STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments to Pharmacy Rules Relating to Licensure Fees, Internship, Pharmacy Equipment, Licensure Requirements, Continuing Education, Return of Drugs, Prescription Labeling, Controlled Substance Samples, Transfer of Prescriptions, Controlled Substances, Registration of Researchers, Prescription Order Communication, Emergency Kits, Labeling of Large Volume Parenterals, Waivers of Board Requirements, and Reorganization of Existing Rules

STATEMENT OF NEED FOR AND FACTS ESTABLISHING REASONABLENESS OF AMENDMENTS

The Minnesota Board of Pharmacy (hereinafter "Board"), pursuant to Minn. Stat. § 15.0412, subd. 4 (1980), hereby affirmatively presents the need for and facts establishing the reasonableness of adopting the above-captioned amendments to the Board rules. The statutory authority for the proposed amendments is set forth in Minn. Stat. § 151.06 and Minn. Stat. § 152.02 subd. 7-9. The approval of the Commissioner of Finance of Provisions relating to fee adjustments is contained in a separate document.

The need to adopt these proposed amendments to the Board's existing rules arises: out of the necessity that licensure fees be set at a level which, over the biennium, will, as nearly as possible, match the appropriation which has been granted the Board by the legislature; from changes in the curriculum at the College of Pharmacy; from changes in the Federal Controlled Substances Act; from studies and recommendations done by the Board's Continuing Education Advisory Committee and because of advances and changes in the profession of pharmacy which must be addressed. Some of the proposed changes are for clarification only and do not change the substance of existing rules. Other proposed rule changes reflect changes in the profession and may, in a few instances, involve substantive changes in existing rules. Each of the proposed changes will be more fully explained below.

7 MCAR § 8.004 and § 8.013

The intent of the proposed changes in 7 MCAR 8.004 is to allow the Board to meet its statutory requirement of adjusting its fees to meet the expenditures over each biennium. Minn. Stat. § 16A.028 already allows the Commissioner of

Finance to approve the adjustment of fees without the necessity of a public hearing as long as the amount of fee requested equals anticipated expenditures. The Board, however, believes that it is to the advantage of its licensees and the public to have information regarding fees in the rule document itself. The figures contained in exhibit one, attached hereto, provide the basis upon which the Board based its need for increased revenue from fees.

In that individual pharmacist licensees bore the brunt of the last required fee increase the Board is proposing that its facility license fees be the focal point for this next required fee increase.

7 MCAR § 8.010

The Board proposes to eliminate the current edition or revision of United States Pharmacopeia-National Formulary as a required reference in each pharmacy and instead placed the United States Pharmacopeia-National Formulary and the United States Pharmacopeia-Dispensing Information among those references that are optional. This change is being proposed because, while the United States Pharmacopeia-National Formulary is still the official compendium for the United States, recent editions of this reference have been revised to the point where they have lost a good deal of their usefulness to the dispensing pharmacist. The reference is quite expensive and the Board is of the opinion that to require this reference of every pharmacy is unreasonable.

7 MCAR § 8.026

There are two changes being proposed to this section, which deals with the qualifications for licensure.

The first proposed change deletes from the licensure requirement the necessity of the candidate having filed and proved their intention of becoming citizens of the United States. The Board is acting to eliminate this requirement due to a lack of proof that citizenship in the United States or the filing of intention to become a citizen of the United States bears any relationship to competency in the practice of pharmacy.

The second change being proposed recognizes a trend in education at the colleges of pharmacy in the United States, which provides for either a B.S. degree or a Pharm D degree as the first professional undergraduate degree. This change makes it clear that the Board will recognize either a B.S. Degree or a Pharm D Degree as meeting the educational requirement for licensure.

7 MCAR 8.027

The Board's authority to require continuing professional education is found in Minn. Stat. § 214.12. Prior to the enactment of that statutory section a legislatively mandated continuing education provision was found in Minn. Stat. ch. 151.

Currently pharmacists are required to report continuing education participation at the time of their license renewals in every other year. The timing of the continuing education reporting makes it administratively impossible to determine non-compliance prior to the time of expiration of current registration for pharmacists. This means that pharmacists who find themselves short of continuing education hours have no time to acquire additional hours before their current registration expires.

By separating the reporting of continuing education participation from license renewal the Board has more time to determine compliance by licensees and licensees notified of shortages of acceptable hours have some time to participate in additional programs prior to the expiration of their existing license.

License renewal is March 1. By requiring continuing education reporting on October 1 of the preceeding year pharmacists will have approximately six months to obtain additional continuing education hours before their current license expires.

During the year of the reporting date change only the Board will pro-rate the hours required to be reported on October 1 on a basis of 1¼ hours per month from the last reporting date. Thus only 24 hours of continuing education must be reported on October 1, 1982. Further, this time only, the Board will allow pharmacists who have more than 24 hours accumulated by October 1, 1982 to carry those hours in excess of 24 over to the next reporting period.

This reporting date change should serve to benefit both the Board and the pharmacist licensee.

7 MCAR § 8.032

For a number of years the Board had a blanket prohibition against the return of dispensed medications for reuse or reissuance. This requirement was justifiable as part of the Board's rules in order that pharmacists would not be found to be in violation of FDA regulations concerning adulteration and misbranding. Developments in the drug packaging industry over the past several

years have brought about the subsequent wide spread use of unit of use packaging and unit dose distribution systems which allowed a reconsideration of the previously existing position. In 1978 the Board revised the total prohibition on returns allowing medications, where each individual tablet or capsule was wrapped and labeled, to be returned for reuse or reissuance if certain essential criteria were met.

The Board has now been approached by the users of a blister pack card type of packaging system requesting that they too be allowed to accept dispensed drugs for reuse or reissuance. The Board acted on this request by establishing an adhoc committee to review the issue and incorporated the essential parts of the committee's recommendations in its proposal to revise 7 MCAR 8.032.

As it is proposed, the pharmacist dispensing medications where each tablet and capsule has been individually wrapped and labeled will continue to be able to accept returns under the same essential criteria as has been the case since 1978. The proposed amendments would expand the return allowance to those pharmacists using blister pack card systems if the user can demonstrate that their packaging material and procedures will provide a package that will meet or exceed the criteria for Class B packaging established by the United States Pharmacopeia and that procedures have been developed in the pharmacy that will prevent the co-mingling of dosage units from different lot numbers once they are returned. Meeting these criteria will enable the pharmacist involved to avoid violation of FDA regulations as well.

7 MCAR § 8.040

The small change proposed for this section is made simply to clarify what is meant by the previously existing phrase "Identification of Pharmacy". It has been the experience of the Board that pharmacists have interpreted that phrase differently. The new wording will make it clear that "identification of pharmacy" means more than just the name, it also means the address and telephone number.

7 MCAR § 8.042

This is simply a renumbering change, old rule 7 MCAR § 8.041 has now been renumbered as 8.042.

7 MCAR § 8.047

This change simply reflects the correction of a typographical error.

7 MCAR § 8.049

The Food and Drug Administration and the Minnesota Board of Pharmacy have long held that a copy of a prescription transferred from one pharmacy to another is not a valid prescription order and pharmacists receiving such a copy must contact the prescribing practitioner for verification. No system of uniformity has ever been established relative to the transferring of prescriptions from one pharmacy to another and as a result the records maintained in both the receiving pharmacy and the providing pharmacy have often been incomplete. This has posed significant problems in patient compliance and has resulted in patients often obtaining the same prescription from more than one pharmacy at the same time. The National Association of Boards of Pharmacy, in conjunction with the Federal Drug Enforcement Administration, has developed a model regulation for the transfer of prescription information between pharmacies. DEA, in addition, is proposing a formal rule on the transfer of prescription information for Schedule III, IV and V controlled substance prescriptions between pharmacies. The Board's proposal takes into account both the proposals for formal rule by DEA and the NABP model regulation.

7 MCAR § 8.050

The Minnesota Legislature, in the 1981 session, passed a bill requiring all drug manufacturers to identify all solid oral dosage forms of their products being distributed in Minnesota by placing an identifying mark or symbol on the product. The companies are further required to supply the Board with a list of their products showing or describing the identifying mark. This rule serves to clarify the statutory requirements, particularly in the area of petitioning for exemption from the requirements.

7 MCAR § 8.051

The changes proposed by the Board in this rule are made primarily to bring state law on the use of controlled substances into conformity with the Federal law.

The provisions of the Federal Controlled Substances Act are applicable to all pharmacists in Minnesota. The changes proposed by the Board thus will not have any effect on pharmacy practice as such.

Under the provisions of Minn. Stat. § 152.02 subd. 7, 8 and 9 rescheduling done by the Board through its rules will affect prosecutions of drug related felonies in the state court system. The changes being proposed by the Board in 7 MCAR § 8.051 will serve the people of Minnesota by allowing state law enforcement agencies the same latitudes in pursuing drug related felonies in the state courts as is now available to the federal authorities in federal court.

7 MCAR § 8.052

As a result of the Federal Controlled Substances Act, pharmacists have not been allowed to partially fill a Schedule II controlled substance prescription and provide the remaining amount at a later time. According to the Federal Controlled Substances Act a pharmacist had 72 hours in which to fill and dispense the entire amount indicated on a prescription for a Schedule II controlled substance. This posed a significant problem for pharmacists dispensing medications to patients in long term care facilities via unit dose dispensing systems.

Unit dose dispensing systems offer significant advantages in the areas of patient safety and drug accountability in long term care facilities. The unit dose dispensing system, however, provides that only a limited number of dosage units of each drug are dispensed to the home at any one time. The amounts dispensed ordinarily range from a one to five day supply. For prescriptions written for Schedule II controlled substances this posed a problem in that the federal law required that the entire amount of the prescription be dispensed within 72 hours while the unit dose dispensing system would allow only a three day supply to be dispensed during that same time period.

The Federal Drug Enforcement Administration has recognized this problem and has adopted a regulation that will allow the partial filling of prescriptions for Schedule II controlled substances if the state develops similar provisions. The proposed rule 7 MCAR § 8.052 is designed to meet, at the state level, the federal requirement and allowances.

7 MCAR § 8.053

The registration of researchers involved in the use of controlled substances has not been previously done in Minnesota. There are several statutory sections which indicate that it is not only appropriate but expected that the Board of Pharmacy will perform this function.

Minnesota Statutes 151.37 subd. 4 clearly seems to require that someone is to determine what is meant by "bonafide" research. In that Minn. Stat. § 151.37

is part of the Pharmacy Practice Act it seems entirely logical that that responsibility fall to the Board. Minn. Stat. § 152.101 also refers to "bonafide" research.

Minn. Stat. § 152.12 subd. 3 is more specific in that it very clearly requires that researchers register with the Board. For its part, the Federal Drug Enforcement Administration seems to expect that states will register researchers in controlled substances. Their procedure for registration at the Federal level requires the applicant to indicate on the application form what his state registration number is. Minnesota has for years confused DEA in that we do not have a system for state registration. The vast majority of other states do have a registration requirement not only for researchers in controlled substances but for anyone who is going to handle controlled substances, including pharmacies, hospitals, physicians, and others.

Judging by the number of contacts we receive from reseachers who are perplexed at the questions asked on their federal registration application it is anticipated that somewhere between ten and fifteen researchers would be registered each year.

7 MCAR § 8.054

Controlled substances as defined in Minn. Stat. § 152.01 subd. 4 are subject to state and federal control in all aspects of their manufacture and distribution except where they are distributed as manufacturer "samples" by manufacturer's sales representatives. There have been several instances of careless distribution by drug company representatives in recent months. It is hoped that this rule will eliminate the haphazard approach to controlled substance sample distribution that has occurred while still allowing access to these drugs by physicians and pharmacists.

7 MCAR § 8.061

As a result of a competency study done in 1973 the Minnesota Board of Pharmacy instituted an internship requirement that limited internship to a time subsequent to the third year of the standard five year pharmacy curriculum and required 520 hours of post-graduate experience. The competency study showed that a significant amount of learning took place during this post-graduate period.

Since 1973 the College of Pharmacy at the University of Minnesota implemented first a one quarter college directed internship and now has expanded to a two quarter community and hospital based college directed internship.

It is the belief of the Board that the structured and supervised internship experiences now obtained by University of Minnesota graduates will provide a level of competency equal to or greater than that provided by a relatively unstructured post-graduate experience.

The Board will continue to require students to demonstrate a minimal level of competency obtained through their internship experience by continuing to require participation in the Board's Internship Competency Exam.

7 MCAR § 8.071

The method by which prescription orders can be communicated from the prescribing practitioner to the dispensing pharmacist in the case of patients housed in long term care facilities continues to be a problem. Ideally the prescription order would be communicated directly from the prescriber to the pharmacist personally but in the case of long term care facilities this is seldom actually the case. In long term care facilities the usual situation is that the physician will write an order in the patient's chart or phone an order to the staff at the long term care facility. That order then is redirected to the pharmacist by someone on the staff of the facility. In order to achieve a legally defensible chain of authority in responsibility between the prescriber and the pharmacist a couple of different systems have been tried. All systems tried have been found wanting in one way or another.

The Board's proposal for change in 7 MCAR § 8.071 comes through the recognition that the existing system is too cumbersome to operate efficiently. Representatives from the Minnesota Medical Association and the Minnesota Pharmaceutical Association have met, discussed the issue and have requested that the Board consider revising this section. The proposal submitted here by the Board was found to be acceptable by both the Pharmaceutical and Medical Associations.

7 MCAR § 8.074

In the Board rule changes that were made in 1978 the pharmacists became responsible for the contents of the emergency kit at long term care facilities. The rule that was promulgated at that time also delineated certain restrictions applicable to the use of the emergency kit. Previously the primary physician at the facility 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 stocking of controlled substance drugs in the emergency kit has always posed a problem from a recordkeeping and accountability aspect. Under previously existing federal law the physician who wished to have controlled substances kept in the emergency kit was required to obtain a federal registration in his name at the address of the long term care facility. This then would give him the authority to use controlled substances at that address. The problem was that under a strict interpretation of the federal law no other physician could use the controlled substances in the emergency kit that were placed there by the registration of the primary physician. This posed a significant problem for patients at the home.

The Federal Drug Enforcement Administration has recognized the problem that is posed by their current regulations in the area of controlled substances in emergency kits and has taken action to change their rules. The Drug Enforcement Administration will allow controlled substances to be placed in the emergency kits of nursing homes if the state develops regulations to control the drugs in conformity with guidelines established by the DEA. The Board's proposal in 7 MCAR § 8.074 is designed to meet these federal requirements.

7 MCAR § 8.088

This addition to the labeling requirements found in the hospital pharmacy section comes about as a result of recommendations made by the Committee on Institutional Pharmacy of the National Association of Boards of Pharmacy. The Chairman of the Committee on Institutional Pharmacy served as a member on the National Coordinating Committee on Large Volume Parenterals and brought back to the Committee on Institutional Pharmacy recommendations from the NCCLVP regarding the proper labeling of large volume parenterals in a hospital setting. These recommendations were adopted by the Committee on Institutional Pharmacy and recommended to the individual Boards of Pharmacy by the National Association of Boards of Pharmacy. The Board's proposal in 7 MCAR § 8.088 will implement these recommendations.

7 MCAR § 8.118

Recent legislative changes in Minn. Stat. § 15.0412 subd. 1A indicates that before an agency may grant a variance to an existing rule it shall have promulgated rules setting forth procedures and standards by which variances shall be granted and denied. The Board's proposal in 7 MCAR § 8.118 represents the procedures that the Board will follow in addressing requests for variances to its currently existing rules.