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# MINNESOTA BOARD OF PHARMACY

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November 18, 2009

Minnesota Legislative Reference Library  
645 State Office Building  
100 Rev. Dr. Martin Luther King Jr. Blvd.  
St. Paul, MN 55155-1050

To Whom It May Concern:

The Board of Pharmacy intends to adopt rule amendments relating to the scheduling of controlled substances. Pursuant to Minnesota Statutes, sections 14.131 and 14.23, the Board is providing you with a copy of the Statement of Need and Reasonableness. The Notice of Intent to Adopt Rules is scheduled to be published in the *State Register* on Monday, November 23, 2009.

Sincerely,

A handwritten signature in blue ink that reads "Cody Wiberg".

Cody Wiberg, Pharm.D., M.S., R.Ph.  
Executive Director

Enclosures: Statement of Need and Reasonableness

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule  
Amendments Relating to the Scheduling of  
Controlled Substances, Minnesota Rules, 6800.4210 et. seq.

STATEMENT OF NEED AND  
REASONABLENESS

## **I. INTRODUCTION**

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. Sections 14.22 through 14.28 and Minn. Rules 1400.2000 through 1400.2570, hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendments to portions of the Board's rules relating the scheduling of controlled substances.

## **II. ALTERNATIVE FORMAT**

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request for an alternative format, contact Cody Wiberg at the Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, Minnesota 55414-3251, phone (651) 201-2825, or fax (651) 201-2837. TTY users may call (800) 627-3529.

## **III. STATUTORY AUTHORITY**

The statutory authority for these proposed rule changes is contained in Minn. Stat. Sections 151.06, which provides the Board with general rule-making authority relating to the practice of pharmacy, and 152.02, subd. 7, which specifically provides the Board with authority to reschedule controlled substances. Minn. Stat. Section 152.02, subd. 12 further requires the Board to coordinate state controlled substance regulation with federal law.

## **IV. NEED FOR THE RULES**

The United States Drug Enforcement Administration (DEA), pursuant to 21 USC Sec. 811, has added a number of substances to the federal schedules of controlled substances. Minn. Stat. Section 152.02, subd. 12 requires the Board to coordinate state controlled substance regulation with federal law. Consequently, the Board needs to make these rule changes in order to comply with Minn. Stat. Section 152.02, subd. 12. The DEA, after consultation with the United States Food and Drug Administration, has found that the substances being added to the state schedules have a potential for abuse. Some of the substances have also been found to have no currently accepted medical use and it is known that they are being sold illicitly in Minnesota.

## V. REASONABLENESS OF THE RULES

Substances that the Board proposes to add to Schedule I (**Minnesota Rules 6800.4210**) have been found by the United States Drug Enforcement Administration, after consultation with the United States Food and Drug Administration, to have a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted safety for use under medical supervision. The Board has been notified by several county attorneys that some of these substances are being sold illicitly within this state as “street drugs”. The county attorneys have been unable to prosecute the individuals involved in such sales - since the substances have not yet been added to the state’s Schedule I.

Substances that the Board proposes to add to Schedule II (**Minnesota Rules 6800.4220**) have been found by the United States Drug Enforcement Administration, after consultation with the United States Food and Drug Administration, to have a high potential for abuse, but currently accepted medical uses in the United States, or currently accepted medical uses with severe restrictions. Abuse of these substances may lead to severe psychological or physical dependence.

Substances that the Board proposes to add to Schedule III (**Minnesota Rules 6800.4230**) have been found by the United States Drug Enforcement Administration, after consultation with the United States Food and Drug Administration, to have a potential for abuse that is less than the substances listed in Schedules I and II, but currently accepted medical uses in the United States. Abuse of these substances may lead to moderate or low physical dependence or high psychological dependence.

Substances that the Board proposes to add to Schedule IV (**Minnesota Rules 6800.4240**) have been found by the United States Drug Enforcement Administration, after consultation with the United States Food and Drug Administration to have a low potential for abuse relative to the substances in Schedule III, but currently accepted medical uses the United States. Abuse of these substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

Substances that the Board proposes to add to Schedule V (**Minnesota Rules 6800.4250**) have been found by the United States Drug Enforcement Administration, after consultation with the United States Food and Drug Administration, to have a low potential for abuse relative to the substances listed in Schedule IV, but currently accepted medical uses in the United States. Abuse of these substances may lead to limited physical dependence and/or psychological dependence liability relative to the substances listed in Schedule IV.

Minnesota Statutes Sec. 152.02, subd. 7 authorizes the Board to “regulate and define additional substances which contain quantities of a substance possessing abuse potential in accordance” with specified criteria that match those used by the DEA to place drugs in the federal schedules. Consequently, it is reasonable for the Board to place substances in the state schedules that correspond to the federal schedules in which they have been placed. In addition, the Board is required by Minnesota Statutes §152.02, subd. 12 to coordinate state schedules of controlled substances with the federal schedules. Since the substances that are the subject of

these proposed rule changes have been added to the federal schedules, the Board's proposed rule changes are reasonable.

## VI. REGULATORY ANALYSIS

Minnesota Statutes, Section 14.131 (2000), sets out several factors that must be considered in the Statement of Need and Reasonableness. Each factor will be listed separately and will be followed by the Board's analysis.

1. **“... a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;”**

Since pharmacists are already obliged to meet the federal requirements regarding the handling of the various controlled substance drugs, no new activities will be required of Minnesota pharmacists through the adoption of these rule changes. Similarly, practitioners must also prescribe controlled substances in accordance with the federal Controlled Substances Act. Therefore, there will be no impact on practitioners or pharmacists.

However, adopting these rule changes would give state law enforcement agencies the ability to take action under state law when these substances are sold illicitly. At present, individuals involved in such illicit sales have to be prosecuted under federal law. Unfortunately, federal authorities do not always have the resources to prosecute cases involving quantities of controlled substance that are below certain threshold amounts. As an example, law enforcement authorities in a southeastern Minnesota city arrested an individual who was in possession of a thousand doses of the substance n-benzylpiperazine. (Which is sold on the street as a substitute for the illicit drug known as “Ecstasy”). The officials believe he may have been intending to sell it to high school students, since he was found in a car in close proximity to the high school. However, they could not prosecute him under state law and a thousand doses did not meet the federal threshold for prosecution.

2. **“... the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule, and any anticipated effect on state revenues;”**

There will be no fiscal impact on the Board (other than the costs associated with this rule-making process). There should be no effect on state revenues. There may be a fiscal impact on law enforcement agencies, county attorneys and the courts – to the extent that these rule changes are used to arrest and prosecute individuals involved in the illicit sale of the newly added controlled substances. However, the Board has been contacted by several county attorney offices, requesting that these proposed rule changes be made.

**3. "... a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;"**

There are no less costly or less intrusive methods for achieving the purpose of the proposed rule changes. The purpose of the rule is to comply with Minnesota Statutes §152.02, subd. 12, which requires the Board to coordinate the state controlled substances schedules with the federal schedules. The only way to do that is to adopt these rule changes.

**4. "... a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;"**

No alternative methods for achieving the purpose of the proposed rule changes were considered. Minnesota Statutes §152.02, subd. 12, requires the Board to coordinate the state controlled substances schedules with the federal schedules. The only way to do that is to adopt these rule changes.

**5. "... the probable costs of complying with the proposed rule;"**

Since pharmacists are already obliged to meet the federal requirements regarding the handling of the various controlled substance drugs, no new activities will be required of Minnesota pharmacists through the adoption of these rule changes. Similarly, practitioners must also prescribe controlled substances in accordance with the federal Controlled Substances Act. Therefore, pharmacists and practitioners should not have any new costs associated with complying with these rule changes.

Individuals involved in the illicit sale of controlled substances will probably find the risk of prosecution to be higher than it is now. If they comply with these proposed rules to avoid prosecution, they will lose all of their sales. But, of course, those sales are illicit and illegal under federal law – and thus not deserving of protection.

**6. "... an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference."**

The Board's proposed rule changes will actually better coordinate state controlled substance schedules with federal schedules. In regards to the drugs and substances being added to the state schedules, there will be no differences with the federal schedules.

**7. "... a description of how the Board, in developing the rules, considered and implemented the legislative policies supporting performance--based regulatory systems set forth in Section 14.002."**

As mentioned above, pharmacists are already obliged to meet the federal requirements regarding the handling of the various controlled substance drugs, so no new activities will be required of Minnesota pharmacists through the adoption of these rule changes. Similarly,

practitioners must also prescribe controlled substances in accordance with the federal Controlled Substances Act, so they we not have to make any changes in their practices.

Adopting these rule changes would give state law enforcement agencies the ability to take action under state law when these substances are sold illicitly. However, the rule changes do not obligate law enforcement agencies to conduct investigations or to prosecute individuals found to be engaged in the illicit sale of controlled substances.

## **VII. Additional Notice**

Minnesota Statutes, Sections 14.131 and 14.23, require the Board to describe the efforts made to provide additional notification to persons or classes affected by the proposed rule or explain why such efforts were not made.

The Board proposes the following steps to provide notice to any affected parties:

1. The Board has published a request for comments in the State Register and has mailed a copy of it to all persons on the Board's rulemaking list.
2. The Board will be publishing the official notice of intent in the State Register and will mail copies of it to all persons on the Board's rulemaking list.
3. The Board will post a notice of its intent to engage in the rulemaking process, the statement of need and reasonableness, and the proposed rules on the Board's website. A notice of the website posting of the aforementioned documents will be sent, via e-mail, to every pharmacist, pharmacist intern, and pharmacy technician for whom the Board has an e-mail address. A notice will also be sent to the Minnesota Chiefs of Police Association, the Minnesota Sheriffs' Association and the Minnesota County Attorneys Association.
4. The Board will make copies of the aforementioned documents available in alternative formats, as requested.

## **VIII. List of Witnesses**

If the rules go to a public hearing, the Board anticipates having the following witness testify in support of the need and reasonableness of the rule:

Cody Wiberg, Pharm.D., M.S., R.Ph.  
Executive Director  
Minnesota Board of Pharmacy

This individual would testify regarding all aspects of the Board's proposal.


## IX. Contact with Legislative Sponsors About the Proposed Rule

According to Minnesota Statutes § 14.116, if the mailing of a Notice of Intent to Adopt Rules is within two years of the effective date of the law granting the agency authority to adopt the proposed rules, an agency must make reasonable efforts to send a copy of the Notice and the Statement of Need and Reasonableness to all sitting legislators who were chief house and senate authors of the bill granting the rulemaking authority. Since the law granting the Board of Pharmacy the authority to develop rules to regulate pharmacy practice appears to have been passed in 1937, the requirement to notify the chief authors expired long ago.

Minnesota Statutes § 14.116 also requires an agency to send a copy of the Notice and the Statement of Need and Reasonableness to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules. Therefore, a copy of the Notice of Intent to Adopt Rules and a copy of the Statement of Need and Reasonableness will be sent to: Senators John Marty and Paul E. Koering, Chair and Ranking Minority Member, respectively, of the Health, Housing and Family Security Committee; Senators Linda Berglin and Michele L. Fischbach, Chair and Ranking Minority Member, respectively, of the Health and Human Services Budget Division; Senators Mee Moua and Warren Limmer, Chair and Ranking Minority Member, respectively, of the Judiciary Committee; Senators Linda Higgins and Bill G. Ingebrigtsen, Chair and Ranking Minority Member, respectively, of the Public Safety Budget Division; Representatives Paul Thissen and Jim Abeler, Chair and Ranking Minority Member, respectively of the Health Care and Human Services Policy and Oversight Committee; Representatives Tom Huntley and Matt Dean, Chair and Ranking Minority Member, respectively, of the Health Care and Human Services Finance Division; Representatives Michael Paymar and Paul Kohls, Chair and Ranking Minority Member of the Public Safety Finance Division and Representatives Debra Hilstrom and Bruce Anderson, Chair and Ranking Minority Member of the Public Safety Policy and Oversight Committee. A certificate of mailing will be done to acknowledge the mailings and will be included with the documents submitted to the Office of Administrative Hearings as part of the rulemaking record.

## X. Summation

The Board is proposing the adoption of these rules in order to comply with Minn. Stat. Section 152.02, subd. 12, which requires the Board to coordinate state controlled substance regulation with federal law. The DEA, after consultation with the United States Food and Drug Administration, has found that certain substances have a potential for abuse and that some have accepted medical uses. The Board is proposing to place those substances in the state schedules that correspond to the federal schedules in which they have been placed.

  
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Cody Wiberg, Executive Director  
Minnesota Board of Pharmacy

9/21/09  
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Date