AMEND AND REPEAL RULES WITHOUT A PUBLIC HEARING AND FOR NOTICE OF INTENT TO AMEND AND REPEAL RULES WITH A PUBLIC HEARING IF TWENTY-FIVE OR MORE PERSONS REQUEST A HEARING

IT IS HEREBY ORDERED that Notice of Intent to Adopt Rules Without a Public Hearing and Notice of Intent to Adopt Rules with a Public Hearing if Twenty-Five or More Persons Request a 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, the hearing shall be cancelled and all remaining procedures for the adopting of rules without a public hearing shall be followed.

IT IS FURTHER ORDERED that if twenty-five or more persons request a public hearing, the hearing shall be held in Courtroom No. 12, at the Minnesota Office of Administrative Hearings, 400 Summit Bank Building, 310 South Fourth Avenue, Minneapolis, Minnesota 55415, on June 19, 1984, commencing at 9:00 a.m., and continuing until all interested or affected persons have had an opportunity to participate.

Dated: May 1, 1984

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. 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 23rd day of April, 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 directed to sign and publish an order and a notice of hearing and an order and a notice of intent to adopt rules without a public hearing for the purpose of amending and repealing existing Board rules relating to prohibited conduct and to the public promotion of drugs; to proceed with a hearing if the statutorily required number of persons request a hearing in response to the notice; and to cancel the hearing and proceed by noncontroversial rulemaking if less than the statutorily required number of persons request a hearing. Mr. Holmstrom is also granted the authority and directed to perform any and all acts incidental thereto, including requesting the appointment of a hearing examiner, and complying with all applicable provisions of the Minnesota Administrative Procedure Act and the rules of the Office of Administrative Hearings.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 26th day of April, 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 Prohibited Conduct and the Public Promotion of Drugs

NOTICE OF INTENT TO AMEND AND REPEAL RULES WITHOUT A PUBLIC HEARING AND NOTICE OF INTENT TO AMEND AND REPEAL RULES WITH A PUBLIC HEARING IF TWENTY-FIVE OR MORE PERSONS REQUEST A 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. §§ 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.

PLEASE NOTE THAT IF TWENTY-FIVE OR MORE PERSONS SUBMIT WRITTEN REQUESTS FOR A PUBLIC HEARING WITHIN THE 30-DAY COMMENT PERIOD, A HEARING WILL BE HELD ON JUNE 19, 1984, IN ACCORDANCE WITH THE NOTICE OF PUBLIC HEARING ON THESE SAME RULES PUBLISHED IN THIS STATE REGISTER AND MAILED TO PERSONS REGISTERED WITH THE BOARD. To verify whether a hearing will be held, please call the Board before June 19, 1984, at (612) 623-5411.

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
Room 351, 717 Delaware St. SE
Minneapolis, Minnesota 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. § 151.06, subd. 1(9).

If adopted, the proposed changes would clarify an existing rule prohibition against claims of professional superiority and repeal current prohibitions against the public promotion of prescription drugs and pharmaceutical services. A copy of the proposed changes relative to claims of professional superiority and a citation to the rule to be repealed 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 could reduce costs to consumers by affecting price competition among pharmacies. In accordance with Minn. Stat. § 14.115, the Board's consideration of any such 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: May 2, 1984

DAVID E. HOLMSTROM
Executive Secretary
Minnesota Board of Pharmacy

Rules as Proposed

6800.0900 UNPROFESSIONAL CONDUCT.

Subpart 1. **Prohibited conduct.** Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. the assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy; that cannot be substantiated;

B to J [unchanged]

Subpart 2. [unchanged]

Subpart 3. ~~**Public promotion of drugs.** The direct or indirect public promotion of drugs requiring a prescription, narcotics, depressants, or stimulants is hereby declared to be an act of unprofessional conduct. The reference in any advertisement in any media or other means of the term "cut rate," "discount," "bargain," or terms of similar connotation in connection with drugs requiring a prescription or for pharmaceutical services related thereto shall be included within the meaning of public promotion.~~

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

In the Matter of the Proposed Amendment and Repeal of Rules Concerning Prohibited Conduct and the Public Promotion of Drugs

AFFIDAVIT OF MAILING

Alice D. Hummer, being first duly sworn, deposes and says:

That on the 10th day of May, 1984, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached rulemaking notices by depositing in the United States mail at said City of Minneapolis one copy each thereof, properly enveloped, with postage prepaid, to all persons and associations who have requested that their names be placed on file with the Minnesota Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by the Minnesota Board of Pharmacy.

Alice D. Hummer

Subscribed and sworn to before me
this 10 day of May, 1984.
Kathleen M. Anderson

KATHLEEN M. ANDERSON
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSON EXPIRES MARCH 31, 1991

Board of Pharmacy

Proposed Rules Governing Unprofessional Conduct

Notice of Intent to Amend and Repeal Rules without a Public Hearing and Notice of Intent to Amend and Repeal Rules with a Public Hearing if Twenty-Five or More Persons Request a 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. §§ 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.

PLEASE NOTE THAT IF TWENTY-FIVE OR MORE PERSONS SUBMIT WRITTEN REQUESTS FOR A PUBLIC HEARING WITHIN THE 30-DAY COMMENT PERIOD, A HEARING WILL BE HELD ON JUNE 19, 1984, IN ACCORDANCE WITH THE NOTICE OF PUBLIC HEARING ON THESE SAME RULES PUBLISHED IN THIS *STATE REGISTER* AND MAILED TO PERSONS REGISTERED WITH THE BOARD. To verify whether a hearing will be held, please call the Board before June 19, 1984, at (612) 623-5411.

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
Room 351, 717 Delaware St. SE
Minneapolis, Minnesota 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. § 151.06, subd. 1(9).

If adopted, the proposed changes would clarify an existing rule prohibition against claims of professional superiority and repeal current prohibitions against the public promotion of prescription drugs and pharmaceutical services. A copy of the proposed changes relative to claims of professional superiority and a citation to the rule to be repealed 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 could reduce costs to consumers by affecting price competition among pharmacies. In accordance with Minn. Stat. § 14.115, the Board's consideration of any such 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 receive a copy of the final rules' changes as proposed for adoption, should submit a written statement of such request to David E. Holmstrom.

May 2, 1984

David E. Holmstrom
Executive Secretary
Minnesota Board of Pharmacy

Notice of Hearing and Notice of Intent to Cancel Hearing if Fewer Than Twenty-five Persons Request a Hearing in Response to Notice of Intent to Amend and Repeal Rules without a Hearing

NOTICE IS HEREBY GIVEN that a public hearing in the above-entitled matter will be held in Courtroom No. 12, at the Minnesota Office of Administrative Hearings, 400 Summit Bank Building, 310 South Fourth Avenue, Minneapolis, Minnesota

55415, on June 19, 1984, commencing at 9:00 a.m. PLEASE NOTE, HOWEVER, THAT THE HEARING WILL BE CANCELLED IF FEWER THAN TWENTY-FIVE PERSONS REQUEST A HEARING IN RESPONSE TO THE NOTICE OF INTENT TO AMEND AND REPEAL THE SAME RULES WITHOUT A HEARING PUBLISHED IN THIS *STATE REGISTER* AND MAILED TO PERSONS REGISTERED WITH THE BOARD OF PHARMACY. To verify whether a hearing will be held, please call the Board before June 19, 1984 at (612) 623-5411.

All interested or affected persons will have an opportunity to participate. Such persons may present their views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence presented should be pertinent to the matter at hand. Written material not submitted at the time of hearing which is to be included in the hearing record may be mailed to Peter C. Erickson, Hearing Examiner, Office of Administrative Hearings, 400 Summit Bank Building, 310 South Fourth Avenue, Minneapolis, Minnesota 55415, telephone (612) 341-7606. Unless a longer period not to exceed 20 calendar days is ordered by the Hearing Examiner at the hearing, the hearing record will remain open for the inclusion of written material for five working days after the hearing ends. The rule hearing procedure is governed by Minn. Stat. §§ 14.01-14.56 and by Minn. Rules p. 1400.200-1400.1200 (9 MCAR §§ 2.101-2.113). Questions about procedure may be directed to the Hearing Examiner.

If adopted, the proposed rules' changes would clarify an existing rule prohibition against claims of professional superiority and repeal current prohibitions against the public promotion of prescription drugs and pharmaceutical services. A copy of the proposed changes relative to claims of professional superiority and a citation to the rule to be repealed is attached to this Notice. One additional, free copy may be obtained by writing to the Board of Pharmacy, 717 Delaware Street Southeast, Room 351, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing.

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

The proposed rules' changes may be modified as a result of the rule hearing process. Those who are potentially affected in any manner by the substance of the proposed changes are therefore advised to participate in the process.

Minn. Stat. Ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11 as any individual:

(a) Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including his own travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

(b) Who spends more than $250, not including his own traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone (612) 296-5615.

Notice is hereby given that 25 days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the office of the Board of Pharmacy and at the Office of Administrative Hearings. This Statement of Need and Reasonableness will include a summary of all of the evidence which will be presented by the Board at the hearing justifying both the need for and the reasonableness of the proposed rules' changes. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Hearing Examiners at a minimal charge.

Pursuant to rules of the Office of Administrative Hearings please note that:

Any person may request notification of the date on which the Hearing Examiner's Report will be available, after which date the Board may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted (or resubmitted) to the Attorney General by the Board. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the Hearing Examiner (in the case of the Hearing Examiner's Report), or the Board (in the case of the Board's submission or resubmission to the Attorney General).

Please also note, however, that the immediately preceding procedures have been modified in accordance with 1984 legislative amendments. Under the amendments, submissions to the Attorney General are no longer made. Further, the Board shall give

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.

notice to all persons who request to be informed that the proposed rules' changes have been adopted and filed with the Secretary of State. For more information about the effects of the pertinent 1984 legislative amendments, please contact the Hearing Examiner.

Promulgation of these proposed rules' changes will not result in the expenditure of public monies by local public bodies. The proposed changes could reduce costs to consumers by affecting price competition among pharmacies. In accordance with Minn. Stat. § 14.115, the Board's consideration of any such effect on small business will be addressed in the Statement of Need and Reasonableness. Persons representing small businesses are invited to participate in the rule hearing process.

May 2, 1984

David E. Holmstrom
Executive Secretary
Minnesota Board of Pharmacy

Rules as Proposed

6800.0900 UNPROFESSIONAL CONDUCT.

Subpart 1. **Prohibited conduct.** Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. the assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated;

B. to J. [Unchanged.]

Subp. 2. [Unchanged.]

Subp. 3. [See repealer.]

Subp. 4. [Unchanged.]

REPEALER. Minnesota Rules, part 6800.0900, subpart 3 is repealed.

ADOPTED RULES

The adoption of a rule becomes effective after the requirements of Minn. Stat. § 14.13-14.28 have been met and five working days after the rule is published in the *State Register*, unless a later date is required by statutes or specified in the rule.

If an adopted rule is identical to its proposed form as previously published, a notice of adoption and a citation to its previous *State Register* publication will be printed.

If an adopted rule differs from its proposed form, language which has been deleted will be printed with strike outs and new language will be underlined, and the rule's previous *State Register* publication will be cited.

A temporary rule becomes effective upon the approval of the Attorney General as specified in Minn. Stat. § 14.33 and upon the approval of the Revisor of Statutes as specified in § 14.36. Notice of approval by the Attorney General will be published as soon as practicable, and the adopted temporary rule will be published in the manner provided for adopted rules under § 14.18.

Department of Revenue
Income Tax Division

Adopted Rules Relating to Income Tax; Reciprocity with Michigan

The rule proposed and published at *State Register*, Volume 8, Number 35, pages 1919-1921, February 27, 1984 (8 S.R. 1919) is adopted as proposed.

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of the Proposed Amendment and Repeal of Rules Concerning Prohibited Conduct and the Public Promotion of Drugs

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. §§ 14.14, subd. 2, and 14.23 and Minn. Rules p. 1400.0500 (formerly 9 MCAR § 2.104), hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendment and repeal of portions of a Board rule. The statutory authority for these proposed rule changes is contained in Minn. Stat. § 151.06, subd. 1 (9), which authorizes the Board to make and publish uniform rules and regulations to enforce the provisions of the statute. Minnesota Statutes §151.06, subd. 1 (6)(e), gives the Board the power to discipline a registrant or licensee or to deny the application of an applicant on the ground of unprofessional conduct. Minnesota Rules p. 6800.0900 (1983) (formerly 7 MCAR § 8.037) is the Board's current rule on unprofessional conduct. The Board is proposing to amend subpart 1.A. (formerly 7 MCAR § 8.037A) and to repeal subpart 3 (formerly the last paragraph of 7 MCAR § 8.037K) of the rule.

The Board is proposing to amend these portions of its unprofessional conduct rule because of concerns that they may present constitutional and antitrust problems. The two subparts are currently under investigation by the Federal Trade Commission (FTC) to determine whether they unreasonably restrain competition in the market for pharmacy services and sales of prescription drugs in

violation of section 5 of the FTC Act. The FTC has indicated that the Board's imposition or threat of imposition of sanctions such as suspension, revocation, or other discipline for the assertion or implication of professional superiority or for certain types of advertising, by a Board composed largely of fellow professionals and competitors and in the absence both of a showing that the advertising is false or deceptive and a clear mandate from the state legislature, may offend federal antitrust laws. Recent antitrust actions by the FTC against licensing board's in other states have also brought this potential problem to the attention of the Board. Finally, the Antitrust Division of the Minnesota Attorney General's Office has also expressed concerns that the questioned portions of the Board's rule may violate antitrust law. Based on these concerns, the Board believes that it is appropriate at this time to make the proposed rule changes.

This Statement of Need and Reasonableness summarizes the Board's legal research in the area, applies the results of that research in addressing the necessity and reasonableness of the specific rule changes proposed, and reviews the Board's consideration of the impact, if any, the proposed changes would have on small businesses. In addition, the Statement identifies experts invited to testify at any hearing in this matter in support of the Board's positions.1/

1/ The Board is publishing notice of the proposed adoption of the above subject rule changes both by a hearing and by noncontroversial procedures without a hearing. In the event fewer than 25 persons request a hearing within the statutorily prescribed time period, the Board will cancel the hearing and proceed noncontroversially. No testimony by experts or others will be taken should this occur. The instant Statement of Need and Reasonableness is designed to satisfy requirements for the preparation of such a document whether hearing or noncontroversial procedures are followed.

I. Recent Decisions Regarding Restrictions on Advertising by Licensed Professionals

Traditionally, licensees in the health care and legal professions have been prohibited from directly advertising to the public, but have been allowed to solicit referrals in professional journals and other intra-professional advertising. In the 1930's, the United States Supreme Court, in Semler v. Oregon State Board of Dental Examiners, 294 U.S. 608 (1934), upheld what were then rather typical advertising restrictions of the Oregon State Board of Dental Examiners. The restrictions included bans on untruthful or misleading advertising, advertising professional superiority, price advertising, and advertising of free dental work. The Court held that such state-imposed restrictions did not violate the professional's rights under the due process or equal protection clauses of the Fourteenth Amendment, nor did they unconstitutionally impair contracts since the state regulation was a reasonable exercise of the state's police power. The court noted that the legislature was concerned not only with preventing deception and insuring competency of individual practitioners, but also with preventing practices which would tend to "demoralize the profession by forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous." Id. at 612. The Court stated that the truthfulness of the claim of "professional superiority" was no defense. Rather, the legislature was entitled to consider the general effects of the prohibited practices, and if these effects facilitated unwarranted or misleading claims, the legislature could enact a general rule of prohibition even though in particular instances there might be no actual deception or misstatement. Id. at 613.

Semler has never been specifically overruled or modified by the Supreme Court and still provides strong authority for the ability of a state to impose on its professions reasonable restrictions for the protection of the public. However, recent decisions in the area of advertising have questioned whether and to what extent advertising restrictions are reasonably necessary to protect the public or whether they are in fact injurious to the public. These cases have considered this issue in light of First Amendment freedom of speech guarantees and antitrust laws.

In Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975), the Court addressed the issue of whether the state bar's enforcement of a minimum fee schedule violated the antitrust provisions of section 1 of the Sherman Act. Section 1 of the Sherman Act prohibits conspiracies in restraint of trade or commerce. The Court held that the practice of law was not exempt from this provision and that anti-competitive activities by lawyers could and in this case did exert a restraint on commerce. Although the Court held that certain anti-competitive conduct by lawyers fell within the Sherman Act, the Court specifically noted that it intended no diminution of the state's authority to regulate its professions. Id. at 793.

The issue of whether commercial speech was protected by the First Amendment was addressed in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Counsel, 425 U.S. 748 (1976). The Court held that a statute which prohibited drug price advertising and which was enforced by the Virginia State Board of Pharmacy was unconstitutional. The statute made a pharmacist guilty of unprofessional conduct if he published, advertised or promoted the amount, price, fee, premium, discount, rebate or credit term of any prescription drug. The Court

held that the First Amendment protected this type of commercial speech and that the state's essential blanket prohibition on advertising of prices of prescription drugs was unconstitutional. The Court reasoned that the free flow of commercial information in a free enterprise system is indispensable to consumer decision making. The Court suggested, however, that false or misleading advertising of drugs by pharmacists could be regulated.

In Virginia Pharmacy Board, the Court stressed that it was considering only commercial advertising by pharmacists and not other professionals such as physicians or lawyers who may render a professional service rather than dispense a standardized product. It suggested that certain kinds of advertising of professional services might enhance the possibility of confusion and deception. Id. at 773 n. 25.

In Bates v. State Bar of Arizona, 433 U.S. 350 (1977), the Court considered the issue of whether the First Amendment protection of commercial speech which was announced in Virginia Pharmacy Board applied to the advertising of routine services by lawyers. Although the Court was faced with the argument that the advertising restrictions in the Arizona Supreme Court's disciplinary rules violated the Sherman Act, it determined that the state in this case was exempt from the Sherman Act under a doctrine known as the state action exemption. However, the Court found that lawyer advertising was a form of commercial speech protected by the First Amendment and that advertising by lawyers may not be subjected to blanket suppression. Specifically, the Court held that advertising prices for routine legal services deserved First Amendment protection. The Court emphasized, however, that false, deceptive, or misleading advertising was subject to restraint. The Court also noted that although it was not addressing the issue of whether claims of quality of services could be restricted, such claims may not be

susceptible to measurement or verification and may be so likely to mislead as to warrant restriction. Id. at 383-84.

The issue of in-person solicitation was addressed in Ohralik v. Ohio State Bar Association, 436 U.S. 447 (1978). The Court held that the state bar could discipline a lawyer for in-person solicitation for pecuniary gain under circumstances which were likely to pose a danger that the state had a right to prevent. In this case, protection of the public from solicitation that involved fraud, undue influence, intimidation, and overreaching were legitimate and important state interests. Thus, the state bar's application of its disciplinary rule in this case did not violate the First and Fourteenth Amendments.

In contrast, the Court in In re Primus, 436 U.S. 412 (1978), held that prohibitions against the offering of free legal services by mail by a civil rights attorney violated the First Amendment's protection of freedom of expression and association. In this case, the Court emphasized that there was no evidence that the solicitation was misleading, overbearing, or involved any feature of deception or improper influence.

In National Society of Professional Engineers v. U.S., 435 U.S. 679 (1978), the Court considered the issue of whether a professional society's cannon of ethics which prohibited competitive bidding by its members violated section 1 of the Sherman Act. Using antitrust analysis, the Court considered whether the prohibition on competitive bidding promoted or suppressed competition. The Court noted that the Sherman Act reflects a legislative determination that competition will produce not only lower prices but also better goods and services. In this case, the Court determined that the ban on competitive bidding prevented customers from making price comparisons and thus constituted a restraint on trade. Although

the Court noted that professional services may differ significantly from other business services, and thus the nature of the competition in the services may vary, ethical norms may serve to regulate and promote competition and thus fall within antitrust analysis. Id. at 695-696.

The Supreme Court's most recent articulation of the permissible scope of professional advertising and solicitation is in In re R.M.J., 455 U.S. 191 (1982). In this case, an attorney had listed areas of practice that deviated from the language that was required by a bar advisory committee. The attorney's advertisements stated that he was licensed to practice in two states and was admitted to practice before the United States Supreme Court. The ads were distributed in the form of announcement cards in a general mailing. The Court held that the state bar's restrictions were unconstitutional since the advertisements were neither misleading nor outweighed by a substantial state interest. The Court applied a four-prong test2/ that it had set forth in Central Hudson Gas and Electric Corporation v. Public Service Commission of New York, 447 U.S. 557 (1980), a public utility advertisement case. The Court noted that only truthful advertisements relating to lawful activity would be protected by the First Amendment while misleading advertisements could be prohibited entirely. However, the Court

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2/ "In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine [1] whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask [2] whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine [3] whether the regulation directly advances the governmental interest asserted, and [4] whether it is not more extensive than is necessary to serve that interest."

Id. at 566.

warned that states could not absolutely prohibit potentially misleading information if the information could be presented in a non-deceptive manner. Although the states retain the authority to regulate non-deceptive advertising, the Central Hudson test must be satisfied.

The question of whether a professional association's ethical restrictions on advertising and solicitation violated section 5 of the Federal Trade Commission Act was at issue in American Medical Association v. FTC, 94 F.T.C. 701 (1979), aff'd 638 F.2d 443 (2d Cir. 1980), aff'd 455 U.S. 676 (1982). The FTC found that the American Medical Association (AMA) code of ethics which prohibited certain types of advertising had the effect and purpose of severely inhibiting competition among health care providers. Using a "rule of reason" analysis,3/ the FTC found that the advertising restrictions were by their very nature anti-competitive and had the effect and purpose of being anti-competitive. In balancing the pro-competitive virtues against the anti-competitive evils to determine whether the restrictions were reasonable or unreasonable, the FTC rejected the AMA's justification that the restrictions on advertising were a means of preventing fraud and deception. The FTC concluded that the restraints bore no reasonable relationship to legitimate,

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3/ Under a rule of reason analysis, the court will examine whether the imposed restraint merely regulates and thereby promotes competition or whether it suppresses or destroys competition. The court will examine the nature and purpose of the restriction and the effect the restriction has on competition. The court will then balance the pro-competitive virtues of the restraint against the anti-competitive evils. In order to withstand scrutiny, the pro-competitive virtues will be considered a valid justification only if they are not overly broad and if they promote competition, rather than merely foster other social goals. The court will also consider whether there are less restrictive alternatives available that can be substituted for the imposed restraint. See FTC v. American Medical Association 94 F.T.C. 701, 1004-1010 (1979), citing Chicago Board of Trade v. U.S., 246 US 231 (1918) and National Society of Professional Engineers v. U.S., 435 US 679 (1978).

pro-competitive concern and, because they unreasonably impeded competition, the restrictions were an unfair method of competition in violation of section 5 of the Federal Trade Commission Act. The FTC did note, however, that advertising prohibitions which were narrowly directed toward false or deceptive advertising were permissible since such restrictions could enhance competition by ensuring the communication of accurate information. However, the FTC cautioned that prohibitions must be drawn with specificity and that a total ban on advertising is too broad.

In general, it is the Board's view that the foregoing cases indicate that any restrictions on professional advertising which are not facially false, misleading or related to an unlawful activity are suspect on both constitutional and antitrust grounds. Further, a substantial burden rests with the state to demonstrate that the restrictions are not overly broad or anti-competitive.

II. The Proposed Changes in the Pharmacy Board Rule are Both Necessary and Reasonable

As previously indicated, the Board is proposing two changes in its rule on unprofessional conduct, Minn. Rules p. 6800.0900 (formerly 7 MCAR § 8.037). The Board wishes to amend subpart 1. A. (formerly 7 MCAR § 8.037A) to prohibit any material claims of professional superiority that cannot be substantiated. Secondly, the Board proposes to repeal subpart 3 of its current rule (formerly the last paragraph of 7 MCAR § 8.037K). Subpart 3 prohibits the public promotion of prescription drugs.

A. Professional Superiority

Currently, any assertion or inference in a public manner of professional superiority in the practice of pharmacy constitutes unprofessional conduct. The

Board proposes to amend this section of its unprofessional conduct rule in the following manner:

> Subpart 1. **Prohibited conduct.** Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:
>
> A. the assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy~~;~~ that cannot be substantiated;

The effect of this proposed amendment would be to allow claims of professional superiority in the practice of pharmacy if those claims could be substantiated. Any claims which could not be substantiated would constitute unprofessional conduct. It should be noted, however, that even if a claim of professional superiority were substantiated, such a claim could still be prohibited if the claim in the context in which it was used were misleading. The Board presently has authority under Minn. Rules p. 6800.0900, subp. 1.B., to regulate false, misleading, or otherwise deceptive statements.

The rule as it currently stands may present First Amendment and antitrust problems. The United States Supreme Court has not directly addressed the issue of what restrictions may be placed on claims of professional superiority. In Bates v. State Bar of Arizona, supra, the Court specifically noted that it was not addressing the issue of claims of quality of services and whether such claims could be restricted. As has been discussed, however, it did note that claims of quality of services may not be susceptible to measurement or verification and may be so likely to mislead as to warrant restriction. Although this dicta suggests sympathy with a prohibition on such advertising, claims of quality may encompass a wide range of types of advertising. Thus, stating that a pharmacist is "the best pharmacist in the city" could probably be prohibited since such a claim is probably

incapable of verification. Similarly, testimonials would likely be unprotected even if true since patients' medical conditions could not easily be compared, and a testimonial could thus be misleading. However, factual information capable of being verified even if it implies quality would appear to be arguably permissible under the standards the Court has used to evaluate commercial speech.4/

It is because the Board believes that the current rule sweeps too broadly in prohibiting all claims of professional superiority that it is proposing to amend the rule to apply only to material claims of professional superiority that cannot be substantiated. If a pharmacist's claim of professional superiority could not be substantiated, such a claim would not be permissible advertising and would constitute unprofessional conduct.

The Board is also proposing the indicated changes in its rule because of possible antitrust problems. The prohibition on any assertion or inference of professional superiority constitutes basically a ban on "self-laudatory" advertising. This type of advertising has traditionally been prohibited by licensed professionals. However, in American Medical Association v. FTC, supra, the Court held that the Association's code of ethics which included a ban on self-laudatory advertisements constituted a restraint on trade in violation of section 5 of the FTC Act.

The FTC has informed the Board that prohibitions on self-laudatory advertising may stifle competition in a number of ways. It believes that the prohibition on self-laudatory advertising prohibits discussion of superior aspects of

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4/ For a discussion of the possible permissible limits of advertising the quality of services see, Advertising Restrictions on Health Care Professionals and Lawyers: The First Amendment Limitations, 50 UMKC L.Rev. 82, 90-91 (1981); Canby and Gellhorn, Physician Advertising: The First Amendment and the Sherman Act, Duke L.J. 543, 560 (1978).

an advertiser's services in a direct manner. In the FTC's view, this results in a stifling of competition on the merits, discourages innovation, and makes it difficult for consumers to find services and prices they desire. If the advertisement is truthful, such a prohibition prevents consumers from receiving nondeceptive information which could assist them in making informed choices, thereby damaging the operation and efficiency of the competitive market.

The FTC is also concerned that the Board's ban on assertions of professional superiority may be so ambiguous as to produce effects which are broader than the Board intends. Thus, a pharmacy or pharmacist may refrain from making truthful statements regarding qualifications, experience, and performance because of fear that such statements may be construed as an inference of superiority.

Thus, because of potential First Amendment and antitrust problems, the Board is proposing that the current prohibition on claims of professional superiority be narrowed to prohibit only "material claims of professional superiority that can not be substantiated." The FTC has indicated in an advisory opinion to the American Academy of Ophthalmology, which requested an opinion on an ethical code which contained an identically worded provision, that prohibiting material claims of superiority that cannot be substantiated would not pose an unreasonable threat to competition or consumers. The opinion also indicated that such a rule is tailored to prevent false or deceptive advertising which serves to enhance competition and provide valuable consumer protection. 1983 Trade Reg. Rep. (CCH) ¶ 22,037 (June 24, 1983).

Further, the Board has chosen to use the word "material" claims to reflect the concept that information in advertising will be considered material if it

would assist a consumer in purchasing a product. Thus, any claim that would be used by a consumer in making a decision on a product or service is a material claim and must be capable of being substantiated. This concept of materiality is somewhat analogous to the FTC doctrine of material non-disclosure under which an advertisement will be deemed unfair or deceptive when it fails to disclose material information to consumers.5/ It may also be noted that the inclusion of the word material is directly supported by its use in a similar prohibition against a variety of forms of improper advertising under Minn. Stat. § 325F.67, a general consumer protection statute.

B. Public Promotion of Prescription Drugs

Under the current Board rule, the direct or indirect public promotion of prescription drugs constitutes unprofessional conduct. This rule defines public promotion to include use of the terms "cut rate," "discount," "bargain," or other terms of similar connotation in any advertisement for prescription drugs or pharmaceutical services related to prescription drugs. The Board proposes to entirely repeal this prohibition against the public promotion of prescription drugs. However, repeal of the rule would not prevent the Board from regulating prescription drug advertisements. The Board would continue to have authority under Minn. Rules p. 6800.0900, subp. 1.B, to regulate as unprofessional conduct the publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy. Thus, false, misleading, or deceptive advertisements concerning prescription drugs would still be prohibited.

5/ For discussion of the material non-disclosure and ad substantiating doctrines, see 30 DePaul L. Rev. 355, 567-576 (1981).

The Board is proposing repeal of the rule because a portion of it is inconsistent with other rules and statutes and because the entire rule may present constitutional and antitrust problems. The first sentence of Minn. Rules p. 6800.0900, subp. 3, makes the "direct or indirect public promotion of drugs requiring a prescription, narcotics, depressants, or stimulants" unprofessional conduct. On its face, this statement could be interpreted to prohibit price advertising of all prescription drugs as well as the posting of price information in a pharmacy. Currently, Minn. Stat. § 151.06, subd. 2a, requires the posting of prices for the 60 most frequently dispensed prescription drugs. In addition, Minn. Rules p. 6800.0900, subp. 2, permits advertising of all prescription drug prices except Schedule II-IV controlled substances. Thus, the ban on all direct or indirect public promotion of prescription drugs as contained in subpart 3 is contrary to another rule and the statute which permit price advertisements. Because of this inconsistency the rule should be repealed.

The prohibition on discount advertising may also be inconsistent with Minn. Stat. § 151.26 which permits a pharmacy to give senior citizens a discount. Because of the rule's breadth, a pharmacist may mistakenly believe that the advertising of such discounts is prohibited even when information provided is wholly truthful.

The repeal of the rule in its entirety is also necessary because of certain of the previously cited recent U. S. Supreme Court decisions which permit greater freedom of advertising by licensed professionals and, as a result, have limited the restrictions which licensing boards or professional associations can impose. Under these decisions, the Board's rule may be an impermissible restriction on First Amendment freedom of speech. As has been noted, for

example, in Virginia State Board of Pharmacy, supra, the Court struck down a statute which made it unprofessional conduct to publish, advertise, or promote the amount, price, fee, premium, discount, rebate, or credit term of any prescription drug. The Court held that such a blanket prohibition on advertising of prices of essentially standardized products is unconstitutional.

Similarly, in Bates, supra, the Court struck down on First Amendment grounds the advertising prohibitions on routine services. It declared that "[A]dvertising is the traditional mechanism in a free-market economy for a supplier to inform a potential purchaser of the availability and terms of exchange." Id. at 376.

Although these two decisions were narrowly applied to specific types of professional advertising, the Court, in In Re R.M.J., supra., has clearly indicated that the same principles have general application:

> Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proven that in fact such advertising is subject to abuse, the states may approve appropriate restrictions. Misleading advertising may be prohibited entirely. But the states may not place an absolute prohibition on certain types of potentially misleading information, e.g., a listing of areas of practice, if the information also may be presented in a way that is not deceptive. . . . Although the potential for deception and confusion is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to present the deception.
>
> Even when a communication is not misleading, the state retains some authority to regulate. But the state must assert a substantial interest and the interference with speech must be in proportion to the interest served. (citation omitted) Restrictions must be narrowly drawn, and the state lawfully may regulate only to the extent regulation furthers the state's substantial interest.

Id. at 203.

All of these cases send a clear message that truthful advertising by licensed professionals cannot be banned entirely. Restrictions can be placed on false, misleading or deceptive advertising. However, even when regulating in these areas, the restrictions cannot be overly broad and must go no further than necessary to prevent deception. The Board believes that a ban on all promotion of prescription drugs is overly broad and may be constitutionally impermissible. A less restrictive alternative would be to prohibit false, misleading, or deceptive advertising. This type of advertising is already prohibited under current Minn. Rules p. 6800.0900, subp. 1.B, which makes such advertising unprofessional conduct. Thus, use of terms such as "cut rate," "discount," "bargain," or other similar terms would still be prohibited if the use of such terms were false, misleading, or deceptive. In other words, if the truth of any such advertising claims could not be substantiated, the advertising pharmacist or pharmacy would be guilty of unprofessional conduct and subject to discipline.

The Board is also proposing the repeal of this rule because of possible antitrust problems. As has previously been discussed, in analyzing whether a practice constitutes a restraint of trade or a violation of the antitrust laws, the courts and the FTC have applied a rule of reason analysis. See e.g., American Medical Association v. FTC, supra. The threshold consideration before applying a rule of reason analysis is to determine whether the practice in question constitutes a restraint. Clearly, in this case, the prohibition on all direct or indirect public promotion of prescription drugs, would constitute such a restraint. Under the rule of reason analysis, the question is whether the restraint is reasonable or unreasonable. This determination is made by examining the purpose and the effect of the restraint and by balancing the pro-competitive virtues of the restraint against the anti-competitive evils.

The original purpose of the prohibition on the public promotion of drugs, now contained in Minn. Rule p. 6800.0900, subp. 3, was to prevent the unnecessary promotion of prescription drugs which would tend to increase the demand for drugs and consequently increase the probability of abuse. See, Transcript of Public Hearing in the Matter of Proposed Adoption of Revised Regulation 37K Relating to the Advertising of Prescription Drugs, April 2, 1975. At the time of the rule's adoption in its present form, the Board distinguished the public promotion of drugs from the advertising of price information. The rule permitting advertising of price information on prescription drugs, now contained in Minn. Rule p. 6800.0900, subp. 2, was adopted in response to Minn. Stat. § 151.06, subd. 2a, which allows the advertising of prescription prices. The Board termed such advertising "information advertising" since it was intended to convey scientific or price information about the product. In contrast, the Board believed that promotional advertising should be regulated since it may have a tendency to increase demand for drugs and thus increase the possibility of abuse. See, Rule Hearing Transcript, supra, at 3-8. However, in light antitrust concern, the Board has reevaluated whether such a justification is still valid.

The second factor under a rule of reason analysis is whether the regulation has an anti-competitive effect. The FTC has indicated that the prohibition on the use of terms such as "cut rate" or "discount," terms which connote lower prices, have a number of potential anti-competitive effects. The FTC believes that this restriction may impede the ability of advertisers to communicate important non-deceptive information about prices in a direct and easily understandable manner, even though the advertising of prices is permitted. The FTC believes that effective communication of price information, through the

use of descriptive terms such as "discount", is critical to the functioning of a competitive market. The prohibition on advertising of this type of information might impede competition and result in higher prices to consumers. In contrast, it is difficult to conceive of any pro-competitive effects that would result from retaining the prohibition of this type of advertising, especially when the advertising of drug price information is already permitted by both statute and rule. Thus, under an antitrust rule of reason analysis, the Board's current rule may unreasonably restrain competition for pharmacy services and the sale of prescription drugs. Because of these potential antitrust problems, and because of United States Supreme Court decisions in the area of commercial speech for licensed professionals, the Board is proposing that its prohibition on the public promotion of drugs, contained in Minn. Rules p. 6800.0900, subp. 3, be repealed. The Board will continue to regulate false, misleading, or deceptive advertising under existing Minn. Rules p. 6800.0900, subp. 1.B.

III. Small Business Impact

Whenever an agency proposes a new rule or seeks to amend an existing rule, Minn. Stat. § 14.115 (Supp. 1983) 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 subdivision 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 wholesalers. Minn. Stat. §§ 151.19 and

151.25. The Board has reviewed the impact, in any, its proposed rule changes would have on such businesses. It has discovered and is aware of no empirical studies on the subject and, therefore, does not know with a certainty whether there would be any impact or, if there would be, whether it would be positive or negative. In accordance with the FTC's position, however, it is believed that the proposed easing of existing advertising restrictions under Minn. Rules p. 6800.0900 subpart 1.A and their entire deletion under subpart 3 could result in some increased advertising of professional and pharmaceutical services and prescription drugs. If such advertising is effective, it may reasonably be assumed that the business volumes of pharmacies, manufacturers and wholesalers could expand.

At the same time, if increased advertising resulting particularly from the repeal of subpart 3 of the rule has the effect suggested by the FTC of fostering lower prescription drug prices to consumers, it is at least arguable that smaller pharmacies could be at a competitive disadvantage in geographic areas where larger and higher volume chain store pharmacies also exist. It is the Board's view, however, that any such impact would be insignificant because all pharmacies are presently required to post the prices of their 60 most frequently dispensed prescription drugs, must inform consumers of all current prescription drug prices upon request, and may already advertise the prices of all prescription drugs except Schedules II-IV. See Minn. Stat. § 151.06, subd. 2a, and Minn. Rules P.6800-0900 subp. 2 (formerly 7 MCAR § 8.037 K). Thus, consumers already have the ability to comparison shop for low-priced prescription drugs. In this respect, the proposed changes would not have any appreciable detrimental effect on small businesses. Indeed, the proposed changes could conceivably work to the competitive benefit of smaller pharmacies because of a less restrictive atmosphere for the advertising of personalized services which may not be available from the larger chain stores.

Minn. Stat. § 14.115, subd. 2 (Supp. 1983) 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 of 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.

Parts (a)-(d) of subdivision 2 are not applicable to the Board's advertising rules since they relate to compliance or reporting requirements or performance standards. The Board's advertising rules do not contain any reporting requirements, deadlines for compliance or performance standards. Subdivision 2(e) suggests exempting small businesses from any or all requirements of the rules. Because of the reasons why the Board is proposing the rule changes, the exemption of small businesses would defeat the purpose of the changes and would in fact put small businesses at a disadvantage when competing with larger businesses. As indicated previously, the Board is proposing the rule changes because of concerns that the current restrictions on advertising, including prescription drug advertising, may be an impermissible, overly broad restriction on First Amendment rights to commercial speech and violative of antitrust law. The effect of the proposed changes would be to allow greater freedom of advertising by pharmacies and other Board licensees. Since greater freedom of advertising is designed to

benefit both consumers and pharmacy businesses, there is no logical purpose achieved by exempting small pharmacies from the opportunity to advertise prescription drugs. Even if this were possible, any exemption would risk violating equal protection requirements and would restrict rather than encourage competition for antitrust purposes. Thus, the method suggested in subdivision 2(e) would not be appropriate in this situation.

IV. Expert Witnesses

Minnesota Rules p. 1400.0500 (formerly 9 MCAR § 2.104) requires that an agency include in its statement of need and reasonableness a list of any expert witnesses to be called to testify on its behalf at hearing, together with a brief summary of the expert opinion to be elicited. Should a hearing be required, the Board expects to call the following experts:

> Either Ms. Nancy Bode or Mr. Stephen Kilgriff of the Antitrust Division of the Minnesota Attorney General's Office. Ms. Bode or Mr. Kilgriff are expected to testify that, as currently constituted, the two advertising rule subparts in question do raise antitrust problems or potential problems. It is also expected that either will testify that the proposed changes in the rule would eliminate the problems.

In addition, the Board may invite an expert from the FTC's Bureau of Competition to testify. It is likewise expected that any such expert would address the antitrust difficulties presented by the Board's rule and state that the changes proposed would satisfactorily remedy the difficulties.

Minnesota State Pharmaceutical Association
Donald A. Dee, Executive Director
Health Associations Center, Suite 326 • 2221 University Avenue, SE, Minneapolis, Minnesota 55414 • (612) 378-1414

June 1, 1984





David E. Holmstrom
Executive Secretary
Minnesota Board of Pharmacy
Room 351
717 Delaware Street SE
Minneapolis, Mn. 55414

RE: PROPOSED REPEAL OF RULE CONCERNING PUBLIC PROMOTION OF DRUGS

Dear Mr. Holmstrom:

The Minnesota State Pharmaceutical Association is a 100 year old professional association of over 2,000 pharmacists and pharmacy students and represents the profession in the State of Minnesota. I am registered as a lobbyist with the State Ethical Practices Board.

In behalf of the Minnesota State Pharmaceutical Association, I would like to register opposition to the proposed action of the Minnesota Board of Pharmacy which would repeal the language in Rule 37k, subpart 3, as proposed in your Notice of Intent dated May 2, 1984. It is the position of the Minnesota State Pharmaceutical Association that the unbridled public promotion of drugs requiring a prescription is contrary to the best interests of the public health and welfare. Removing appropriate constraints as currently represented in the language of existing 37k does the public a dis-service. We ask the Board of Pharmacy to reconsider and reverse its position leading toward repeal of this rule.

As indicated in your letter of May 2, 1984, we wish to be advised of the submission of materials to the Attorney General and a copy of the final rule as proposed for adoption.

Thank you for your consideration in this matter.

Sincerely,

Donald A. Dee
Executive Director

DAD/nd

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An Affiliate of the American Pharmaceutical Association

Bureau of Competition
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

JUN 1984
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HEALTH

June 6, 1984

Mr. Robert T. Holley
Special Assistant Attorney General
State of Minnesota
136 University Park Plaza Bldg.
2829 University Avenue, S.E.
Minneapolis, MN 55414

Re: Minnesota Board of Pharmacy
File No. 841 0043

Dear Mr. Holley:

With regard to your standing invitation to appear at the June 19, 1984 rulemaking hearing, if one is required, the Bureau has not yet made any decision. It might be useful to point out, however, that we do have some comments on the proposed change in Minn. Rule p. 6800.900 subp. 1.A, which would prohibit material claims of superiority that cannot be substantiated. As the Commission advised the American Academy of Opthalmology (AAO) in its June 17, 1983 Advisory Opinion Letter, such a provision is not unlawful. However, the manner in which such a provision is enforced can be unlawful if nondeceptive claims are prohibited. The Commission therefore noted in its letter to the AAO that the substantiation requirement should not be used to prevent advertising that is not false or deceptive. Similarly, we recommend that the Board state in its explanation accompanying the amendments that it will not interpret its new regulation in such a manner as to prevent the advertising of claims that are not false or deceptive.

Sincerely

N. Scott Sacks
Attorney

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

In the Matter of the Proposed
Amendment and Repeal of
Rules Concerning Prohibited Conduct
and the Public Promotion of Drugs

AFFIDAVIT OF
MAILING NOTICE OF
SUBMISSION TO THE
ATTORNEY GENERAL

Alice D. Hummer, being first duly sworn, deposes and says:

That on the 29th day of June, 1984, in the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Submission to the Attorney General by depositing in the United States mail at said City of Minneapolis, a copy thereof, properly enveloped, with postage prepaid, on all persons and associations who requested notice that the rules in the above-entitled matter have been submitted to the Attorney General.

Alice D. Hummer

Subscribed and sworn to before me
this 29 day of June, 1984.
Kathleen M. Anderson

KATHLEEN M. ANDERSON
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSON EXPIRES MARCH 31, 1991

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed
Amendment and Repeal of
Rules Concerning Prohibited Conduct
and the Public Promotion of Drugs

NOTICE OF
SUBMISSION TO THE
ATTORNEY GENERAL

Pursuant to your request and in accordance with the Minnesota Statute, section 14.26:

PLEASE TAKE NOTICE that the above-captioned rules have been submitted to the Office of the Attorney General on this date, June 29, 1984, for review as to form and legality. Pursuant to Minn. Rules pt. 2000.0700, subp. 2 (1983), the Attorney General will not approve the rules for at least eight calendar days after receipt to allow any person or association time to comment on the legality of the rules, after which that Office will complete its review. If you desire to comment on the legality of the above-captioned rules, you should direct your comments to the Office of the Attorney General, 204 State Administration Building, 50 Sherburne Avenue, St. Paul, Minnesota 55155, telephone (612) 296-1288. Please note that the above-cited rule of the Attorney General also provides that a copy of any written comments submitted to the Attorney General must be submitted simultaneously to this agency.

If you are interested in determining what changes, if any, were made in the proposed rules changes after the publication in the State Register and before submission to the Attorney General, you may contact the undersigned at the Minnesota Board of Pharmacy, 717 Delaware Street Southeast, Room 351, Minneapolis, Minnesota 55414 (telephone: (612) 623-5411).

Dated: June 29, 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 Prohibited Conduct
and the Public Promotion of Drugs

CERTIFICATE OF
AGENCY'S MAILING LIST

I, Alice D. Hummer, Office Manager of the Minnesota Board of Pharmacy, hereby certify that I am responsible for maintaining the list of all persons who register with the Minnesota Board of Pharmacy for the purpose of receiving notices of rulemaking, pursuant to Minn. Stat. §§ 14.14, subd. 12, and 14.22, and further certify that the list attached hereto and made a part hereof constitutes the complete lists of the persons, associations, and other interested groups who, as of 8^00 a.m., this 10th day of May, 1984, have so registered with the Minnesota Board of Pharmacy.

STATE OF MINNESOTA

BOARD OF PHARMACY

Alice D. Hummer

ALICE D. HUMMER
Office Manager

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444 Lafayette Rd., Box 43208
St. Paul, MN 55164

MN Board of Dentistry
717 Delaware St. SE #338
Mpls., MN 55414

Governor's Comm. on Drug Abuse
Attn: Director
Capitol Square Bldg.
St. Paul, MN 55155

MN Board of Nursing Home Admin
717 Delaware St. SE #340
Mpls., MN 55414

Susan P. Robertson, Exec. Dir
LCRAR
Room 430 State Ofc. Bldg.
St. Paul, MN 55155

MN Board of Psychologists
717 Delaware St. SE #343
Mpls., MN 55414

MN Board of Nursing
717 Delaware St. SE #350
Mpls., MN 55414

MN Board of Veterinary Medicine
717 Delaware St. SE #337
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717 Delaware St., SE
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Pharmacy Director
United Hospitals
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John Nicolais
Route 2, Box 30
Lake City, MN 55041

CERTIFICATE OF BOARD'S

RESOLUTION ADOPTING RULES

I, J. Roger Vadheim, do hereby certify that I am a member and the Vice 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 28th day of June, 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 prohibited conduct and the public promotion of drugs be and they hereby are approved and adopted, pursuant to authority vested in us by Minn. Stat. § 151.06, subd. 1(9) and that Arnold D. Delger, President 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 my name this 28th day of June, 1984.

STATE OF MINNESOTA

BOARD OF PHARMACY

J. ROGER VADHEIM
Vice President

Attest:

Board Member

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of the Proposed
Amendment and Repeal of
Rules Concerning Prohibited Conduct
and the Public Promotion of Drugs

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 Aministrative Procedure Act, the rules of the Office of Administrative Hearings, and the rules of the Attorney General have been followed without any exceptions.

Dated: June 29, 1984

Robert T. Holley

ROBERT T. HOLLEY
Special Assistant Attorney General