

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

#503 Dept of Health

RULES REVIEW CHECKLIST

DATE RULES RECEIVED 1-26-79 Temporary Rule _____

Resubmitted and Received _____

DUE DATE 2-16-79

Dated returned back in office: 3/12/79

a. Returned to Agency w/o filing w/Secy of State 2/16/79
b. Approved _____ Date Sent Back to Agency _____

- -

1. Rules as Adopted ✓
2. Rules as Proposed ✓
3. Certificate of Board's Authorizing Resolution, where applicable ✓
4. Order for Hearing ✓
5. Notice of Hearing ✓
   (i) Sufficiency O.K under old rule
6. Secretary of State's List _____
7. Certificate of Acquisition of Secretary of State's List OK.
8. Affidavit of Mailing _____
   (i) At least 30 days prior to hearing _____
9. Statement of Need and Evidence ✓
10. Hearing Examiner's Report ✓
11. Agency's Findings of Fact ✓
12. Certificate of Board's Resolution Adopting Rules, where applicable ✓
13. Order Adopting ✓
14. Report of Chief Hearing Examiner ✓
    (i) Finding of No Substantial Change ✓
    (ii) Permission to Incorporate by Reference, where applicable N/A
15. Certificate of Compliance with Rulemaking Procedures ✓
16. Copy of Notice of Intent to Solicit Outside Opinion, where applicable N/A
17. Petition by Public, where applicable N/A.

OUR FILE NO. 503

DAVID E. HOLMSTROM
Executive Secretary
Pharmacy Board

March 15, 1979

WILLIAM G. MILLER
Special Assistant
Attorney General

Joanie

- Department of Health relating to Unit Drug Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters

cc: Duane Harves

ADMIN 1000 (Rev. 1/78) Our File No. 503

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT ATTORNEY GENERAL

TO : DAVID E. HOLMSTROM
Executive Secretary
Pharmacy Board

DATE: 2/16/79

FROM : WILLIAM G. MILLER
Special Assistant
Attorney General

JOANNE E. HINDERAKER JEH
Special Assistant
Attorney General

PHONE: 296-4692

SUBJECT: In the Matter of Proposed Amendments Relating to Unit Drug Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters.

As I have previously discussed with Mr. Holmstrom by telephone, on February 14, 1979, the above-captioned rule amendments have not been approved by this office for the following reasons:

1.) Many of these amendments are changes in rules or make reference to rules which have previously been published in the MCAR series. Considerable confusion results if these particular amendments do not incorporate the MCAR citation format. Therefore these amended rules should adopt the MCAR format in any and all of the citations included therein. References such as Pharm 36 or Regulation 40 should be changed accordingly.

2.) In Pharm 36 F. 4. "medication record" was changed to "medication profile", however a second reference to "record" in that clause was not changed to "profile". Such a change should be made to ensure that the rule is consistent.

3.) In Pharm 71 C.2. the statutory reference therein should read: Minn. Stat. § 152, not Minn. Stat. 152.

4.) In Pharm 84 B.1. the phrase "the following measures related to the control, accessibility, dispensing and administration of drugs", should be followed by a colon, not a semi-colon.

5.) In the text of various rules the internal cross-reference citations therein were not changed in accordance with changes made to the proposed amendments. Such internal citations should be corrected. For example: Pharm 84 B.2. a (9) should refer to 84 B.1. e and f, not to 84 B.1. f and g; Pharm 84 B.2. a. (10) should refer to 84 B.1. d, not 84 B.1. e; Pharm 88 C. should refer to 84 B.1. e, and not 84 B. 1. f. The staff should be attentive to any other such changes which should be made in the above-captioned amendments as the examples set out herein are not intended to be an exhaustive list.

6.) In Pharm 86 C. there is a reference to the U.S.P./N.F. which apparently is a reference document well-recognized by experts in the pharmacy field. Such a document should most likely be incorporated by reference and under Minn. Stat. § 15.0412 subd. 4, and HE Rule 108, the Chief Hearing Examiner's approval of such incorporation is required. I request that you contact Mr. Duane Harves in this regard. If his approval is required you should obtain such, and then provide this office with the appropriate documentation reflecting the approval.

Upon consideration of the comments made above, I request that you make the requisite changes in the rules. After doing so, please submit at least 3 corrected copies of the rules as adopted to this office.

Do not hesitate to contact me if there are any questions regarding this memorandum or any other matters relating to these amendments.

JEH/bw
cc: Duane Harves

ADMIN. 1000
3

STATE OF MINNESOTA

DEPARTMENT BOARD OF PHARMACY

Office Memorandum

TO : Joanne E. Hinderaker
Special Assistant
Attorney General

DATE: March 9, 1979

FROM : David E. Holmstrom
Executive Secretary

SUBJECT: In the Matter of the Proposed Amendments Relating to Unit Dose Drug Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters.

Enclosed are three copies of the proposed rules incorporating the minor changes which you outlined in your memorandum to me of February 16, 1979. Also enclosed is a signed report of the Chief Hearing Examiner relating to the incorporation by reference which you also requested in your February memorandum.

In your February 16 memorandum to me you indicate that upon our making the requisite changes in the rules you felt that you would be able to sign off on these rules. I would greatly appreciate it if you could accomplish this as soon as possible.

Thank you.

DEH:pe

Encl. (4)

RECEIVED
MAR 12 1979
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

~~Pharm-21~~ 8.021 Pharmacist-in-charge, requirements, definitions and duties. No person shall conduct a pharmacy without a pharmacist-in-charge who shall be a pharmacist regularly employed in the pharmacy department and shall be designated in the application for license, each renewal thereof or pursuant to ~~Pharm-23~~ 7 MCAR 8.023. 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. to establish for the employees of the pharmacy, policies and procedures for the procurement, storage, compounding and dispensing of drugs, and the communication of information to the public in relation to drug therapy;

B. to supervise all of the professional employees of the pharmacy;

C. to supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the procurement, sale and/or storage of drugs;

D. to develop appropriate detailed written procedures directing activities of supportive personnel and to submit these procedures to the Board in accordance with ~~Pharm-47~~ 7 MCAR 8.047;

E. to establish and supervise the method and manner for the storing and safekeeping of drugs;

F. to establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping and return of drugs;

G. to notify the board immediately upon his knowledge that his services as pharmacist-in-charge have been or will be terminated;

H. to respond to 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.

~~Pharm-32~~ 8.032 Return of drugs and devices. ~~prohibited.~~

A. Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale any drugs, prescribed medications, chemicals, poisons or medical devices; except that in a hospital with a licensed pharmacy, drugs, devices or other items dispensed for hospital in-patient use may be returned to the pharmacy for disposition by a pharmacist in accordance with good professional practice.

B. Drugs and prescribed medications from nursing homes may be returned to the dispensing pharmacy provided that: ~~proper-storage-conditions-in-the-home can-be-assured;-provided-that-the-drugs-and-prescribed-medications-are-received by-the-pharmacy-in-the-original-manufacturer's-packaging-or-pharmacist-packager's single-Unit-Dose,-single-Unit-of-Use-or-strip-packaging-indicating-the-drug name-and-strength,-the-manufacturer's-or-packager's-name-and-the-manufacturer's or-packager's-lot-or-batch-number;-and-provided-that-the-integrity-of-such packaging-remains-intact.--No-reconstituted-drugs,-drugs-requiring-refrigeration or-controlled-substances-may-be-so-returned.~~

1. the consultant pharmacist can assure proper storage conditions for the drug in the facility as specified in the United States Pharmacopeia,

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

3. the drugs and prescribed medications are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's single Unit-Dose, single Unit-of-Use or strip packaging indicating the drug name and strength, the manufacturer's or packager's name and the manufacturer's or packager's lot or batch number,

4. the integrity of such packaging remains intact, and

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

C. Commingling of returned medication or mixing of lot numbers of returned medication, upon or prior to repackaging, shall result in such medication being deemed misbranded and subject to embargo under Minn. Stat. § 151.38. This prohibition shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale or ~~re-rent~~ rerent thereof.

~~Pharm-36~~ 8.036 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~~ profile, when utilized, for possible therapeutic incompatibilities and the accuracy of the addition to the ~~record~~ profile 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.~~ G. ~~Obtaining,~~ Assuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized prescribers or their agents, and then 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.

H. Supervising nonpharmacist clerical personnel in limited nonprofessional duties such as looking up prescription refills, filing prescriptions, record keeping, nonprofessional aspects of presenting completed medications to patients and completing the transaction.

I. Supervising nonpharmacist supportive personnel utilized in the performance of certain pharmacy tasks. The use of such supportive personnel shall be in accordance with the provisions of ~~Pharm-47~~ 7 MCAR 8.047.
The provisions of this rule shall apply to all pharmacies provided, however, that nothing in this rule shall prevent pharmacists in hospitals from dispensing to hospital in-patients according to the provisions of 7 MCAR 8.081-8.100.

~~Pharm-38~~ 8.038 Prepackaging.

A. Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall cause to be prepared and kept a packaging control record containing the following information.

1. Date.

2. Identification of drug.

a. Name.

b. Dosage form.

c. Manufacturer.

d. Manufacturer's lot number.

e. Strength.

f. Manufacturer's expiration date (if any).

3. Container specification.

4. Copy of the label.

5. Initials of the packager.

6. Initials of the supervising pharmacist.

7. Quantity per container.

8. Internal control number or date.

B. Each prepackaged container shall bear a label containing the following information:

1. Name of drug.

2. Strength.

~~3.--Dosage-form.~~

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

4. Manufacturer's expiration date (if any), or any earlier date which, in the pharmacist's professional judgment, is preferable.

~~4.~~ 5. Internal control number or date.

~~5.--Manufacturer's-expiration-date-(if-any).~~

~~6.--Auxiliary-labels,-as-needed.~~

~~Pharm-47~~ 8.047 Supportive personnel. Supportive personnel may be used in performing pharmacy tasks not specifically reserved in these rules to a licensed pharmacist, assistant pharmacist or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Supportive personnel may perform functions which do not involve professional pharmaceutical judgment.

B. Pharmaceutical products prepared by supportive personnel must be certified for accuracy by a licensed pharmacist (as provided for in ~~Pharm-36~~ 7 MCAR 8.036 F) prior to release for patient use.

C. Written procedures for the use of supportive personnel shall be prepared by the pharmacist-in-charge, shall be submitted to the board, and a copy shall be kept on file in the pharmacy. These procedures must ~~be-approved by-the-board-prior-to-implementation-of-the-procedure.~~ comply with the standards set forth in this rule and will be approved on that basis. Approval must be obtained prior to implementation of the procedures.

1. These procedures shall indicate in detail the tasks performed by the supportive person and the certification steps performed by the licensed pharmacist.

2. New procedures or changes in procedures shall be submitted to the board for approval as specified above.

3. The submitted procedures shall be automatically approved 90 days after receipt by the board unless the pharmacist-in-charge is notified by the board of the specific reasons the procedures are unacceptable. (This paragraph shall become effective one year after final promulgation of this rule.)

D. Supportive personnel shall be supervised by a licensed pharmacist ~~physically-present~~ stationed within the same work area who has the ability to control and is responsible for the action of the supportive person.

1. The basic ratio of supportive personnel allowed by this rule to work with one pharmacist shall be 1:1. Specific functions shall be excepted from the 1:1 ratio as follows:

a. intravenous admixture preparation (~~Pharm-84~~ 7 MCAR 8.084), 3:1;

b. Unit Dose dispensing (~~Pharm-42~~ 7 MCAR 8.048), 3:1;

c. prepackaging (~~Pharm-38~~ 7 MCAR 8.038), 3:1;

d. bulk compounding (~~Pharm-39~~ 7 MCAR 8.039), 3:1.

2. Personnel used solely for clerical duties such as typing, looking up refills, filing prescriptions, recordkeeping, etc. need not be included in the ratios of the functions performed by supportive personnel.

3. A pharmacist-intern submitting hours toward completion of the 1500-hour requirement is not considered a supportive person for the purpose of determining the number of supportive persons supervised by a licensed pharmacist.

4. A pharmacist-in-charge of any pharmacy may petition the board for use of supportive personnel in ratios in excess of those allowed under these rules or for functions not specified in these rules. This petition for the use of additional personnel must be based on evidence that patient care and safety is maintained. The burden of persuasion is on the pharmacist-in-charge. Such a petition shall be automatically approved 90 days after receipt by the board unless the board shall send to the pharmacist-in-charge notification of the specific reasons why the petition is unacceptable.

E. The use of supportive personnel in the performance of delegated tasks not included in approved written procedures may be considered to be unprofessional conduct on the part of the pharmacist supervising the supportive personnel and the pharmacist-in-charge.

~~Pharm-48~~ 8.048 Unit Dose dispensing. A Unit Dose system shall be under the control of the pharmacist-in-charge. The act of drug dispensing is reserved for licensed pharmacists and registered pharmacist-interns acting under the supervision of licensed pharmacists, as set forth in ~~Pharm-36~~ 7 MCAR 8.036. A Unit Dose system may be used as an alternative to ~~Pharm-36~~ 7 MCAR 8.036 D, ~~G, and H~~ F, and G, according to the following paragraphs.

A. Definitions.

1. Unit Dose packaging. Unit Dose packaging is the packaging of individual doses of medication in containers which will preserve the identity and integrity of the drug from the point of packaging to the point of administration to the patient. Packaging may be accomplished by a manufacturer or by a pharmacy in accordance with ~~Pharm-38~~ 7 MCAR 8.038. ~~Packaging procedures and packaging materials must conform to existing state and federal laws including those found in The Code of Federal Regulations and known as the "Good Manufacturing Procedures."~~

a. Individual doses of medication shall be properly labeled from the manufacturer with the name of the drug, dosage form and strength, manufacturer's name and lot number and expiration date of all time dated drugs or labeled in accordance with ~~Pharm-38~~ 7 MCAR 8.038 if prepackaged by the pharmacy.

b. Unit Dose packaging may provide individual doses of medication attached to each other by placement in a card or other container. Such packaging shall be labeled in accordance with ~~Pharm-38~~ 7 MCAR 8.038 in such a manner as to provide continuous identification of the contents and, when dispensed, the name and location of the patient, name of the prescribing practitioner,

prescription number, date, the directions for use and identification of the pharmacy.

2. Unit Dose system. The Unit Dose system is that drug distribution system which is pharmacy based and which uses Unit Dose packaging in a manner which removes traditional drug stocks from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled.

The system must provide and the pharmacist must utilize:

a. a means of separating medications by patient name and bed number;

b. a means of separating medications by day of administration;

c. a means of identifying individual doses dispensed, doses administered and doses returned;

d. a means of identifying the dosage regimen of each drug, including the date of the original order and the date of changes, if any, in the prescriber's drug order;

e. a means of identifying the total dosage regimen of each patient;

f. a means of identifying the time of administration of each drug;

g. a means for the pharmacist to verify the original prescriber's order;

h. a means for the pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient.

B. Each pharmacy utilizing a Unit Dose dispensing system shall establish written policies specifying the categories of drugs which will or categories of drugs which will not be dispensed under the Unit Dose distribution system. Such policies shall be available in the pharmacy for inspection by the board.

1. Proper utilization of the Unit Dose system requires that in as far as is practicable all medications be in Unit Dose packaging when dispensed.

2. Schedule II, III, and IV controlled substances may be included in the Unit Dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

3. ~~Drugs not dispensed under the Unit Dose dispensing system must be dispensed in accordance with Pharm-36.~~ Legend drugs not dispensed under the Unit Dose dispensing system must be dispensed in accordance with 7 MCAR 8.036 and labeled in accordance with 7 MCAR 8.040 and 8.041.

C. Selection of individual Unit Dose packaging for placement in individual patient containers, bins, compartments or drawers is not dispensing under ~~Pharm-36~~ 7 MCAR 8.036 and may be performed by supportive personnel. Dispensing occurs upon the certification of the accuracy of the selected Unit Dose packages which shall be done by the pharmacist before the dose is delivered for administration to the patient.

D. All medication shall be stored in a locked area or locked cart.

E. Unit Dose systems shall comply with existing law with respect to provisions of pharmaceutical services to hospitals and nursing homes and as set forth in ~~Pharm-71-100~~ 7 MCAR 8.071-8.100.

~~Pharm-49-50~~ 8.049-.050 Reserved for future use.

Chapter Five Internship

~~Pharm-61~~ 8.061 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 Board of Pharmacy.

A. Definitions.

1. "Pharmacist intern" and "intern" means:

a. a natural person satisfactorily progressing toward the degree in pharmacy required for licensure; or

b. a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

c. a qualified applicant awaiting examination for licensure.

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

3. "Hour" means the standard 60 minute division of time.

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. "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. "Approved clinical program" means a clinical program approved by the Internship Advisory Committee and the 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. "Approved externship program" means an undergraduate program of practical experience administered by a college of pharmacy approved by the board.

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

B. Registration and reporting.

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. 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. All registered interns shall notify the board immediately upon change of employment or residence address.

4. The intern 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. These examinations shall be of a pre-test and post-test nature bracketing such segments of the intern's experience as the board deems appropriate. Interns completing the first quarter of their internship experience will be required to ~~show~~ attain~~ment of~~ a score of 65% on the post test examination before credit will be granted by the board for that experience. Interns participating in subsequent quarters will be required to attain a score of 75% on the post-test examination before credit will be granted by the board for that experience.

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 pharmacist-intern shall take, use, or exhibit the title of pharmacist-intern, pharmacist-apprentice, pharmacist-extern, or any other term of similar or like import.

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

2. When an intern desires to obtain credit for training received in a state other than Minnesota, he shall abide by all the provisions of the internship regulations 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. No more than one intern shall be trained by a preceptor at one time.

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

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

a. 400 hours of internship credit may be acquired by any combination of the following: internship experience gained concurrent with attendance at a college of pharmacy during the fourth and fifth year, or participation in approved clinical pharmacy programs or approved internship demonstration projects.

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

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

D. 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~~ 7 MCAR 8.028.

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 Six Pharmaceutical Services to Patients in Nursing Homes and Residents of Boarding Care Homes

The provisions of ~~Regulations-71~~ 7 MCAR 8.071 through ~~80~~ 8.080 are applicable to pharmaceutical services provided to patients in long term care facilities, provided, however, that ~~Regulations-1~~ 7 MCAR 8.001 through ~~70~~ 8.070 shall also be applicable to such pharmaceutical services, unless specifically exempted by ~~Regulations-71~~ 7 MCAR 8.071 through ~~80~~ 8.080 or are in direct conflict therein, in which case ~~Regulations-71~~ 7 MCAR 8.071 through ~~80~~ 8.080 shall apply.

~~Pharm-71~~ 8.071 Prescription order communication.

A. Pharmacists and pharmacies shall accept orders for dispensing and refilling only if such orders are communicated directly from the prescriber or transmitted through his designated agent.~~,-a-nurse-employed-by-the-facility and-designated-in-writing-by-the-prescriber-to-act-as-his-agent-for-the-sole and-exclusive-purpose-of-communicating,-either-orally-or-in-writing,-said~~

~~physician's-medication-orders-to-any-pharmacy.~~ Such an agent shall be an employee of the physician or a nurse employed by the facility and designated in writing by the prescriber as authorized to communicate, either orally or in writing, the prescriber's medication orders to a pharmacy.

B. Such orders may be in writing or, except for Schedule II controlled substances, an oral order reduced to writing by the pharmacist and may include authorization for multiple refills consistent with good practice and legal limitations. A facsimile copy of the prescriber's medication order may be accepted and filed as a prescription by the pharmacy.

C. Schedule II controlled substances shall be dispensed only upon receipt of an original written order signed by the prescribing individual practitioner ~~or-orally-in-emergency-situations-as-allowed-by-Federal-Regulations.~~ or upon an oral order reduced to writing given in emergency situations as allowed by these criteria:

1. Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user; and,

2. No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of Minn. Stat. § 152 and Pharmacy Rule 7 MCAR § 8.051; and,

3. It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the person dispensing the substance, prior to dispensing.

~~Pharm-72~~ 8.072 Prescription labeling. All prescription containers, other than those dispensed pursuant to ~~Pharm-48~~ 7 MCAR 8.048, shall be properly labeled in accordance with ~~Regulation-40~~ 7 MCAR 8.040 and shall also contain at least the following information:

A. ~~Name-of-drug.~~ Quantity of drug dispensed.

B. ~~Potency-of-drug.~~ Date of original issue, or in the case of a refill, the most recent date thereof.

C. ~~Quantity-of-drug-dispensed.~~ Expiration date of all time dated drugs.

~~D.--The-name-of-the-manufacturer-of-the-finished-dosage-form-of-the-drug.~~

~~E.--Specific-directions-for-use.~~

~~F.--Date-of-original-issue,-or-in-the-case-of-a-refill,-the-most-recent date-thereof.~~

~~G.--Expiration-date-of-all-time-dated-drugs.~~

~~H.--Auxiliary-labels-as-needed.~~

Directions for use on labels of medications shall be changed only by a pharmacist acting on the instructions of the prescriber or his agent. Such medications shall be returned to the pharmacist provider to be so relabeled, or a pharmacist shall relabel such medications at the facility.

~~Pharm-73~~ 8.073 Labeling of insulin. Insulin, shall be dispensed with a label affixed to the vial showing at least the patient's full name and location.

~~Pharm-74~~ 8.074 Drugs for use in emergency kits. Pharmacists may ~~dispense,~~ provide, upon a written or oral order from a licensed practitioner, limited supplies of drugs for use in an emergency kit.

~~A.~~ Only emergency drug supplies, as determined by the patient care policy committee or pharmaceutical service committee ~~only~~ necessary for patient care in life threatening emergencies, may be made available. The drugs in the emergency kit are the ~~property~~ responsibility of the ~~pharmacy~~ pharmacist and, therefore, shall not be used or altered in any way except as outlined herein. ~~Long-term-care-facilities-shall-store-a-supply-of-emergency-drugs on-at-least-one-nursing-station-and:~~ Such emergency drug supplies shall comply with the following:

~~1.~~ A. such drugs shall be limited to a maximum of six single doses, in either sealed ampuls, vials or prefilled syringes to the extent possible, of any one emergency drug. If an emergency drug is not available in parenteral form, a supply of the drug in inhalation or sublingual form may be obtained in the smallest sealed manufacturer's package. Inclusion of other oral legend drugs is to be discouraged. All drugs in this supply shall be properly labeled;

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

~~3.~~ C. the pharmacist shall be notified by the ~~director-of-nursing services~~ facility when drugs have been used from the emergency kit or when the seal has been broken;

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

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

~~6.~~ F. the supply shall be checked monthly by the pharmacist who is responsible for control of the kit.

~~Pharm-75~~ 8.075 Pharmacist consultative services to long term care facilities.

~~A.--The-nursing-home-facility-shall-retain-a-pharmacist-other-than-the vendor-pharmacist,-whenever-possible,-who-devotes-a-sufficient-number-of-hours during-a-regularly-scheduled-visit,-for-the-purpose-of-coordinating,-supervising, and-reviewing-the-pharmaceutical-services-within-the-facility.--There-shall be-a-formal-arrangement-for-such-qualified-pharmaceutical-services-between the-facility-and-the-pharmacist,-including-an-arrangement-for-remuneration separate-and-apart-from-that-provided-to-vendor-pharmacists.~~

~~B.--The-responsibilities-of-the-pharmacist-shall-include,-but-are-not limited-to-the-following:~~

~~1.--serving-on-the-pharmaceutical-services-committee-and/or-patient care-policy-committee-and-assisting-in-the-preparation-and-revision-of-policies and-procedures-governing-the-pharmaceutical-services;~~

~~2.--developing,-coordinating-and-directing-or-supervising-all pharmaceutical-services-provided-in-the-facility;~~

~~3.--reviewing-the-drug-regimen-of-each-patient-and-resident-at-least monthly-and-preparing-appropriate-reports-and-recommendations.--This-review shall-include-at-least:~~

~~a.--a-review-of-all-drugs-currently-ordered;~~

~~b.--information-concerning-the-patient's-condition-as-it-relates to-drug-therapy;~~

~~c.--medication-administration-records-and,-where-appropriate, physician-progress-notes,-nurses'-notes,-and-laboratory-test-results;~~

A. A pharmacist providing pharmacy consultative services to a long term care facility shall devote a sufficient number of hours during regularly scheduled visits to the long term care facility for the purpose of reviewing the quality of the pharmaceutical services provided to the long term care facility residents. There shall be a written agreement, separate and apart from that provided to pharmacists supplying prescription drug services to residents, for such pharmaceutical consultative services between the facility and the pharmacist which shall be available for review by the Board.

B. The pharmacist shall be responsible for but not limited to the following:

1. preparation and revision of policies and procedures governing the pharmaceutical services;

2. development, coordination and direction or supervision of all pharmaceutical services provided in the facility;

3. review of the drug regimen of each resident and preparation of appropriate reports and recommendations. This shall include at least a review of:

a. all drugs currently ordered;

b. information concerning the patient's condition as it relates to drug therapy;

c. medication administration records and, where appropriate, physician progress notes, nurses' notes, and laboratory test results.

4. reporting, in writing, irregularities in the storage, dispensing and administration of drugs and other matters relating to the review of the

drug regimen, to the administrator, ~~appropriate attending physician, and vendor pharmacist;~~ and other appropriate health professionals as may be determined by the administrator and consultant pharmacist;

5. preparing, at least quarterly, a written report on the status of the pharmaceutical service and staff performance and submitting this report to the administrator and patient care policy committee and/or the pharmaceutical services committee.

6. developing policies for destroying, in the prescribed manner, any unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued;

a. unused portions of controlled substances shall be handled by contacting the Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the facility for two years;

b. any other unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued shall be destroyed by the facility in the presence of a pharmacist or registered nurse who shall witness such destruction or shall be handled in accordance with ~~Pharm 32;~~ 7 MCAR ~~8.023;~~ 8.032 jcH

c. the drugs shall be destroyed by flushing them into the sewer system or by incineration;

7. providing in-service training to nursing personnel. ~~on pharmacologic action or use of drugs, scope of pharmacy services, and drug interactions.~~

~~Pharm-76~~ 8.076 Freedom of choice. No pharmacist shall participate in any agreement or plan which infringes on any patient's right to freedom of choice as to the provider of prescription services.

~~Pharm-77-80~~ 8.077-8.080 Reserved for future use.

Chapter Seven Pharmaceutical Services to Patients in Hospitals

The provisions of ~~Rules-81~~ 7 MCAR 8.081 through ~~100~~ 8.100 are applicable to pharmaceutical services provided to patients in hospitals, including state hospitals, provided, however, that ~~Rules-1~~ 7 MCAR 8.001 through ~~70~~ 8.070 and ~~100~~ 8.100 through ~~120~~ 8.120 shall also be applicable to such pharmaceutical services, unless specifically exempted by ~~Rules-81~~ 7 MCAR 8.081 through ~~100~~ 8.100 or unless in direct conflict therewith, in which case ~~Rules-81~~ 7 MCAR 8.081 through ~~100~~ 8.100 shall apply.

~~Pharm-81~~ 8.081 Pharmaceutical service definitions.

A. Pharmaceutical service. "Pharmaceutical service" means the control of the utilization of drugs, biologicals and chemicals including procuring, manufacturing, compounding, dispensing, distributing and storing of drugs, biologicals and chemicals under the conditions prescribed by this section. The provisions of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

B. "Credentialed" means registered with, certified by, or similarly recognized by a health-related agency or department of the State of Minnesota.

C. "Supervision," as used in connection with this rule, means ~~physical presence~~ stationed within the same work area, coupled with the ability to control and responsibility for an action.

D. "Drug administration" means to deliver by or pursuant to the lawful order of a licensed practitioner a single dose of a drug to a patient by injection, inhalation, ingestion or by any other immediate means and shall include:

1. preparing the individual dose from a previously dispensed, properly labeled container;

2. verifying the dose as prescribed;

3. giving the individual dose by the proper route to the correct patient at the proper time;

4. assuring that the dose is taken; and,

5. promptly recording the time and dose given.

E. ~~"Drug-dispensing"-means-to-deliver-one-or-more-doses-of-a-drug-prepared in-compliance-with-Pharm-36-A-I-or-48-A-E,-in-a-suitable-container,-properly labeled,-for-subsequent-administration-to,-or-use-by-a-patient-or-human-research subject.~~ "Drug dispensing" means to deliver one or more doses of a drug for subsequent administration to, or use by a patient or human research subject. Such drug dispensing shall be performed by the pharmacist in compliance with 7 MCAR 8.036 A-I or 8.048 A-E with delivery being made in a suitable container properly labeled.

~~Pharm-82~~ 8.082 ~~Pharmaceutical-service-general-requirements.--The-hospital shall-maintain-an-organized-pharmaceutical-service-under-the-direction-of-a qualified-pharmacist.~~

~~A.--On-site-pharmacy.--A-hospital-with-a-licensed-capacity-of-40-beds-or more-shall-maintain-an-on-site-pharmacy,-licensed-by-the-board-which-shall-provide at-least-five-day-per-week-service.~~

~~B.--Drug-room.--A-hospital-not-maintaining-an-on-site-pharmacy-shall provide-a-drug-room-and-obtain-service-from-a-licensed-pharmacy.--A-written agreement-between-such-parties-shall-specify-the-duties-and-responsibilities of-the-contracting-parties-and-be-available-for-Board-of-Pharmacy-inspection.~~ Pharmaceutical service general requirements. Pharmaceutical services in hospitals shall be organized and directed by a pharmacist.

~~Pharm-83~~ 8.083 Pharmaceutical Service Staff

A. ~~Director.~~ Pharmacist-in-charge.

1. Qualifications. The ~~director-of-the-pharmaceutical-service,~~ pharmacist-in-charge, regardless of his title or designation, shall be a pharmacist licensed in this state.

2. Availability.

a. On-site pharmacies. A pharmacist providing pharmaceutical services to a hospital maintaining an on-site pharmacy shall shall ~~have-its pharmaceutical-service-under-the-direction-of-a-pharmacist~~ be engaged by the hospital ~~full-time-or-part-time.~~ and shall provide at least part-time, 5 day/week services.

b. Drug Room. A pharmacist providing pharmaceutical services from off-site to a hospital maintaining a drug room shall ~~have-its-pharmaceutical services-under-the-direction-of-a-pharmacist-who-is-on-premises-on-at-least-a-weekly-scheduled-basis.~~ schedule on-premises visits on at least a weekly basis.

3. Responsibilities. The responsibilities and duties of the ~~director of-the-pharmaceutical-service-or~~ hospital pharmacist-in-charge include at

least the following specific duties in addition to the duties of the pharmacist-in-charge found in ~~Pharm-21:~~ 7 MCAR 8.021:

a. the procurement, identification, security, storage and distribution of all drugs, as well as the disposition of drugs whose effectiveness has expired or which, for other reasons, are deemed no longer usable;

b. the development, implementation, coordination, supervision and review of pharmaceutical services in the hospital and policies related thereto;

~~e.--the-implementation-of-recommendations-of-the-pharmacy-and-therapeutics-committee,-or-its-equivalent;~~

~~d.~~ c. the supervision of the preparation and sterilization of parenteral drugs in the hospital;

~~e.~~ d. the supervision of bulk compounding of pharmaceuticals;

~~f.~~ e. the establishment of specifications for procurement of drugs and chemicals for direct patient use;

~~g.~~ f. the development of a hospital formulary system;

~~h.~~ g. the dispensing of drugs and chemicals for direct patient use;

~~i.~~ h. the maintaining of a stock of antidotes and emergency drugs in the hospital;

~~j.~~ i. the maintaining of pharmaceutical service records; and

~~k.~~ j. cooperating in the teaching and research programs of the hospital.

4. Span of Control. The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than ~~bimonthly~~ every two months inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, ~~presence~~ absence of outdated drugs, and the integrity of the required emergency drug supply.

5. Directors absence. In the absence of the director of the pharmaceutical service, pharmaceutical services shall be directed by a pharmacist designee.

B. Other staff.

1. Generally. Pharmaceutical services shall be provided only by pharmacists and other personnel under a pharmacist's supervision.

~~Pharm-84~~ 8.084 Pharmaceutical service policies.

A. Patient care. Pharmaceutical service policies shall cover at least the following:

1. the providing of drug information to patients and health professionals;

2. the limiting of drug administration; ~~to individuals licensed or credentialed to do so;~~

3. the immediate reporting of drug related errors; ~~to the responsible practitioner, to the director of nursing and to the pharmacy. Drug errors shall be recorded in the patient's record and reported to the pharmacy and therapeutics committee, or its equivalent;~~

4. the immediate reporting of adverse drug reactions; ~~to the responsible practitioner, to the director of nursing and to the pharmacy. Adverse drug~~

~~reactions shall be recorded in the patient's record and reported to the pharmacy and therapeutics committee, or its equivalent;~~

5. the ~~permitting of~~ self administration of drugs by patients; ~~only when specifically ordered by licensed practitioners under standards set by the pharmacy and therapeutics committee or its equivalent;~~

6. the ~~permitting~~ use of drugs brought into the hospital by or with the patient. ~~to be administered only when so ordered by a licensed practitioner, who shall specify in the patient's record the identity, strength and dosage schedule of such medication. If such drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored and returned to the patient at the time of discharge, with instructions as to use written by the discharging physician.~~ If such drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored and returned to the patient at the time of discharge.

B. Administration. Pharmaceutical service policies shall cover at least:

1. the following measures related to the control, accessibility, dispensing and administration of drugs; :

~~a. requiring the existence of a pharmacy and therapeutics committee, or an equivalent body, which shall have the responsibility of meeting at least quarterly to consider the issues raised in the delivery of pharmaceutical services;~~

~~b.~~ a. developing, implementing and maintaining a system assuring the availability of prescribed drugs at all times;

~~c.~~ b. ~~prohibiting the~~ dispensing of legend drugs; ~~by persons other than pharmacists and licensed practitioner;~~

~~d.~~ c. ~~permitting the~~ changing of labels or the transfer of drugs from one container to another; ~~only by pharmacists or licensed practitioners;~~

~~e.~~ d. maintaining security and emergency access in accordance with the following:

(1) Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth below:

(a) In the case of disaster the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.

(b) For purposes of withdrawing limited doses of drugs for administration in emergencies when the pharmacy is closed, a designated registered nurse may make emergency withdrawal of a dose required by a patient. Only a designated registered nurse in any given shift may have emergency access.

The person withdrawing from a bulk stock container the limited doses for administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing:

(i) the patient's name;

(ii) the name of the drug and dose prescribed;

(iii) drug strength;

(iv) the amount taken;

(v) the time and date;

(vi) the signature of nurse ~~or physician~~ withdrawing drug.

The person withdrawing the drug from a bulk stock container or unit dose packaging bin shall place upon the record of withdrawal the container from which the limited doses were taken so that the withdrawal may be verified by the pharmacist.

(2) The ~~director~~ pharmacist-in-charge shall develop an emergency access procedure and may make provision for pre-packaged drugs for emergency withdrawal provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.

~~f.~~ e. ~~if a~~ supplying of pre-packaged legend drugs which is accessible for use without entering either the pharmacy or drug room ~~is~~ maintained for use when a pharmacist is not available. Such supply ~~shall~~ may be located in nursing units, with access limited to designated registered nurses. No hospital pharmacy shall utilize a floor stock drug distribution system of this or any other type as its primary system of drug delivery;

~~g.~~ f. maintaining a supply of drugs for use in medical emergencies;

~~h.~~ g. specifying the maintenance of permissible supplies of non-prescription drugs in nursing service units;

~~i.~~ h. assuring that unused patient drugs, discontinued and outdated drugs, and containers with worn, illegible or missing labels be returned to a pharmacist for disposition;

~~j.~~ i. maintaining a drug recall procedure which can be implemented no more than 24 hours after recall notification by the manufacturer;

~~k. assuring that drugs be administered only upon the order of a licensed practitioner;~~

~~l.~~ j. permitting the dispensing of drugs only pursuant to orders ~~to be written~~ initiated ~~only~~ by a licensed practitioner. ~~Abbreviations and chemical symbols used in drug orders must be approved individually or as part of a standard list, by the pharmacy and therapeutics committee or its equivalent. Verbal orders for drugs shall be communicated only to pharmacists or registered nurses by licensed practitioners. Only pharmacists may act as an intermediary in communicating a verbal order from a licensed practitioner to a registered nurse. Verbal orders must be reduced to writing immediately and countersigned by the licensed practitioner;~~

~~m.~~ k. assuring that all orders for drugs ~~be~~ are transmitted to the pharmacy by the prescriber or by means of an order format which produces a direct copy or an eletronically reproduced facsimile;

~~n.~~ l. requiring authorization for a standing order to be noted on the patient's medical record. ~~and countersigned by a licensed practitioner.~~ Such orders shall specify the circumstances under which the drug is to be administered, the drug, dosage, route, frequency of administration and duration;

~~o. assuring that when drug therapy is not renewed on at least a weekly basis such therapy is limited either by the prescribers specific indication or by automatic stop orders. Such stop orders shall include at least schedule II controlled substances and such other drugs as established by the P & T Committee or its equivalent;~~

m. assuring that when drug therapy is not renewed on an established regular basis such therapy is limited either by the prescribers specific indication or by automatic stop orders.

~~p.~~ n. assuring that precautionary measures for the safe admixture of parenteral products be developed in writing. Admixture preparation shall be limited to pharmacists, supportive personnel under the supervision of a pharmacist, licensed practitioners and licensed nurses. Furthermore, admixtures shall be labeled as in ~~Pharm-88-D.;~~ 7 MCAR 8.088 D;

~~q.~~ o. assuring that investigational drug use is in accordance with state and federal law. ~~Such-drugs-shall-be-administered-only-on-the-order of-a-member-of-the-organized-medical-staff.--The-prescribing-by-the-staff-member shall-be-under-the-direction-of-the-principal-investigator.~~ Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs shall be available in the pharmacy. ~~and-at-any-nursing-service-unit where-such-drugs-are-administered.~~ Investigational drugs shall be distributed only from the pharmacy;

~~r.~~ p. assuring that the practice of drug reconstitution be performed only by pharmacists, licensed practitioners, licensed nurses, or hospital-authorized personnel under the supervision of licensed pharmacists, licensed practitioners or licensed nurses.

2. The following measures related to the maintenance of documents:

a. ~~pharmaceutical-service-director-and-pharmacist-in-charge's responsibility-in-addition-to-those-in-Pharm-21.--The-director-of-the-pharmaceutical service-and-pharmacist-in-charge-shall-maintain-at-least-the-following-written documents:~~ The pharmacist-in-charge shall maintain at least the following written documents:

(1) a statement of service philosophy and objectives;

(2) a job description for each classification of personnel;

(3) a list of pharmaceutical service committees; and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;

(4) procurement records for controlled substances for two years or as required by law;

(5) prescriptions or other forms initiated by the prescriber, for two years or as required by law;

(6) records of packaging, bulk compounding or manufacturing for two years or as required by law;

(7) records of action taken pursuant to drug recalls for two years or as required by law;

(8) special reports concerning narcotics and other drugs for two years or as required by law;

(9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room as permitted under ~~Pharm-84-B.-1.-f. and-g.~~ 7 MCAR 8.084 B. 1. e. and f. for two years;

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room as permitted under ~~Pharm-84-B.1.e.~~ 7 MCAR 8.084 B.1.d. for one month;

b. other necessary documents. The following documents relative to pharmaceutical services shall also be maintained:

(1) a current organization chart delineating intra-service structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff and other relevant hospital services;

(2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;

(3) a record of the number of persons, by job description, employed full time and part time in the pharmaceutical services;

(4) copies of current staffing patterns and weekly work schedules;

(5) receipted invoices for all drugs, chemicals and pharmaceutical service supplies purchased and received over the immediately preceding two years; and

(6) any agreement between an off-premises pharmacy and the hospital.

~~Pharm-85~~ 8.085 Pharmaceutical service equipment and supplies. In addition to the requirements of ~~Pharm-10~~ 7 MCAR 8.010, equipment and supplies shall be maintained by the pharmacy as necessary to fulfill the further needs of patients and the scope of services offered.

~~Pharm-86~~ 8.086 Drug handling and storage. At least the following provisions for the safe handling and secure storing of drugs shall be observed:

A. storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security;

B. drugs shall be protected from contamination; and

C. drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

~~Pharm-87~~ 8.087 Pharmaceutical service space.

A. The pharmacy or drug room shall be surrounded by a continuous partition or wall extending from floor to ceiling. All doors and windows shall be securely locked when the pharmacy or drug room is closed, so as to prevent entry by unauthorized persons.

B. ~~Space shall be available at each nursing service unit for storage, safeguarding and preparation of medication doses, to include provisions of at least the following:~~ When drugs are stored on nursing service units space shall be available at each unit for the storage, safeguarding and preparation of medication doses, and shall include provision of at least the following:

1. A well-illuminated, locked drug cabinet or room shall be equipped with clearly labeled cubicles to ensure physical separation of individual patient prescribed medications. Medications may be stored in secured individual patient storage areas or secured portable storage carts providing separate compartments for individual patients.

2. A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

~~Pharm-88~~ 8.088 Labeling.

A. Out-patient prescriptions. Labels for out-patient prescriptions shall comply with ~~Regulation--40-and-41~~ 7 MCAR 8.040 and 8.041. Labels for out-patient

nonprescription drugs shall comply with the federal regulations. Drugs originally dispensed to an in-patient shall be returned to the pharmacy for proper labeling before leaving the hospital premises.

B. In-patient prescriptions. All prescriptions dispensed to in-patients, other than those dispensed pursuant to ~~Pharm-48~~ 7 MCAR 8.048, shall be labeled with the following information:

1. identification of pharmacy;
2. name of patient;
3. name of drug;
4. route of administration of drug when necessary for clarification;
5. strength of drug;

~~6.--the-name-of-the-manufacturer-of-the-finished-dosage-form-of-the drug;~~

~~7.~~ 6. auxiliary labels as needed;

~~8.~~ 7. expiration date, if applicable;

~~9.~~ 8. date dispensed.

C. Drugs prepackaged for emergency use. All drugs dispensed under ~~Pharm 84-B.-1.-f.~~ 7 MCAR 8.084 B. 1. e. shall be labeled with the following information:

1. identification of pharmacy or other source;
2. name of drug or list of ingredients;
3. strength of drug or amount of ingredients;
4. auxiliary labels as needed;
5. expiration date, if any;
6. usual dose;
7. control number or date of issue;

~~8.--the-name-of-the-manufacturer-of-the-finished-dosage-form-of-the drug.~~

D. Whenever a drug is added to a parenteral solution a distinctive supplementary label shall be firmly affixed to the container. The label shall indicate the name and amount of drug added, the date and time of the addition, ~~and-expiration-of-the-drug,~~ the date and time of the expiration of the admixture, and the identify of the person preparing or certifying the integrity of the admixture.

~~Pharm-89~~ 8.089 Extension of pharmacy services under license. A licensed pharmacy in a hospital may utilize additional locations within the hospital without the necessity of securing additional licenses, provided however, that the ~~director-of-pharmaceutical-services~~ pharmacist-in-charge of any such hospital pharmacy shall designate another licensed pharmacist to assume professional responsibility, in accordance with ~~Regulation-21-23~~ 7 MCAR 8.021-8.023, for the practice of pharmacy in each such additional location.

~~Pharm-90~~ 8.090 Use of supportive personnel. The use of supportive personnel shall be in accordance with the provisions of ~~Pharm-47~~ 7 MCAR 8.047.

~~Pharm-91-100~~ 8.091-8.100 Reserved for future use.

APPROVED AS TO FORM AND LEGALITY

MAR 15 1979

_____ 19_____

WARREN SPANNAUS, ATTORNEY GENERAL

BY Joanne Henderson

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
MAR 15 1979
Joan Anderson Growe
Secretary of State

9:20 AM

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA BOARD OF PHARMACY

IN THE MATTER OF THE PROPOSED AMENDMENTS RELATING TO UNIT DOSE DISTRIBUTION, SUPPORTIVE PERSONNEL, DRUG RETURNS, NURSING HOME PRACTICE, HOSPITAL PRACTICE AND OTHER MISCELLANEOUS MATTERS.	ORDER OF THE CHIEF HEARING EXAMINER RELATING TO INCORPORATION BY REFERENCE

The above-entitled matter was heard before Hearing Examiner Peter C. Erickson on July 24, 1978, following which the Examiner issued his report recommending adoption of the rules as proposed with certain amendments, which report was issued on November 6, 1978.

On January 23, 1979, the proposed rules, as amended, were submitted to the Chief Hearing Examiner for his review pursuant to Minn. Stat. § 15.052, Subd. 4, and Rule 9 MCAR § 2.110, on which date the Chief Hearing Examiner issued his report indicating that the rules as adopted were not substantially different from those which had been proposed and that the Board had met all requirements of Minn. Stat. § 15.0412, Subd. 4.

Subsequent to the submission of the rules as adopted to the Attorney General for his review as to form and legality, the Board was informed that in rule Pharm 86C a reference to the United States Pharmacopeia was most likely an incorporation by reference requiring approval of the Chief Hearing Examiner.

On March 9, 1979, the Board submitted the adopted rules and a copy of the document entitled United States Pharmacopeia, Copy-write, 1974, Library of Congress Catalog Card Number 35-37146, the 19th Revision, to the Chief Hearing Examiner for review and approval for incorporation by reference of that publication.

The Chief Hearing Examiner, having reviewed the adopted rules and the above-referenced publication, having found that the publication exceeds 3,000 words in length, would exceed five printed pages in the Minnesota State Register, that the document is readily available and accessible to the public at the Board's office for viewing and copying, and upon representation by the Board finds that all pharmacies licensed by the Board are required to maintain a copy in their pharmacy.

NOW, THEREFORE, the Chief Hearing Examiner herewith gives approval to the Minnesota Board of Pharmacy for the incorporation by reference of the above-entitled document in their proposed rules relating to the matter of the proposed amendments relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other miscellaneous matters.

Dated this 12th day
of March, 1979.

Duane R. Harves

DUANE R. HARVES
Chief Hearing Examiner

Board of Pharmacy

Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, and Hospital Practice

Notice of Hearing

Notice is hereby given that a public hearing in the above entitled matter will be held pursuant to Minn. Stat. § 15.0412, subd. 4 (1976), in the Board Room of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on July 24, 1978, commencing at 9:30 a.m.

All interested or affected persons will have an opportunity to participate concerning the adoption of the proposed amendments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted by mail to Peter Erickson, Hearing Examiner, at Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, (612) 296-8113, either before the hearing or within five (5) days after the close of the hearing. All such statements will be entered into and become part of the record. Testimony or other evidence to be submitted for consideration should be pertinent to the matter at hand. For those wishing to submit written statements or exhibits, it is requested that at least three (3) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The conduct of the hearing shall be governed by the rules of the Office of Hearing Examiners.

The proposed amendments, if adopted, would fix requirements for unit dose distribution systems, set forth allowable functions for the utilization of supportive personnel, allow returns of certain medications, expand the responsibilities of the pharmacist in nursing home and hospital practice settings and make other more minor changes.

Copies of the proposed amendments are now available and at least one free copy may be obtained by writing to the Minnesota Board of Pharmacy, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing.

Pharm 21

A Statement of Need explaining the Board of Pharmacy's position relative to the necessity for the proposed amendments and a Statement of Evidence outlining the testimony and evidence which will be introduced by the Board in support of the proposed amendments 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. The statutory authority of the Board of Pharmacy to promulgate and adopt these rules is contained in Minn. Stat. ch. 151 (1976).

In addition, please be advised that Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five (5) days after he commences lobbying. Lobbying includes attempting to influence rulemaking by communicating or urging others to communicate with public officials. A lobbyist is generally any individual who spends more than $250 per year for lobbying or any individual who is engaged for pay or authorized to spend money by another individual or association and who spends more than $250 a year or five (5) hours per month at lobbying. The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, (612) 296-5615.

David E. Holmstrom
Executive Secretary

June 5, 1978

Rules as Proposed

Pharm 21 Pharmacist-in-charge, requirements, definitions and duties. No person shall conduct a pharmacy without a pharmacist-in-charge who shall be a pharmacist regularly employed in the pharmacy department and shall be designated in the application for license, 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. to establish for the employees of the pharmacy, policies and procedures for the procurement, storage, compounding and dispensing of drugs and the communication of information to the public in relation to drug therapy;

B. to supervise all of the professional employees of the pharmacy;

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Pharm 21

C. to supervise all of the nonprofessional 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.~~

D. to develop appropriate detailed written procedures directing activities of supportive personnel and to submit these procedures to the Board in accordance with Pharm 47;

~~D.~~ E. to establish and supervise the method and manner for the storing and safekeeping of drugs.

~~E.~~ F. to establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping and return of drugs;

~~F.~~ G. to notify the board immediately upon his knowledge that his services as pharmacist-in-charge have been or will be terminated;

~~G.~~ H. to respond to 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.

Pharm 32 Return of drugs and devices prohibited. Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale any drugs, prescribed medications, chemicals, poisons or medical devices; except that in a hospital with a licensed pharmacy, drugs, devices or other items dispensed for hospital in-patient use may be returned to the pharmacy for disposition by a pharmacist in accordance with good professional practice. ~~This regulation shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale or re-rent thereof.~~ Drugs and prescribed medications from nursing homes may be returned to the dispensing pharmacy provided that proper storage conditions in the home can be assured; provided that the drugs and prescribed medications are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's single Unit-Dose, single Unit-of-Use or strip packaging indicating the drug name and strength, the manufacturer's or packager's name and the manufacturer's or packager's lot or batch number; and provided that the integrity of such packaging remains intact. No reconstituted drugs, drugs requiring refrigeration or controlled substances may be so returned. Commingling of returned medication or mixing of lot numbers of returned medication shall result in such medication being deemed misbranded and subject to embargo under Minn. Stat. § 151.38.

This prohibition shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale or re-rent thereof.

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 of 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 prescription, 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.~~

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 or 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 nonpharmacist supportive personnel utilized in the performance of certain pharmacy tasks. The use of supportive personnel shall be in accordance with the provisions of Pharm 47.

Pharm 38 Prepackaging.

A. Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall cause to be prepared and kept a packaging control record containing the following information.

~~(a)~~ 1. Date.

~~(b)~~ 2. Identification of drug.

~~(1)~~ a. Name.

~~(2)~~ b. Dosage form.

~~(3)~~ c. Manufacturer.

~~(4)~~ d. Manufacturer's lot number.

~~(5)~~ e. Strength.

~~(6)~~ f. Manufacturer's expiration date (if any).

~~(c)~~ 3. Container specification.

~~(d)~~ 4. Copy of the label.

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Pharm 38

~~(e)~~ 5. Initials of the packager.

~~(f)~~ 6. Initials of the supervising pharmacist.

~~(g)~~ 7. Quantity per container.

~~(h)~~ 8. Internal control number or date.

B. Each prepackaged container shall bear a label containing the following information:

~~(a)~~ 1. Name.

~~(b)~~ 2. Strength.

3. Dosage form.

~~(c)~~ 4. Internal control number or date.

~~(d)~~ 5. Manufacturer's expiration date (if any).

~~(e)~~ 6. Auxiliary labels, as needed.

Pharm 47 Supportive personnel. Supportive personnel may be used in performing pharmacy tasks not specifically reserved in these rules to a licensed pharmacist, assistant pharmacist or pharmacist-intern under the immediate and personal supervision of a pharmacist.

A. Supportive personnel may perform functions which do not involve professional pharmaceutical judgment.

B. Pharmaceutical products prepared by supportive personnel must be certified for accuracy by a licensed pharmacist (as provided for in Pharm 36 F) prior to release for patient use.

C. Written procedures for the use of supportive personnel shall be prepared by the pharmacist-in-charge, shall be submitted to the board, and a copy shall be kept on file in the pharmacy. These procedures must be approved by the board prior to implementation of the procedure.

1. These procedures shall indicate in detail the tasks performed by the supportive person and the certification steps performed by the licensed pharmacist.

2. New procedures or changes in procedures shall be submitted to the board for approval as specified above.

3. The submitted procedures shall be automatically approved 90 days after receipt by the board unless the pharmacist-in-charge is notified by the board of the specific reasons the procedures are unacceptable. (This paragraph shall become effective one year after final promulgation of this rule.)

D. Supportive personnel shall be supervised by a licensed pharmacist physically present within the same work area who has the ability to control and is responsible for the action of the supportive person.

1. The basic ratio of supportive personnel allowed by this rule to work with one pharmacist shall be 1:1. Specific functions shall be expected from the 1:1 ratio as follows:

a. intravenous admixture preparation (Pharm 84), 3:1;

b. Unit Dose dispensing (Pharm 42), 3:1;

c. prepackaging (Pharm 38), 3:1;

d. bulk compounding (Pharm 39), 3:1.

2. Personnel used solely for clerical duties such as typing, looking up refills, filing prescriptions, recordkeeping, etc. need not be included in the ratios of the functions performed by supportive personnel.

3. A pharmacist-intern submitting hours toward completion of the 1500-hour requirement is not considered a supportive person for the purpose of determining the number of supportive persons supervised by a licensed pharmacist.

4. A pharmacist-in-charge of any pharmacy may petition the board for use of supportive personnel in ratios in excess of those allowed under these rules or for functions not specified in these rules. This petition for the use of additional personnel must be based on evidence that patient care and safety is maintained. The burden of persuasion is on the pharmacist-in-charge. Such a petition shall be automatically approved 90 days after receipt by the board unless the board shall send to the pharmacist-in-charge notification of the specific reasons why the petition is unacceptable.

E. The use of supportive personnel in the performance of delegated tasks not included in approved written procedures may be considered to be unprofessional conduct on the part of the pharmacist supervising the supportive personnel and the pharmacist-in-charge.

Pharm 48 Unit Dose dispensing. A Unit Dose system shall be under the control of the pharmacist-in-charge. The act of drug dispensing is reserved for licensed pharmacists

and registered pharmacist-interns acting under the supervision of licensed pharmacists, as set forth in Pharm 36. A Unit Dose system may be used as an alternative to Pharm 36 D, G, and H according to the following paragraphs.

A. Definitions.

1. Unit Dose packaging. Unit Dose packaging is the packaging of individual doses of medication in containers which will preserve the identity and integrity of the drug from the point of packaging to the point of administration to the patient. Packaging may be accomplished by a manufacturer or by a pharmacy in accordance with Pharm 38. Packaging procedures and packaging materials must conform to existing state and federal laws including those found in The Code of Federal Regulations and known as the "Good Manufacturing Procedures."

a. Individual doses of medication shall be properly labeled from the manufacturer with the name of the drug, dosage form and strength, manufacturer's name and lot number and expiration date of all time dated drugs or labeled in accordance with Pharm 38 if prepackaged by the pharmacy.

b. Unit Dose packaging may provide individual doses of medication attached to each other by placement in a card or other container. Such packaging shall be labeled in accordance with Pharm 38 in such a manner as to provide continuous identification of the contents and, when dispensed, the name and location of the patient, name of the prescribing practitioner, prescription number, date, the directions for use and identification of the pharmacy.

2. Unit Dose system. The Unit Dose system is that drug distribution system which is pharmacy based and which uses Unit Dose packaging in a manner which removes traditional drug stocks from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled.

The system must provide and the pharmacist must utilize:

a. a means of separating medications by patient name and bed number;

b. a means of separating medications by day of administration;

c. a means of identifying individual doses dispensed, doses administered and doses returned;

d. a means of identifying the dosage regimen of each drug, including the date of the original order and the date of changes, if any, in the prescriber's drug order;

e. a means of identifying the total dosage regimen of each patient;

f. a means of identifying the time of administration of each drug;

g. a means for the pharmacist to verify the original prescriber's order;

h. a means for the pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient.

B. Each pharmacy utilizing a Unit Dose dispensing system shall establish written policies specifying the categories of drugs which will or categories of drugs which will not be dispensed under the Unit Dose distribution system. Such policies shall be available in the pharmacy for inspection by the board.

1. Proper utilization of the Unit Dose system requires that in as far as is practicable all medications be in Unit Dose packaging when dispensed.

2. Schedule II, III, and IV controlled substances may be included in the Unit Dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

3. Drugs not dispensed under the Unit Dose dispensing system must be dispensed in accordance with Pharm 36.

C. Selection of individual Unit Dose packaging for placement in individual patient containers, bins, compartments or drawers is not dispensing under Pharm 36 and may be performed by supportive personnel. Dispensing occurs upon the certification of the accuracy of the selected Unit Dose packages which shall be done by the pharmacist before the dose is delivered for administration to the patient.

D. All medication shall be stored in a locked area or locked cart.

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Pharm 48

E. Unit Dose systems shall comply with existing law with respect to provisions of pharmaceutical services to hospitals and nursing homes and as set forth in Pharm 71-100.

Pharm ~~47-50~~ 49-50 Reserved for future use.

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 Board of Pharmacy.

A. Definitions.

1. "Pharmacist intern" and "intern" means:

~~(1)~~ a. a natural person satisfactorily progressing toward the degree in pharmacy required for licensure; or

~~(2)~~ b. a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

~~(3)~~ c. a qualified applicant awaiting examination for licensure.

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

3. "Hour" means the standard 60 minute division of time.

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. "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. "Approved clinical program" means a clinical program approved by the Internship Advisory Committee and the 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. "Approved externship program" means an undergraduate program of practical experience administered by a college of pharmacy approved by the board.

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

B. Registration and reporting.

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. 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. All registered interns shall notify the board immediately upon change of employment or residence address.

4. The intern 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. These examinations shall be of a pre-test

and post-test nature bracketing such segments of the intern's experience as the board deems appropriate. Interns completing the first quarter of their internship experience will be required to show attainment of a score of 65% on the post-test examination before credit will be granted by the board for that experience. Interns participating in subsequent quarters will be required to attain a score of 75% on the post-test examination before credit will be granted by the board for that experience.

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 pharmacist-intern shall take, use, or exhibit the title of pharmacist-intern, pharmacist-apprentice, pharmacist-extern, or any other term of similar or like import.

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

2. When an intern desires to obtain credit for training received in a state other than Minnesota, he shall abide by all the provisions of the internship regulations 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. No more than one intern shall be trained by a preceptor at one time.

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

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

~~(a)~~ a. 400 hours of internship credit may be acquired by any combination of the following: internship experience gained concurrent with attendance at a college of pharmacy during the fourth and fifth year, or participation in approved clinical pharmacy programs or approved internship demonstration projects.

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

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

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. 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 Six Pharmaceutical Services to Patients in Nursing Homes and Residents of Boarding Care Homes

The provisions of Regulations 71 through 80 are applicable to pharmaceutical services provided to patients in ~~nurs-~~

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Pharm 61

~~ing homes and boarding care homes,~~ long term care facilities, provided, however, that Regulations 1 through 70 shall also be applicable to such pharmaceutical services, unless specifically exempted by Regulations 71 through 80 or are in direct conflict therein, in which case Regulations 71 through 80 shall apply.

Pharm 71 Prescription order communication.

A. Pharmacists and pharmacies shall accept orders for dispensing and refilling only if such orders are communicated directly from the prescriber or transmitted through his designated agent~~.~~, a nurse employed by the facility and designated in writing by the prescriber to act as his agent for the sole and exclusive purpose of communicating, either orally or in writing, said physician's medication orders to any pharmacy.

B. Such orders may be in writing or, except for Schedule II controlled substances, an oral order reduced to writing by the pharmacist and may include authorization for multiple refills consistent with good practice and legal limitations. A facsimile copy of the prescriber's medication order may be accepted and filed as a prescription by the pharmacy.

C. Schedule II controlled substances shall be dispensed only upon receipt of an original written order signed by the prescribing individual practitioner or orally in emergency situations as allowed by Federal Regulations.

Pharm 72 Prescription labeling. All prescription containers, other than those dispensed pursuant to Pharm 48, shall be properly labeled in accordance with Regulation 40 and ~~in addition thereto~~ shall also contain at least the following information:

~~(a)~~ A. Name of drug.

~~(c)~~ B. Potency of drug.

~~(b)~~ C. Quantity of drug dispensed.

D. The name of the manufacturer of the finished dosage form of the drug.

E. Specific directions for use.

~~(d)~~ F. Date of original issue, or in the case of a refill, the most recent date thereof.

~~(e)~~ G. Expiration date~~, when applicable~~ of all time dated drugs.

H. Auxiliary labels as needed.

Directions for use on labels of medications shall be changed only by a pharmacist acting on the instructions of the prescriber or his agent. Such medications shall be returned to the pharmacist provider to be so relabeled.

Pharm 73 Labeling of insulin. Insulin~~, if sold without a prescription~~, shall be dispensed with a label affixed to the vial showing the patient's full name and ~~expiration date of the drug.~~ location.

Pharm 74 Drugs for use in emergency kits. Pharmacists may dispense, upon a written or oral order from a licensed practitioner, ~~licensed to prescribe drugs,~~ limited supplies of drugs for use in an emergency kit. ~~maintained by the physician in compliance with Minnesota State Board of Health Regulations.~~

A. Emergency drug supplies as determined by the patient care policy committee or pharmaceutical service committee only may be made available. The drugs in the emergency kit are the property of the pharmacy and, therefore, shall not be used or altered in any way except as outlined herein. Long-term care facilities shall store a supply of emergency drugs on at least one nursing station and:

1. such drugs shall be limited to a maximum of six single doses, in either sealed ampuls, vials or prefilled syringes to the extent possible, of any one emergency drug. If an emergency drug is not available in parenteral form, a supply of the drug in inhalation or sublingual form may be obtained in the smallest sealed manufacturer's package. Inclusion of other oral legend drugs is to be discouraged. All drugs in this supply shall be properly labeled;

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

3. the pharmacist shall be notified by the director of nursing services when drugs have been used from the emergency kit or when the seal has been broken;

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

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

6. the supply shall be checked monthly by the pharmacist who is responsible for control of the kit.

Pharm 75 Pharmacist consultative services to long term care facilities.

A. The nursing home facility shall retain a pharmacist other than the vendor pharmacist, whenever possible, who devotes a sufficient number of hours during a regularly scheduled visit, for the purpose of coordinating, supervising, and reviewing the pharmaceutical services within the facility. There shall be a formal arrangement for such qualified pharmaceutical services between the facility and the pharmacist, including an arrangement for remuneration separate and apart from that provided to vendor pharmacists.

B. The responsibilities of the pharmacist shall include, but are not limited to the following:

1. serving on the pharmaceutical services committee and/or patient care policy committee and assisting in the preparation and revision of policies and procedures governing the pharmaceutical services;

2. developing, coordinating and directing or supervising all pharmaceutical services provided in the facility;

3. reviewing the drug regimen of each patient and resident at least monthly and preparing appropriate reports and recommendations. This review shall include at least:

a. a review of all drugs currently ordered;

b. information concerning the patient's condition as it relates to drug therapy;

c. medication administration records and, where appropriate, physician progress notes, nurses' notes, and laboratory test results;

4. reporting, in writing, irregularities in the storage, dispensing and administration of drugs and other matters relating to the review of the drug regimen, to the administrator, appropriate attending physician, and vendor pharmacists;

5. preparing, at least quarterly, a written report on the status of the pharmaceutical service and staff performance and submitting this report to the administrator and patient care policy committee and/or the pharmaceutical services committee.

6. developing policies for destroying in the prescribed manner, any unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident from whom they were prescribed or any prescriptions permanently discontinued;

a. unused portions of controlled substances shall be handled by contacting the Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the facility for two years;

b. any other unused portion of prescription drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued shall be destroyed by the facility in the presence of a pharmacist or registered nurse who shall witness such destruction or shall be handled in accordance with Pharm 32;

c. the drugs shall be destroyed by flushing them into the sewer system or by incineration;

7. providing in-service training to nursing personnel on pharmacologic action or use of drugs, scope of pharmacy services, and drug interactions.

Pharm 76 Freedom of choice. No pharmacist shall participate in any agreement or plan which infringes on any patient's right to freedom of choice as to the provider of prescription services.

Pharm ~~75-80~~ **77-80** Reserved for future use.

Chapter Seven Pharmaceutical Services to Patients in Hospitals

The provisions of Rules 81 through 100 are applicable to pharmaceutical services provided to patients in hospitals, including state hospitals, provided, however, that Rules 1 through 70 and 100 through 120 shall also be applicable to such pharmaceutical services, unless specifically exempted by Rules 81 through 100 or unless in direct conflict therewith, in which case Rules 81 through 100 shall apply.

~~Pharm 81 Functions of the Hospital Pharmacy. In the interest of good patient care, the functions of the hospital pharmacy include, but are not limited to the following:~~

~~(a) Procurement, bulk compounding, identification, security, storage, record-keeping, compounding, and~~

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Pharm 81

~~dispensing of all drugs in compliance with Federal and State laws and regulations.~~

~~(b) Inspection of drugs throughout the hospital for evidence of proper storage, labeling, potency and use.~~

~~(c) Provisions for product information and drug education service.~~

~~(d) Maintenance of a policy and procedure for emergency pharmaceutical services.~~

~~(e) Preceptor supervision in the training of pharmacist interns.~~

~~(f) Participation in the hospital's Pharmacy and Therapeutics Committee.~~

~~(g) Orientation of hospital personnel in matters pertaining to pharmacy policy.~~

~~(h) Establishment of policies and procedures for mixing or preparation of drugs for parenteral administration to in-patients.~~

Pharm 81 Pharmaceutical service definitions.

A. Pharmaceutical service. "Pharmaceutical service" means the control of the utilization of drugs, biologicals and chemicals including procuring, manufacturing, compounding, dispensing, distributing and storing of drugs, biologicals and chemicals under the conditions prescribed by this section. The provision of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

B. "Credentialed" means registered with, certified by, or similarly recognized by a health-related agency or department of the State of Minnesota.

C. "Supervision," as used in connection with this rule, means physical presence within the same work area, coupled with the ability to control; and responsibility for an action.

D. "Drug administration" means to deliver by or pursuant to the lawful order of a licensed practitioner a single dose of a drug to a patient by injection, inhalation, ingestion or by any other immediate means and shall include:

1. preparing the individual dose from a previously dispensed, properly labeled container;

2. verifying the dose as prescribed;

3. giving the individual dose by the proper route to the correct patient at the proper time;

4. assuring that the dose is taken; and,

5. promptly recording the time and dose given.

E. "Drug dispensing" means to deliver one or more doses of a drug prepared in compliance with Pharm 36 A.-I. or 48 A.-E., in a suitable container, properly labeled, for subsequent administration to, or use by a patient or human research subject.

~~Pharm 82 Hours of Operation. The hours of operation shall be sufficient to adequately provide all of the professional pharmacy services required by Regulation 81 and such services shall be provided not less than five days out of each calendar week, provided that when the pharmacy is closed emergency pharmaceutical services shall be provided in accordance with Regulation 83.~~

Pharm 82 Pharmaceutical service general requirements. The hospital shall maintain an organized pharmaceutical service under the direction of a qualified pharmacist.

A. On-site pharmacy. A hospital with a licensed capacity of 40 beds or more shall maintain an on-site pharmacy, licensed by the board which shall provide at least five day per week service.

B. Drug room. A hospital not maintaining an on-site pharmacy shall provide a drug room and obtain service from a licensed pharmacy. A written agreement between such parties shall specify the duties and responsibilities of the contracting parties and be available for Board of Pharmacy inspection.

~~Pharm 83 Security and Emergency Access. Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth below:~~

~~(a) In case of disaster the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.~~

~~(b) For purposes of withdrawing limited doses of drugs for administration in emergencies when the pharmacy is closed, if the drugs are not available in floor or emergency drug supplies, a designated registered nurse may make emergency withdrawal of sufficient doses required by a patient until the pharmacy reopens. Only a designated registered nurse in any given shift may have emergency access.~~

~~The person withdrawing from a bulk stock container the limited doses for administration shall leave in~~

~~the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing:~~

~~(1) The patient's name~~

~~(2) The name of the drug and dose prescribed~~

~~(3) Drug strength~~

~~(4) The amount taken~~

~~(5) The time and date~~

~~(6) The signature of nurse or physician withdrawing drug~~

~~The person withdrawing the drug from a bulk stock container shall place upon the record of withdrawal the container from which the limited doses were taken so that the withdrawal may be verified by the pharmacy.~~

~~The pharmacist in charge shall develop an emergency access procedure, and may make provision for pre-packaged drugs for emergency withdrawal provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.~~

Pharm 83 Pharmaceutical service staff.

A. Director.

1. Qualifications. The director of the pharmaceutical service, regardless of his title or designation, shall be a pharmacist licensed in this state.

2. Availability.

a. On-site pharmacies. A hospital maintaining an on-site pharmacy shall have its pharmaceutical service under the direction of a pharmacist engaged by the hospital full time or part time.

b. Drug room. A hospital maintaining a drug room shall have its pharmaceutical services under the direction of a pharmacist who is on-premises on at least a weekly scheduled basis.

3. Responsibilities. The responsibilities and duties of the director of the pharmaceutical service or hospital

pharmacist-in-charge include at least the following specific duties in addition to the duties of the pharmacist-in-charge found in Pharm 21:

a. the procurement, identification, security, storage and distribution of all drugs, as well as the disposition of drugs whose effectiveness has expired or which, for other reasons, are deemed no longer usable;

b. the development, implementation, coordination, supervision and review of pharmaceutical services in the hospital and policies related thereto;

c. the implementation of recommendations of the pharmacy and therapeutics committee, or its equivalent;

d. the supervision of the preparation and sterilization of parenteral drugs in the hospital;

e. the supervision of bulk compounding of pharmaceuticals;

f. the establishment of specifications for procurement of drugs and chemicals for direct patient use;

g. the development of a hospital formulary system

h. the dispensing of drugs and chemicals for direct patient use;

i. the maintaining of a stock of antidotes and emergency drugs in the hospital;

j. the maintaining of pharmaceutical service records; and

k. cooperating in the teaching and research programs of the hospital.

4. Span of control. The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than bimonthly inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, presence of outdated drugs, and the integrity of the required emergency drug supply.

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Pharm 83

5. Directors absence. In the absence of the director of the pharmaceutical service, pharmaceutical services shall be directed by a pharmacist designee.

B. Other staff.

1. Generally. Pharmaceutical services shall be provided only by pharmacists and other personnel under a pharmacist's supervision.

~~Pharm 84 Required Records. The following records shall be filed and maintained by the pharmacy for a period of time as required by law:~~

~~(a) All records of procurement required by Federal and State laws or regulations.~~

~~(b) All drug orders, requisitions, prescriptions or other suitable forms initiated by the prescriber from which drugs are dispensed.~~

~~(c) All control records of packaging, bulk compounding or manufacturing.~~

~~(d) All records of drug recalls.~~

Pharm 84 Pharmaceutical service policies.

A. Patient care. Pharmaceutical service policies shall cover at least the following:

1. the providing of drug information to patients and health professionals;

2. the limiting of drug administration to individuals licensed or credentialed to do so;

3. the immediate reporting of drug errors to the responsible practitioner, to the director of nursing and to the pharmacy. Drug errors shall be recorded in the patient's record and reported to the pharmacy and therapeutics committee, or its equivalent;

4. the immediate reporting of adverse drug reactions to the responsible practitioner, to the director of nursing and to the pharmacy. Adverse drug reactions shall be recorded in the patient's record and reported to the pharmacy and therapeutics committee, or its equivalent;

5. the permitting of self administration of drugs by patients only when specifically ordered by licensed practitioners under standards set by the pharmacy and therapeutics committee or its equivalent;

6. the permitting of drugs brought into the hospital by or with the patient to be administered only when so ordered by a licensed practitioner, who shall specify in the patient's record the identity, strength and dosage schedule of such medication. If such drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored and returned to the patient at the time of discharge, with instructions as to use written by the discharging physician.

B. Administration. Pharmaceutical service policies shall cover at least:

1. the following measures related to the control, accessibility, dispensing and administration of drugs:

a. requiring the existence of a pharmacy and therapeutics committee, or an equivalent body, which shall have the responsibility of meeting at least quarterly to consider the issues raised in the delivery of pharmaceutical services;

b. developing, implementing and maintaining a system assuring the availability of prescribed drugs at all times;

c. prohibiting the dispensing of legend drugs by persons other than pharmacists and licensed practitioners;

d. permitting the changing of labels or the transfer of drugs from one container to another only by pharmacists or licensed practitioners;

e. maintaining security and emergency access in accordance with the following:

(1) Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth below:

(a) In the case of disaster the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.

(b) For purposes of withdrawing limited doses of drugs for administration in emergencies when the pharmacy is closed, a designated registered nurse may make emergency withdrawal of a dose required by a patient. Only a designated registered nurse in any given shift may have emergency access.

The person withdrawing from a bulk stock container the limited doses for administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing:

(i) the patient's name;

(ii) the name of the drug and dose prescribed;

(iii) drug strength;

(iv) the amount taken;

(v) the time and date;

(vi) the signature of nurse or physician withdrawing drug.

The person withdrawing the drug from a bulk stock container shall place upon the record of withdrawal the container from which the limited doses were taken so that the withdrawal may be verified by the pharmacist.

(2) The ~~director~~ Pharmacist-in-charge shall develop an emergency access procedure and may make provision for pre-packaged drugs for emergency withdrawal provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.

f. if a supply of pre-packaged legend drugs which is accessible for use without entering either the pharmacy or drug room is maintained for use when a pharmacist is not available, such supply shall be located in nursing units, with access limited to designated registered nurses. No hospital pharmacy shall utilize a floor stock drug distribution system as its primary system of drug delivery;

g. maintaining a supply of drugs for use in medical emergencies;

h. specifying the maintenance of permissible supplies of non-prescription drugs in nursing service units;

i. assuring that unused patient drugs, discontinued and outdated drugs, and containers with worn, illegible or missing labels be returned to a pharmacist for disposition;

j. maintaining a drug recall procedure which can be implemented no more than 24 hours after recall notification by the manufacturer;

k. assuring that drugs be administered only upon the order of a licensed practitioner;

l. permitting drug orders to be written only by a licensed practitioner. Abbreviations and chemical symbols used in drug orders must be approved individually or as part of a standard list, by the pharmacy and therapeutics committee or its equivalent. Verbal orders for drugs shall be communicated only to pharmacists or registered nurses by licensed practitioners. Only pharmacists may act as an intermediary in communicating a verbal order from a licensed practitioner to a registered nurse. Verbal orders must be reduced to writing immediately and countersigned by the licensed practitioner;

m. assuring that all orders for drugs be transmitted to the pharmacy by the prescriber or by means of an order format which produces a direct copy or an electronically reproduced facsimile;

n. requiring authorization for a standing order to be noted on the patient's medical record and countersigned by a licensed practitioner. Such orders shall specify the circumstances under which the drug is to be administered, the drug, dosage, route, frequency of administration and duration;

o. assuring that when drug therapy is not renewed on at least a weekly basis such therapy is limited either by the prescribers specific indication or by automatic stop orders. Such stop orders shall include at least schedule II controlled substances and such other drugs as established by the P & T Committee or its equivalent;

p. assuring that precautionary measures for the safe admixture of parenteral products be developed in writing. Admixture preparation shall be limited to pharmacists, supportive personnel under the supervision of a pharmacist, licensed practitioners and licensed nurses. Furthermore, admixtures shall be labeled as in Pharm 88 D.;

q. assuring that investigational drug use is in accordance with state and federal law. Such drugs shall be administered only on the order of a member of the organized medical staff. The prescribing by the staff member shall be under the direction of the principal investigator. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs shall be available in the pharmacy and at any nursing service unit where such drugs are administered. Investigational drugs shall be distributed only from the pharmacy;

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Pharm 84

r. assuring that the practice of drug reconstitution be performed only by pharmacists, licensed practitioners, licensed nurses, or hospital-authorized personnel under the supervision of licensed pharmacists, licensed practitioners or licensed nurses.

2. The following measures related to the maintenance of documents:

a. pharmaceutical service director and pharmacist-in-charge's responsibility in addition to those in Pharm 21. The director of the pharmaceutical service and pharmacist-in-charge shall maintain at least the following written documents:

(1) a statement of service philosophy and objectives;

(2) a job description for each classification of personnel;

(3) a list of pharmaceutical service committees; and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;

(4) procurement records for controlled substances for two years as required by law;

(5) prescriptions or other forms initiated by the prescriber, for two years as required by law;

(6) records of packaging, bulk compounding or manufacturing for two years;

(7) records of action taken pursuant to drug recalls for two years;

(8) special reports concerning narcotics and other drugs for two years as required by law;

(9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room as permitted under Pharm 84 B.1.f. and g. for two years;

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room as permitted under Pharm 84 B.1.e. for one month;

b. other necessary documents. The following documents relative to pharmaceutical services shall also be maintained:

(1) a current organization chart delineating intra-service structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff and other relevant hospital services;

(2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;

(3) a record of the number of persons, by job description, employed full time and part time in the pharmaceutical services;

(4) copies of current staffing patterns and weekly work schedules;

(5) receipted invoices for all drugs, chemicals and pharmaceutical service supplies purchased and received over the immediately preceding two years; and

(6) any agreement between an off-premises pharmacy and the hospital.

~~Pharm 85 Automatic Stop Orders. Drugs for individual patients shall be dispensed in limited quantities in compliance with the automatic stop order policy set by the medical staff.~~

Pharm 85 Pharmaceutical service equipment and supplies. In addition to the requirements of Pharm 10, equipment and supplies shall be maintained by the pharmacy as necessary to fulfill the further needs of patients and the scope of services offered.

~~Pharm 86 Responsibility for Quality of Drugs Dispensed. The pharmacist-in-charge shall be responsible for the quality of drugs dispensed and shall establish procedures and records to control product specifications.~~

Pharm 86 Drug handling and storage. At least the following provisions for the safe handling and secure storing of drugs shall be observed:

A. storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security;

B. drugs shall be protected from contamination; and

C. drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

~~Pharm 87 Pharmaceutical Services to Hospitals from Off Premises Pharmacies. An off premises pharmacy may com-~~

~~pound and dispense drugs to a hospital upon the order of an agent of such hospital provided that the pharmacy keeps records of all drugs dispensed. Such dispensing shall not be considered to be drug wholesaling. The services offered to the hospital by the off premises pharmacy shall include but shall not be limited to those enumerated in Regulation No. 81~~

Pharm 87 Pharmaceutical service space.

A. The pharmacy or drug room shall be surrounded by a continuous partition or wall extending from floor to ceiling. All doors and windows shall be securely locked when the pharmacy or drug room is closed, so as to prevent entry by unauthorized persons.

B. Space shall be available at each nursing service unit for storage, safeguarding and preparation of medication doses, to include provision of at least the following:

1. A well-illuminated, locked drug cabinet or room shall be equipped with clearly labeled cubicles to ensure physical separation of individual patient prescribed medications. Medications may be stored in secured individual patient storage areas or secured portable storage carts providing separate compartments for individual patients.

2. A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

Pharm 88 Labeling.

~~(a)~~ A. Out-patient prescriptions. Labels for out-patient prescriptions shall comply with Regulation 40 and 41. Labels for out-patient nonprescription drugs shall comply with the federal regulations. Drugs originally dispensed to an in-patient shall be returned to the pharmacy for proper labeling before leaving the hospital premises.

~~(b)~~ B. In-patient prescriptions. All prescriptions dispensed to in-patients, other than those dispensed pursuant to Pharm 48, shall be labeled with the following information:

~~(1)~~ 1. identification of pharmacy;

~~(2)~~ 2. name of patient;

~~(3)~~ 3. name of drug;

~~(4)~~ 4. ~~Dosage form of drug (if parenteral only)~~ route of administration of drug when necessary for clarification;

~~(5)~~ 5. strength of drug;

6. the name of the manufacturer of the finished dosage form of the drug;

~~(6)~~ 7. auxiliary labels as needed;

~~(7)~~ 8. expiration date, if ~~any~~ applicable;

~~(8)~~ 9. date dispensed.

~~(c) Floor stock: All drugs dispensed as floor stock shall be labeled with the following information:~~

C. Drugs prepackaged for emergency use. All drugs dispensed under Pharm 84 B. 1. f. shall be labeled with the following information:

~~(1)~~ 1. identification of pharmacy or other source;

~~(2)~~ 2. name of drug or list of ingredients;

~~(3)~~ 3. strength of drug or amount of ingredients;

~~(4)~~ 4. auxiliary labels as needed;

~~(5)~~ 5. expiration date, if any;

~~(6)~~ 6. ~~Average~~ usual dose;

~~(7)~~ 7. control number or date of issue;

8. the name of the manufacturer of the finished dosage form of the drug.

D. Whenever a drug is added to a parenteral solution a distinctive supplementary label shall be firmly affixed to the container. The label shall indicate the name and amount of drug added, the date and time of the addition and expiration of the drug, and the identity of the person preparing or certifying the integrity of the admixture.

Pharm 89 Extension of pharmacy services under license. A licensed pharmacy in a hospital may utilize addi-

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Pharm 89

tional locations within the hospital without the necessity of securing additional licenses, provided, however, that the ~~pharmacist in charge~~ director of pharmaceutical services of any such hospital pharmacy shall designate another licensed pharmacist to assume professional responsibility, in accordance with Regulation 21-23, for the practice of pharmacy in each such additional location.

Pharm 90 Use of supportive personnel. The use of supportive personnel shall be in accordance with the provisions of Pharm 47.

Pharm ~~90-100~~ 91-100 Reserved for future use.

Department of Public Welfare
Income Maintenance Bureau

Proposed Amendment of DPW 44 Governing the Aid to Families with Dependent Children Program

Notice of Hearing

Notice is hereby given that a public hearing in the above-entitled matter will be held in the State Office Building, Room 83, Wabasha Street (between Aurora and Fuller), St. Paul, Minnesota 55155, on July 19, 1978, commencing at 9:00 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, Office of Hearing Examiners, 1745 University Avenue, St. Paul, Minnesota 55104, (612) 296-8118, either before the hearing or within five working days after the public hearing ends, or for a longer period not to exceed 20 days if ordered by the hearing examiner.

The Aid to Families with Dependent Children (AFDC) Program provides maintenance and medical care to families as a result of death, absence or incapacity of a parent or the unemployment of the father. The amendments to DPW 44, if adopted, would incorporate various changes in federal and state law, court decisions and change department policy into the existing rule. Provisions of the amended rule include: the addition of a provision concerning advocacy to the application process; a provision requiring local agencies to act upon an existing application prior to considering a reapplication; a provision requiring income maintenance to refer to social services cases of child abuse; a change in residency requirements from twelve to two months and accompanying changes in service and financial responsibility; a definition of eligible relatives; a change in law allowing concurrent receipt of unemployment insurance and AFDC in the unemployed fathers program; a change in the sanctions required for failure to register and/or participate in the unemployed fathers program; an increase in real property standards from $7,500 to $15,000; a change in law allowing the exemption of an automobile up to $1650 in value; a provision for liberalizing property limitations to the least restrictive limits when some members are eligible for AFDC and other members are eligible for various assistance programs; a new method for determining tax obligation and a change in the treatment of tax refunds; a revised method for determining work expenses which allows using a percentage of gross income up to a maximum; a revised method for determining income from child care using a percent of gross income; an increase in boarder and roomer allowances; an increase in the amount deducted from rental income for upkeep and repairs; a provision requiring clients to report new sources or amounts of income within ten days; a change in the family allowance standard from family-child to a child-adult standard; a definition of special needs (formerly supplements) and the inclusion of a state standard for special needs; a provision requiring payments to be made at the address where the recipient resides unless otherwise approved by the local agency; a provision which lists and defines appealable issues; a provision defining fraud, assigning responsibility for taking and reporting actions and outlining available recovery methods; a provision allowing recovery of over payments due to agency error; an increase in the relative responsibility scale and a provision allowing recovery only after a notice; a provision clarifying contribution in relative responsibility; a provision allowing the unemployed father to claim the WIN exemption concerning a child under six; an increase in AFDC foster care and difficulty of care rates; a provision requiring the local agency to refer cases of minor caretakers to social services; and numerous grammatical changes.

Copies of the proposed rule are now available and one free copy may be obtained by writing to Marcia Glass, Minnesota Department of Public Welfare, Fourth Floor, Centennial Office Building, St. Paul, Minnesota 55155, (612) 296-1383. Additional copies will be available at the door on the date of the hearing. The agency's authority to promulgate the proposed rule is contained in Minn. Stat. § 256. A Statement of Need explaining why the agency feels the proposed rule is necessary and a Statement of Evidence outlining the testimony they will be introducing will be filed with the Hearing Examiners Office at least 25

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

REPORT OF HEARING EXAMINER

The above-entitled matter came on for hearing before Hearing Examiner Peter C. Erickson of the State Office of Hearing Examiners at 9:30 a.m. on Monday, July 24, 1978 in the Board Room, Department of Health Building, Minneapolis, Minnesota.

William G. Miller, Special Assistant Attorney General, appeared as counsel on behalf of the Board of Pharmacy. David Holmstrom, Executive Secretary of the Board, testified in support of the proposed rules. 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, the Chief Hearing Examiner granted an extension for the completion of this Report through November 6, 1978.

Pursuant to Minn. Stat. § 15.0412, subd. 4, this Report shall be available for review to all affected individuals upon request for at least five 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 five days subsequent to the receipt of this Report. This submission shall 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 of Pharmacy shall be responsible for filing the rules with the Attorney General and for notifying persons who have indicated that they wish to be notified of such filing.

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

FINDINGS OF FACT

1. On June 29, 1978, the Board 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 June 19, 1978, a Notice of Hearing and a copy of the proposed rules were published at 2 State Register 2251.

3. On June 21, 1978, the Board 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 June 29, 1978, the Board 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;
(g) The Statement of Evidence, including the names of witnesses to be called; and
(h) The names of Board 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 Monday, August 14, 1978, for the receipt of written comments and statements.

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

7. As the hearing opened, Mr. Holmstrom stated that as a result of a meeting he had had with Dan McInerny and Mike Tripple, Health Department attorneys, a number of amendments to the proposed rules had been suggested by the Department of Health. These amendments were printed and available to the public at the time of hearing. The Board of Pharmacy had not officially accepted the amendments to the proposed rules; however, Mr. Holmstrom discussed them during the hearing. Neither Mr. McInerny nor Mr. Tripple testified in support of the amendments. The Statements of Need and Reasonableness spoke only to the rules as initially proposed and published in the State Register. The Health amendments were entitled "proposed Amendments to Proposed Rules" and amended the published amendments to Pharm 38, 48, 71, 73, 74, 75, 81-84, 87 and 88.

K. Craig Wildfang, staff counsel for the Minnesota Association of Health Care Facilities (MAHCF), commented as follows regarding the appropriateness of the "Proposed Amendments":

> Initially, we must state our view that the procedure used by the Board of Pharmacy and Mr. David Holmstrom was irregular if not improper. We were specifically concerned about the use of the document entitled "Proposed Amendments to Proposed Rules". We hesitate to object too strenuously because these proposed amendments were, in many cases, a substantial improvement over the published proposed rules. However, the procedure used where by Mr. Holmstrom, in effect, substituted the "Proposed Amendments" for the published proposal fairly clearly conflicts with the mandate of Minn. Stat. § 15.0412, subd. 4, that the full text of the proposed rule be published 30 days prior to the date of the hearing. The purpose of this provision, without question, is to afford interested persons the opportunity to review proposed rules in advance so that they may intelligently comment on them at the hearing. The effect of the procedure used in this case by Mr. Holmstrom was to subvert the purpose of the statute.
>
> We found it difficult to comment at the hearing and now find it difficult to comment in writing because of the unclear status of the proposed rules and the proposed amendments. The difficulty is in knowing which of these documents to comment on. We find ourselves in agreement with many of the "proposed amendments" and are unsure whether we should simply direct our comments at these proposals or at the original published proposed rules. Although, as previously indicated, the "proposed amendments" are substantively superior to the published proposals, we believe it would be proper for the Hearing Examiner to point out the irregularity of the procedure used in this case.

There was another irregularity in the use of the document entitled "Proposed Amendments to Proposed Rules". Mr. Holmstrom indicated that this document grew out of a meeting between himself and representatives of the Minnesota Department of Health, and that it represented the views of the Health Department. However, no representative of the Department offered any testimony relating to this document and Mr. Holmstrom read it into the record as if the proposed amendments were the position of the Pharmacy Board. We believe that the proper method for a state agency to comment on published proposed rules of another agency is to offer comments at the hearing and not to sit down in private prior to the hearing. Such a procedure carries substantial risks for the policies of openness and public participation that are to be fostered by the Administrative Procedures Act.

9. Mr. Wildfang also commented that the Board of Pharmacy has not complied with Minn. Stat. § 15.0412, subd. 7, which requires a cost estimate if the agency reasonably estimates that the cost of rule implementation to local public bodies will exceed $100,000 per year. In addition, Laws 1977, Chapter 453, section 16, requires that health-related boards must provide the Legislature with fiscal notes prior to putting into effect any rule which has a fiscal impact in excess of $100,000. The Board contends that the fiscal impact of all of the proposals would "come nowhere near approaching the $100,000 limit."

The Examiner finds that the Board did reasonably estimate that the cost would not exceed $100,000. There was insufficient evidence offered on which a contrary finding could be made.

10. The Board has proposed to amend Pharm 21 by clarifying the language directing the submission of reports concerning support personnel procedures. The Examiner finds that proposed Pharm 21 is both needed and reasonable.

11. The Board has proposed to amend Pharm 32 to allow for certain exceptions to the prohibition of any return of medication for re-use or re-issue. Recent developments in drug packaging now permit the safe return of drugs to the dispensing pharmacy. Several comments were made favoring a greater liberalization of return policies. The Examiner finds that proposed Pharm 32 is both needed and reasonable.

12. The Board has proposed to amend Pharm 36 to redefine the process of compounding and dispensing which is restricted only to licensed pharmacists. The use of support personnel is then set out in new Pharm 47. The Minnesota State Pharmaceutical Association (MSPhA) and the Minnesota Society of Hospital Pharmacists (MSHP) suggested that certain clarifying amendments be made to Pharm 36. The Board stated that it "would not be opposed" to those amendments. Gary Persons, R.Ph., Director of Pharmacy Services at Methodist Hospital, St. Louis Park, stated that Pharm 36 does not fit hospital practice.

The Examiner finds that proposed Pharm 36 is both needed and reasonable.

13. The Board has proposed to amend Pharm 38 to include additional information which must be entered on the packaging control record and on each prepackaged container. The Board supported the amendments to Pharm 38 B. proposed by the Department of Health (attached hereto). Mr. Holmstrom stated that it was necessary to include the name of the manufacturer of the finished dosage form on propackaged containers so that it could be entered on

prescription labels. The Board also stated support for an amendment proposed by MSPhA which would allow the pharmacist discretion to put a shorter expiration date than the manufacturer suggests on the prepackaged label.

The Examiner finds that proposed Pharm 38, as amended above, is both needed and reasonable.

14. New Pharm 47 sets forth the responsibilities of pharmacists in the use and supervision of supportive personnel. A general ratio of 1:1, support persons to pharmacists, is established with exemptions for specified functions. The rule mandates submission of written procedures for the use of supportive personnel to the Board for its approval.

Several comments were made concerning the appropriateness of submitting procedures to the Board for its completely discretionary approval. Current Pharm 21 already mandates these submissions. As proposed, Pharm 47 does not list any criteria for the approval or rejection of procedures. Such criteria must be set forth for the rule to be valid and enforceable. As drafted, the rule is unreasonable. The Examiner suggests the following language as a possible remedy:

> "these procedures must comply with the standards set forth in this rule and will be approved on that basis. Approval must be obtained prior to implementation of the procedure."

Several comments questioned the supervisory standard of a ". . . licensed pharmacist physically present within the same work area. . . ." The Board contends that "a rule of reasonableness will prevail." The Examiner finds that allowing the Board to use "a rule of reasonableness" when interpreting language that is clear on its face is unreasonable. The rule would have the same effect with the "ability to control" and "responsible" qualifiers if the words stationed or employed were substituted for "physically present."

As proposed, Pharm 47 is not reasonable. However, if amendments such as those set forth above are made, the Examiner finds that the rule is both needed and reasonable.

15. New Pharm 48 is necessary to spell out minimum standards and safeguards for unit dose dispensing systems. These standards had been in "guideline" form previously and are now being promulgated pursuant to the APA. The MSPhA suggested several clarifying amendments to Pharm 48. The Board again stated that it does not oppose the suggested amendments. The Board did support, however, the clarifying amendments to Pharm 48 B.3. proposed by the Health Department (see attachment). In Pharm 48 A.1., the Board has attempted to incorporate by reference federal laws and regulations. This incorporation is invalid absent compliance with Minn. Stat. § 15.0412, subd. 4.

If the incorporated material is inserted or the above-referenced statute is complied with, the Examiner finds that proposed Pharm 48, with the Health amendment, is both needed and reasonable.

16. The Board has proposed to amend Pharm 61 to make the requirements for registered interns more exact and include minimum competency levels. The Examiner finds that proposed Pharm 61 is both needed and reasonable.

17. The Board has proposed to amend Pharm 71 to set forth specific procedural requirements for handling prescription orders from long-term care

facilities. The amended rule allows facility staff to communicate physicians' prescriptions to pharmacies. The Board supported the Department of Health amendments to PHarm 71A. which it contends is substantively the same but easier to understand (see attachment). Pharm 71C. attempts to incorporate unspecified federal regulations by reference. The Board has summarized the regulations and proposes to insert the following language within Pharm 71 C:

1. Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user; and,

2. No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and,

3. It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be prepresented to the person dispensing the substance, prior to the dispensing.

Also, the title of Chapter 6 should be amended to conform to the amendment in the introductory paragraph. The Examiner finds that proposed Pharm 71, as amended above, is both needed and reasonable.

18. The Board has proposed to amend Pharm 72 to clarify prescription labeling and relabeling requirements. The MSPhA contends that several of the labeling requirements listed in Pharm 72 are a duplication of Pharm 40 and are unnecessary. The Examiner finds that there is no need to duplicate language and that those requirements should be deleted. Mr. Robert Gale, representing Twin City Geriatric Drug, commented that pharmacists should be permitted to relabel medications at facilities and not have to require the return of the drug. The Board concurred in this suggestion. As amended above, the Examiner finds that proposed Pharm 72 is both needed and reasonable.

19. The Board has proposed to amend Pharm 73 to include the location of the patient on the prescription label. The Board concurred in the slightly reworded version proposed by the Department of Health (see attachment). As amended, the Examiner finds that proposed Pharm 73 is both needed and reasonable.

20. Pharm 74 has been amended by the Board to set forth requirements for the dispensing of drugs to be used in emergency kits at long-term care facilities. Mr. Holmstrom stated that these kits are not to be viewed as convenience kits or mini-drugstores; but rather as emergency kits for life-saving use only. The Board supported the Health Department amendments to Pharm 74 (see attachment), but nowhere in the record is there any rationalization for the deletion of input from the patient care or pharmaceutical services committees. The MSPhA commeted as follows:

> Pharm 74. The proposed amendment substantially changes the intent of the proposed rule. As proposed at 2 S.R. 2258, Pharm 74 permitted the pharmaceutical service committee to select those drugs necessary for emergency patient care in the particular facility. Because of the broad range of services provided by facilities, from supervision of minimally impaired elderly residents to care of severely ill residents with heart and lung diseases who must remain in bed resting at all times, no one standard is feasible in the proposed rule. Without defining

"life threatening emergencies", the Board of Pharmacy is forcing the pharmacist to guess which drugs may be in compliance with the rule. In contrast, the proposed rule allows the pharmacist, as a member of the pharmaceutical services committee in consultation with other health professionals at the facility, to determine the drug needs of the facility.

Mr. Wildfang also expressed support for the retention of committee input regarding the emergency kit.

The Examiner finds that proposed Pharm 74, as amended by the Health Department, with the exception of the elimination of committee input, is both needed and reasonable. The "necessary for patient care in life threatening emergencies" language should be included as it expresses the Board's intent. There are sufficient criteria embodied in the rule so as to avoid illegal delegation problems.

21. New Pharm 75 sets out the responsibilities and functions required of long-term care facility consulting pharmacists. These standards are necessary for participation in HEW Title 19 reimbursement. As proposed, the rule regulates facilities, rather than the profession of pharmacy. The Board concurred in the Department of Health amendment which remedies the problem by putting the onus on pharmacists rather than the facility. Both the proposed and amended language contains the provision that a consultant shall be retained "whenever possible". There are no criteria listed on which to base a decision if it is possible or not. As such, the rule is both vague and unenforceable. The Board will either have to mandate that consultants always be retained or establish criteria on which to base a decision as to whether or not it is possible to retain a consultant. The Board concurred in the Health amendment to delete consultant membership on the patient care or pharmaceutical services committees because all facilities do not have such committees or do not desire a pharmacist member. There is no evidence in the record to support the Health amendment to Pharm 75 B.3. which adds the language "when requested to do so." (see attachment)

The Examiner finds that as proposed, Pharm 75 is unreasonably vague. If this problem is remedied, the rule is both needed and reasonable, as amended by the Health Department, with the exception of the language in B.3.

22. New Pharm 75 sets forth a freedom of choice clause which must be complied with by pharmacists.

23. The Board has proposed to amend the introduction to Chapter 7 to also include extended care facilities because they are in the same category as hospitals and state hospitals.

24. The Board has entirely rewritten Pharm 81 to more fully set out the definitions of pharmaceutical services. The Health Department amendments to Pharm 81 A. and E. were accepted by the Board (see attachment). Mr. Holmstrom explained that the language deleted in A. was vague and that the amendment to E. more clearly states what was intended by the Board. The Examiner finds that proposed Pharm 81, as amended by the Health Department, is both needed and reasonable.

25. The Board has rewritten Pharm 82 to require hospitals to furnish certain kinds of pharmaceutical services. The Board admitted that the pro-

posed rule is outside of its statutory authority and agreed to the Department of Health amendments which delete most of the rule (see attachment). The Examiner finds that proposed Pharm 82, as amended by the Health Department, is both needed and reasonable.

26. The Board has rewritten Pharm 83 to spell out the responsibilities of hospital pharmaceutical staff. The Health Department suggested that Pharm 83 A.2.a. and b. be amended to include some of the language stricken in Pharm 82 and that Pharm 83 A.3.c. be deleted as it is inappropriate to require a hospital pharmacy to implement all of the recommendations of the pharmacy and therapeutics committee. The Board concurred with those amendments. The MSPhA commented that because Minnesota Statutes recognize only two types of pharmacy practitioner, a pharmacist and a pharmacist-in-charge, the term "Director" in Pharm 83 should more appropriately be pharmacist-in-charge. Several comments suggested that the word "duties" be deleted from A.3. because it does not describe what the actual functions are and that the word "bimonthly" be replaced with <u>every two months</u> or <u>twice a month</u> for the sake of clarity. The Examiner finds that proposed Pharm 83, as amended above, is both needed and reasonable.

27. The Board has rewritten Pharm 84 to set out in detail what must be contained in pharmaceutical service policies. The Department of Health suggested that much of the language in the rule be deleted. Mr. Holmstrom stated that the proposed rules dictate how a pharmacist should address issues, not merely that certain issues should be addressed as was intended by the Board. Consequently, the Board did agree to the Health amendments which delete language in Pharm 84 A. and B. (see attachment). Also, a necessary alternative was added to B.1.e.(1)(b)(vi) for hospitals which have a unit dose packaging bin rather than a bulk stock container (see attachment).

The Examiner finds that the proposed rule, as amended by the Department of Health, is both needed and reasonable.

28. The Board has rewritten Pharm 85 to require that adequate accessory equipment and supplies is maintained by the pharmacy.

29. Pharm 86 has been rewritten by the Board to require the safe handling and secure storage of drugs.

30. Pharm 87 has been rewritten to mandate adequate secure space for the storage of drugs both in the pharmacy and on nursing stations. The Health Department proposed to amend Pharm 87 B. by changing the wording so that the rule would regulate the profession of pharmacy and not facility nursing services. The Board concurred in that amendment (see attachment). The Examiner finds that the proposed rule, as amended, is both needed and reasonable.

31. The Board proposed to amend Pharm 88 to require that certain additional information be included on prescriptions dispensed to in-patients at hospitals. Mr. Holmstrom stated that because the name of the manufacturer of the finished dosage form of the drug is not required by law to be on in-patient prescription labels, the Board withdraws that proposed amendment. Also, the Board concurred in the Health Department amendment which clarifies the wording of Pharm 88 D. The Examiner finds that the proposed rule, as amended above, is both needed and reasonable.

32. The Board proposed to amend Pharm 89 to change "pharmacist-in-charge" to director of pharmaceutical services and Pharm 90 to reference Pharm 47 regarding the usage of supportive personnel. In conjunction with Finding 26, the term "pharmacist-in-charge" should be retained. As amended, the Examiner finds that proposed Pharm 89 and 90 are both needed and reasonable.

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, with the exception noted in Finding 15 regarding incorporation by reference.

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 presentation made by the Board at hearing was somewhat confusing. Mr. Holmstrom spoke in support of proposed rules published in the State Register as amended by Department of Health recommendations which had not been sanctioned or approved by the Board. Consequently, it was unclear as to what was really being proposed for adoption by the Board as the Health Department did not offer any support for its recommendations. This procedure was inappropriate; however, the Examiner does not conclude that it was fatal to the proceeding. In most instances, Mr. Holmstrom did provide evidence demonstrating the need for and reasonableness of the Health amendments. Many of the changes were merely clerical in nature and did not change the substance of the rule.

4. Many other amendments were suggested by the MSPhA, the MSHP, the MAHCF and other interested individuals. The Board took no position on most of those proposals but rather stuck with the rules as originally proposed and amended by the Health Department (a posthearing submission from the Board did approve the Health amendments). Consequently, as is mandated by Minn. Stat. § 15.052, subd. 3, this Examiner only has authority to make a finding as to whether or not the Board demonstrated the need for and reasonableness of the proposed rules. The Board has the statutory responsibility to determine policy issues for the pharmacy profession and to determine what is the best form of the rule.

5. The Examiner concludes that the Board has documented its statutory authority to promulgate the proposed rules.

6. The Examiner concludes that the Board has demonstrated the need for and reasonableness of the proposed rules, as amended, with the exceptions noted in Findings 14, 20 and 21.

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

R E C O M M E N D A T I O N

That the Board of Pharmacy adopt the proposed rules, as amended, after taking appropriate action in regard to Findings 14, 15, 20 and 21.

Dated this 6 day of November, 1978.

Peter C. Erickson

PETER C. ERICKSON
Hearing Examiner

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Unit Dose Distribution,
Supportive Personnel, Drug Returns,
Nursing Home Practice, Hospital
Practice and other Miscellaneous Matters.

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 above captioned rules represent step 2 in a general revision being developed by the Board. Step 1 (consideration of relatively less controversial changes) was accomplished approximately one year ago.

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. Some 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 changes in Pharm 21 are basically for clarification purposes. The wording deleted from Pharm 21 C is returned in Pharm 21 D with some clarification.

2. The Board's current rule 32 specifically prohibits the return of medication for re-use or re-issue. This has been generally defendable from a misbranding and adulteration standpoint. Recent developments in drug packaging have brought about widespread use of unit-of-use packaging which allows a reconsideration of the previously existing position. This reconsideration is found in Pharm 32.

3. 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, 36, and 47.

4. The development of the unit-of-use packaging concept together with Pharmacists' increasing involvement in providing services to nursing homes has led to the utilization of Unit Dose dispensing systems of various design and sophistication. Pharm 48 is needed to establish a discriptive minimum of what these systems must provide in the way of services and safeguards.

5. Since 1973 the Board has been requiring participation on the part of pharmacist-interns in a competency based examination. The Board feels that there is a need to more explicitly set forth the requirements of such an exam. Pharm 61 B. 4. is included to help meet this need.

6. Over the past several years HEW has been mandating and nursing homes themselves have been requesting increased involvement on the part of pharmacists in the delivery of pharmacy services to long term care facilities. It has been the experience of the Board that many pharmacists are not aware of what their duties, responsibilities and authorities are in this area. The Board feels that there is a definate need for Rules in this area. To meet this need the rules found in chapter six, Pharm 71-80, were developed.

7. Since 1969 the Board has been relying on the minimal and broadly worded concepts of Pharm 81-100 to guide the pharmacist in hospital practice. Pharmacy services to patients in hospitals during this intervening time period has changed considerably in scope and in sophistication. To meet the needs of hospital pharmacists, as well as the hospitalized patient, new, more detailed rules have been proposed by the Board. These are the new rules 81-100.

In conclusion and as was stated above, these proposed rules are badly needed to meet the changing directions and responsibilities of pharmacy

practice and are the second half of the general rules revision process undertaken by the Board. These proposed rules are needed to maintain uniformity with the first half changes and to keep the Board's rules consistent with and relevant to currently available pharmacy practice.

DATED June 28, 1978.

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

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. The changes proposed in Pharm 21 involve basically a relettering change. The last sentence of Pharm 21 C was made a separate statement under 21 D with directions added to aid the Pharmacist-in-charge in determining which procedures must be developed and submitted to the Board and under what circumstances such submission must be made. These criteria are found in Pharm 47 to which reference is made here in Pharm 21. The changes in Pharm 21 are both simple and reasonable.

2. For quite a number of years the Board has enforced its regulation prohibiting returns of dispensed medications for re-use or re-issue. This requirement has been incorporated as part of the Board's rule in order that pharmacists would not be found to be in violation of FDA regulations concerning adulteration and misbranding.

In recent years the development and subsequent widespread use of Unit-of-use packaging and unit dose distribution systems have obviated the need for total bans on returns of medications in that each tablet or capsule is sealed in its own properly labeled package.

Even though medication costs have risen at a lesser rate than have the other aspects of health care costs the Board is of the opinion that where the properly labeled unit dose package remains intact and has been stored under proper conditions as in hospitals and nursing homes there is no longer a valid reason for preventing returns to the pharmacy for appropriate credit.

The change in the drug return prohibition which would authorize returns under certain conditions is both just and reasonable.

3. 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. The requirement is contained in Pharm 36 E.

Pharm 36 F contains the basics of the changes which allow an expanded role to both pharmacists 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 erraneous 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 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 patient's 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 both 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 do so only in accordance with Board rules.

4. Pharm 47 is the key that is tied in by reference to both Pharm 36 and Pharm 90. In order that pharmacists may be freed up to be able to participate more fully in their important and expanding role of clinical advisor on drug therapy and in order that the fraction of the health care dollar associated with pharmaceutical services remain at its present low figure the Board proposes to expand the allowable functions for pharmacy supportive personnel.

While the Board is doing this, however, it must remain cognizant of its responsibility to protect the public from unsafe pharmacy practices. This is true whether those practices originate with supportive personnel or with the pharmacist himself. For this reason the Board has broken down the manipulative aspects of pharmacy practice into several areas and established maximum ratios for the use of supportive personnel for each of those areas.

While arguments may be heard from some sources that the proposed rules are more restrictive than the current operating procedures at some institutions, one should not be misled into comparing existing procedures with the new rules but should instead compare the existing rule with the proposed rule.

The existing rule limits the use of supportive persons to a strictly clerical role thereby limiting their involvement and usefulness as an aid to the pharmacist. Under the proposed rules their allowable functions and thus their usefulness is much expanded. Under these proposed rules supportive personnel may perform virtually all the manipulative tasks previously reserved to the pharmacist.

This proposed rule essentially limits the use of pharmacy supportive personnel engaged in drug preparation to a basic 1:1 ratio with pharmacists responsible for their supervision. It also requires the pharmacist-in-charge of any institution or facility which proposes to utilize supportive personnel in tasks which were previously reserved to the pharmacist to prepare written procedures directing these activities and submit them to the Board for review and approval. Exceptions to the basic ratio may be applied for according to proposed function. The clerical type functions which were traditionally those of pharmacy supportive personnel remain such but persons utilized solely for clerical purposes need not be included in the ratio limitations.

The Board believes that there may be a large number of "technician procedures" submitted upon passage of these requirements and thus proposes that the automatic approval provisions of Pharm 47 not be put into effect until one year after the proposed rule is finally promulgated.

The Board does not believe that any of the requirements of Pharm 47 constitute an unreasonable requirement for those seeking to utilize supportive personnel.

5. Pharm 48 deals with Unit Dose Drug distribution systems. Since 1973 the Board has had "Guidelines" on the use of Unit Dose dispensing systems. Recent legislation requiring all agency guidelines to be placed in rule form and the increased sophistication of the systems in use have obliged the Board to develop the rules as proposed here under Pharm 48.

Most, if not all, of the pharmacists utilizing Unit Dose systems in Minnesota are familiar with or are at least aware of the Board's previously existing guidelines. The proposed rule follows closely the old "guideline" requirements and where deviations occur such deviations will not pose any significant problems for any of the existing systems.

All of the provisions found in Pharm 48 are reasonable and pharmacies should be able to easily comply with them.

6. Since 1973 when the Board first established its competency based internship the Board has required pharmacist-interns to participate in a series of pre-test and post-test examinations. These examinations were administered under the general provisions of the previously existing examination statement in Pharm 61. The new language seeks to make clearer the exact requirements the Board is and has been placing on its registered interns and includes the minimum competency levels established by the Board and validated by the Board's tests and measurements consultant.

7. Chapter Six, containing Pharm 71-80, has been and will continue to be the section dealing with pharmacy services to patients in long term care facilities.

In the past few years the Federal Department of Health Education and Welfare has taken several steps to upgrade the care being received by patients in long term care facilities. The changing requirements have included a number of areas of interface between the pharmacy profession and the long term care patient.

For the first time many pharmacists were being called on to provide services to long term care facilities in their locales. Many pharmacists were not familiar with all of the nuances of pharmaceutical services these patients needed nor were they familiar with what was expected of them by HEW under its various requirements. The provisions contained in Pharm 71-80 are aimed at aiding the pharmacist involved in providing services, whether it be as a consultant pharmacist or as a pharmacist providing medications, to patients in the facility.

Significant changes from past requirements exist in Pharm 74, 75 and 76. Pharm 74 now makes the pharmacist responsible for the contents of the emergency kit and delineates the restrictions applicable to the use of the kit. Previously the primary physician at the home was responsible, on paper, for the kit but it was the pharmacist, in reality, who saw to it that it remained properly stocked and that proper records of use were kept. The change proposed here simply conforms the "paper responsibility" to the actual responsibility. Pharm 75 sets down the minimum level of effort that is expected from any pharmacist that is contacted by a long term care facility to act as their consultant pharmacist and who agrees to do so. In the past, pharmacists had been acting in a void and many of those contacted did not know what was expected of them in their role as consultant pharmacist. In many cases the administrative personnel at the nursing home did not know either and both may have found themselves acting in violation of HEW requirements. With proposed Pharm 75 a pharmacist aspiring to the role of consultant pharmacist can determine at least the minimum functions he should perform. This brings us to Pharm 76 which is a straightforward, self-explanatory statement on infringement of a patients right to freedom of choice of pharmacist provider.

8. As can be plainly seen from a review of the Board's proposal significant changes have been made to the rules in Chapter 7. Where the previously existing rules regarding pharmacy services to hospitals had been very brief and rather broadly and somewhat vaguely written, the Board's new proposals for pharmacy services in the hospital setting are quite complete and specific.

At the very beginning the rules make it clear that all hospitals must have an organized pharmacy services department. Larger hospitals, those with 40 beds or more, are required to obtain their pharmacy services from an on-site pharmacy. Smaller hospitals may obtain their services through a contractual agreement with an off-premises provider.

In most areas of the proposed hospital rules a technique has been borrowed from the Joint Commission on Accreditation of Hospitals in that requirements are made for the development of procedures. Rather than stating what each hospital pharmacy must or must not do the Board is simply requiring that the director of pharmacy services or the pharmacist-in-charge develop procedures appropriate for their institution and address at least certain specified issues.

In some areas the Board does set forth specific requirements applicable to all hospitals. One such area is found in 84 B. 1. e. Here specific information is required on the records left in the pharmacy by nursing personnel when medications

are removed pursuant to the "emergency access" procedures. These records are not different from those records already obtained by most hospitals.

In Pharm 88 some clarifying changes have been made. The state legislature, in 1975, (MN Laws 1975, chpt. 101) required that the name of the manufacturer of the finished dosage form of the drug be placed on the label of all drugs dispensed in Minnesota. Pharm 88 B. 6. makes this requirement clear.

The proposed rules of Chapter 7, dealing with pharmacy services to hospitals, leave much of the development of the specifics for each hospital in the hands of the director of pharmacy services requiring him only to address certain issues in a manner appropriate to his institution in the procedures he is required to develop. This being the case it becomes readily apparent that the proposed rules in this chapter are indeed reasonable.

This entire package of proposed rule changes is designed to serve as guidelines for pharmacists in several areas of expanding involvement by pharmacists, to meet the needs of the public in maintaining economical pharmaceutical services and yet assure the public of adequate protection from any potentially hazardous pharmaceutical practices. These proposed rules are quite reasonable given these broad goals.

Dated: June 28, 1978

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

ADMIN 1000 (Rev. 1/78)

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO : Lee Sheehy
Special Assistant Attorney General
G-25 Administration Building

DATE: January 19, 1979

FROM : William G. Miller
Special Assistant Attorney General

PHONE: 5500

SUBJECT: In the Matter of Proposed Amendments Relating to the Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.
Hearing Examiner No. BP-79-001-PE

I have enclosed for your review, pursuant to Minn. Stat. § 15.0412, subd. 4 (1978), the record, the Board's findings and the Order adopting the above-referenced rules. Included for your convenience in each document package is a copy of the rules as proposed and the rules as adopted. You will note that the changes made to the rules, as reflected in the Board findings, closely parallel the comments in the report of the hearing examiner.

WGM:mt
Enclosure

ADMIN. 1000
3

STATE OF MINNESOTA

DEPARTMENT BOARD OF PHARMACY

Office Memorandum

TO : Mr. Lee Sheehy
G 25 State Admin. Bldg.
50 Sherburne Ave.
St. Paul, MN 55155

DATE: January 31, 1979

FROM : David E. Holmstrom
Executive Secretary

SUBJECT: Proposed Rules

Enclosed is a copy of the Notice, the list of persons the notice was sent to and an Affidavit of Mailing which should be incorporated into the documents regarding the matter of proposed amendments relating to unit dose distribution, supportive personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other miscellaneous matters that I brought to your office last week.

If you have any questions regarding anything in the proposed rules referenced above please contact me.

The Board of Pharmacy would be most appreciative of anything you might be able to do to expidite the review of the proposed rules.

DEH:pe

Enc.

RECEIVED
FEB 1 1979
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of Proposed Amendments
Relating to Unit Dose Distribution,
Supportive Personnel, Drug Returns,
Nursing Home Practice, Hospital
Practice and other Miscellaneous Matters.

AFFIDAVIT
OF MAILING

Patricia A. Eggers, being first duly sworn, deposes and says:

That on the 21st day of June, 1978, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations at the addresses listed on the Certificate of the Secretary of State attached and made a part hereof as Exhibit A, to all persons and associations at the addresses listed on Exhibit B, attached and made a part hereof, as well as to all members of the Minnesota Legislature as of the date of mailing.

Patricia A. Eggers

Subscribed and sworn to before
me this 28th day of June, 1978.

Mary Wickholm
Notary

MARY WICKHOLM
NOTARY PUBLIC—MINNESOTA
HENNEPIN COUNTY
My Commission Expires April 6, 1995.

STATE OF MINNESOTA

MINNESOTA BOARD OF PHARMACY

COUNTY OF HENNEPIN

In the Matter of Proposed Amendments
Relating to Unit Dose Distribution,
Supportive Personnel, Drug Returns,
Nursing Home Practice, Hospital
Practice and other Miscellaneous Matters.

AFFIDAVIT

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 19th day of June, 1978, 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 21st day of June, 1978, 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 19th day of June 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.

MARY WICKHOLM
NOTARY PUBLIC—MINNESOTA
HENNEPIN COUNTY
My Commission Expires April 6, 1985.

David E. Holmstrom
Executive Secretary

Subscribed and sworn to before
me this 28th day of June

Mary Wickholm
Notary Public

STATE OF MINNESOTA

COUNTY OF RAMSEY

In the Matter of Proposed
Amendments Relating to Supportive
Personnel, Unit Dose Distribution,
Return of Medication, Pharmacy
Services to Nursing Homes and Hospitals
and Other Clarifying Amendments.

CERTIFICATE OF
SECRETARY OF STATE

I hereby certify that the attached 4 Sheets 485 labels and sheet constitute the complete list of persons, associations, and other interested groups who as of 3:40 o'clock p.m., this 19th day of June, 1978, have requested pursuant to 15.0412, 1976 MS, that their names be placed on file with the Secretary of State for the purpose of receiving notice of public hearing on proposed rules on the subject captioned above.

SECRETARY OF STATE

Joan Anderson Growe

BY Cheri L. Mattson

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

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 4th day of June, 1978, 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 July 24, 1978, commencing at 9:30 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

David E. Holmstrom
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

NOTICE OF HEARING

NOTICE IS HEREBY GIVEN that a public hearing in the above entitled matter will be held pursuant to Minn. Stat. § 15.0412 subd. 4 (1978), in the Board Room of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on July 24, 1978, commencing at 9:30 a.m.

All interested or affected persons will have an opportunity to participate concerning the adoption of the proposed amendments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted by mail to Peter Erickson, Hearing Examiner, at Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone (612) 293-0113, either before the hearing or within five (5) days after the close of the hearing. All such statements will be entered into and become part of the record. Testimony or other evidence to be submitted for consideration should be pertinent to the matter at hand. For those wishing to submit written statements or exhibits, it is requested that at least three (3) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The conduct of the hearing shall be governed by the rules of the Office of Hearing Examiners.

The proposed amendments, if adopted, would fix requirements for unit dose distribution systems, set forth allowable functions for the utilization of supportive personnel, allow returns of certain medications, expand the responsibilities of the pharmacist in nursing home and hospital practice settings and make other more minor changes.

Copies of the proposed amendments are now available and at least one free copy may be obtained by writing to the Minnesota Board of Pharmacy, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing.

A Statement of Need explaining the Board of Pharmacy's position relative to the necessity for the proposed amendments and a Statement of Evidence outlining the testimony and evidence which will be introduced by the Board in support of the proposed amendments 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. The statutory authority of the Board of Pharmacy to promulgate and adopt these rules is contained in Minn. Stat. ch. 151 (1978).

In addition, please be advised that Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five (5) days after he commences lobbying. Lobbying includes attempting to influence rule making by communicating or urging others to communicate with public officials. A lobbyist is generally any individual who spends more than $250 per year for lobbying or any individual who is engaged for pay or authorized to spend money by another individual or association and who spends more than $250 a year or five (5) hours per month at lobbying. The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone (612) 296-5615.

Dated: June 5, 1978

STATE OF MINNESOTA

BOARD OF PHARMACY

/s/ David E. Holmstrom
DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

CERTIFICATE OF RESOLUTION

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 23rd day of March, 1978, that a quorum of said Board was present at this meeting, that said Resolution, set forth below, was passed by a majority vote of the members of the Board, and that said Resolution, set forth below, is also set forth in the Minute Book of the Minnesota Board of Pharmacy and has not been rescinded or modified:

March 23, 1978

The board next entered into a rather lengthy discussion of the most recent drafts of the proposed changes to the pharmacy rules and regulations. After making several minor changes in the latest draft of these proposed rule 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 unit dose distribution, supportive personnel, drug returns, nursing home practice, hospital practice and other miscellaneous matters 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."

David E. Holmstrom

Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of Proposed Amendments Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and other Miscellaneous Matters.

MINNESOTA BOARD OF PHARMACY

STATEMENT OF EVIDENCE

The Minnesota Board of Pharmacy, at this time, intends to introduce its evidence through David E. Holmstrom, its Executive Secretary. The evidence proposed will be along the lines set out in the Statement of Need and the Statement of Facts Extablishing Reasonableness of Amendments.

MINNESOTA BOARD OF PHARMACY

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 Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters

ORDER ADOPTING RULES

The above-entitled matter came on for hearing before the Minnesota Board of Pharmacy on the 24th day of July, 1978, at 9:30 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 10th day of January, 1979, pursuant to authority vested in me by the Board.

MINNESOTA BOARD OF PHARMACY

David C. 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 Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters

FINDINGS OF FACT

The above-entitled matter came on for hearing before the Minnesota Board of Pharmacy on the 24th day of July, 1978, at 9:30 a.m. in the Minnesota Department of Health Building after proper notice required by M.S. 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 E. Kathrud

Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters

CERTIFICATE OF BOARD 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 November, 1978. 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 has not been rescinded or modified.

After an additional brief discussion of the Hearing Examiners Report Mrs. Kitty Alcott moved and Mr. Ove Wangensteen seconded the following resolution:

> "Resolve, that the rules relating to unit dose distribution, supportive personnel, drug returns, nursing home practice, hospital practice, and other miscellaneous matters which were considered at a public hearing held on the 24th day of July, 1978, as amended, are found to be reasonable, necessary, and supported by the evidence contained in the record, and are hereby approved and adopted pursuant to authority invested in the Board of Pharmacy by Minnesota Statutes 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 the Hearing Examiner relating to this matter be and hereby is expressly adopted by the Board as its own."

The motion passed unanimously.

David E Holmstrom

Executive Secretary

Subscribed and sworn to before me this 10th day of January, 1979.

Alice D. Hummer

Notary Public

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

Ramsey County, Minnesota

My Commission expires 11-18-81.

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 proposed rules relating to Unit Dose Distribution, Supportive Personnel, Drug Returns, Nursing Home Practice, Hospital Practice and Other Miscellaneous Matters and all related documents and that based on such examinations and my personal familiarity with the applicable procedures, the Manual of Rule Making Procedures has been followed.

Dated: 1-19, 1979

William G. Miller
Special Assistant
Attorney General

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 UNIT DOSE)
DISTRIBUTION, SUPPORTIVE PERSONNEL,)
DRUG RETURNS, NURSING HOME PRACTICE,)
HOSPITAL PRACTICE AND OTHER MISCELLANEOUS)
MATTERS.)

REPORT OF THE
CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on July 24, 1978, before Peter 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; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, Subd. 3, was issued to the Minnesota Board of Pharmacy on November 6, 1978; and

WHEREAS, the Board of Pharmacy has now determined to adopt rules pursuant to Minn. Stat. § 15.0412, Subd. 4; and

WHEREAS, the Board of Pharmacy has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, Subd. 4, 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.

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

Dated this 23rd day of January, 1979.

Duane R. Harves

DUANE R. HARVES
Chief Hearing Examiner