

Minnesota Attorney General: Administrative Rules Proceedings

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August 20, 2018

ADMIN 1000

G 4 K Adm.

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT Attorney General

TO : David E. Holmstrom
Executive Secretary
State Board of Pharmacy

DATE: October 26, 1977



FROM : Mike Miller
Michael B. Miller
Special Assistant
Attorney General

PHONE: 296-4692

OCT 1977
RECEIVED
MINNESOTA STATE BOARD OF PHARMACY

SUBJECT: Amendments to Rules of the Board of Pharmacy

The above-captioned rules are returned herewith as the suggested revision to Pharm 36B was evidently overlooked.

MBM:mb

Enclosure

ADMIN 1000

STATE OF MINNESOTA

DEPARTMENT Attorney General

Office Memorandum

TO : David E. Holmstrom
Executive Secretary
State Board of Pharmacy

DATE: September 21, 1977

FROM : Michael B. Miller
Special Assistant
Attorney General

PHONE: 296-4692

SUBJECT: Amendments to Rules of the Board of Pharmacy

Dave,

The above-captioned rules are returned herewith for revision of the following sections:

✓ 10.D.8 - unnecessary, since the pharmacist-in-charge is not forbidden to keep any equipment by this section;

✓ 36B -"verbal" should be changed to "oral", "spoken" or "telephone";

✓ 106 - the phrase "good professional practice" is vague.

MBM:mb

Enclosure

cc: Bill Miller

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

RESOLUTION

"Resolved, that David E. Holmstrom, Secretary of the Minnesota Board of Pharmacy, be and hereby is granted the authority and directed to call a hearing for the purpose of promulgating rules of the Board of Pharmacy relating to various topics as well as perform any and all acts incidental thereto, including that without being limited to, signing an order for hearing and notice of hearing as well as completing the documents necessary for securing the appointment of a hearing examiner for all hearings."

MINNESOTA BOARD OF PHARMACY

By David E. Holmstrom

David E. Holmstrom
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

ORDER FOR HEARING

To effectively implement the powers and duties of the Minnesota Board of Pharmacy, the Board deems it necessary to consider adoption of proposed Revisions to the rules, 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 Minnesota Statute 151.06 Subd. 1 (10).

NOW THEREFORE, IT IS ORDERED this 27th day of December, 1976, that a public hearing on the proposed rules set forth in said Exhibit "A" be held in Room 105 of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota on March 18, 1977, commencing at 9:00 o'clock a.m. and continuing thereafter until all representatives of associations or other interested groups or persons have had an opportunity to be heard.

IT IS FURTHER ORDERED that notice of 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 BOARD OF PHARMACY

By _____
David E. Holmstrom
Executive Secretary

BOARD OF PHARMACY

Adopted Rules Relating to Pharmacy Licenses, Continuing Education Requirements, Pharmacy Internship and Practice and Nuclear Pharmacy

Pharm 1 Pharmacy defined. /~/~ at retail /~/~ to the consuming public

Pharm 2 License required. No person or persons shall conduct a pharmacy in the state of Minnesota unless such pharmacy is licensed by the Board of Pharmacy. A fee set by the Board and indicated in Pharm 4 shall be charged for each license.

Pharm 4 License, annual /~/~ licensing /~/~ renewal date and fees.

2nd Para. /~/~ at retail /~/~ to the consuming public ....., shall expire on /~/~ 10th /~/~ 1st day of June of each year and shall be renewed annually upon the filing of an application, therefor , on or before May 1 of each year together with a fee of $50. (Beginning January 1, 1978 said fee shall be $75). Renewal applications received after June /~/~ 10 /~/~ 1 shall be subject to a late filing fee of $25 in addition to the renewal fee.

Pharm 10 Minimum equipment required in pharmacies.

.... at least one current reference from each category:

B. 2. American Hospital /~/~ Formulatory /~/~ Formulary Service

D. 1. /~/~ Class "A" /~/~

2. /~/~ gm. /~/~ g.

3. /~/~ cc. /~/~ ml. /~/~ cc. /~/~ ml.

5. /~/~ refrigeration /~/~ refrigerator for drug storage with a thermometer.

/~/8. Other equipment deemed necessary by Pharmacist-in-charge. /~/~

Pharm 21 Pharmacist-in-charge, requirements, definition and duties.

/~/~ prescription department /~/~ pharmacy department

A. ..... and the communication of information to the public in relation to drug therapy.

C. /~/~ in accordance with Pharm 36. /~/~

/ / Pharm 118 / / G.

Pharm 25 Pharmacist licenses, annual renewal, fees, posting.

/ / March 4 / / March 1

/ / March 1 / / February 1

/ / March 4 / / March 1

/ / readily visible to the public / / within the pharmacy in which he is practicing his profession. For community pharmacies, this place shall be a place which is readily visible to the public.

Pharm 26 Licensure

A. / / 7th Edition / / current edition

C. or refunded.

Pharm 27 Continuing Education Requirements.

B. / / Rule / / rule

F. / / he / / be

H. Such records may be made available to any registrant upon request.

J. Program promotion. No reference shall be made by a program sponsor in publicizing a program that he is an "accredited program sponsor" unless he is so accredited by the American Council on Pharmaceutical Education or other reference indicating endorsement by the Board except as follows: "This program is accredited by the Minnesota Board of Pharmacy for _____ hours of continuing education credit."

Pharm 36 Compounding and dispensing.

/ / The practice of compounding and dispensing a prescription includes, but is not limited to the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Determination of brands and suppliers.

B. Receipt of verbal prescriptions.

C. Verifying the prescription order. Verification of validity and propriety must be of the original prescription order. A copy, rewritten or verbal is not acceptable.

D. Selecting the drug to be used in filling the prescription.

E. Extemporaneous compounding on an individual basis.

F. Certifying the completed prescription. In certifying and documenting the completed prescription order, the pharmacist shall include:

1. Checking of the original labeled container from which the medication was withdrawn,
2. Checking of the labeling on the prescription medication container,
3. Checking the contents of the prescription medication container and the appearance of the total product,
4. Checking the patient's medication record, when utilized, for possible therapeutic incompatibilities and the accuracy of the addition to the record of the medication dispensed,
5. Initialing of the prescription by the pharmacist performing the certification.

G. Issuing the prescription to the patient in order to assure that the patient understands the use of the medication, the cautions and the proper storage of the drug when in the professional judgment of the pharmacist such counsel is necessary.

H. Obtaining, when required by law or by the best professional practice, permission to refill from authorized prescribers of their agents, and noting on the reverse side of the prescription the following data:

1. Date refilled,
2. Name of practitioner authorizing refill (if different from original prescriber),
3. Quantity of drug dispensed (if different from the original prescription),
4. Initials of the pharmacist refilling the prescription.

I. Supervising non-pharmacist supportive personnel utilized in the performance of certain pharmacy tasks. (The nature of these tasks shall be such that they permit adequate checking by a pharmacist and do not require professional judgment. Non-pharmacist supportive personnel may be utilized in the performance of these tasks only after appropriate detailed written procedures directing

these activities have been developed by the pharmacist-in-charge and have been submitted to and approved by the board).

The ratio of supportive personnel performing allowable delegated tasks to pharmacists responsible for their supervision shall not exceed 1:1 at any time, proveded, however, that pharmacist preceptors responsible for the supervision of a pharmacist-intern may supervise one such supportive person in addition to the intern. Appropriate procedures directing the activities of non-pharmacist, personnel performing non-professional, clerical duties such as typing, looking up refills, filing prescriptions, recordkeeping, etc., are to be maintained in the pharmacy. / /

Pharm 37 Unprofessional Conduct

K. 2. / / Rules / / rules

Pharm 41 Labeling of controlled substances and certain other drugs.

/ / classified / / administered systemically

Pharm 43 Electronic data processing.

A. When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed / / only by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information to be entered and verify the prescription order at the time of entry. The identity of such pharmacist must be carried in the record. / / by a physician or a pharmacist. If orders are entered by other personnel the pharmacist must certify the accuracy of the information entered and verify the prescription order prior to the dispensing of the medication. The identity of the person entering the order and the pharmacist verifying the order must be retained in the record.

Pharm 45 Sale of poisons.

/ /registered / / licensed

/ / pharmacy / / pharmacist intern

C. The word "POISON" in letters no smaller than the largest print on the label accompanied by the "Mr. Yuk" symbol.

Pharm 106 Recordkeeping. Pharmacists handling radioactive drugs shall maintain records of acquisition and disposition of all radioactive drugs for a period of not less than two (2) years.

In the case of investigational radioactive drugs such pharmacy records shall include an investigators protocol for the preparation of radioactive drugs, a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the manufacturer- "sponsor" indicating the physician requesting the radioactive drug is a qualified investigator / / ; and such other records as good professional practice would indicate.

Additional records shall be maintained as required by any other statute or regulation of any federal or state agency. / / .

Additional records shall be maintained as required by statute or regulation of any other state or federal agency.

Pharm 116 Order for and notice of hearing.

/ /past / / post office address. / / and shall be subject to the Administrative Procedures Act Minn. Stat. 15.01 et seq., and the Rules for contested cases of the Office of Hearing Examiners, Minn. Rules HE 201-222. / / All hearings shall be conducted pursuant to Chapter 15 and the Rules for Contested Cases of the Office of Hearing Examiners.

327

David E. Holmstrom
Executive Secretary
State Board of Pharmacy

11-7-77

- Pharm 1, 2, 4, 10, 21, 25, 26, 27, 36, 37, 41, 43, 45, 106, 116

327

327

Attorney General

David E. Holmstrom
Executive Secretary
State Board of Pharmacy

October 26, 1977

Michael B. Miller
Special Assistant
Attorney General

296-4692

Amendments to Rules of the Board of Pharmacy

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MBM:mb

Enclosure

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Attorney General

David E. Holmstrom
Executive Secretary
State Board of Pharmacy

September 21, 197

Michael B. Miller
Special Assistant
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296-4692

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Enclosure

cc: Bill Miller

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD

OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules

STATEMENT OF COMPLIANCE WITH MANUAL OF RULE MAKING PROCEDURES

I, Special Assistant Attorney General William G. Miller, do hereby declare that I have examined the above-referenced rules and all related documents thereto, and that, based upon them and my personal familiarity with the applicable procedures, the Manual of Rule Making Procedures and the provisions of the Administrative Procedure Act related thereto have been followed.

Dated: 8-1, 1977.

WILLIAM G. MILLER
Special Assistant
Attorney General

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINER

FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

REPORT OF THE CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on March 18, 1977, before Peter C. Erickson, a Hearing Examiner of the State Office of Hearing Examiners, on the above-entitled matter in compliance with Minn. Stat. § 15.0412 subd. 4 (1976; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052 subd. 3 was issued to the Minnesota Board of Pharmacy (hereinafter "Board") on April 28, 1977; and

WHEREAS, the Board has now determined to adopt rules pursuant to Minn. Stat. § 15.0412 subd. 4 (1976); and

WHEREAS, the Board has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052 subd. 4 (1976), and Rule HE 107; and

WHEREAS, the Chief Hearing Examiner finds that the final proposed rules are not substantially different from those proposed at the public hearing and that the Board has met all requirements of Minn. Stat. § 15.0412 subd. 4 (1976):

NOW, THEREFORE, upon receipt of this Report, the Board has the responsibility of submitting the complete hearing record and the rules as adopted by the Board to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, subd. 4 (1976).

Dated this 3rd day of August, 1977.

/S/ Duane R. Harves

DUANE R. HARVES
Chief Hearing Examiner

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

CERTIFICATE OF RESOLUTION OF 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 20th day of October, 1976 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:

October 20, 1976

The board next entered into a rather lengthly discussion of the most recent draft of the proposed changes to the pharmacy rules and regulations. After making several minor changes in the latest draft of these proposed rules changes, the board passed the following resolution:

> "Resolved, that David E. Holmstrom, Secretary of the Minnesota Board of Pharmacy, be and hereby is granted the authority and directed to call a hearing for the purpose of promulgating rules of the Board of Pharmacy relating to various topics as well as perform any and all acts incidental thereto, including that without being limited to, signing an order for hearing and notice of hearing as well as completing the documents necessary for securing the appointment of a hearing examiner for all hearings."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 14th day of July, 1977.

Alice D. Hummer

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

David E. Holmstrom
Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

CERTIFICATE OF BOARDS ADOPTION OF RULES 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 29th day of April, 1975. 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.

The board next embarked on a rather lengthy discussion of the hearing examiners report on the proposed rules for which a public hearing was held on March 16. After discussing the amendments to the proposed rules suggested by the hearing examiner, Mrs. Kitty Alcott moved and Mrs. Rosetta Stark seconded the following Resolution:

> "Resolved, that the rules relating to Pharmacy Practice, License fees and Continuing Education identified as Pharm 1-120 which were considered at a public hearing held on the 18th day of March, 1977, are found to be reasonable, necessary and supported by the evidence contained in the record, and are hereby approved and adopted, pursuant to authority vested in the Board of Pharmacy by Minn. Stat. 151 and 152 and that David E. Holmstrom, Executive Secretary of the Board, be and hereby is authorized to sign an order adopting those rules.
> Be it further resolved that the Report of Hearing Examiner relating to this matter be and hereby is expressly adopted by the Board as its own."

Motion passed.

David E. Holmstrom
Executive Secretary

Subscribed and sworn to before me
this 14th day of July 1977.

Alice D. Hummer

Notary Public,
Ramsey County, Minnesota
My Commission expires 11-18-81.

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

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

FINDINGS OF FACT

The above-entitled matter came on for hearing before the Minnesota State Board of Pharmacy on the 18th day of March, 1977, at 9:00 a.m. in The Minnesota Department of Health Building after proper notice required by M.S. in 1976, Sec. 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, and upon the report of the Hearing Examiner the Board does adopt as their own the Findings of Fact Prepared and Presented to the Board by the Hearing Examiner.

MINNESOTA BOARD OF PHARMACY

David C. Katzenstein

Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

ORDER ADOPTING RULES

The above-entitled matter came on for hearing before the Minnesota Board of Pharmacy on the 18th day of March, 1977, at 9:00 A.M. in the Minnesota Department of Health Building, Minneapolis, Minnesota, after proper notice required by M.S. 1976, 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, 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 Rules of the Minnesota Board of Pharmacy are adopted this 15th day of June, 1977, pursuant to authority vested in me by the Board.

MINNESOTA BOARD OF PHARMACY

David E. Hathaway

Executive Secretary

RECEIVED
FEB 23 1977
OFFICE OF HEARING
EXAMINERS

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarifications of Existing Rules.

STATEMENT OF FACTS ESTABLISHING REASONABLENESS OF AMENDMENTS

The Minnesota Board of Pharmacy (herein after "Board"), pursuant to Minn. Stat. 15.0412 Subd. 4 (Supplement 1975), hereby affirmatively presents facts establishing the reasonableness and justifying the adoption of the above captioned amendments to the Board's rules. The need and statutory authority for the proposed amendments is set forth in the Statement of Need.

1. Minn. Rules Pharm 1, 2, and 3 are reorganized and clarified pursuant to requirements found in Minn. Laws 1976, Chapter 222 which makes certain changes in terminology necessary and clarifies and distinguishes between "registration" and "licensure". This same legislation also deletes the word "State" from the title of this agency. These proposed actions to assist in clarifying the rules are reasonable ones.

2. As explained in the Statement of Need, the reason for adopting fees by rules resulted from legislative action repealing statutory fees and authorizing their establishment by rule. The guide for the amount of the fees is stated in Minn. Laws 1976, Chapter 222, Section 3 which provides that "total fee . . . will as closely as possible equal anticipated expenditures." The estimated revenue based on the fees here proposed will come within just a few dollars of anticipated expenditures for fiscal years 1978 and 1979.

Until fiscal year 1977 the Board operated through a revolving or dedicated fund. All moneys collected by the Board where available to it for its use. Effective with fiscal year 1977, the legislature has required the Board to

Ex # 8

seek its operating funds from it in the form of an appropriation. The fees collected by the Board, then, are deposited in the general fund. However, under Minn. Laws 1975, Chapter 434 the Board will not have access to the total appropriation unless its anticipated revenue fees will at least equal the appropriation for the biennium. In view of the above referenced legislative and fiscal limitations, the fees proposed in Pharm 4 are reasonable since their total, when taken with the fees found in Pharm 25, 26, 28, and 61, will as closely as possible equal anticipated expenditures. One particular fee requires an explanation. The Board has registered pharmacist-interns for several years but the regulatory process with respect to them was relatively minimal. No registration fee was ever charged. In recent years the Board has developed a competency based internship program including pre-test and post-test examinations based on competency based objectives of the internship experience. The restructuring of a practical experience program cannot be accepted as an end in itself; therefore, both program evaluation and intern evaluation must be continuous. Only in this manner can the student participate in a meaningful, content valid practical experience program. The administrative costs associated with the internship program have risen fairly dramatically with the advent of these valuable changes in the internship program. It is no longer feasible, therefore, that the costs of the internship program be passed on to other board licensees. For these reasons, charging pharmacy interns a one time fee for registration as provided for in most other states throughout the country and as set forth in proposed Pharm 61 is reasonable and justified.

Finally, Proposed Pharm 4 is not in reality a new rule but is merely a rewritten version of the previously existing Pharm 4.

3. Minn. Rules Pharm 8 has required that any person contemplating a change in location, demension, or security of a licensed pharmacy notify the Board setting forth such changes but did nothing to indicate the time frame

associated with such notice. The proposed actions associated with Pharm 8 would indicate that any remodeling, changes of security, or changes of location be reported to the Board at least 60 days prior to such proposed change so that the Board may have a reasonable opportunity to respond to such proposals. The 60 day notice period when taken with the 30 day response period placed upon the Board is designed to reasonably protect the Board and the licensee.

4. Minn Rules Pharm 9 was repealed through the Board action in 1959 and has remained unused since that time. The remaining sections of Chapter 1 thus are renumbered to utilize consecutive numbers.

5. Minn Rules Pharm 10, previously Pharm 11, remains basically unchanged and retains the principle that the public has the right to an assurance that each pharmacy will have the equipment and library materials necessary to meet at least a minimum standard of practice.

Through experience, the Board has learned that the most frequently reoccurring problems associated with this aspect of pharmacy practice revolves round the state and federal laws, rules, and standards applicable to pharmacy practice. As a result, the Board is requiring each pharmacy to maintain copies of the laws and regulations of the state and a copy of the US Pharmacopia. These items were previously optional.

6. Minn Rules Pharm 11, previously Pharm 12 is not actually being repealed. The substance of the rule, up-dated to reflect the present state of pharmacy practice, is being retained in Pharm 11.

7. In Minn Rules Pharm 25, as in 4, the Board has adopted an annual license renewal cycle which is identical to that which was specified in statute. Also, as is noted previously, the annual renewal of licenses is necessary since the Board's operating income is tied to the revenue raised by fees with the largest amounts coming through the renewal process. In addition, the statutory

repeal of this renewal basis does not mean that the Legislature intended that the Board adopt some other basis for license renewals. Over the past several years the legislature has deleted statutory licensing fee provisions and procedures and has authorized the respective administrative agencies to establish them by rule. Authorizing the administrative agencies to promulgate the rules in these areas permits their adjustment on a more feasible and flexible basis as the need arises. Further, Minn Stat 15.0412, Subd. 3 requires the Board to promulgate its procedures in rule form.

8. The qualification of applicants for examination was found in Minn Stat 151.10. The Board has to have a process which is consistantly applied to every applicant by which it can determine whether or not an applicant is qualified to sit for the licensure examination. Basic information is obtained from an application form. In addition, the applicant must demonstrate that he has satisfactorily completed an accredited training program at a college of pharmacy or department of pharmacy of a university approved by the Board. The key to obtaining Board approval of a curriculum is that it meet at least minimum standards and provide academically sound training. It is obviously reasonable for the Board to require all applicants to have received such training prior to sitting for the licensure examination.

9. A Continuing Pharmacy Education requirement had been specified in detail in Minn Stat 151.13. However, in 1976 the Legislature repealed many sections of Minn Stat 151.13 and provided in lieu thereof a general provision authorizing all licensing boards to implement a Continuing Education requirement. Minn Laws 1976, Chapter 222, Section 7. (Current Continuing Pharmacy Education provisions remain in effect until superseded by Board Rule. Minn Laws 1976, Chapter 222, Section 210). The Board, therefore, is proposing an amendment of Pharm 27 to specify in detail all aspects of the Continuing Pharmacy Education requirement.

The Board has decided under proposed Rule Pharm 27 to continue rather than repeal its Continuing Pharmacy Education requirement, the latter being an option under Section 7 of Chapter 222. There are a number of reasons for this:

(a) The public is demanding and has the right to expect that a professional will keep current with the changes and advancements in knowledge concerning pharmacy.

(b) While a licensee could probably practice for years without keeping abreast of advancements in the field and still probably practice sound pharmacy, his patients would be deprived of receiving the benefits of such advancements. It is recognized that Continuing Pharmacy Education does not insure that the licensee will actually learn, but it does at least provide exposure to learning opportunities. This is a step in the right direction.

(c) Prior to institution of the mandatory Continuing Pharmacy Education Program, licenses and registrations were granted "for life" unless the Board could prove that a licensee could no longer be permitted to practice. There was no affirmative obligation placed upon the licensee as a condition to maintain authority to practice. The Continuing Pharmacy Education requirement provides at least some periodic assurance that pharmacists have met a minimum standard for keeping current or for increasing their professional knowledge.

The two year Continuing Education reporting cycle is continued under Pharm 27. It is considered preferable to a shorter cycle as the longer cycle protects the individual licensee from undue hardship in meeting the requirement because of temporary illness, disablement or other valid reasons.

The 30 hour, two year Continuing Pharmacy Education requirement for all pharmacists is reasonable. It averages out to 15 hours a year which is not in any way overburdensome.

10. Reciprocity has long been a method of licensure available to pharmacists from other states who seek licensure in Minnesota. Minnesota enjoys reciprocity agreements with all states except California, Florida, and Hawaii.

The National Association of Boards of Pharmacy, which acts as a clearing house for reciprocity candidates, has, in its bylaws, general reciprocity requirements which all candidates for reciprocity between any state must meet and suggests that the basics of these reciprocity guidelines be incorporated into the policies held by each of the individual member states. The board developed reciprocity guidelines based on the general provisions of the NABP bylaws some years ago and have been applying those guidelines to candidates for reciprocity for a number of years. In that Minn Stat 15.0412, Subd. 3 requires the Board to promulgate all of its procedures and guidelines in rule form, the reciprocity guidelines have been incorporated into Pharm 28. The fee for reciprocity set forth in Section A of Pharm 28 is a reasonable fee and is in line with the reciprocity fees charged by a good proportion of the other member states participating in the preciprocity agreement of NABP.

11. During the 1976 legislative session interest was expressed by certain members of the legislature in the loosening of the requirements of Pharm 31 dealing with the use of vending machines for the distribution of legend drugs. Pursuant to conversations with these legislators, the amendments proposed for Rule 31 were developed. These changes would allow the use of vending machines for legend drugs in a hospital setting only, only when the hospital has a licensed pharmacy on the premises and would limit the utilization of such a device to hours other than the regular pharmacy hours. The pharmacist would retain control over the storage and recordkeeping of the drugs involved in the vending machine device

and would be responsible for seeing that all of the state and federal laws regarding the distribution of legend drugs are complied with. By requiring that the pharmacist retain control over the operation of the vending machine device, patient safety can be assured through the maintenance of adequate labeling, recordkeeping, and storage of the medication. Likewise, undetected diversion of medications from the device should be protected against through the controls being placed in the hands of the pharmacist. These proposed changes are reasonable in that they allow additional flexibility in the drug distribution system of small hospitals and at the same time retain pharmacy control over the vital aspects of medication delivery.

12. The changes in Pharm 33 dealing with mail order sale of prescription medications are minimal and are simply aimed at clarifying somewhat the requirements of the section and plugging a loophole found in the existing rule. The changes here are reasonable and they do not involve any changes in present pharmacy practice.

13. Approximately two years ago the board established an advisory committee to look into the feasibility of changing the rules of the board to enable pharmacists to utilized pharmacy technicians in an expanded role thus freeing themselves to become involved in the more clinical aspects of pharmacy practice. The committee, made up of pharmacy practitioners from hospital, community, and chain pharmacies met regularly for over a year before submitting a recommendation to the Board that the Board consider allowing an expanded role for pharmacy technicians. In that Rule 36 defines compounding and dispensing and limits the practice of compounding and dispensing a prescription to a pharmacist, assistant pharmacist, or pharmacist intern, the Board feels, and correctly so, that rather than attempting to spell out the duties that are allowed by a pharmacy technician, the more reasonable approach would be to redefine the act of compounding and dispensing which sets forth the acts that

a pharmacist is required to do. The acts which the board feels must be performed by a pharmacist in the preparation of a prescription in order to adequately safeguard the public are set forth in Rule 36.

The Board feels that, in light of the recently enacted drug product selection legislation and other changes and advancements in the scope of pharmacy practice, the determination of the brands and suppliers of medication to be utilized by a pharmacy must be kept in the hands of the pharmacist. Minn Stat 151.21 in fact indicates that the pharmacist must utilize his professional judgment in determining when two generically equivalent products are therapeutically equivalent. This mandate would tend to require that the pharmacist himself select the brands of the various products he intends to stock in his pharmacy. This is accomplished in Pharm 36 A.

Pharmacists are currently required to personally receive oral prescriptions from practitioners. The Board feels that the public safety would demand that this be so. It is continued in Pharm 36 B.

The pharmacist alone is adequately trained to evaluate and verify the prescription order. In order for the pharmacist to adequately safeguard the patient he must interpret the original of the physicians order. A copy which has been transcribed by another individual may contain errors of transcription and should not be accepted. These requirements are found in Pharm 36 C.

The Board feels that, again, only the pharmacist, has been adequately trained to make an informed choice of the drug to be used in filling any prescription. This original selection is obviously of the most vital importance in preparing a correctly compounded prescription. This selecting is required in Pharm 36 D.

The pharmacist has traditionally been personally responsible for the extemporaneous compounding of individual prescriptions. This requirement is contained in Pharm 36 E.

Pharm 36 F contains the basics of the changes which allow an expanded role to both pharmacist and pharmacy supportive personnel. The pharmacist is required only to certify and document his certification of the completed prescription. This certification must contain certain steps needed to safeguard the patient against preventable problems associated with the use of his prescription. These steps involve:

1. checking of the original labeled container from which the medication was withdrawn. Only the pharmacist has been adequately trained to interpret the physicians order and determine, by comparing this with the manufacturers container from which the medication was withdrawn, that the correct ingredients have been placed in the patients medication container.
2. checking the labeling on the prescription container. While a pharmacy supportive person may be utilized with proper training by the pharmacist to transfer directions from the physicians order to the prescription label, the pharmacist remains the final responsible party and the final preventative measure capable of preventing a misunderstood or mistyped direction from causing harm to a patient. The pharmacist must check the labeling.
3. checking the contents of the prescription medication container and the appearance of the total product. The check is the final safeguard the patient has to protect him from being harmed by receiving an erroneous prescription. There should be no question that the pharmacist personally must be involved here. Patient safety requires that this final check be non-delegable. Obviously, it is reasonable to require this check be done by the pharmacist.

4. checking the patients medication record, when utilized, for possible therapeutic incompatibilities and the accuracy of the addition to the record of the medication dispensed. This section is not, repeat not, making the maintenance of patient medication records (patient profiles) mandatory but is simply making the procedure of reviewing the patient medication profile, when this is done in any pharmacy, a procedure that must be accomplished by the pharmacist and not a delegatee. Only pharmacists have the education and training necessary to enable one to recognize therapeutic, chemical or physical incompatibilities in drug regimens of their patients. This is not something that can be done by a lay person. Even the pharmacist may be hindered in this if the patient is seeing more than one doctor and more than one pharmacy but many pharmacists are attempting to provide this service to their patients.

The maintenance of patient profile systems is probably established as the standard of care by which a pharmacist would be judged in a malpractice situation. At least three states (Maine, New Jersey and Washington) have made maintenance of patient profiles mandatory. These rules are not attempting to make the maintenance of these patient care systems mandatory nor are they attempting to spell out how the systems are to be utilized or what information must be included in the system when the profiles are kept by a pharmacy. These rules are simply stating that when patient profile systems are maintained and when they are utilized for the purpose of attempting to further patient safety through the prevention of drug interactions and allergic responses, as opposed to being utilized simply for income tax records, the pharmacist must be the person directly involved in

determining when a clinically significant anomaly in a patients therapy exists through checking with the profile before the medication reaches the patient and assuring that the medication dispensed is properly entered on the profile to keep it up-to-date. This being the case, this rule is certainly reasonable in its scope.

5. initialing of the prescription by the pharmacist performing the certification. In order that any pharmacist in a multiple pharmacist pharmacy and in order that the Board may be able to determine which pharmacist is responsible for the filling of any prescription in the event of a complaint or an investigation the initials of the pharmacist so responsible should be placed on the prescription. This is not of any great burden to the pharmacist involved and is quite a reasonable requirement.

Pharm 36 G requires the pharmacist to become personally involved in the issuance of the prescription to the patient only when in his professional judgment counseling, or an addition to the label information, regarding the use or storage of the patients medication is called for. In that the professional judgment of the pharmacist involved is the determining factor in when special counsel should be given this section is most reasonable.

Recording certain information on the reverse side of prescriptions at the time of refilling such prescriptions has long been a requirement. This is not changed in section H.

In order that the Board might more readily be able to assure the public that non-pharmacist supportive personnel are being properly utilized, section I requires the pharmacist-

in-charge of any pharmacy which intends to utilize such persons to develop and present to the Board for approval a "job description" or procedure manual which sets forth the tasks proposed for these persons. Upon approval by the Board, supportive personnel may be utilized according to the descriptions submitted. This is not an unreasonable requirement of those seeking to utilize supportive personnel.

This rule limits the use of pharmacy technicians to 1:1 ratio with pharmacists responsible for their supervision and requires the pharmacists wishing to utilize pharmacy technicians in tasks which were previously reserved to the pharmacist to prepare written procedures directing these activities and submit them to the board for approval and review. The functions which were traditionally those of pharmacy supportive personnel such as clerical type duties remains such and are not subject to the above provisions and limitations.

14. Pharm 37 involves primarily a relettering of the section to conform with the standardized outline form of rules being instituted statewide but does contain some changes in sections E and L. Section E previously concerns the discrimination in any manner between patients or groups of patients for reasons of religion, race, creed, color, sex or national origin. To this group was added the category of "age". Section L, which is a new section, declares it to be unprofessional conduct to sell, give away, or otherwise expose of various accessories or chemicals which the pharmacist knows or should know are destined for use in illegal activities. In light of the problems found in illegal drug trafficing it is not unreasonable to make it plain to pharmacists that aiding and abetting this illegal activity in any manner is unprofessional conduct.

15. Pharm 40 is again basically a relettering process with the exception of new section G which indicates that in addition to the previously existing requirements for providing information on the label of prescription drugs, the name of

the manufacturer of the finished dosage form of the drug must be included. This requirement was added as a result of a provision in the Minnesota Drug Product Selection Act found in Minn Laws 1975, Chapter 101. Among other things, this statute requires that pharmacists place the name of the manufacturer of the finished dosage form of the drug on the label of each prescription container. The Board is acting in the interest of the pharmacist in placing this labeling requirement in juxtaposition with the other labeling requirements in Pharm 40, as it will hopefully avoid confusion which might otherwise occur.

16. Pharm 41 is also included as a result of legislation passed in the 1975 legislative session. Minn Laws 1975, Chapter 356 as amended by Minn Laws 1976, Chapter 338, Section 5, requires certain warning information to be placed on the labels of controlled substances and certain other drugs dispensed by a pharmacist when the use of such a drug either alone or in combination with alcoholic beverages may impair the ability of the user to operate a motor vehicle. Pharm 41 indicates to the pharmacist the wording to be used in this cautionary statement and indicates the drugs and situations which would require the warning.

17. In recent years the electronic data processing equipment has become more and more prevalent in recordkeeping and other functions in the pharmacy profession. Up until this time, no guidelines for the use of these pieces of equipment have been established and pharmacists were left to their own devices in determining whether the recordkeeping functions of their EDP equipment was sufficient to meet the requirements of the Board and of certain federal agencies such as DEA. Within the past year NABP developed a set of guidelines for the use of electronic data processing equipment in pharmacies. Recently, DEA accepted NABP's guidelines indicating that if any pharmacy installed EDP equipment which met these guidelines, the recordkeeping requirements for DEA could be met. Pharm 43 is very closely parellel to the guidelines that NABP developed, guidelines which were acceptable to DEA in meeting the federal recordkeeping requirements.

The Board believes it is acting quite reasonably in determining that electronic data processing equipment meeting the same guidelines will also meet the record-keeping requirements of the Board.

18. Pharm 44, 45, and 46 attempt to clarify the labeling and recordkeeping requirements pharmacists are subject to when dealing with poisonous substances. Considerable confusion has existed for several years over the requirements set forth in the various statutes dealing with poisons and other hazardous substances. In Pharm 44 through 46 an attempt has been made to simplify and clarify the requirements placed on a pharmacist when handling poisonous substances. No new requirements were placed on the pharmacist that were not previously placed on him by statute but the various statutory provisions were congealed and simplified into these three rules.

19. Minn Laws 1976, Chapter 338 caused several drugs previously classified as controlled substances by the board in previously existing Rule 51 to be included in Chapter 152 of the Minnesota Statutes. Part of this legislative package included five controlled substances not previously set forth in Pharm 51. These drugs are included herein to make identical the provisions of Pharm 51 and MS 152. All of the additions are in Schedule I and thus would not affect pharmacy practitioners acting within the scope of their practices.

20. Pharm 61 deals with internship and with the exception of a few minor changes, results in simply a renumbering process once again. The new provisions include the establishment of a $20 registration fee which is discussed supra, provisions dealing with persons who terminate their efforts toward obtaining a pharmacy degree and persons who falsely assume the identity of an intern. All of these provisions are reasonable and quite clear.

21. Chapter 8, Pharm 101 to 110 deals with the nuclear pharmacy. Nuclear pharmacy is a newly developing field of specialization in pharmacy and

one which very few states have addressed as to control. Rules 101 through 110 were developed with the help of input from the states of Arizona and California which have addressed the problem of nuclear pharmacy and the protection of the public attendant thereto, and with input from the one and only nuclear pharmacist currently operating in Minnesota.

These rules are reasonably established to protect the public from the dangers inherent in the handling of radioactive materials while at the same time allowing the development of the specialty field of nuclear pharmacy without undue restrictions.

22. Chapter 9, deals with the Board's procedures involving pleading and practice and are essentially a restatement of the requirements for a contested case hearing found in the Minnesota Administrative Procedures Act. In that most pharmacists in the state do not have ready access to complete set of the statutes, reiterating the procedures and requirements that they may come into contact with in the rules, a copy of which will be required to be kept in each pharmacy pursuant to Rule 10, will aid the pharmacist in knowing what to expect in his dealings with the Board.

In summary then, the Board is confident that these proposed rules will indeed be found to be quite reasonable and relatively noncontroversial.

MINNESOTA BOARD OF PHARMACY

David E. Holmstrom

David E. Holmstrom
Executive Secretary

RECEIVED
FEB 28 1977
OFFICE OF HEARING EXAMINERS

STATE OF MINNESOTA

MINNESOTA BOARD OF PHARMACY

COUNTY OF HENNEPIN

In the matter of the proposed adoption of revised rules relating to licensure, fees, continuing education, pharmacy practice, nuclear pharmacy, disciplinary actions, and clarification of existing rules.

STATEMENT OF NEED

The above captioned rules are both amendments to existing rules and new rules of the Minnesota Board of Pharmacy. The last time a general revision of the above captioned rules took place was on March 14, 1969.

The need to adopt these proposed changes to the Board's existing rules arises primarily because of the enactment of certain legislation during the 1976 legislative session, to-wit, Minn. Laws 1976, ch 222, and because of advances and changes in the profession of pharmacy which must be addressed. Many of the rule changes are for clarification only and do not change the substance of existing rules. Other rules changes reflect changes in the profession and may, in a few instances, involve substantive changes in existing rules. Each of these will be explained below.

1. The proposed amendments to Minn. Rules Pharm 1-4 are solely for clarification and reorganizational purposes. Since the purpose of rule-making is to inform those affected by the rules of the standards applicable to them, it is always desirable to make any changes which will render the rules more comprehensible. In addition, Minn. Laws 1976, ch. 222 requires making changes between "registration" and "licensure" and in deleting the word "state" from the title of the agency.

Exh # 6

2. Minn Laws 1976, ch. 222 repeals all existing statutory fees presently charged by the Board and requires that the Board establish its fees via the rule-making procedure. The effective date of the repeal is such time as fees established by rule take effect. The need for the proposed changes in Pharm 4 and Pharm 25 arises not only because of the repeal of the statutory fees but also because of other statutory mandates. Pursuant to Minn Laws 1976, ch. 222, such fees shall be adjusted in "... a sufficient amount so that the total fees collected ... will as closely as possible equal anticipated expenditures." This provision is particulary meaningful in light of the provision in the appropriations bill for the Board which prohibits the "...allotment, encumbrance, or expenditure of any funds appropriated in this section in excess of the anticipated biennial revenues." Minn Laws 1975, ch. 434 sec. 4.

Minn Laws 1976, ch. 222 authorizes the Board's adjustment of fees which it is empowered to assess. The fees being proposed and the specific statutory provision for their adoption are as follows:

(a) Pharm 4 - Pharmacy license: Minn Stat 151.19, as amended by Minn Laws 1976, ch. 222.

(b) Pharm 4 - Wholesaler license: Minn Stat 151.25, as amended by Minn Laws 1976, ch. 222.

(c) Pharm 4 - Manufacturers license: Minn Stat 151.25, as amended by Minn Laws 1976, ch. 222.

(d) Pharm 25 - Pharmacist license: Minn Stat 151.13, as amended.

(e) Pharm 26 - Examination fee for pharmacist applicants; Minn Stat 151.07, as amended.

(f) Pharm 28 - Reciprocity application fee; Minn Stat 151.12 as amended.

(g) Pharm - Assistant Pharmacist registration fee; Minn Stat 151.11

(h) Pharm - Reinstatement fee; Minn Stat 151.06 subd 4

3. Pharm 26-28 address examination, continuing education and reciprocity requirements. These changes put in to rule form requirements that heretofore had been "Board policy" requirements thus aiding licenciates and potential licenciates in knowing exactly what is expected of them.

4. In Minn Stat 151.06 subd 1 the Board is required and empowered to regulate the practice of pharmacy. Since one purpose behind the utilization of non-pharmacists in the performance of certain pharmacy functions is to free the pharmacist to perform the tasks for which a greater degree of expertise is required, it is necessary to redefine the process of compounding and dispensing which is restricted to pharmacists personally thereby allowing an expanded role for auxilliary personnel while still protecting the public. This is the reason behind the changes in Pharm 21, 31, 36 and 43.

5. Minn Stat 151.13 subd 2, which placed a continuing education requirement upon pharmacist was repealed by Minn Laws 1976, ch. 222. Section 7 of chapter 222 contains new legislative authority for the Board to establish continuing pharmacy education requirements by rule.

While it is not mandatory for the Board to establish a continuing education requirement, the Board apts to do so since it had established such under M.S. 151.13 and since continuing education provides some periodic assurance that pharmacists have met a minimum standard for keeping current or for increasing their professional knowledge. The board sees an obligation to the public to take appropriate action (continuing education) to offer an assurance that the competancy of practicing pharmacists remain as high as possible.

Besides the existence of a need to establish the requirement itself, the details of the requirement, the procedures and criteria for obtaining approval of programs, the process by which course credit is recorded, the consequences of failure to comply with the requirement, and other aspects of continuing pharmacy education, whether they be procedural or substantive in nature, need to be specified in rule since they directly affect the rights of or procedures available to licensees or the public. The proposed amendments to Pharm 27 are intended to satisfy that need.

6. Minn Laws 1976, ch. 338 sec. 5 calls on the Board to require by rule that notice be prominently set fourth on the label or container of any drug which, when used alone or in conjunction with alcohol, may impair the users ability to operate a motor vehicle. The boards response to this mandate is found in Pharm 41.

7. Nuclear Pharmacy is a newly developing area of pharmacy practice which heretofore was unregulated in Minnesota as it still is many other states. In light of the obvious dangers involved in the handling and transporting of radioactive substances the Board has proposed several rules dealing with Nuclear Pharmacy and the handling of radioactive pharmaceuticals. These rules are found in Pharm 101-106.

8. Lastly, the Board has become cognizant of the fact that most pharmacists called before it for disciplinary matters are unaware of the provisions of the Administrative Procedures Act (Minn Stat 15.052 subd 4) and has described the essence of the statutes and rules of the Office of Hearing Examiners controlling contested case proceedings in rules Pharm 111 etc. sec.

STATE OF MINNESOTA
BOARD OF PHARMACY

David E. Holmstrom
Executive Secretary

STATE OF MINNESOTA

MINNESOTA BOARD OF PHARMACY

COUNTY OF HENNEPIN

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.

AFFIDAVIT

RECEIVED
FEB 25 1977
OFFICE OF HEARING EXAMINERS

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

(1) that he is the Secretary of the Minnesota Board of Pharmacy.

(2) that on the 17th day of January, 1977, he went to 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 M.S. 15.0412.

(3) that on the ~~17th~~ 10th day of ~~January~~ February, 1977, 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 10th day of Feb. at the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Hearing marked Exhibit "B" and made a part hereof, by depositing in the United States mail at said City of Minneapolis a true and correct copy thereof and made available a copy of the proposed regulations, 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 22nd day of February, 1977

Alice D. Hummer
Notary Public

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

Bd Ex #4

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarifications of Existing Rules.

CERTIFICATION BY SECRETARY OF STATE

RECEIVED
FEB 25 1977
OFFICE OF HEARING EXAMINERS

I hereby certify that the attached 505 labels and sheet constitute the complete list of persons, associations, and other interested groups who as of 11:30 o'clock p.m., this 18th day of ~~January,~~ February 1977, have requested pursuant to M.S. 1975, Section 15.0412, that their names be placed on file with the Secretary of State for the purpose of receiving notice of public hearings on proposed rules on the subject captioned above.

SECRETARY OF STATE

Joan Anderson Growe

By Cecil Dixon

AR 94 #3

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

RECEIVED
FEB 23 1977
OFFICE OF HEARING
EXAMINERS

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarifications of Existing Rules.

NOTICE OF HEARING

NOTICE IS HEREBY GIVEN that a public hearing in the above-entitled matter will be held in the Board Room, Minnesota Department of Health Building, 717 Delaware Street, SE, Minneapolis, Minnesota, on March 18 , 1977, commencing at 9:00 o'clock a.m. and continuing until all persons have had an opportunity to be heard.

All interested or affected persons will have an opportunity to participate. Statements may be made orally and written materials may be submitted at the hearing. In addition, written materials may be submitted by mail to Peter Erickson , Hearing Examiner, Office of Hearing Examiners, Room 300, 1745 University Avenue, St. Paul, Minnesota (Telephone: 612-296-8112) either before the hearing or within twenty (20) days after the close of the hearing.

Copies of the proposed rules are now available and one free copy may be obtained by writing to David E. Holmstrom, Minnesota Board of Pharmacy, 717 Delaware Street, SE, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing. The agency's authority to promulgate the proposed rules is contained in Minn. Stat. 151.06 Subd. 1(10). A "Statement of Need" explaining why the agency feels the proposed rules are necessary and a "Statement of Evidence" outlining the testimony they will be introducing will be filed with the Hearing Examiner's Office at least twenty-five (25) days prior to the hearing and will be available there for public inspection.

Please be advised that pursuant to Minn. Stat. S10A.01, Subd. 11 (1974) any individual engaged for pay or other consideration for the purpose of representing persons or associations attempting to influence administrative action, such as the promulgation of these rules, must register with the State Ethics Commission as a lobbyist with five (5) days of the commencement of such activity by the individual.

Dated: December 28, 1976

MINNESOTA BOARD OF PHARMACY

David E. Holmstrom
Secretary

Bds Ex #2

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Licensure, Fees, Continuing Education, Pharmacy Practice, Nuclear Pharmacy, Disciplinary Actions and Clarification of Existing Rules.	REPORT OF HEARING EXAMINER

The above-entitled matter came on for hearing before Hearing Examiner Peter C. Erickson of the Minnesota Office of Hearing Examiners at 9:30 a.m. on Friday, March 18, 1977 in the Board Room of the Department of Health Building, Minneapolis, Minnesota.

William Miller, Special Assistant Attorney General, Department of Health Building, appeared as counsel for the Board of Pharmacy. Four members of the Board were present at the hearing. The hearing continued until all interested groups or persons had an opportunity to be heard concerning the adoption of the proposed rules.

Pursuant to Minn. Stat. § 15.0412, subd. 4 (1976), this Report shall be available for review to all affected individuals upon request for at least ten days.

The Board of Pharmacy shall, if it proposes to adopt the rules as originally proposed or amended, submit the complete hearing record, including its Findings and Order, to the Chief Hearing Examiner no earlier than ten days subsequent to the receipt of this Report. This submission shall also clearly indicate any changes made to the rules as originally proposed, preferably in the format that will be submitted to the State Register for publication. The Chief Hearing Examiner shall complete his review and submit his report to the Board of Pharmacy on the issues of substantial changes in the rule and compliance with Minn. Stat. § 15.0412 within ten calendar days. Thereafter, the Board shall be responsible for filing the rules with the Attorney General.

Based upon all the records and proceedings herein, the Examiner makes the following:

FINDINGS OF FACT

1. On February 23, 1977, the Board of Pharmacy filed the following documents with the Chief Hearing Examiner:

(a) A copy of the proposed rules;
(b) A proposed Order for Hearing;
(c) A proposed Notice of Hearing; and
(d) A Statement of the estimated length and number of people attending the hearing.

2. On January 31, 1977, a Notice of Hearing and a copy of the proposed rules were published at 1 State Register 1138.

3. On February 10, 1977, the Board of Pharmacy mailed the Notice of Hearing to all persons and associations who had registered their names with the Secretary of State for the purpose of receiving such notice.

4. On February 23, 1977, the Board of Pharmacy filed the following documents:

(a) The Order for Hearing;
(b) The Notice of Hearing as mailed;
(c) The Affidavit of Receipt of the Secretary of State's list;
(d) The Affidavit of Mailing;
(e) The Secretary of State's Certificate and list;
(f) The Statement of Need; and
(g) The Statement of Evidence, including the names of witnesses to be called;
(h) The names of agency personnel who will represent the agency.

The documents were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. The record remained open through April 7, 1977 for the receipt of written comments and statements.

6. A Department of Finance Approval was filed on April 7, 1977.

7. Statutory authority to promulgate the proposed rules is contained in Minn. Stat. §§151.06, subd. 1(9) (1976) and 214.06 (1976).

8. The proposed amendments to Pharm 1, 2 and 3 make clarifying changes in terminology pursuant to requirements found in Minn. Laws 1976, Chapter 222.

a. Michael Smith, graduate fellow in the Department of Pharmacy Administration, University of Minnesota, proposed to delete the words "at retail" in Pharm 1 and substitute in place thereof the words <u>to the consuming public</u>. Mr. Smith contends that this amendment will alleviate the problem of interpreting what constitutes retail sale.

b. Mr. Smith proposed to amend Pharm 2 as follows:

> License required. No <u>person or</u> persons...by statute] <u>in accordance with Pharm 4</u> shall be...

This change would more clearly encompass both individuals and groups of individuals within the scope of the rule and reference the rule

setting fees.

9. In 1976, the Minnesota Legislature abolished statutory license fees and declared that all fees be set by rule. Proposed amendments to Pharm 4, 25, 26, 28, and 61 set fees which are anticipated to equal expenditures by the Board of Pharmacy.

a. Donald Dee, executive director of the Minnesota State Pharmaceutical Association (MSPhA), testified in opposition to the increase in fees proposed in Pharm 4 and 25. Mr. Dee contends that the fees paid by small numbers of health providers are disproportionately high and that Board services are extended to institutions which pay no fee at all.

b. Michael Smith proposed to amend Pharm 4 by deleting the words "at retail" and substituting in place thereof the words to the consuming public. The reasons are the same as those stated in Finding No. 8a.

c. The Board proposed to amend the second paragraph of Pharm 4 as follows:

> "...shall expire on June 1 of each year and shall be renewed annually by filing an application therefor, on or before May 1 of each year, together with a fee of $50 (beginning January 1, 1978 said fee shall be $75). Renewal applications received after June 1 shall be subject to a late filing fee of $25 in addition to the renewal fee."

This change is recommended to allow more lead time for the Board to process renewal applications.

10. The proposed amendments to Pharm 6 clarify the relicensure requirements for license transfers.

11. The proposed amendments to Pharm 7 delete outdated and unnecessary language.

a. Richard J. Levine, representing Abbott Northwestern Hospital, proposed that Pharm 7 set out that pharmacies located in nursing homes be classified as institutional pharmacies and not community pharmacies as the current regulations state.

12. The proposed amendments to Pharm 8 set out maximum time limits for the submission of an application for license if a pharmacy changes location or changes its physical dimensions or elements of physical security.

13. Existing Pharm 10 has been renumbered to be Pharm 9 and

amended to conform with 1976 statutory requirements.

14. Proposed Pharm 10 sets out the equipment and library materials necessary for each pharmacy to have at its disposal. The rule requires that each pharmacy have copies of state laws and regulations pertaining to the practice of pharmacy and a copy of the U. S. Pharmacopeia.

a. It was suggested that Pharm 10 be amended to state that current references are required.

b. The typographical error in 10 B. 2. should be corrected to read, "American Hospital Formulary Service."

c. Roger Schroeder, president of the Minnesota Society of Hospital Pharmacists (MSHP), recommended that:

(1) The Merck Manual be replaced by the American Hospital Formulary Service.

(2) The United States Dispensatory be replaced by the Extra Pharmacopeia.

(3) The Dispensatory be moved into group B. replacing the Formulary Service.

d. The MSPhA suggested that 10 D. 1. be amended by deleting the words "Class 'A'" because the term is unnecessary.

e. The MSHP proposed to amend 10 D. 2. and 10 D. 3. by changing "gm." to g. and "cc." to ml. Also, that 10 D. 5. be amended to read, Suitable refrigerator for drug storage with thermometer.

15. Proposed Pharm 11 is existing Pharm 12 with the deletion of inapplicable language.

16. Proposed Pharm 12 sets out the requirement that clean and sanitary conditions shall be maintained in pharmacies.

17. The proposed amendments to Pharm 21 clarify the position of pharmacist-in-charge and require submission of supervisory procedures to the Board.

a. Mr. Andrew Roberts stated that the definition of pharmacist-in-charge might be difficult to comply with in-hospital pharmacies. The Board agreed that "the definition...was not aimed at hospital pharmacies."

b. Mr. Levine proposed that 21 A. be amended by adding the language, "dispensing of drugs and the communication of information to the public in relation to drug therapy."

c. Many comme[illegible]s suggested that the subm[illegible]sion of procedures requirement in 21 C. be changed to read, "and have these procedures available for inspection at the pharmacy." The MSHP contends:

> Policies and procedures should be required to be available for inspection rather than required to be submitted to the State Board of Pharmacy for approval. The logistics of all pharmacies in the state submitting policies and procedures to the Board for approval and subsequent revision of these policies and procedures is such that the proposal is not practical. As the regulation is written, the pharmacy must have prior approval by the Board before a procedure can be implemented. Due to administrative delays on the part of the Board this will place an undue hardship on the pharmacy department implementing revised procedures.

d. The MSPhA asserts:

> That the Board of Pharmacy does need to approve these manuals but recognizes that the pharmacist must reasonably know when the manual will be approved and suggests the following be added after the last sentence of the first paragraph in Pharm 36(I):
>
> "These written procedures shall be automatically approved 90 days after receipt by the Board of Pharmacy unless the pharmacist-in-charge is notified by the Board of the specific reasons the procedures are unacceptable."

e. The Board of Pharmacy argues:

> Section C of Pharm 21 requires the pharmacist-in-charge to submit written procedures directing the activities of pharmacy technicians to the Board for review and approval prior to beginning to utilize these persons in the expanded role being proposed for them in Pharm 36. The responsibility of the Board centers around the protection of the public from the dangers associated with the utilization of prescription drugs. In that the present laws and rules of the board prohibit the use of pharmacy supportive personnel for other than clerical tasks, the Board must have a method by which to monitor the activities and supervision of these people in their expanded role. Requiring submission of proposed utilization procedures to the Board is the most efficient manner in which to do this. This is true for a number of reasons. It is currently anticipated that approximately 25 hospitals will submit procedures soon after promulgation of these rules to legitimatize the utilization of these people that they have already implemented, utilization which is in violation of current rules. An additional 20-30 retail pharmacies can also be expected to submit procedures immediately. After this immediate rush there will not be an oppressive number of submissions at any one time. If these procedures are only kept on file in the pharmacy the Board will be hindered in meeting its obligations to the public in that it will not be able to review the functions of these non-professionals other than during the inspections which occur only on approximately a yearly basis. This could provide for practices by non-professional supportive personnel in a manner not allowed by these rules for up to a year before their activities could be reviewed by the Board. The protection of the public would seem to demand review of the methods of utilization proposed for these supportive persons before they are allowed to begin work.

18. The proposed amendments to Pharm 23 are technical changes made to comply with statutory requirements.

19. Besides dealing with license fees, Pharm 25 is amended to require that pharmacists post their licenses in a place "readily visible to the public."

a. Many comments suggested that the visibility requirement was impractical and, in some cases, impossible in hospital pharmacies because of the number of pharmacists and the physical lay-out.

b. The Board proposed to amend Pharm 25 by changing the date for the submission of renewal applications to February 1 and that the licenses expire on March 1 of each year with a late fee after that date. This change would allow the Board more lead time for processing.

20. The proposed amendments to Pharm 26 set out the application procedures for licensure by examination. The amendments state that fees paid to the board shall not be returned and that licensure by reciprocity will not be granted to one who has previously failed to pass the Minnesota examination.

a. The Board concurred with proposals made at hearing to delete "7th Edition" in 26 A. and insert in lieu thereof the words current edition.

b. Michael Smith suggested that 26 C. be amended by adding the words or refunded to the end of the sentence. He asserts that this added language will clarify the intent of the rule.

21. The proposed amendments to Pharm 27 raise the continuing education requirement from 25 to 30 hours every two years; provide for extensions which can be granted by the Board; and specify the membership of the Advisory Task Force on Continuing Education.

a. Mr. Smith recommended that the word "Rule" in 27 B. be changed to lower case rule.

b. Opposition to the increase in continuing education hours was voiced by Stiles J. Fritz as he feels practicing pharmacists are continually exposed to new materials in daily work activities.

c. Mr. Smith and Mr. Levine expressed concern over the provisions of 27 E. which allow credit for identical programs to be given once in each reporting period. Mr. Smith suggests that the paragraph be amended to read:

> 2. [(2)] Credit for an identical program [[may]] shall be given only once to any individual during any two successive reporting periods.

Mr. Levine proposed that the following sentence be added to 27 E. 2.:

Credit for similar but related topics shall be acceptable for credit, so long as the information presented is such that it is presented in a different context.

d. Mr. Smith suggested that the typographical error in 27 F., changing "he" to be, be corrected.

e. The MSHP and others representing hospital pharmacists recommended that 27 G. be amended to specifically include hospital pharmacists in the make-up of the Task Force. The MSHP contends:

> In designating the makeup of the Continuing Education Advisory Task Force the Board has not included the Minnesota Society of Hospital Pharmacists as one of the major pharmacy organizations in the state. The task force should consist of three members designated by the Minnesota State Pharmaceutical Association, three members designated by the College of Pharmacy, University of Minnesota, two members designated by the Board of Pharmacy and two members designated by the Minnesota Society of Hospital Pharmacists to assure equitable representation of pharmacist groups in the state.

f. The MSPhA responded to the argument made by the MSHP as follows:

> Pharm 27 - The Minnesota Society of Hospital Pharmacists, in their testimony stated that the composition of the Advisory Task Force on Continuing Education should be changed to include representatives from their organization. A few facts concerning the continuing education statute and functioning of the Advisory Task Force are appropriate to note.
>
> In 1973, MS 151.13 was amended to include a mandatory continuing education requirement for relicensure in Minnesota. At that time, MSPhA, representing all pharmacists in Minnesota, presented testimony to the legislature that substantial practitioner and educator input was essential to insure a quality continuing education program. The legislature provided for the then Continuing Education Advisory Council to consist of not more than 10 persons - appointed by the Board of Pharmacy - five of whom shall be designated by the Minnesota State Pharmaceutical Association and three by the College of Pharmacy.
>
> In the four years since enactment of the continuing education requirement, at least two pharmacists practicing in the institutional setting have served on the Advisory Council at all times, and a past chairperson of the Advisory Council was a pharmacist practicing at United Hospitals, St. Lukes Division, St. Paul.
>
> While MSHP has recommended direct representation, other organizations with narrow special interests could request similar representation. In fact, organizations could be formed for such a purpose. MSPhA points to its membership diversity and urges the Board of Pharmacy to retain the existing recommended composition of the Advisory Task Force on Continuing Education.

g. The MSHP further stated:

> Under Section H., we are concerned about the deletion of the availability of continuing education records to any registrant upon request. In the Board of Pharmacy's statements of fact they do not explain the rational [sic] for eliminating this provision. In light of recent legislation regarding availability of information from governmental bodies it would seem inappropriate that the Board would remove such a clause. Without the availability of this information members of the profession or members of the public would be unable to check on the quality of the programs being approved for continuing education credit.

h. The Board asserted that any records of specific CE programs will be available to the public; however, it is next to impossible to publish current updated lists of all programs which have been accredited for any two-year period.

i. Questions were raised by the MSPhA and Mr. Lowell Anderson concerning the "sponsor" requirements in 27 J. The Board responded as follows:

> Both Mr. Dee and Mr. Anderson, in testifying on Pharm 27, indicated that there may soon be "Accredited Program Sponsors" through the American Council on Pharmaceutical Education and that perhaps the Board should reconsider some of the existing wording in Pharm 27 J. which would prohibit a sponsor of Continuing Education Programs in pharmacy from identifying themselves as "accredited program sponsors" which up until this time would have been misleading in that there was no accrediting agency for program sponsors. The Board concurs and suggests added wording of "unless he is so accredited by the American Council on Pharmaceutical Education" to be placed after the phrase "accredited program sponsor" in Pharm 27 J.

22. Proposed Pharm 28 sets forth in rule form the Board policy on reciprocity licensure. This policy coincides with that of the National Association of Boards of Pharmacy.

23. The proposed amendments to Pharm 31 set out special circumstances when vending machines may be used to dispense drugs in licensed hospitals.

a. Mr. Levine proposed to amend 31 by including nursing homes in the exception.

b. The Board responded to Mr. Levine as follows:

> Mr. Levine, in his testimony on proposed Pharm 31 requested that it be expanded to include utilization of vending machines for distributing legend drugs in nursing homes. The Board opposes this not only in principle but also in view of statutory

limitations which preclude the possession of stock supplies of legend drugs in nursing homes. Only medications dispensed to an individual patient by a pharmacy are allowed in nursing homes. Minn. Stat. 151.37 limits stock supplies of legend drugs to drug manufacturers and wholesalers, licensed pharmacies and licensed hospitals. Mr. Levine should pursue legislative change prior to seeking a rule change by the Board in this area.

c. Mr. R. Gary Freund, chief of pharmacy at Saint Joseph's Hospital, made the following proposal:

> In regard to Rule 31, we believe that when the technology is available, a computer tied to a unit dose dispensing machine which is controlled by a pharmacist is the ultimate in drug control and patient safety. We feel that this statement should read "Provided, however, that nothing in this rule shall prohibit a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises, from utilizing such a device(s) when the hospital's pharmacist shall have control over the monitoring of drug therapy, etc.

d. The MSHP supported Mr. Freund as follows:

> Vending machines for the dispensing of drugs have been available for the past decade. Only after receiving outside pressure from the legislature has the Board been willing to consider changes in this regulation which has stifled the development of modern technology in providing pharmaceutical services in thie hospital. As in the past, the wording in this section can be interpreted to curtail the utilization of future technology, which conceivably could produce automated dispensing equipment tied to pharmacist controlled computers. Such a system would be exceedingly cost effective and provide an exemplary system for drug use control in hospitals. If the pharmacist has control over monitoring all aspects of this system, there should be no reason why a properly controlled system should be restricted to after pharmacy hour usage. Therefore, we recommend that the wording "in an emergency after regular pharmacy hours", should be struck from this paragraph. The statement is unnecessary for the protection of the public welfare. Also, the word "complete" used as an adjective before control should be struck. Other sections of these regulations refer to the pharmacist having control over various systems as described here and without using the terminology "complete".
>
> This section provides an exemption clause for hospital pharmacy to use vending machines. Based upon testimony given by Mr. David Holmstrom at the public hearing on March 18, 1977, all regulations and any exemptions to regulations for hospital pharmacy will be included in sections Pharm 81-100. Therefore, Pharm 31 should be modified and the exemption clause for hospital pharmacies be inserted in Pharm 81-100.

24. The proposed amendments to Pharm 33 clarify the solicitation prohibitions for pharmacists.

25. The proposed amendments to Pharm 36 further define the process of compounding and dispensing prescriptions and clarify the pharmacist - auxiliary personnel relationship. This rule was supported by the Board as follows:

> Approximately two years ago the Board established an advisory committee to look into the feasibility of changing the rules of the board to enable pharmacists to utilized pharmacy technicians in an expanded role thus freeing themselves to become involved in the more clinical aspects of pharmacy practice. The committee, made up of pharmacy practitioners from hospital, community, and chain pharmacies met regularly for over a year before submitting a recommendation to the Board that the Board consider allowing an expanded role for pharmacy technicians. In that Rule 36 defines compounding and dispensing and limits the practice of compounding and dispensing a prescription to a pharmacist, assistant pharmacist, or pharmacist intern, the Board feels, and correctly so, that rather than attempting to spell out the duties that are allowed by a pharmacy technician, the more reasonable approach would be to redefine the act of compounding and dispensing which sets forth the acts that a pharmacist is required to do. The acts which the board feels must be performed by a pharmacist in the preparation of a prescription in order to adequately safeguard the public are set forth in Rule 36.
>
> The Board feels that, in light of the recently enacted drug product selection legislation and other changes and advancements in the scope of pharmacy practice, the determination of the brands and suppliers of medication to be utilized by a pharmacy must be kept in the hands of the pharmacist. Minn. Stat. 151.21 in fact indicates that the pharmacist must utilize his professional judgment in determining when two generically equivalent products are therapeutically equivalent. This mandate would tend to require that the pharmacist himself select the brands of the various products he intends to stock in his pharmacy. This is accomplished in Pharm 36 A.
>
> Pharmacists are currently required to personally receive oral prescriptions from practitioners. The Board feels that the public safety would demand that this be so. It is continued in Pharm 36 B.
>
> The pharmacist alone is adequately trained to evaluate and verify the prescription order. In order for the pharmacist to adequately safeguard the patient he must interpret the original of the physician's order. A copy which has been transcribed by another individual may contain errors of transcription and should not be accepted. These requirements are found in Pharm 36 C.
>
> The Board feels that, again, only the pharmacist, has been adequately trained to make an informed choice of the drug to be used in filling any prescription. This original selection is obviously of the most vital importance in preparing a correctly compounded prescription. This selecting is required in Pharm 36 D.
>
> The pharmacist has traditionally been personally responsible for the extemporaneous compounding of individual prescriptions. This requirement is contained in Pharm 36 E.

Pharm 36 F. contains the basics of the changes which allow an expanded role to both pharmacist and pharmacy supportive personnel. The pharmacist is required only to certify and document his certification of the completed prescription. This certification must contain certain steps needed to safeguard the patient against preventable problems associated with the use of his prescription.

Pharm 36 G. requires the pharmacist to become personally involved in the issuance of the prescription to the patient only when in his professional judgment counseling, or an addition to the label information, regarding the use or storage of the patient's medication is called for. In that the professional judgment of the pharmacist involved is the determining factor in when special counsel should be given this section is most reasonable.

Recording certain information on the reverse side of prescriptions at the time of refilling such prescriptions has long been a requirement. This is not changed in section H.

In order that the Board might more readily be able to assure the public that non-pharmacist supportive personnel are being properly utilized, section I requires the pharmacist-in-charge of any pharmacy which intends to utilize such persons to develop and present to the Board for approval a "job description" or procedure manual which sets forth the tasks proposed for these persons. Upon approval by the Board, supportive personnel may be utilized according to the descriptions submitted. This is not an unreasonable requirement of those seeking to utilize supportive personnel.

This rule limits the use of pharmacy technicians to 1:1 ratio with pharmacists responsible for their supervision and requires the pharmacists wishing to utilize pharmacy technicians in tasks which were previously reserved to the pharmacist to prepare written procedures directing these activities and submit them to the board for approval and review. The functions which were traditionally those of pharmacy supportive personnel such as clerical type duties remains such and are not subject to the above provisions and limitations.

a. Much testimony and many written comments to the problems of applying Pharm 36 to hospital pharmacies. The following excerpts are typical of the concerns expressed:

> Hospital pharmacists are very concerned about the implications from the revised Pharm 36 as proposed. It is obvious that this entire section is aimed at controlling retail or outpatient dispensing activities. Many aspects of the routine operation of a retail or outpatient pharmacy service cannot be applied to the practice of hospital pharmacy services. The current regulation recognizes these differences and provides an exclusion that exempts hospital pharmacies from these regulations. Therefore, it is imperative that a similar statement be included in the new proposed Pharm 36.

We would like to propose the addition of the following paragraph to Pharm 36 to provide an exclusion for hospital pharmacy. "Nothing in this section shall be applicable to pharmaceutical services provided to patients in hospitals. Regulations pertaining to hospital pharmacies shall be found in Chapter Seven: Pharm 81-100."

The following are specific concerns to point out why this section is inappropriate as written for hospital pharmacy. Section B. does not allow for automatic recording devices nor the ability of nursing personnel to take verbal medication orders from physicians. Section C. does not allow for a computer generated order input by physicians or direct copy of the original order being received by the pharmacy department. The latter is traditionally used in hospitals as a means of facilitating the receipt of an accurate order of the drugs prescribed by the physician subsequent to his writing orders in the medical chart. The use of a direct copy of the physician's order is far superior to having the nurse transcribe the order on the station and sent to pharmacy.

Section D

The physical act of selecting a drug to be used in filling a prescription relative to removing it from the shelf is not a professional task. This applies to any type of pharmacy operation, not just hospitals. To include this requirement would imply that reading ability is a unique ability of the pharmacist. The retaining of such a provision is not justified relative to the protection of the public welfare. Hospital unit dose systems have traditionally used non-professionals to select the doses to be dispensed within the system. This section conceivably could prohibit the selection of the proper unit dose of medications for placing on unit dose carts or trays to be checked by a pharmacist; therefore, increasing the cost of pharmacy services in the hospital.

Section E

We are concerned that there is no definition for extemporaneous compounding within the current regulations or the proposed regulations. The utilization of technicians in IV additive programs is a recognized standard of practice throughout the United States. The Joint Commission on the Accreditation of Hospitals requires that pharmacists be responsible for drug use control through the hospital. Therefore, hospital pharmacies are taking over the function of preparing IV solutions from the uncontrolled environment of the nursing station to the controlled environment of the pharmacy department. If this statement is interpreted to include the preparation of IV additives, this will have a negative impact on the improvement of hospital pharmacy practice. Pharmacists have been severely curtailed in many states in their ability to delegate technical tasks particularly wherein performance of the tasks infringes upon the traditional duties of the pharmacist such as those of compounding and dispensing. We are concerned that hospital pharmacy in Minnesota will not become curtailed by similar regulations.

Section F

The wording of this entire section is not applicable nor consistent with a hospital unit dose-dispensing system. Statements one, two and three are inappropriate when each medication dose is completely labeled and the instructions for the administration of the drug is traditionally not included on the medication label. The inapplicability of such rules and regulations is obvious to anyone knowledgeable with good hospital pharmacy practice as professed by the Joint Commission for Accreditation and the American Society of Hospital Pharmacists.

Section G

This section refers to the responsibility of the pharmacist, when issuing a prescription to a patient, to assure that the patient understands the use of the medication and to caution him of the proper storage of the drug, "when in the professional judgment of the pharmacist" which council is necessary. This clarifying statement should be stricken as it is doubtful that the pharmacist can make such a judgment without interacting personally with the patient relative to their current medications and their experiences to date with these medications.

Section H

We assume that there is a typographical error in the third line in that it should read "authorized prescribers or their agents".

Section I

Regarding proposed rules for Pharm 36 (Compounding and Dispensing), Section I. This proposed rule to limit the ratio of pharmacist to supportive personnel (e.g. technicians) to 1:1 is prohibitive as well as impractical. In a hospital pharmacy, in particular, this ratio would be costly and difficult to adhere to. During "normal business hours" this ratio is generally met - the usual staff is working and the ratio approximates 1:1. During evening, weekend and holiday hours when one pharmacist is on duty, the proposal would limit his non-pharmacist help to one person. In a total unit-dose operation there is no way that the required work can be done efficiently and <u>accurately</u> under these conditions. There are several phases to a unit dose program (i.e., IV additives, packaging, filling of cabinets, preparation of dosages, filing, etc.) which under optimal conditions requires 3-4 technicians and at the minimum, 2 technicians. No matter how many technicians are on duty at a given time, no orders are filled that are not checked (before and after filling) by a registered pharmacist. The most important consideration is that the patient receive his medications promptly, accurately with every effort made to assure that it is not contra-indicated for that patient, that the right form of the drug is used, that the drug will not interfere with other drugs, lab tests or procedures the patient is receiving, etc. These important considerations become impossible if the pharmacist on duty must spend his time filling drawers and filing vouchers.

b. The Board responded to the criticisms of Pharm 36 as follows:

One should bear in mind at all times when reviewing comments made by all parties on Pharm 36 that the over-all tenor of this rule is to make less strict the scope of functions that make up the act of compounding and dispensing a prescription thus allowing the pharmacist more opportunity to expand his professional field while at the same time affording adequate protection to the public at a possibly reduced cost.

Several of the hospital pharmacists commented that the new rules would increase patient costs. The reverse is actually the case. The current Pharm 36 does not allow the use of "pharmacy technicians" in other than clerical areas. Many larger hospitals claiming "advancements in health care delivery" have chosen to knowingly violate the current Pharm 36 by utilizing pharmacy technicians for support in areas outside of those allowed by the current Pharm 36. The Board recognized that an expansion of the role of both pharmacy technicians and pharmacists could be of significant benefit to the public established a committee to review the issue and make recommendations. This committee was heavily weighted in favor of hospital pharmacy. The Board's proposed Pharm 36 reflects the efforts of this committee.

The hospital pharmacists who testified as to increased patient cost are obviously comparing costs between their current method of operation which is, in most cases, not in compliance with the current Pharm 36 and the requirements of the proposed Pharm 36. This is not a valid comparison. If a cost comparison is to be made it must be made between a system in compliance with the current Pharm 36 and one in compliance with the proposed Pharm 36. If this were done a cost savings would be shown without unduly increasing the risk to the public inherent in the dispensing and administration of legend drugs.

An additional point to bear in mind is that the three or four hospital pharmacists speaking represent only four hospitals all of which are in the Twin Cities. While those hospitals are of substantial size the most advanced and largest hospitals in the state, those associated with the Mayo Clinic in Rochester and Hennepin County Medical Center in Minneapolis, did not appear to find the proposals burdensome. Additionally, the speakers represented four hospitals but there are 154 licensed hospital pharmacies in the state. The majority of these are in compliance with the current Pharm 36 and thus find proposed Pharm 36 to be a benefit and not a hinderance as was alleged by some speakers at the hearing.

While the Board recognizes that there are some differences in the manner in which pharmacy is practiced in hospitals as opposed to retail, pharmacy is pharmacy and basically the patients in the hospital settings deserve the same quality of care and protection as do those obtaining pharmaceutical services from a retail setting. The Board will deal with the differences inherent in hospital practice in Pharm

Rules 81-100 which will be heard this summer.

The comments from the retail sector of pharmacy practice were less emotional than those from hospital representatives and were generally supportive of what the Board is attempting to do.

Some concern was expressed in some areas of proposed 36 by Mr. Dee. These concerns centered around sections F, H, and I.

In section F the Board is attempting to set out for pharmacists the items the pharmacist must check when prescriptions have been prepared by supportive personnel in order to certify the accuracy and completeness of the prescription prior to its delivery to the patient. Subsection 4 indicates that the pharmacist must check the medication record or patient profile as it is sometimes called for possible therapeutic incompatibilities. Medication records are becoming, if they have not already become the standard of practice across the country with three states making their utilization mandatory. Only the pharmacist has been trained to interpret the possibility of drug interactions which obviously must be done before the patient obtains his prescription. The Board is not making the use of profiles mandatory but is requiring the pharmacist personally to deal with the medication record when it is utilized.

Some opposition was also expressed as to the requirement in section H that the pharmacist be required to obtain refill permission from MD's personally while MD's can delegate the transmission of this information to the pharmacist. This is not a change from the current requirement. The Board feels that it is justified in retaining this requirement in that the more times a message must be transferred from one person to another the greater is the possibility for misinterpretation. If a step in the passing down process can be eliminated by requiring direct involvement of the pharmacist, it is to the benefit of the public. Thus the retaining of this requirement.

c. The Board is currently preparing rules for hearing which are specifically aimed at hospital pharmacy practice. The Board stated that these rules would supersede proposed Pharm 36 regarding hospital pharmacies. At this time, however, the rules have not been drafted. Consequently, the actual effect of proposed Pharm 36 on hospitals is only conjectural.

26. The proposed amendments to Pharm 37 involve a relettering of the section to conform with the standardized outline form of rules being instituted statewide and contain some changes in section E and L. Section E previously concerns the discrimination in any manner between patients or groups of patients for reasons of religion, race, creed, color, sex or national origin. To this group was added the category of "age". Section L, which is a new section, declares it

to be unprofessional conduct to sell, give away, or otherwise dispose of various accessories or chemicals which the pharmacist knows or should know are destined for use in illegal activities. In light of the problems found in illegal drug trafficking it is not unreasonable to make it plain to pharmacists that aiding and abetting this illegal activity in any manner is unprofessional conduct.

a. Mr. Smith suggested that "Rules" be changed to rules in 37 2.

b. Mr. Smith recommended that the language, hypodermic needles and syringes and other injection paraphernalia, be added to 37 L. Mr. Miller stated that this prohibition is already set out in statute.

27. The proposed amendments to Pharm 40 are again basically a relettering process with the exception of new section G which indicates that in addition to the previously existing requirements for providing information on the label of prescription drugs, the name of the manufacturer of the finished dosage form of the drug must be included. This requirement was added as a result of a provision in the Minnesota Drug Product Selection Act found in Minn. Laws 1975, Chapter 101.

28. Proposed Pharm 41 is also included as a result of legislation passed in the 1975 legislative session. Minn. Laws 1975, Chapter 356, as amended by Minn. Laws 1976, Chapter 338, Section 5, requires certain warning information to be placed on the labels of controlled substances and certain other drugs dispensed by a pharmacist when the use of such a drug, either alone or in combination with alcoholic beverages, may impair the ability of the user to operate a motor vehicle. Pharm 41 indicates to the pharmacist the wording to be used in this cautionary statement and indicates the drugs and situations which would require the warning.

a. The MSPhA suggested that Pharm 41 be amended to read, "...All drugs administered systemically and classified..." This amendment would exclude topical drugs, for which there is no necessity for a label.

29. Proposed Pharm 43 is the result of new uses of electronic

data processing by pharmacies. In recent years, the electronic data processing equipment has become more and more prevalent in recordkeeping and other functions in the pharmacy profession. Up until this time, no guidelines for the use of these pieces of equipment have been established and pharmacists were left to their own devices in determining whether the recordkeeping functions of their EDP equipment was sufficient to meet the requirements of the Board and of certain federal agencies such as DEA. Within the past year, NABP developed a set of guidelines for the use of electronic data processing equipment in pharmacies. Recently, DEA accepted NABP's guidelines indicating that if any pharmacy installed EDP equipment which met these guidelines, the recordkeeping requirements for DEA could be met. Pharm 43 is very closely parallel to the guidelines that NABP developed, guidelines which were acceptable to DEA in meeting the federal recordkeeping requirements.

a. The MSHP made the following comment in regard to Pharm 43:

> This section does not recognize the existing computer technology relative to their use in hospitals. Computer systems which are now available, provide for direct entry of prescription orders by the physician and the holding of prescription orders entered by nursing or pharmacy non-professional personnel. Orders entered and stored are not acted upon by the pharmacy, relative to dispensing, until they have been recalled and verified by a pharmacist. According to the proposed regulations, such systems would not be acceptable. Therefore, the following wording is suggested: "input of drug information may be performed by a physician or a pharmacist. If orders are entered by other personnel the pharmacist must certify the accuracy of the information entered prior to the dispensing of the medication. The identity of the person entering the order and the pharmacist verifying the order must be retained in the record."

30. Proposed Pharm 44, 45 and 46 clarify the labeling and recordkeeping requirements pharmacists are subject to when dealing with poisonous substances. No new requirements are placed on the pharmacist that are not already included in statute.

a. Mr. Smith noted two small oversights in Pharm 45, i.e., changing "registered" to <u>licensed</u> and "pharmacy" to <u>pharmacist</u>.

b. The MSPhA proposed to amend Pharm 46 C. to read:

> "C. The word "POISON" in letters no smaller than the largest print on the label, accompanied by the "Mr. Yuk" or "skull and crossbone" symbol."

This amendment conforms to recent policies of the National Poison Center Network.

31. The proposed amendments to Pharm 51 include five new controlled substances recently set out in statute.

32. The proposed amendments to Pharm 61 deal with internship and with the exception of a few minor changes, result in simply a renumbering process. The new provisions include the establishment of a $20 registration fee, provisions dealing with persons who terminate their efforts toward obtaining a pharmacy degree and persons who falsely assume the identity of an intern.

33. Proposed Pharm 101 through 108 deal with nuclear pharmacy. Nuclear pharmacy is a newly developing field of specialization in pharmacy and one which very few states have addressed as to control. Rules 101 through 110 were developed with the help of input from the states of Arizona and California which have addressed the problem of nuclear pharmacy and the protection of the public attendant thereto, and with input from the one and only nuclear pharmacist currently operating in Minnesota. These rules are estabished to protect the public from the dangers inherent in the handling of radioactive materials while at the same time allowing the development of the specialty field of nuclear pharmacy without undue restrictions.

34. Proposed Pharm 111 through 118 set out the procedures to be followed in any disciplinary matter before the Board. Appropriate references to Chapter 15 are included.

a. Because of the nature of Pharm 118, the Board proposed to change its placement to Pharm 21 G.

b. The Hearing Examiner suggested that Pharm 116 be amended to read:

> Pharm 116 Hearings and Notices thereof. Notices of hearing...office address. All hearings shall be conducted pursuant to Chapter 15 and the Rules for Contested Cases of the Office of Hearing Examiners.

Based upon the foregoing Findings of Fact, the Hearing Examiner makes the following:

CONCLUSIONS

1. Due, timely and adequate legal notice of the hearing was

properly served and filed by the Board of Pharmacy. All other substantive and procedural requirements of statute or rule have been complied with.

2. Pursuant to Minn. Stat. § 15.052, subd. 3 (1976), it is the duty of the Hearing Examiner to: "...(4)make a report on each proposed agency action...taking notice of the degree to which the agency has (i) documented its statutory authority to take the proposed action, (ii) fulfilled all relevant, substantive and procedural requirements of law or rule, and (iii) demonstrated the need for and reasonableness of its proposed action with an affirmative presentation of facts."

3. The Examiner concludes that Pharm 1 be amended as set out in Finding No. 8a. and Pharm 2 should be amended as set out in Finding No. 8b. for the reasons stated therein.

4. The Board of Pharmacy has many regulatory functions to perform. Expenditures associated with regulation have traditionally been paid for by charging fees for the privilege of practicing the regulated profession. Because of the number of professionals practicing in the many regulated professions, and the extent of the regulation, fees charged are often times disproportionate. In order for the Board of Pharmacy to secure funds from other sources, authorizing legislation would have to be enacted. The concerns of the MSPhA should be directed at the Legislature.

5. The Examiner concludes that Pharm 4 be amended as set out in Findings Nos. 9b. and 9c.for the reasons stated therein.

6. Mr. Levine's concerns regarding the reclassification of nursing homes is a matter which is outside of the noticed scope of the hearing. The Board should take notice of these concerns for possible inclusion in a later rules proceeding. Mr. Levine should also be aware of the procedure set out in Minn. Stat. § 15.0415 whereby any person may petition for the adoption of a rule.

7. The Examiner concludes that Pharm 10 be amended as set out in Findings Nos. 14a., 14b., 14d. and 14e. for the reasons stated therein. Not enough evidence was presented by the MSHP in regard to the suggestion set out in Finding No. 14c. for the Examiner to conclude that it be adopted. However, the Board should look more

closely at that proposal and act accordingly.

8. The Board admitted that the defintion of "pharmacist-in-charge" was "not aimed at hospital pharmacies." As such, the Board has not demonstrated by an affirmative presentation of facts that the revised definition in Pharm 21 is reasonable as applied generally to all pharmacies. The Board should: (a) not propose the revision for adoption until the superseding hospital pharmacy rules are proposed; or (b) revise the definition so that hospital pharmacies could comply; or (c) exempt hospital pharmacies from the definition. Although as the Examiner dislikes drafting, the following is a suggested alternative:

> "...without a pharmacist-in-charge. For community pharmacies, this shall be a pharmacist..."

The Board can then deal with this matter in the upcoming hospital pharmacy rules proposal.

9. The Examiner concludes that Pharm 21 be amended as set out in Finding No. 17b.

10. The Board has demonstrated the reasonableness of submission of written procedures as set out in Pharm 21 C. However, the Examiner agrees with the comments made by the MSPhA as set out in Finding No. 17d. The Examiner concludes that Pharm 21 C. be amended to read:

> "...to submit these procedures to the Board. Non-pharmacist supportive personnel may be utilized in the performance of these tasks only after the procedures have been developed by the pharmacist-in-charge and have been submitted to and approved by the Board. These written procedures shall be automatically approved 90 days after receipt by the Board of Pharmacy unless the pharmacist-in-charge is notified by the Board of the specific reasons the procedures are unacceptable."

11. The reasonableness of the visibility requirement in Pharm 25 as it applies to hospital pharmacies was not demonstrated. The Examiner suggests the following amendment:

> "in a conspicuous place within the pharmacy in which he is practicing his profession. For community pharmacies, this shall be a place which is readily visible to the public."

Further clarification for hospital pharmacies, if in fact needed, can be dealt with in the upcoming rule proposals.

12. The Examiner concludes that Pharm 25 be amended as set

out in Finding No. 19b. for the reasons stated therein.

13. The Examiner concludes that Pharm 26 be amended as set out in Findings Nos. 20a. and 20b. for the reasons stated therein.

14. The Board has demonstrated the reasonableness of the credit provision in Pharm 27 E. 2. Concerns expressed by Mr. Smith and Mr. Levine are conjectural at this point and should be kept in mind by the Board for future examination.

15. The statutory mandate regarding the Advisory Task Force is found in Minn. Stat. § 151.13, subd. 2. It reads:

> Subd. 2. The board shall appoint an advisory task force on continuing education, consisting of not more than ten members, to study continuing education programs and requirements and to submit its report and recommendations to the board. The task force shall expire, and the compensation and removal of members shall be as provided in section 15.059.

The statute does not make any determination as to the make-up of the task force, but rather leaves it up to the discretion of the Board. The Board has proposed to include five members from the MSPhA and none from the more exclusive MSHP. As hospital pharmacists are represented in the MSPhA, the make-up as determined by the Board is reasonable. No showing was made that the MSPhA does not adequately represent the interests of hospital pharmacists. The MSHP should direct its efforts at legislation if it desires to have a mandated membership on the task force.

16. The reasonableness for the deletion of the last sentence of Pharm 27 H. was not demonstrated in light of the need of pharmacists to have that information available to them. The Examiner concludes that 27 H. should not be amended as proposed. The Board can interpret the "made available" language so as to not impose too great a burden on itself.

17. The Examiner concludes that Pharm 27 be amended as set out in Findings Nos. 21a., 21d. and 21i. for the reasons stated therein.

18. The Board has demonstrated the reasonableness of Pharm 31; however, it should bear in mind the meritorious arguments made by Mr. Freund and the MSHP, as set out in Findings Nos. 23c. and 23d., for possible future changes in the rule.

19. Pharm 36 was a focal point of controvery because, primarily, of the fact that conflicting but superseding rules for hospital pharmacists will be proposed for adoption later this year. As yet, they have not been drafted. Consequently, the hospital pharmacists do not know which of the "inapplicable" provisions of Pharm 36 will in fact be inapplicable by the end of the year. Also, there would be an overlap period in which hospital pharmacies would be in "unenforced" violation of the rules in effect. Bearing in mind all of the arguments made, both pro and con to Pharm 36, the Board has not demonstrated the reasonableness of the amendments to the rule. Rather than simply exempt hospital pharmacies, or make additional revisions to the proposal, the Examiner concludes that proposed Pharm 36 should be withdrawn until the hospital pharmacy rules are ready to go to hearing. Present Pharm 36 will suffice until that time.

20. The Examiner concludes that Pharm 37 be amended as set out in Finding No. 26a. Because the "needles and injection paraphernalia" prohibition is already dealt with in statute, and should be salient to pharmacists, there is no need for its inclusion in Pharm 37.

21. The Examiner concludes that Pharm 41 be amended as set out in Finding No. 28a. for the reasons stated therein.

22. The Examiner concludes that Pharm 43 be amended as set out in Finding No. 29a. for the reasons stated therein.

23. The Examiner concludes that Pharm 45 and 46 be amended as set out in Findings Nos. 30a. and 30b. respectively.

24. The Examiner concludes that Pharm 118 and 116 be amended as set out in Findings Nos. 34a. and 34b. respectively.

25. The Board of Pharmacy has documented its statutory authority to take the proposed action.

26. The Board of Pharmacy has demonstrated the need for and reasonableness of the proposed rules, as recommended to be amended in this Report, by an affirmative presentation of facts.

27. The Examiner concludes that the amendments he is suggesting to the rules make the rules more reasonable and that none of these amendments constitute a substantial change.

Based upon the foregoing Conclusions, the Examiner makes the following:

RECOMMENDATION

That the Board of Pharmacy adopt the proposed rules as recommended to be amended in this Report.

Dated: April 28, 1977.

Peter C. Erickson

PETER C. ERICKSON
Hearing Examiner

Rules as Proposed

Chapter One: Pharmacies, Wholesalers, Manufacturers

Pharm 1 Pharmacy defined. The term "pharmacy" means [a drug store or other] **an** established place regularly [registered] **licensed** by the [State] Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded, dispensed, vended or sold at retail. Whenever an applicable **rule or** regulation requires or prohibits action by a "pharmacy", responsibility for said action shall be that of the owner and pharmacist-in-charge thereof, whether said owner is a sole proprietor, partnership, association, corporation or otherwise.

Pharm 2 License required. No persons shall conduct a pharmacy in the state of Minnesota unless [it] **such pharmacy** is licensed [and registered] by the [State] Board of Pharmacy. A fee set by the Board [but not to exceed that prescribed by statute] shall be charged for each license [and registration].

Pharm 3 Form of application and license. Applications for the licensing [and] [registration] of a pharmacy and renewal thereof shall be on such form or forms as the [State] Board of Pharmacy may from time to time prescribe and the license [and registration] of such pharmacy shall be issued by the [State] Board of Pharmacy in such form as it may from time to time prescribe.

[Each license registers the pharmacy for which application for licensing and registration was made.]

[Pharm 4 Licenses, Annual Registration Date and Fees. Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application therefore, on or before June 1 of each year, together with a fee set by the Board but not to exceed that prescribed by statute.]

Pharm 4 License, annual licensing date and fees. Each pharmacy license shall expire on June 30 of each year and shall be renewed annually by filing an application therefor, on or before June 1 of each year, together with a fee of $40. (Beginning January 1, 1978 said fee shall be $50.) Renewal applications received on or after July 1 shall be subject to a late filing fee of $20 in addition to the renewal fee.

Every person engaged in manufacturing or selling of drugs, medicines, chemicals or poisons for medicinal purposes other than at retail shall annually be licensed by the Board. Upon the filing of an application therefor, and upon payment of a fee of $50, the Board may issue a license in such form as it may prescribe to such manufacturer or wholesaler. (Beginning January 1, 1978 said fee shall be $75.) Such license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire on the 10th day of June of each year and shall be renewed annually upon the filing of an application therefor with a fee of $50. (Beginning January 1, 1978 said fee shall be $75.) Renewal applications received after June 10 shall be subject to a late filing fee of $25 in addition to the renewal fee.

Pharm 6 Separate license required. A separate license shall be required for each pharmacy and is not transferable. The following shall be deemed a transfer **requiring relicensure**:

A. [(a)] The sale of all or substantially all of the assets of the pharmacy,

B. [(b)] The addition **or deletion** of one or more partners in a partnership, to which a pharmacy license has been issued.

C. [(c)] The change of ownership of [30%] **20%** or more of the **issued** voting stock of a corporation pharmacy since the issuance of the license or the last renewal thereof. This shall not apply to any corporation, the voting stock of which is actively traded on any securities exchange or in any over the counter market,

D. [(d)] The change in ownership from one form to another; sole proprietor, partnership or corporation.

Pharm 7 Access, space and security requirements. No person shall be issued a license to conduct a pharmacy unless such pharmacy:

A. [(a)] Has an entrance which affords the public reasonable access to the pharmacy,

B. [(b)] Contains more than 400 and less than 12,500 square feet.

[(c) Contains only one floor level devoted to the compounding, dispensing or sale of drugs,]

C. [(d)] Is surrounded by a continuous partition or wall extending from floor to ceiling, which wall shall contain doors capable of being securely locked to prevent entry when the pharmacy is closed.

In the interest of public health the Board may waive any of these provisions for pharmacies located in hospitals. [Any pharmacy, except a pharmacy located in a hospital, which had been granted a license prior to the effective date hereof and which does not comply with one or more of the requirements set forth in Subdivision (a) through (d) above, shall be given one year from the date hereto to comply therewith.]

Pharm 8 Change in location, dimension, or security.

A. Before a duly licensed [and registered] pharmacy changes the location of its business, it shall first submit to the [State] Board of Pharmacy a new application for a license [and registration] setting forth such changes, and shall submit therewith the information and documents required in an intitial application for license [and registration]. **The new application and supporting documents shall be submitted at least 60 days prior to the proposed change in location.** If the [State] Board of Pharmacy approved such application, no additional charge shall be made for such new license.

B. No duly licensed [and registered] pharmacy shall change its physical dimensions or elements of physical security until it has submitted documents and plans of the proposed changes to the [State] Board of Pharmacy. **Such documents and plans shall be submitted at least 60 days prior to the proposed changes.** The Board shall within 30 days after receipt of the proposed changes notify the licensee that the proposed changes either comply or do not comply with Regulation 7. The failure of the Board to respond in writing within said 30 days shall be deemed to be approval of the proposed changes.

[Pharm 9 Qualifications of applicant. Repealed 11-26-69]

Pharm [10] **9** Pharmacist on duty. Each pharmacy shall have at least one [registered] **licensed** pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business.

[Pharm 11 Minimum Equipment Required in Pharmacies. Each pharmacy must have on file the latest edition or revision of at least two of the following references:

(a) U.S. Pharmacopeia

(b) National Formulary

(c) U.S. Dispensatory

(d) Remington's Pharmaceutical Sciences

(e) American Hospital Formulary Service

(f) Physician's Desk Reference

(g) Facts and Comparisons

(h) Merck Manual

(i) Pharmindex

(j) The Pharmacological Basis of Therapeutics

(k) Modern Drug Encyclopedia

(l) An equivalent reference approved by the Board in writing

In addition, each pharmacy must also have the following minimum equipment:

(a) One prescription balance, class "A" as specified in regulations of the Department of Weights and Measures.

(b) One set of accurate Apothecary weights ½ grain to two drams.

(c) One set of accurate Metric weights from 50 mg. to 100 Gm.

(d) Counter scale and weights.

(e) Measuring device capable of accurately measuring volumes from fifteen minims to at least one pint; and from 1cc. to at least 500cc.

(f) Mortars and Pestles — at least one 2 oz; at least one 8 oz; and at least one pint size.

(g) Spatulas — stainless steel, at least three assorted sizes; and one non-metallic medium size.

(h) Funnels, one 2 oz; one 8 oz; one 16 oz.

(i) Stirring rods — at least one each, glass and rubber.

(j) Heating apparatus.

(k) One prescription counter with sufficient drawers and storage space.

(l) Suitable refrigeration.

(m) Narcotic drug locker or safe.

(n) Counter sink.

(o) Toilet with a hand washing lavatory and disposable towels in a location which is reasonably accessible.

(p) Proper sanitary conditions shall be maintained at all times.]

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Pharm [11] 10 Minimum equipment required in pharmacies. Each pharmacy must have on file in addition to the most recent editions of the laws relating to the practice of pharmacy and the rules of the Board of Pharmacy (available through Documents Section, Department of Administration), the latest edition or revision of the U.S. Pharmacopeia — National Formulary and at least one reference from each category:

A. Pharmacology — examples:

1. Pharmacology in Medicine

2. Pharmacological Basis of Therapeutics

3. Merck Manual

4. Pharmindex

5. United States Dispensatory

B. Dosage and Toxicology — examples:

1. Hazards of Medications

2. American Hospital Formulatory Service

3. Facts and Comparisons

4. Pediatric Dosage Handbook

5. Evaluation of Drug Interactions (APhA)

C. Miscellaneous — examples:

1. Handbook of Non-Prescription Drugs

2. Modern Drug Encyclopedia

3. Physician's Desk Reference

4. Remington's Pharmaceutical Sciences

An equivalent reference approved by the Board in writing may be utilized in an appropriate category.

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

1. One prescription balance, Class "A" as specified in regulations of the Department of Weights and Measures,

2. One set of accurate Metric weights from 50 mg. to 100 gm.,

3. Measuring devices capable of accurately measuring volumes from 1cc. to at least 500cc.,

4. Mortars, pestles, spatulas, funnels, stirring rods, and heating apparatus as necessary to meet the needs of that pharmacy,

5. Suitable Refrigeration,

6. Sink with hot and cold running water,

7. Toilet with a handwashing lavatory and disposable towels in a location which is reasonably accessible.

8. Other equipment deemed necessary by Pharmacist-in-charge.

[Pharm 12 Sale of drugs restricted to limited area under supervision. Hereafter the Board of Pharmacy of the State of Minnesota shall refuse to register or grant a license to any pharmacy which advertises, sells, or proposes to sell therein, merchandise in any manner, like or similar to the manner in which merchandise is sold in super markets or other stores commonly known as self-service stores using one or more check-out counters, unless there is provided in such pharmacy a drug area which shall be used exclusively for the display, sale, compounding and dispensing of drugs, medicines, chemicals, poisons, and for the display and sale of other items used in the cure, mitigation, treatment, or prevention of disease in man or other animals; which drug area shall include within it the prescription department of such pharmacy. Any sale of drugs, medicines, chemicals or poisons must be made and completed in its entirety within the drug area by or under the personal supervision of a pharmacist or of an assistant pharmacist in the temporary absence of the pharmacist.]

Pharm [12] 11 Sale of drugs restricted to limited area under supervision. Hereafter the Board of Pharmacy shall refuse to grant a license to any pharmacy or proposed pharmacy unless there is provided in such pharmacy a prescription department and a drug area which shall be used exclusively for the display, sale, compounding and dispensing of drugs, medicines, chemicals, poisons, and for the display and sale of other items used in the cure, mitigation, treatment, or prevention of disease in man or other animals.

Pharm 12 Each pharmacy shall maintain clean and sanitary conditions at all times.

[Pharm 13 Self-service of drugs. Repealed 11-26-69]

Pharm [14-20] 13-20 Reserved for future use.

Chapter Two: Pharmacists

Pharm 21 Pharmacist-in-charge, requirements, definition

and duties. No person shall conduct a pharmacy without a pharmacist-in-charge who shall be a pharmacist regularly employed in the prescription department and shall be designated in the application for license [and registration,] each renewal thereof or pursuant to Pharm 23. The term "pharmacist-in-charge" means a duly licensed pharmacist in the State of Minnesota who has been so designated, and it shall be his duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations:

A. [(a)] To establish for the employees of the pharmacy, policies and procedures for the procurement, storage, compounding and dispensing of drugs.

B. [(b)] To supervise all of the professional employees of the pharmacy.

C. [(c)] To supervise all of the non-professional employees of the pharmacy insofar as their duties relate to the procurement, sale and/or storage of drugs, **to develop appropriate detailed written procedures directing these activities, and to submit these procedures to the Board in accordance with Pharm 36.**

D. [(d)] To establish and supervise the method and manner for the storing and safekeeping of drugs.

E. [(e)] To establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping and return of drugs.

F. [(f)] To notify the Board immediately upon his knowledge that his services as pharmacist-in-charge have been or will be terminated.

Pharm 23 Pharmacist-in-charge, termination of service. Each pharmacy shall notify the [State] Board of Pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the [State] Board of Pharmacy of such designation. The [State] Board of Pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the [State] Board of Pharmacy within 10 days after receipt thereof.

Pharm 25 [Posting of License] **Licenses: annual renewal, fees, posting. Each pharmacist license shall expire on March 4 of each year and shall be renewed annually by filing an application therefor on or before March 1 of each year, together with a fee of $25. (Beginning January 1, 1978 said fee shall be $35). Any pharmacist license renewal application submitted after March 4 shall be subject to a late filing fee of $15 in addition to the renewal fee.**

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

Pharm 26 [Re-Examinations] **Licensure.**

A. Applicants for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicants' birth certificate and a recent photograph. Applicants not citizens of the United States must have filed and proved their intention of becoming citizens. All applicants shall show evidence of graduation from a college of pharmacy or a department of pharmacy of a university approved by the Board and meeting at least the minimum standards set by the American Council on Pharmaceutical Education in the 7th Edition of its accreditation manual. Such evidence shall be shown by submitting a final transcript showing the date on which degree was conferred. The above listed documents together with a check for $75 must be submitted to the Board at least 30 days prior to the examination.

B. Any applicant who has failed to pass the examination required by Minn. Stat. §§ 151.06, 151.07, 151.10 or 151.12, may retake such examination within the next ensuing fourteen months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the Board. The applicant shall, at least 30 days before an examination, notify the Board in writing of his intentions to retake the examination, certifying that information furnished on his original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of [$50] $75 payable to the State Treasurer. The board reserves the right to request a full and complete application.

C. Examination or license fees paid to the board shall not be returned.

D. An applicant who has failed to successfully pass the Minnesota Board of Pharmacy licensure examination shall not be eligible for licensure by reciprocity.

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Pharm 27 Continuing education requirements.

A. [(a)] Definitions.

1. [(1)] Continuing pharmaceutical education shall include but is not limited to professional post graduate education in any of the following subjects:

(a) [(aa)] Properties and actions of drugs and drug dosage forms;

(b) [(bb)] Etiology, characteristics and therapeutics and the disease state;

(c) [(cc)] Pharmacy practice;

(d) [(dd)] Legal, psychological and socio-economic aspects of health care delivery.

2. [(2)] Accredited program of Continuing Pharmaceutical Education means that a pharmacist must complete at least [25] **30** hours of credit in programs which are accredited by the [State] Board of Pharmacy.

3. [(3)] Accredited programs means those classes, conferences, correspondence study courses, institutes, lectures, professional meetings, programmed learning courses, journal readings, seminars, study groups, or comparable educational activities in Continuing Pharmaceutical Education which are accredited by the [State] Board of Pharmacy.

B. [(b)] Requirements for Continuing Pharmaceutical Education. Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minn. Stat. § 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he has completed an accredited program of Continuing Education during the previous two year period. Thereafter, each pharmacist shall submit such evidence every two years. **The Board may grant a pharmacist, upon application, an extension of time not to exceed one year to comply with the requirements of this Rule. Such extension shall not relieve the pharmacist from complying with the Continuing Education requirements for any other two year period.**

C. [(c)] Accreditation of programs. Application may be made by an association, corporation, educational institution, organization, or person to have a program designated as an accredited program and shall be made on forms provided by the board. The applicant shall show evidence of an ability to conduct the program and must maintain records of program content and attendance for not less than three years following completion of such program. Applications shall be submitted not less than 60 days prior to the commencement of the program. The Board shall assign the number of credit hours to each program and shall accredit or deny accreditation of such application within 30 days of receipt of the application.

D. [(d)] Revocation or suspension of an accredited program. The Board may deny, refuse to renew, revoke, or suspend authorization or accreditation previously furnished to sponsors of an accredited program if the program fails to conform to its application accredited by the Board, fails to furnish program content as publicized, or if the sponsor or program violates any provision of Laws of 1973, ch. 655, or this [regulation] **rule.**

E. [(e)] Hours of credit.

1. [(1)] Credit shall be earned on the basis of attendance or, in the case of correspondence courses, completion of a program. Failure to attend or complete an accredited program shall be the only reason for rejecting program credit hours.

2. [(2)] Credit for an identical program may be given only once to any individual during any reporting period.

F. [(f)] Credit for a presentation of professional lectures. Pharmacists may apply for credit of presentation of in-service training programs or lectures consisting of subjects included in the definition of Continuing Pharmaceutical Education, however, credit shall not be allowed for the preparation or presentation of programs or lectures for which academic credit may be granted to the pharmacy student. Such pharmacists need not apply for accreditation of the program provided that hours of credit applied for do not exceed the number of hours required to present the in-service training program or lecture, and, further provided that information, such as a class syllabus or lecture manuscript, he made available upon requests to document the presentation of the in-service training. Credit for presentation of the in-service training programs or other lectures will be granted only once for any given program or lecture.

G. [(g)] Advisory [Council] **Task Force** on Continuing Education. **The Advisory Task Force shall consist of not more than ten members. Five members of the Advisory Task Force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the College of Pharmacy of the University of Minnesota and two members shall be designated by the Board.** The Advisory [Council] **Task Force** on Continuing Education shall meet at least quarterly and shall annually elect a chairman and vice chairman from its membership. The secretary of the [State] Board of Pharmacy shall act as secretariat to the Advisory [Council] **Task Force.**

H. [(h)] List of accredited programs. The Board shall maintain a record of accredited programs including the

hours of credit assigned to each program. [Such] [records are to be made available to any registrant upon request.]

I. [(i)] Non-accredited programs. Pharmacists may apply for credit for inclusion of programs not previously accredited by the Board, provided that the name and address of the program sponsor and all of the information required by the Board in compliance with Section C is submitted to the Board within 45 days after completing the program. Such programs shall be subject to all of the standards herein provided.

J. [(j)] Program promotion. No reference shall be made by a program sponsor in publicizing a program that it is an "accredited program sponsor" or other reference indicating endorsement by the Board except as follows: "This program is accredited by the Minnesota [State] Board of Pharmacy for ___ hours of Continuing Education credit."

Pharm 28 Reciprocity.

A. Applications for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of $150 shall be filed with the secretary of the Board at least 30 days prior to the date said application is to be considered by the Board. The Board will consider applications for reciprocity in at least January and June of each calendar year.

B. To be found eligible for consideration by the Board;

1. Candidate must have practiced in the profession for at least one year after licensure in another state which is an active member of National Association of Boards of Pharmacy before he will be deemed eligible to reciprocate to Minnesota.

2. Applicant, if examined and licensed prior to January 1, 1973, shall show that he has acquired 2,080 hours of practical pharmacy experience under the instruction of a licensed pharmacist.

3. Applicant, if examined and licensed after January 1, 1973, shall show that he has acquired 1,500 hours of practical pharmacy experience under the instruction of a licensed pharmacist; said 1,500 hours to be acquired after the successful completion of the third year of the standard five year pharmacy curriculum, 400 hours of which may be acquired: concurrently with college attendance, in clinical pharmacy programs, or in demonstration projects which have been approved by the Tripartite Committee on Internship and the Board of the active member state from which he applies.

C. Defects in internship experience will not preclude an applicant from being deemed eligible provided that said applicant shall have practiced as a licensed pharmacist for one year, plus one week at 40 hours per week for each week or portion thereof that he is deficient in internship experience. (i.e., the number of weeks in excess of one year the applicant has practiced as a licensed pharmacist prior to applying for reciprocity must be equal to or greater than the number of weeks or portions thereof that he is deficient in internship experience.)

D. The Board may compel applicants who have not engaged in practice as a licensed pharmacist for the two years immediately preceding the time of filing of their application for reciprocity to take a practical examination.

E. Applicants for reciprocal licensure shall be required to display their familiarity with the laws regulating the practice of pharmacy in Minnesota by submitting to a written and oral examination on the Minnesota laws and regulations and the federal laws and regulations governing the practice of pharmacy.

Pharm [28-30] **29-30** Reserved for future use.

Chapter Three: Professional Practice

Pharm 31 Vending machines. It shall be deemed unlawful to distribute, dispense or vend any legend drug by automatic or vending machine. **Provided, however, that nothing in this rule shall prohibit a licensed hospital receiving pharmaceutical services from a licensed pharmacy on the premises, from utilizing such a device in an emergency, after regular pharmacy hours, when the hospital's pharmacist shall have complete control over the monitoring of drug therapy, packaging, labeling, filling, recordkeeping and security of the drugs involved and of the device, and when such device is utilized in compliance with all other state and federal laws and regulations regarding the distribution of legend drugs.**

Pharm 33 Mail order sale. Hereafter no pharmacist or pharmacy shall solicit **or participate in the solicitation,** by advertising of any kind the sale or distribution of drugs [by] requiring a prescription by any mail order plan of any form. The mail order sale **or distribution** of drugs [by] requiring a prescription is prohibited whenever such sale

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has been solicited by advertising of any kind by any person or persons. No pharmacists or pharmacy shall accept or fill a prescription which has been received by mail and that has been written by a practitioner not licensed to practice his profession in this state.

[Pharm 36 Compounding and Dispensing. The practice of compounding and dispensing a prescription includes, but is not limited to the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

(a) Receipt of prescriptions, written or oral, (except that written prescriptions may be received by an agent of the pharmacist if the patient is immediately adjacent to prescription area and pharmacist to enable professional communication and consultation directly with the pharmacist).

(b) Verification of prescribed dosage within proper limits.

(c) Reading, interpretation and transcription to the prescription label, or verification of the transcription by initialing the label, of the prescriber's directions for use in a manner that communicates his directions for use precisely, and with assurance of understanding by the patient.

(d) Selecting, compounding, mixing, combining, measuring, counting or otherwise preparing the drug or drugs needed to fill the individual prescription.

(e) Permanently affixing properly prepared label to the container of the prescription medication.

(f) Return of completed prescription medication to patient (except that completed prescription medication may be transmitted by an agent of the pharmacist if patient is immediately adjacent to pharmacist and prescription area to enable professional communication and consultation with the pharmacist).

(g) Obtaining, when required by law and in the best professional practice, permission to refill from authorized prescribers, and noting on the reverse side of the prescription the following data:

(1) Date refilled,

(2) Initials of practitioner authorizing refill (if different from original prescriber),

(3) Quantity of drug dispensed if different from the original prescription,

(4) Initials or signature (when required) of person refilling prescription.

(h) Supervision of non-pharmacist personnel in limited non-professional duties such as: looking up prescription refills, filing prescriptions, recordkeeping, non-professional aspects of presenting completed medications to patients and completing transaction, delivery.

Nothing in paragraphs one and six of this regulation shall prevent hospital pharmacists from accepting prescription orders or returning prescription medications via normal accepted in-patient hospital drug distribution practices.]

Pharm 36 Compounding and dispensing. The practice of compounding and dispensing a prescription includes, but is not limted to the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Determination of brands and suppliers.

B. Receipt of verbal prescriptions.

C. Verifying the prescription order. Verification of validity and propriety must be of the original prescription order. A copy, rewritten or verbal is not acceptable.

D. Selecting the drug to be used in filling the prescription.

E. Extemporaneous compounding on an individual basis.

F. Certifying the completed prescription. In certifying and documenting the completed prescription order, the pharmacist shall include:

1. Checking of the original labeled container from which the medication was withdrawn,

2. Checking of the labeling on the prescription medication container,

3. Checking the contents of the prescription medication container and the appearance of the total product,

4. Checking the patient's medication record, when utilized, for possible therapeutic incompatibilities and the accuracy of the addition to the record of the medication dispensed,

5. Initialing of the prescription by the pharmacist performing the certification.

G. Issuing the prescription to the patient in order to assure that the patient understands the use of the medication, the cautions and the proper storage of the drug

when in the professional judgment of the pharmacist such counsel is necessary.

H. Obtaining, when required by law or by the best professional practice, permission to refill from authorized prescribers of their agents, and noting on the reverse side of the prescription the following data:

1. Date refilled,

2. Name of practitioner authorizing refill (if different from original prescriber),

3. Quantity of drug dispensed (if different from the original prescription),

4. Initials of the pharmacist refilling the prescription.

I. Supervising non-pharmacist supportive personnel utilized in the performance of certain pharmacy tasks. (The nature of these tasks shall be such that they permit adequate checking by a pharmacist and do not require professional judgment. Non-pharmacist supportive personnel may be utilized in the performance of these tasks only after appropriate detailed written procedures directing these activities have been developed by the pharmacist-in-charge and have been submitted to and approved by the board).

The ratio of supportive personnel performing allowable delegated tasks to pharmacists responsible for their supervision shall not exceed 1:1 at any time, provided, however, that pharmacist preceptors responsible for the supervision of a pharmacist-intern may supervise one such supportive person in addition to the intern.

Appropriate procedures directing the activities of non-pharmacist, personnel performing non-professional, clerical duties such as typing, looking up refills, filing prescriptions, recordkeeping, etc., are to be maintained in the pharmacy.

Pharm 37 Unprofessional conduct. Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:

A. [(a)] The assertion or inference in a public manner of professional superiority in the practice of pharmacy,

B. [(b)] The publication or circulation of false, misleading or otherwise deceptive statements concerning the practice of pharmacy,

C. [(c)] Refusing to compound and dispense prescriptions which may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists,

D. [(d)] Participation in agreements or arrangements with any person, corporation, partnership, association, firm, or others involving rebates, "kickbacks", fee-splitting, or special charges in exchange for professional pharmaceutical services,

E. [(e)] Discriminating in any manner between patients or groups of patients, for reasons of religion, race, creed, color, sex, age or national origin,

F. [(f)] Refusing to consult with patrons or patients concerning contents, therapeutic values and uses of prescription or non-prescription drugs, chemicals or poisons,

G. [(g)] Requiring an individual patient to be a member of any organization, association or other group as a condition for obtaining the professional services of a pharmacist,

H. [(h)] The violation of any law, rule, regulation or ordinance of the State or any of its political subdivisions, including the [State] Board of Pharmacy, or the United States government or any agency thereof relating to the practice of pharmacy,

I. [(i)] Divulging or revealing to others the nature of professional pharmaceutical services rendered to a patient without his expressed consent orally or in writing or by order or direction of a Court. This shall not prevent pharmacies from providing information copies of prescriptions to other pharmacies or to the person to whom the prescription was issued and shall not prevent pharmacists from providing drug therapy information to physicians for their patients,

J. [(j)] Participation in institutional drug distribution as a consultant without providing pharmaceutical services in accordance with accepted principles of pharmacy practice and in compliance with Federal and State laws or regulations,

K. [(k)] Prescription drug price information may be provided to the public only by a pharmacy, so long as it is not violative of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. [(1)] No representation or suggestion concerning the drug's safety, effectiveness, indications for use or competitive comparison shall be made;

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2. [(2)] No reference shall be made to controlled substances listed in Schedule II-IV of the latest revision of the Federal Controlled Substances Act, and the [Regulations] **Rules** of the Minnesota [State] Board of Pharmacy;

3. [(3)] The termination date for the prices listed shall be stated in the ad.

The public promotion, direct or indirect, of drugs requiring a prescription, narcotics, depressants, or stimulants is hereby declared to be an act of unprofessional conduct. The reference in any advertistement 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 thereto shall be included within the meaning of public promotion.

L. The selling, giving away, or otherwise disposing of accessories (i.e., glassine papers, empty capsules, quinine, lactose, or similar products found in illegal drug traffic), chemicals, or drugs by a pharmacist when he knows or should have known of their intended use in illegal activities.

Pharm 40 Prescription labeling. All drugs dispensed to or for a patient (other than an in-patient of a hospital) shall be labeled with the following information:

A. [(a)] Identification of pharmacy

B. [(b)] Patient's name

C. [(c)] Prescription number

D. [(d)] Name of prescribing practitioner

E. [(e)] Directions for use

F. [(f)] Generic or trade name of drug and strength (except when specified by prescriber to the contrary).

1. [(1)] In the case of combining premanufactured drug products, the names of the products, or a category of use name shall suffice.

2. [(2)] In the case of compounding basic pharmaceutical ingredients, the common pharmaceutical name (if such exists), the names and strengths of the principle active ingredients or a category of use label shall suffice.

[Some Examples

Equanil, 400 mg.

Meprobamate, 400 mg.

Donnatal

Coriforte

Cosanyl/Cheracol a.a.

Calamine Lotion/Phenol 0.5%

Compounded Expectorant

White Lotion

Salicylic Acid 5%, Resorcin 5%, in Flexible Collodion

Keratolytic Ointment]

G. Name of the manufacturer of the finished dosage form of the drug.

H. [(g)] Auxiliary labels, as needed

I. [(i)] Date of original issue or renewal

Pharm 41 Labeling of controlled substances and certain other drugs. All drugs classified as controlled substances under Minn. Stat. § 152 and Pharm 51, antihistamines, psycho-therapeutic agents, and other drugs deemed appropriate in the professional judgment of the pharmacist and dispensed to or for an adult patient (other than an in-patient of a hospital or nursing home) shall be labeled according to the requirements of Pharm 40 and in addition shall contain the following:

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

Pharm 43 Electronic data processing.

A. When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed only by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information to be entered and verify the prescription order at the time of entry. The identity of such pharmacist must be carried in the record.

B. Electronic data processing equipment, when used to store prescription information must:

1. Guarantee the confidentiality of the information contained in the data bank.

2. Be capable of producing a hard copy daily summary of controlled substance transactions.

3. Be capable of recording and carrying in the record all dates of refills of any prescription and initials of the pharmacist which shall act in lieu of the requirements of Pharm 36 (h)(4).

4. Be capable of producing a patient profile indicating all drugs being taken and the dates of refills of these prescriptions.

5. Be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank.

C. In all cases where electronic data processing equipment is used the original prescription must be retained on file according to law to assure access to the information contained thereon in the event of a computer breakdown.

Pharm 44 Poisons. For the purpose of this regulation, poisons shall be deemed to mean any substance except drugs or medicines which has the inherent capability to produce bodily harm, injury, or morbidity to man or beast through ingestion, inhalation, or absorption through or from any body organ or surface and shall include, but not be limited to, substances that are toxic, caustic, corrosive, sensitizing, extremely flammable or explosive alone or in mixtures and whose label bears the signal word "Poisons" or cautionary words such as "Caution", "Warning", "Danger", etc. intended to signal a use alert.

Pharm 45 Sale of poisons. Sales of poisons or hazardous substances shall be made only by a registered pharmacist or by a pharmacy intern under the direct supervision of a pharmacist. Each such transaction shall be entered into a poison register with pen and each entry shall show the date and time of day, the name and quantity of substance, the proposed use, the name, address, and signature of the purchaser, and the signature of the seller. No such substance shall be sold without the pharmacist first determining the propriety of the purported use and satisfying himself that such purchaser has produced proof of identity and legal age.

Economic poisons and simple proprietory preparations in the original manufacturer's container may be entered into the poison register pursuant to the above requirement if called for by the best professional judgment of the pharmacist.

Pharm 46 Labeling of poisons. All poisons sold, except when in the original manufacturer's container or on the written prescription of a licensed practitioner, shall bear a label containing the word "Poison", the name and quantity of the substance, and the name and business address of the seller. In addition the package labeling shall contain the following information in accordance with the Hazardous Substance Labeling Act.

A. Name of the substance

B. The name and business address of the manufacturer or repackager

C. The word "POISON" in letters no smaller than the largest print on the label. For extremely dangerous substances this must be accompanied by the "skull and crossbone."

D. The word "Caution", "Warning", "Danger" or some such signal word of warning together with the specific indication necessitating its use.

E. The name and quantity of each toxic, poisonous, caustic, or corrosive constituent together with directions for treatment in case of accidental injury.

F. The added warning "Keep Out of the Reach of Children".

Pharm [41-50] **47-50** Reserved for future use.

Pharm 51 Controlled substances.

Sections (a) (1), (2), (4) remain unchanged.

3. [(3)] Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

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Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
3, 4-Methylenedioxy Amphetamine	MDA
4-Bromo-2, 5-Dimethoxyamphetamine	
2, 5-Dimethoxyamphetamine	
4-Methoxyamphetamine	
5-Methoxy-3, 4-Methylenedioxy Amphetamine	MMDA
Bufotenine	
Diethyltryptamine	DET
Dimethyltryptamine	DMT
3, 4, 5-Trimethoxy Amphetamine	TMA
4-Methyl-2, 5-Dimethyloxyamphetamine	DOM, STP
Ibogaine	
Lysergic Acid Diethylamide	LSD
Marijuana	
Mescaline	
N-ethyl-3-Piperidyl Benzilate	JB-318
N-methyl-3-Piperidyl Benzilate	JB-336
Psilocybin	
Psilocyn	
Tetrahydrocannabinols	THC
1- [1-(2-Thienyl) Cyclohexy] Piperidine	

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

Chapter Five: Internship

Pharm 61 Internship. A regulation for the purpose of defining and regulating the internship experience of prospective pharmacists as required by Minn. Stat. § 151.10 and § 151.101.

This regulation shall take effect immediately but the provisions contained herein shall not nullify any period of internship service by any individual previous to its adoption provided such period of internship is filed in a proper manner with the secretary of the [State] Board of Pharmacy.

A. [(a)] Definitions.

1. [(1)] "Pharmacist Intern" and "Intern" means (1) a natural person satisfactorily progressing toward the degree in pharmacy required for licensure, or (2) a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the [State] Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist, or (3) a qualified applicant awaiting examination for licensure.

2. [(2)] "Preceptor" means a natural person licensed as a pharmacist by the [State] Board of Pharmacy, and who participates in instructional programs approved by the Board.

3. [(3)] "Hour" means the standard 60 minute division of time.

4. [(4)] "Supervision", as used in connection with this regulation, means that in the pharmacy where the intern is being trained, a registered pharmacist designated as preceptor, or another registered pharmacist, shall be in continuous personal contact with and actually giving instructions to the intern during all professional activities of the entire period of his internship.

5. [(5)] "Concurrent time" means internship experience gained during the fourth and fifth academic years only, while a person is a full-time student carrying, in any given school term, at least 75% of the average number of credit hours per term needed to graduate within five years.

6. [(6)] "Approved clinical program" means a clinical program approved by the Internship Advisory Committee and the [State] Board of Pharmacy, which is a patient oriented instructional program involving actual patient contact activities, including, but not limited to; patient rounds, medication histories, patient drug education and clinical conferences.

7. [(7)] "Approved Externship Program" means an undergraduate program of practical experience administered by a college of pharmacy approved by the board.

8. [(8)] "Quarter" means that amount of internship time gained during a three month period of time, but not to exceed 700 hours.

B. [(b)] Registration and reporting.

1. [(1)] Every person shall register with the board before beginning his internship in this state. **Applications for the registration of a pharmacist-intern shall be on such form or forms as the Board of Pharmacy may from time to time prescribe and shall be accompanied by a fee of $20.** Registration shall remain in effect during successive quarters of internship training if progress reports, examinations, and affidavits of experience as required by the board are submitted promptly upon beginning or terminating employment, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy.

Credit for internship time will not be granted unless registration, progress reports and affidavits of experience for preceding time are completed and received.

2. [(2)] The pharmacist-intern shall be so designated in his professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall upon proper registration issue to the intern a pocket registration card for purposes of identification and verification of his role as an intern, which card shall be surrendered to the secretary of the board upon termination of the internship program.

3. [(3)] All registered interns shall notify the board immediately upon change of employment or residence address.

4. [(4)] The intern [shall] **may be required** to maintain additional records of his professional activities. Such records, which shall be submitted after the completion of each quarter of internship, are to be prescribed by the board for the purpose of recording details of the scope of internship experience and may include examinations to test the competency of interns. **Such examinations shall be administered approximately quarterly at such times and locations as the board may designate.**

5. No person who terminates his efforts towards the completion of the educational prerequisites of licensure is entitled to the continued privileges of internship registration.

6. No person not properly registered with the board as a pharmacy intern shall take, use, or exhibit the title of pharmacy intern, pharmacy apprentice, pharmacy extern, or any other term of similar or like import.

C. [(c)] Training requirements. The intent of this regulation is to provide a proper preceptor-intern (teacher-student) relationship within the context of the employer-employee relationship; provide a broad base of internship experience and to supplement didactic academic training in a manner which prepares the intern for all aspects of the practice of pharmacy.

1. [(1)] Nothing in this regulation shall imply that the standards described herein are acceptable to other states on a reciprocal basis.

2. [(2)] When an intern desires to obtain credit for training received in a state other than Minnesota, he shall abide by all the provisions of the internship regulations in that state, and shall provide evidence from that state's board of pharmacy that his internship training has been completed in compliance with the internship standards of the National Association of Boards of Pharmacy and with the standards herein provided. Where a possible conflict may exist between the provisions of this regulation and the requirements of the state in which the intern is training the intern shall contact the secretary of the State Board of Pharmacy in his state and outline any possible problem.

3. [(3)] No more than one intern shall be trained by a preceptor at one time.

4. [(4)] Upon registration, interns and preceptors will be furnished guides and objectives for internship training. The guides are furnished to suggest appropriate types and order of training experience and shall be used to insure that the intern's practical experiences are commensurate with his educational level, and broad in scope.

5. [(5)] Applicants for licensure as pharmacist who are examined and licensed after September 17, 1973, shall submit evidence that they have successfully completed not less than 1,500 hours of internship under the instruction and supervision of a preceptor. Credit for internship shall be granted only to registered interns who have begun the fourth year of the five year pharmacy curriculum, provided, however, that:

(a) [(aa)] 400 hours of internship credit may be acquired by any combination of the following: internship experience gained concurrent with attendance at a college of pharmacy during the fourth and fifth year, or participation in

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approved clinical pharmacy programs [, approved externship] [programs] or approved internship demonstration projects.

(b) [(bb)] At least 520 hours of the required internship time shall be completed after graduation from a college of pharmacy approved by the board and shall consist of advanced internship training involving the compounding and dispensing of drugs and drug consultation with patients.

(c) [(cc)] Not more than 700 hours of intership credit may be given during any internship quarter.

D. [(d)] Reciprocity standards. The board may accept internship credit from applicants for licensure by reciprocity who have submitted evidence of completion of internship training in another state, provided that the training is, in the opinion of the board, substantially equivalent to the standards herein provided, and is in compliance with the internship standards of the National Association of Boards of Pharmacy, and provided, further, that the applicant has practiced pharmacy for one year prior to being examined for licensure in this state pursuant to the requirements of Pharm 28.

E. [(e)] Advisory committee. The board shall appoint an Advisory Committee on Internship to advise the board on the administration of this regulation. The committee shall include practicing pharmacists, pharmacist-educators, pharmacy interns and representatives of the board.

Chapter Eight: Nuclear Pharmacy The provisions of Pharm 101-110 are applicable to pharmacies and manufacturers dealing with radioactive pharmaceuticals, provided, however, that Pharm 1 through 70 shall also be applicable to such pharmacies, unless specifically exempted by Pharm 101-110 or are in direct conflict therewith, in which case Pharm 101 through 110 shall apply.

Pharm 101 Definitions.

A. Radioactive drug. A radioactive drug is any substance defined as a drug in Section 201 (g) (1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or nuclide generator which is intended to be used in the preparation of such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

B. Nuclear pharmacy. A nuclear pharmacy is any area, place or premises described in a license issued by the board with reference to plans approved by the board where radioactive drugs are stored, prepared, manufactured, derived, manipulated, compounded or dispensed.

C. Manufacturers of radioactive drugs. Any person, firm or hospital compounding, mixing, deriving, repackaging or otherwise preparing a radioactive drug for use, other than in the medical facility of which it may be physically attached, shall be licensed as a manufacturer.

Pharm 102 Minimum standards. Proof of adequate space and equipment for storage, manipulation, manufacture, compounding, dispensing, safe handling and disposal of radioactive material must be submitted to and approved by the board before a pharmacy license is issued by the board.

Compliance with all laws and regulations of the U.S. Nuclear Regulatory Commission and other applicable Federal and State agencies shall be deemed minimal compliance with this section and further requirements, as the board in its opinion finds necessary and proper for health and safety in the production, compounding, dispensing and use of radioactive drugs, may be imposed as a condition of licensure. A pharmacy exclusively handling radioactive materials may be exempt from the building and equipment standards of Pharm 7 through 11 if the board finds it is in the public interest.

Pharm 103 Pharmacists handling radioactive drugs. A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the board. Education and experience in non-approved programs may be accepted if, in the opinion of the board, such programs provide a level of competence substantially the same as approved programs.

Pharm 104 Pharmacist-in-charge. A pharmacy handling radioactive drugs shall not function without having a pharmacist who is competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs in charge of the licensed premises. All personnel performing tasks within such pharmacy shall be under the immediate and direct supervision of the pharmacist competent in handling radioactive drugs.

Pharm 105 Acquisition, storage and distribution of radioactive drugs. Only radioactive drugs which are approved by the US Food and Drug Administration or which are investigational drugs having IND or NDA status may be dispensed by a nuclear pharmacy.

All radioactive materials shall be kept locked and secure from unauthorized personnel.

Radioactive drugs shall not be transferred, distributed or dispensed to any person or firm not licensed or authorized to receive or possess such drugs.

Pharm 106 Recordkeeping. Pharmacists handling radioactive drugs shall maintain records of acquisition and disposition of all radioactive drugs for a period of not less than two (2) years.

In the case of investigational radioactive drugs such pharmacy records shall include an investigators protocol for the preparation of radioactive drugs, a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the manufacturer-"sponsor" indicating the physican requesting the radioactive drug is a qualified investigator; and such other records as good professional practice would dictate.

Additional records shall be maintained as required by any other statute or regulation of any federal or state agency.

Chapter Nine: Pleading, Practice and Procedure

Pharm 111 Definitions as used in these rules:

A. "Board" means the Minnesota Board of Pharmacy;

B. "Hearing" includes a joint hearing of the board and any other administrative agency;

C. "License" means any license, permit, certificates of registration or other grant of authority, issued or subject to suspension or revocation by the board;

D. "Revocation or Suspension" of license includes refusal to renew the same.

Pharm 112 How proceedings initiated. Proceedings to revoke or suspend licenses may be initiated in one of two ways, except insofar as any order of suspension or revocation which may be issued pursuant to a statute not requiring hearing.

A. On a verified complaint by an individual or an agency required by law to enforce the law in question, filed with the Board of Pharmacy;

B. By the board on its own motion whenever its investigation discloses probable grounds for disciplinary action. The board president or secretary may act for the board in initiating proceedings under this section.

Pharm 113 Procedure upon filing of complaint. All complaints received pursuant to the provisions of Rule Pharm 112 shall be dealt with in accordance with the requirements of Minn. Stat. § 214.10.

Pharm 114 Style of pleadings. All pleadings, notices, orders, and other papers filed in such proceedings shall be captioned "BEFORE THE MINNESOTA BOARD OF PHARMACY", and shall be entitled "IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE _____ OF _____ RESPONDENT." The party whose license is involved shall be known and designated as the "Respondent".

Pharm 115 Form of charges. If the alleged offense is a continuing one, its general nature and the approximate time covered shall be stated in the complaint or notice of hearing, if a specific incident is relied on, it shall be alleged with such particularity as to time, place and circumstances, as may be necessary to enable the respondent to prepare his defense; and in either case the offense may be alleged in the language of the statute or rule claimed to have been violated. Separate charges shall be stated in separate paragraphs and numbered consecutively.

Pharm 116 Order for and notice of hearing. Notices of hearing shall be addressed to the respondent at his last known past office address and shall be subject to the Administrative Procedures Act Minn. Stat. § 15.01 et seq., and the Rules for Contested Cases of the Office of Hearing Examiners, Minnesota Rules HE 201-222.

Pharm 117 Service and filing of papers. Unless otherwise provided by law, all orders, notices and other papers may be served by the secretary or the board by first class, certified, or registered mail addressed to the party at his last known post office address, or to his attorney of record. Papers required to be filed with the board may be mailed to the following address: 717 Delaware Street, SE, #351, Minneapolis, Minnesota 55414.

Pharm 118 Deficiency reports. The pharmacist-in-charge of any pharmacy wherein deficiencies are noted upon inspection by the board or its staff shall, within 30 days of receiving notice of such deficiency, submit in writing to the board the steps taken or proposed to eliminate the deficiency. Failure to submit such report or to eliminate such deficiency shall be grounds for the institution of disciplinary action by the board.

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