CHAPTER 6800
MINNESOTA BOARD OF PHARMACY
PHARMACISTS' LICENSING AND OPERATION

6800.1500 CONTINUING PHARMACEUTICAL EDUCATION.

Subpart 1. **Definitions.** Definitions:

A. "Approved continuing education" means those continuing pharmacy education programs approved by the board or made available by an approved provider. These programs may take the form of classes, conferences, correspondence study courses, institutes, lectures, professional meetings, programmed learning courses, journal readings, seminars, study groups, or other program formats commonly accepted by educators as legitimate adult educational activities.

B. "Approved provider" means any association, corporation, educational institution, organization, group, or person who has been recognized by the Board of Pharmacy, in accordance with subpart 3, as having met its criteria indicative of the ability to provide quality continuing education programs or who has been recognized by the board as being approved by the American Council on Pharmaceutical Education for the provision of quality continuing education programs.

C. "Continuing pharmaceutical education" is a planned learning experience beyond a formal undergraduate degree program designed to promote the continual development of professional knowledge, professional skills, and professional attitudes on the part of the practitioners and shall include but is not limited to professional postgraduate education in any of the following subjects:

(1) properties and actions of drugs and drug dosage forms;

(2) etiology, characteristics, and therapeutics of the disease state;

(3) pharmacy practice; or

(4) legal, psychological, and socioeconomic aspects of health care delivery.

Subp. 2. **Minimum hours required; reporting.** Commencing March 4, 1975, no annual license renewal shall be issued to a pharmacist pursuant to Minnesota Statutes, section 151.13 until such pharmacist shall have submitted to the board satisfactory evidence that he or she has completed at least 30 hours of approved continuing education during the previous two-year period. Thereafter, each pharmacist shall submit such evidence every two years. Beginning with the 1981-1983 reporting period, participation in continuing education shall be reported on October 1 of each even-numbered year. The board may grant a pharmacist, upon application, an extension of time not to exceed one year to comply with the requirements of this subpart. Such extension shall not relieve the pharmacist from complying with the continuing education requirements for any other two-year period.

Subp. 3. **Approval of providers.** Application may be made by an association, corporation, educational institution, organization, or person to be designated as an approved provider on forms provided by the board. The applicant shall provide, at a minimum, information regarding administrative and recordkeeping procedures used for past programs, a history of the content, methods of delivery,

and faculty qualifications for past programs; methods of program needs assessment and development that the applicant has used, and evaluation mechanisms that the applicant has used. The applicant shall agree to maintain records of program content, evaluation summary, and attendance for at least three years following completion of each program. The application must cover the two-year reporting period for which provider approval is sought.

The board shall approve an applicant as a continuing education provider based on the applicant's compliance with the following criteria:

A. The continuing education programs must have had an identifiable administrative authority who was responsible for meeting all quality criteria and for maintaining records of program content, planning, delivery, evaluation, and attendance.

B. The programs' administrative requirements must have included:

(1) promotion and advertising of continuing education activities in a responsible fashion clearly indicating m promotional material the educational objectives of the particular activity, the nature of the audience that may best benefit from the activity, the schedule of the activity, the cost of the activity to the participant and the items covered by that cost, the amount of continuing education credit that can be earned through participation in the activity, and the credentials of the faculty;

(2) maintenance and availability of records of participation in continuing education activities adequate to serve the needs of the participants and others requiring this information; and

(3) provision of evidence to the participant, in the form of a certificate or other document, of satisfactory completion of a continuing education activity as reasonably required by the participant.

C. The educational content development must have included.

(1) Advance planning that includes a statement of educational goals, behavioral objectives, or both, that are measurable.

(2) Activities designed to satisfy educational needs which the board has determined to be appropriate.

(3) Involvement of members of the intended audience m identifying their own continuing education needs.

(4) Activities designed to explore one subject or a group of closely related subjects. If an activity involves multiple components, such as a lecture series, all segments must be devoted to integrally related subjects.

(5) Appropriate mediated material and supportive instructional material. Previously offered activities, including those in mediated forms, must have been reviewed by the provider prior to being offered to new audiences, with a view toward maintaining technical quality, timeliness, and currency of content, and faculty must have had the opportunity to update material, if they desired, before an activity was offered to a new audience.

D The methods of delivery must have been consistent with the special needs of the program.

E The teaching staff for a particular continuing education activity must have been competent in the subject matter and qualified by experience or preparation to the tasks and method of delivery.

F. An evaluation mechanism must have been provided to allow the participants to assess their achievement of program objectives.

G. The provider must have developed and employed evaluation techniques that assess the effectiveness of the continuing education activities, and the level of fulfillment of the stated objectives, for the purpose of provider and activity improvement if indicated.

Applicants with no history of program development in compliance with

items A to G or with an incomplete history will be judged on their willingness and ability to comply with these criteria in the future.

Subp. 3a. **Approval of programs.** Application may be made by an association, corporation, educational institution, organization, group, or person, not presently approved as a provider, to have a program designated as an approved program. The board shall approve a continuing education program if it complies with the following criteria:

A. The provider shall submit evidence that promotion and advertising of the program will be done in a responsible fashion. For example, the promotional material should state the educational objectives of the program, the nature of the audience for which the program is intended, the program schedule, the cost of the program and the items covered by that cost, the amount of continuing education credit that can be earned through the program, and the credentials of the program faculty.

B. The provider agrees to maintain records of participation in or attendance at the program for not less than three years and agrees to make them available to the board upon request.

C. The provider agrees to provide evidence to the participant of satisfactory completion of the program.

D. The program provider submits evidence that:

(1) program planning involved members of the intended audience;

(2) the program is designed to satisfy identified educational needs;

(3) the program includes a statement of educational goals, behavioral objectives, or both, that are measurable,

(4) the program, if it involves multiple components, is devoted to integrally related subjects, and

(5) any mediated and supportive instructional material is designed to be used in a suitable and appropriate manner.

E. The method of program delivery is consistent with the special needs of the program.

F The teaching staff appears to be competent in the subject matter and is qualified by experience or preparation to the task and method of delivery.

G. An evaluation mechanism is provided for the purpose of allowing the participants to assess their achievement of program objectives.

H. The provider has developed and will employ evaluation techniques that assess the effectiveness of the continuing education activities, and the level of fulfillment of the stated objectives for the purpose of provider and activity improvement if indicated.

Applications for program approval must be submitted not less than 45 days prior to the commencement of the program. The board shall assign the number of credit hours to each program and shall grant approval or deny approval of such application within 30 days of receiving the application

Subp. 4. **Revocation or suspension of approval.** The board may deny, refuse to renew, revoke, or suspend authorization, recognition, or approval previously furnished to programs or providers if the program or provider fails to conform to its application approved by the board, fails to furnish program content as publicized, or if the program or provider violates any provision of Minnesota Statutes, section 214.12, or this rule.

Subp 4a. **Programs not previously submitted for approval.** Pharmacists may apply for credit for attendance at programs not previously submitted to the board for approval provided that the pharmacist completes a continuing education program approval form, obtainable from the board, and submits it to the board within 45 days after completing the program. The applicant shall provide, at a minimum, the title, site, date, type, and length of the program being proposed

for approval, a program outline, and a description of the type of evaluation mechanism used at the program. Approval of the program is subject to all the standards of Minnesota Statutes, section 214.12 and subparts 1, item C, and 4, items B to G.

Subp. 5. **Hours of credit.** Credit shall be earned on the basis of attendance at or, in the case of correspondence courses, completion of a program. Credit for an identical program may be given only once to any individual during any reporting period.

Subp. 6. **Credit for presentation of professional lectures.** Pharmacists may apply for credit for presentation of in-service training programs or lectures consisting of subjects included in the definition of Continuing Pharmaceutical Education. Credit for these presentations will be granted only once to any individual during any reporting period.

Subp. 7. **Record of approved programs.** The board shall maintain a record of approved providers and approved programs including the hours of credit assigned to each program.

Subp. 8. [Repealed, 10 SR 2007]

Subp. 9. **Program promotion.** No reference shall be made by a program provider in publicizing a program that it is an "approved program provider" unless the provider is so approved by the board or the American Council on Pharmaceutical Education. No other reference indicating endorsement by the board may be made except as follows: "This program is approved by the Minnesota Board of Pharmacy for ___ hours of continuing education credit."

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.1600 CONTINUING EDUCATION ADVISORY TASK FORCE.

The continuing education advisory task force shall consist of not more than ten members. Five members of the advisory task force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the College of Pharmacy of the University of Minnesota, and two members shall be designated by the board. The continuing education advisory task force shall meet at least quarterly and shall annually elect a chairman and vice-chairman from its membership The executive director of the board of pharmacy shall act as secretary to the task force.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.2250 UNPROFESSIONAL CONDUCT.

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

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

B. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.

C Refusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed m pharmacies by pharmacists.

D. Participation in agreements or arrangements, with any person, corporation, partnership, association, firm, or others involving rebates, "kickbacks," fee-splittmg, or special charges in exchange for professional pharmaceutical services, including but not limited to the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility

as compensation or inducement for placement of business with that pharmacy or pharmacist. Monetary rebates or discounts which are returned to the actual purchaser of drugs as a cost justified discount or to meet competition are permitted if the rebates or discounts conform with other existing state and federal rules and regulations.

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

F. Refusing to consult with patrons or patients concerning contents, therapeutic values, and uses of prescription or nonprescription drugs, chemicals, or poisons.

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

H. The violation of any law, rule, regulation, or ordinance of the state or any of its political subdivisions, including the board of pharmacy, or the United States government, or any agency thereof relating to the practice of pharmacy.

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

J. Participation in institutional drug distribution as a consultant without providing pharmaceutical services in accordance with accepted principles of pharmacy practice and in compliance with federal and state laws or rules.

Subp. 2. **Improper advertising.** Prescription drug price information may be provided to the public only by a pharmacy, so long as it is not violative of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

A. No representation or suggestion concerning the drug's safety, effectiveness, indications for use, or competitive comparison shall be made.

B. No reference shall be made to controlled substances listed in schedule II-IV of the latest revision of the Federal Controlled Substances Act, and the rules of the Minnesota Board of Pharmacy.

C. The termination date for the prices listed shall be stated in the ad.

Subp. 3. **Accessories to illegal drug traffic.** The selling, giving away, or otherwise disposing of accessories (i.e., glassine papers, empty capsules, quinine, lactose, or similar products), chemicals, or drugs found in illegal drug traffic is unprofessional conduct by a pharmacist when he or she knows or should have known of their intended use in illegal activities.

Statutory Authority: *MS s 151 06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3100 COMPOUNDING AND DISPENSING.

Subpart 1. **Duties.** 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:

[For text of items A to H, see M.R. 1985]

I. supervising nonpharmacist supportive personnel utilized in the performance of certain pharmacy tasks (the use of such supportive personnel shall be in accordance with part 6800.3850).

Subp. 2. **Verification.** Verification of validity and propriety under subpart 1, item C, must be of the original prescription order. A copy, rewritten or verbal, is not acceptable.

Subp. 3. **Certification.** In certifying and documenting the completed prescription order under subpart 1, item F, the pharmacist shall include.

A. checking of the original labeled container from which the medication was withdrawn,

B. checking of the labeling on the prescription medication container,

C. checking the contents of the prescription medication container and the appearance of the total product;

D. checking the patient's medication profile for possible therapeutic incompatibilities and the accuracy of the addition to the profile of the medication dispensed, and

E. initialing of the prescription by the pharmacist performing the certification.

Subp. 4. **Exception.** 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 inpatients according to parts 6800.7100 to 6800.7950.

Statutory Authority: *MS s 151 06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3110 PATIENT MEDICATION PROFILES.

Subpart 1. **System required.** A patient profile record system must be maintained in all pharmacies for persons for whom prescriptions are dispensed. The patient profile record system must be designed for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing One profile record may be maintained for all members of a family living at the same address and possessing the same family name.

Subp. 2. **Minimum information required.** The following information, at a minimum, must be recorded.

A. the family name and the first name of the person for whom the medication is intended;

B. the address of the patient;

C. an indication of the patient's age group, such as infant, child, or adult; and

D. a list of all prescriptions obtained by the patient at the pharmacy maintaining the profile during the two years immediately preceding the most recent entry showing the prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber

Subp. 3. **Recording allergies.** The pharmacist shall request from the patient or the patient's agent and shall record any allergies, idiosyncrasies, and chronic conditions of the patient and the identity of any other medications being taken by the patient which may relate to drug utilization. If there are none, this must be indicated on the profile

Subp 4. **Drug interactions.** Upon receiving a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potentially harmful interaction or reaction, the pharmacist shall take appropriate steps to avoid or minimize the problem which shall, if necessary, include consultation with the prescriber.

Subp 5. **Duration of recordkeeping.** A patient profile record must be maintained for a period of not less than two years from the date of the last entry m the profile record. This record may be in a hard copy or a computerized form.

Subp 6. **Certain profiles not required.** Patient profiles are not required in the following circumstances.

A. If a patient does not want a patient profile established, the patient shall state it in writing to the pharmacist. The pharmacist shall not then be required to prepare a profile as otherwise would be required by this part.

B. Hospital pharmacies serving only inpatients of the hospital are not required to prepare patient profiles for those patients being discharged or receiving discharge prescriptions.

Statutory Authority: *MS s 151 06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

Subpart 1. **Authorization to dispense transferred prescription.** A prescription label, a written copy of the prescription, or a telephone report of a prescription from another pharmacy may be used for informational purposes only and has no legal status as a valid prescription order. A pharmacist who receives a label, copy, or report of a prescription from another pharmacist shall either contact the prescribing practitioner for authorization to dispense the prescription or shall comply with subparts 2 to 6.

Subp. 2. **Conditions of transfer.** A pharmacy may transfer original prescription information for the purpose of refilling a prescription if the information is communicated directly by one licensed pharmacist to another.

Subp. 3. **Duties of transferring pharmacist.** The transferring pharmacist shall:

A. write the word "VOID" across the face of the original prescription to make the prescription invalid;

B. record on the reverse side of the invalidated prescription the name and address of the receiving pharmacy; and

C. record the date of the transfer.

For controlled substances in Schedules III-V, parts 6800.4230 to 6800.4250, the transferring pharmacist shall also record on the reverse side of the invalidated prescription the Drug Enforcement Administration registration number of the receiving pharmacy and the names of the receiving and transferring pharmacists.

Subp. 4. **Duties of receiving pharmacist.** The pharmacist receiving the transferred prescription information shall write the word "transfer," "copy," or a word of similar import on the face of the transferred prescription, and shall provide all information required by law to be on a prescription, including:

A. the date of issuance and of filling of the original prescription;

B. the original number of refills authorized,

C. the number of valid refills remaining;

D. the date of last refill from original prescription;

E. the original prescription number from which the prescription information was transferred; and

F. the transferring pharmacy's name and address and, in the case of a controlled substance in Schedules III-V, parts 6800.4230 to 6800.4250, the transferring pharmacy's Drug Enforcement Administration registration number and name of transferring pharmacist.

Subp. 5. **Retention of prescription.** The transferring pharmacist shall keep the original prescription for at least two years from the date of last filling. The receiving pharmacist shall keep the transferred prescription for at least two years from the date of last filling.

Subp. 6. **Notice to patient of prescription invalidation.** The pharmacist conferring with the patient at the time of the transfer request shall inform the patient that the original prescription has been invalidated at the pharmacy from which it was obtained.

Subp. 7. **Computerized prescription recordkeeping system.** A computerized prescription recordkeeping system must satisfy all the requirements of subparts 2 to 6 including invalidation of the original prescription. Pharmacies accessing a common electronic file or data base used to maintain required dispensing information are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided; however, that any such common file must contain complete records of each prescription and refill dispensed and further, that a hard copy record of each prescription transferred or accessed for purposes of refilling must be generated and maintained at the pharmacy refilling the prescription or to which the prescription has been transferred.

Subp. 8. **Transfer of prescription by presentation of container.** Except as provided in subpart 7, when the transfer of original prescription information is initiated by the receipt of a prescription container previously filled at another pharmacy, the receiving pharmacist shall notify the transferring pharmacist that the prescription is being transferred. All information required by subparts 2 to 6 must be exchanged.

Subp. 9. **Unprofessional conduct.** The board shall consider it evidence of unprofessional conduct to reveal to others the nature of professional pharmaceutical services rendered to a patient without the express oral or written consent of the patient or without an order or direction of a court. A pharmacy may, however, provide informational copies of a prescription to another pharmacy or to the person to whom the prescription was issued as provided in this part. A pharmacist may also provide drug therapy information to a physician for the patient.

The board shall consider it evidence of unprofessional conduct for a pharmacist to refuse to provide a transfer of original prescription information to another pharmacist who is acting on behalf of a patient and who is making a legal request for this information under this part.

Subp. 10. **Schedule II controlled substances.** Nothing in this part authorizes the transfer of a prescription for a Schedule II controlled substance. A new written prescription personally signed by the prescribing practitioner is required prior to dispensing a Schedule II controlled substance.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*

6800.3650 LABELING OF POISONS.

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

A. name of substance,

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

C. the word "POISON" in letters no smaller than the largest point on the label (for extremely dangerous substances this must be accompanied by the "skull and crossbones");

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

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

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

Statutory Authority: *MS s 151 06 subd 1 cl (9)*

History: *10 SR 2007*

WAIVERS AND VARIANCES

6800.9900 VARIANCES.

Subpart 1. **Right to request variance.** A person subject to the rules of the Board of Pharmacy may request that the board grant a variance from any rule of the Board of Pharmacy.

Subp. 2. **Submission and contents of request.** A request for a variance must be submitted to the board in writing. Each request must contain the following information:

A. the specific rule for which the variance is requested;

B. the reason for the request;

C. the alternative measures that will be taken if a variance is granted;

D. the length of time for which a variance is requested; and

E. any other relevant information necessary to properly evaluate the request for the variance.

Subp. 3. **Decision on variance.** The board shall grant a variance if it determines that:

A. the variance will not adversely affect directly or indirectly, the health, safety, or well-being of the public;

B. the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the variance is requested, and

C. compliance with the part for which the variance is requested would impose an undue burden upon the applicant.

The board shall deny, revoke, or refuse to renew a variance if the board determines that item A, B, or C has not been met.

Subp. 4. **Notification.** The board shall notify the applicant m writing withm 60 days of the board's decision. If a variance is granted, the notification shall specify the period of time for which the variance will be effective and the alternative measures or conditions, if any, to be met by the applicant.

Subp. 5. **Renewal.** Any request for the renewal of a variance shall be submitted in writing prior to the expiration date of the existing waiver. Renewal requests shall contain the information specified in subpart 2. A variance shall be renewed by the board if the applicant continues to satisfy the criteria contained in subpart 3 and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance was granted.

Statutory Authority: *MS s 151.06 subd 1 cl (9)*

History: *10 SR 2007*