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STATE OF MINNESOTA

COUNTY OF RAMSEY

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments relating to Controlled Substances

STATEMENT OF NEED AND REASONABLENESS

I. Introduction

The Minnesota Board of Pharmacy, pursuant to Minn. Stat. Sections 14.22 through 14.28 and Minn. Rules Parts 1400.2300 through 1400.2320, hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendments and additions to portions of the Board's rules.

The statutory authority for these proposed rule changes is contained in Minn. Stat. Section 152.02, Subd. 7 through 12.

II. Small Business Considerations

Minn. Stat. 14.115, Subd. 2, requires that when an agency proposed a new rule, the agency shall consider five suggested methods for reducing the impact on small business. The five suggested methods, enumerated in Subd. 2, are as follows:

(a) the establishment of less stringent compliance or 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) the exemption of small businesses from any or all requirements of the rule.

The Board has given due consideration to the above five suggested methods to reduce the impact of the proposed rules on small businesses.

While most pharmacies in Minnesota fit the definition of a "small business", the proposed rules do not impact small business, in that the rules do not require any action or reporting by

pharmacies. Further, the rules, as proposed, are designed to bring the classifications of various drugs in Minnesota into compliance with the classification schedules already in place at the federal level. As a result, pharmacists and pharmacies, handling these drugs, are already doing so in accordance with federal laws.

While method (e), above, would seem to be applicable here, the proposed rules do not establish any new compliance or reporting requirements for small businesses and, as was indicated previously, the scheduling of the various substances at the state level simply brings the state controlled substance schedules into conformity with federal schedules, which are already applicable to small businesses in Minnesota. As a result, any exemption of small businesses, which the Board might contemplate regarding these rules, would not impact, in any way, the activities of pharmacies within Minnesota.

III. Expenditure of Public Money by Local Public Bodies

There is no requirement in the proposed rules requiring the expenditure of money by any public body.

IV. Impact on Agricultural Lands

The proposed rules relate to the categorization of various drugs of abuse and there is no impact on agricultural land.

V. Proposed Rules

In 1970, the United States Congress passed what was then called the Drug Abuse Control Act of 1970. This act, among other things, established what we now know as the Drug Enforcement Administration (DEA), and established five "schedules" of drugs with potential for abuse. Schedule I drugs were those drugs that did not have a recognized, legitimate medical use in the United States, but had a high potential for abuse. Schedule II through Schedule V drugs do have recognized medical uses in the United States, and have abuse potentials that are high, in the case of Schedule II drugs, to a relatively lower potential for abuse for Schedule V substances.

In 1971, the Minnesota Legislature followed the lead of Congress by re-writing the state laws regarding drugs of abuse and established what is now Chapter 152 of the Minnesota Statutes.

At the federal level, DEA was given the authority to periodically update a list of controlled substances found in the various schedules as the need arises. New prescription drugs, coming onto the legitimate market, have been added to the various schedules based on their potential for abuse on a regular basis. Illicit designer drugs have also been added to the schedule as Schedule I substances as their existence has become known to DEA.

At the state level, the Legislature gave the Board of Pharmacy the authority to schedule, re-schedule, or delete from scheduling the same various drug substances.

While DEA, at the federal level, has virtually continuous on-going re-scheduling proposals, the Board of Pharmacy, given the expense and complexity of rule-making at the state level, has only periodically brought state controlled substance schedules into conformity with federal schedules. The current proposal is the first such update, proposed by the Board, since 1993. The listing of the substances at the state level, as well as at the federal level, allows state authorities to prosecute individuals found to be in illegal possession of these substances at the state court level.

The proposed changes, found in 6800.4210, represent additions, deletions, or changes in scheduling of Schedule I substances. Schedule I substances, again, are those that do not have a legitimate medical use in the United States, and which have a very high potential for abuse. Schedule I substances are all illicit street drugs.

Bringing the state list of Schedule I substances into conformity with the federal list of Schedule I substances will allow prosecution of illegal drug dealers and operators of clandestine drug laboratories within the state court system.

Minn. Rule 6800.4220 contains the list of controlled substance drugs that do have a legitimate medical use in the United States, but which also have a high potential for abuse. One drug, Levo Alpha Acetylmethadol, or LAAM, is being changed from a Schedule I substance to a Schedule II substance, in that a legitimate medical use for the product has been developed.

One additional drug, Glutethimide, is being changed from a Schedule III substance to a Schedule II substance, in that its potential for abuse has been found to be higher than what was first thought. Again, both of these changes merely bring the state schedules into conformity with federal schedules.

Minn. Rule 6800.4230 contains listings of those substances categorized as Schedule III substances. Schedule III substances do have legitimate medical uses in the United States and, while having substantial potential for abuse, have less abuse potential than Schedule II substances. The drugs Tiletamine and Zolazepam are new drugs, which only recently came on the market.

Minn. Rule 6800.4240 is a listing of drugs categorized as Schedule IV substances. Schedule IV substances have less potential for abuse than Schedule III substances and, again, do have a legitimate medical use in the United States. One depressant and three stimulant drugs are being added as Schedule IV substances.

The classes of persons, who will probably be affected by the proposed rule, will be those individuals engaged in the illegal use

and abuse of drugs, and law enforcement officials, including county attorneys and the judiciary, who will be involved in prosecuting drug cases. At this time, the Board has no information on the extent to which the drugs, being added to the various schedules, are being illegally distributed in Minnesota, nor does the Board have any information on the extent to which those, who may be engaged in the illegal distribution of these drugs, will be arrested and prosecuted. As a result, it is impossible to estimate the cost to any other agency of the implementation and enforcement of the proposed rule, and any anticipated effects such prosecution might have on state revenues. The probable costs to the Board of Pharmacy are non-existent.

It is the determination of the Board that there are no methods for achieving the purpose of the proposed rule that are less costly or less intrusive. An alternative method for achieving the purpose of the proposed rule is through the legislative process. Since the legislative process is sometimes uncertain, and since it is important that the re-scheduling be done in a reasonably timely manner, the Board determined that the rule-making process, authorized by Minn. Stat. 152.02, was the appropriate mechanism for accomplishing the re-scheduling.

To the best of the Board's information and belief, there are no costs associated with complying with the proposed rule. The proposed rule does not require affirmative action by anyone.

Minn. Stat. 14.131 requires that the Board conduct an assessment of any differences between the proposed rule and existing federal regulations, and conduct a specific analysis of the need for and reasonableness of each difference. The rule, currently being proposed by the Board, is specifically designed to bring state law into conformity with existing federal regulations and, as a result, upon the adoption of this rule, there will be no differences between the rule and existing federal regulations.

Minn. Stat. 14.131 requires that the Board describe its efforts to provide additional notifications to persons or classes of persons who may be affected by the proposed rule, or explain why these efforts were not made. As has been indicated, the primary impact of these rule changes will be upon those individuals engaged in illegal drug abuse or illegal drug distribution, and it is impossible for the Board to know who those individuals might be. As a result, the Board did not make an effort to contact such individuals regarding these proposed rules.

VI. Summary

Both state and federal law enforcement agencies rely on the categorization and scheduling of drugs for enforcement of criminal statutes relating to illicit drug use. At the federal level, the Drug Enforcement Administration makes recommendations for the scheduling of substances based on potential for abuse. At the state level, the Board of Pharmacy has been given the authority to

schedule substances in a manner consistent with federal actions. The current proposal, by the Board of Pharmacy, reflects recent changes in federal scheduling so that schedules of controlled substances, at the state level, will be identical to those at the federal level. The proposed rule does not require action by pharmacists, pharmacies, or small businesses within Minnesota.

Nov 15, 1995
Date

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Executive Director