STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Pharmacy Governing Examination Fees, Foreign Pharmacy Graduates, Make-up of Continuing Education Advisory Task Force, and Scheduling of Controlled Substances

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. section 14.22 and 14.23 and Minn. rules part 1400.0500, hereby affirmatively presents the needs for and facts establishing the reasonableness of the above captioned proposed amendment to portions of the Board's rules. The statutory authority for these proposed rule changes is contained in Minn. Stat. sections 151.06 subdivision 1 (9), 151.13 subdivision 2, and 214.06, which authorize the Board to make and publish uniform rules and regulations to enforce the provisions of the statute. The rules captioned above are being adopted according to the procedures set forth in Minn. Stat. section 16A.128. A copy of the approval of the Commissioner of Finance is incorporated herein. Minnesota rules part 6800.1250 is the Board's current rule addressing examination fees. Minnesota rules part 6800.1600 is the Board's current rule on the Continuing Education Advisory Task Force.

The Board is proposing to amend these rules to establish fees that will ensure that the Board generates sufficient revenue to cover increased costs of administering the "national" examination. It has been determined that Minn. Stat. section 14.11 does not apply to this proposed rule

therefore the Statement of Need and Reasonableness does not address the topic referenced in that statute. The intent of the proposed changes in Board rules is to allow the Board to meet its statutorily requirement of adjusting its fees to meet the expenditures over each biennium.

The Board, in furtherance of its responsibilities under Minnesota Statutes Chapter 214.03, utilizes a national standardized test as the objective, non-practical portion of its licensure examination given to prospective licensees. The National Association of Boards of Pharmacy produces the test called "NABPLEX", which is utilized by the Board. The Board also utilizes a Federal Drug Law Examination that is distributed on a nationwide basis as the examination for knowledge of federal drug laws. The cost of the NABPLEX examination is being raised. In addition, the costs of the laboratory examination has increased. At the Board's examination that was administered in June of 1987 the Board found itself in the unenviable position of actually losing money on every candidate that was examined. The Board finds that it must raise the examination fees to the candidates for licensure in order to break even on the examination costs.

The second proposal involves a new rule to implement the provisions of M.S. 151.10, subd. 2.

The legislature, in 1986, gave the Board the authority to recognize graduates of colleges of pharmacy outside of the United States as candidates for licensure as pharmacists. The legislation required foreign graduates to demonstrate equivalency of education and competency in English.

The Board, through these rules, recognizes and accepts the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) as the examination that must be passed in order to demonstrate equivalency of education and recognizes and accepts the passing of the Test of English as a Foreign Language (commonly called the TOEFL exam) as demonstrating competency in English.

The FPGEE is an examination produced by the Foreign Pharmacy Graduate Examination Commision in Chicago. This exam was developed with the assistance of the American College Testing Service and was validated by administration to last year students at United States Colleges of Pharmacy. It meets all EEOC guidelines.

The TOEFL is administered by teh Educational Testing Service of New York. It has been available for many years and is used by many universities and other institutions as "the standard" for determining competency in English.

In that the Board has neither the funding nor the expertice to develope its own examinations in these areas the Board proposes to utilize these nationally recognized examiation instruments.

The third proposal change involves representation on the Board's Continuing Education Advisory Task Force. The make-up of this Task Force has been the same since continuing education was made mandatory for pharmacists in 1973. The Task Force includes representatives of the Board, the College of Pharmacy and the Minnesota State Pharmaceutical Association.

Since this make-up was established the Minnesota Society of Hospital Pharmacists has become a second viable and active professional association.

The Minnesota Society of Hospital Pharmacists has now met with representatives of the Board, the College of Pharmacy and the Minnesota State Pharmaceutical Association regarding representation on the Continuing Education Task Force. Various possibilities for representation of the Minnesota Society of Hospital Pharmacists have been explored and the parties are all in agreement on the change being proposed by the Board.

The Minnesota Society of Hospital Pharmacists will receive two positions from the Minnesota State Pharmaceutical Association and one from the College of Pharmacy. Thus the total composition remains at ten with three appointments being made by each of the two professional organizations and two each by the board the the College.

This format will provide the Board with input from all aspects of pharmacy within the state.

The Board has determined that input from all major organizations affecting pharmacy practice and continuing education programming is essential thus this proposed change.

The fourth area of proposed change relates to the rescheduling of controlled substance drugs. Under M.S. 152.02 subd. 7 and subd. 8 the Board of Pharmacy has been given the authority to make and publish uniform rules relating to the scheduling and rescheduling of controlled substance drugs. The Board has regularly exercised this authority in an attempt to keep state schedules in line with federal schedules and in attempts to address specific state problems of drug abuse. The Board is proposing to amend these rules in order to bring state controlled substance schedules once again into conformity with the federal schedules. Part of the

rescheduling involves the placement of a specific dosage form of THC, the active ingredient in marijuana, in Schedule II. This change is perhaps the most noteworthy of the reschedulings being proposed by the Board.

Nabilone, like Dronabinol which was rescheduled in December of 1986, has, in the past few years, been found to be effective in treating nausea associated with cancer chemotherapy in patients who have been unable to control the nausea with previously available drug entities. Nabilone has been scheduled as a Schedule II substance federally. The Board is proposing, herein, to do likewise at the state level so that this product can be used in Minnesota by oncology specialists for their cancer patients.

The Board is proposing, in Minnesota Rule 6800.4210, to clarify the description of a previously scheduled substance "para-fluorofentanyl".

In Minnesota rule 6800.4220 the Board is proposing to place into its proper location in the Board's schedules of controlled substances the drug Alfentanil, sold as Alfenta, which the 1987 legislature acted on and changed from Schedule I to Schedule II. Also involved in this section is the scheduling of Nabilone, which was discussed above.

Schedule II substances are those which do have a recognized medical use in the United States but which exhibit a high potential for abuse. The Board has found, based on the available literature, that:

1. Nabilone has a high potential for abuse;
2. Nabilone has a currently accepted medical use in the United States or a currently accepted medical use with severe restrictions, and;
3. Nabilone may lead to severe psychological or physical dependence.

The above findings are consistant with placement of Nabilone into Schedule II of the Controlled Substances Act.

Whatever an agency proposes a new rule or seeks to amend an existing rule, Minn. Stat. section 14.115 requires the agency to consider whether the rule change will have an impact on small businesses. If the agency determines that they will, the agency must consider whether certain methods, set forth in subdivision two of the statute, could be adopted to reduce the impact of the rule changes on small businesses. The statute requires the agency to document in its Statement of Need and Reasonableness how it consided these methods and the feasibility of adopting any of the specific methods.

In addition to the licensure of pharmacists, the Board licenses pharmacies, drug manufacturer, and drug wholesalers. The Board has reviewed the impact, if any, its proposed rule changes would have on such businesses.

Since the examination fee increase affects individuals and not "small businesses" as that term is defined there is no impact on small business from the fee change provision.

Similarly, there is no impact on small business from the change in the representation on the Board's Continuing Education Advisory Task Force or from the changes in the scheduling of controlled substances.

Minnesota Statutes section 14.115, subd. 2 enumerates the following five methods an agency must consider to reduce the impact of the rules on small businesses:

A. The establishment of less stringent compliance and reporting requirements for small businesses;

B. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

C. The consolidation or simplification of compliance or reporting requirements for small businesses;

D. The establishment of performance standards for small businesses to replace design or operational standards required in the rule, and;

E. Exemption of small businesses from any or all requirements.

Parts B, C and D of subdivision 2 are not applicable to the Board's rules since they relate to reporting requirements or performance standards which are not involved here. The Board is unable to establish a less stringent compliance requirement for a small business and is unable to exempt small businesses from any or all of the requirements of the controlled substance rules in that the federal government has already completed the rescheduling of the substances now being proposed for rescheduling at the state level by the Board. All pharmacies, wholesalers and manufacturers in the state are already required to conform to the scheduling of these products under the federal law therefore exemption under state law would not reduce or eliminate any requirements they might have under this rule.

Attached is a copy of the approval of the fee increase from the Department of Finance.

DAVID E. HOLMSTROM
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MN Board of Pharmacy