
MINNESOTA BOARD OF PHARMACY



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October 5, 2010

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645 State Office Building
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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. We have made the SONAR available to the public but are still awaiting approval from the Governor's Office so have not scheduled publication of the Notice of Intent to Adopt Rules yet.

Sincerely,

A handwritten signature in cursive script 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

STATEMENT OF NEED AND
REASONABLENESS

I. INTRODUCTION

The Minnesota Board of Pharmacy (Board), pursuant to Minnesota Statutes §§ 14.22 through 14.28 and Minnesota 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 to 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 Minnesota Statutes §152.02, subs. 7 and 8, which specifically provide the Board with authority to add substances to the state's controlled substance schedules.

IV. NEED FOR THE RULES

The Board became aware in June of 2010 that certain products are being sold in Minnesota under names such as "Spice" and "K2". They are frequently marketed as "incenses" but they are actually plant materials that have been sprayed with synthetic cannabinoids (chemicals that act as agonists of cannabinoid receptors and that therefore have similar pharmacological effects to marijuana). Even though the products are typically labeled "not for human consumption", individuals who buy these products do, in fact, smoke them.

Over 50 cases involving adverse reactions to these products have been reported to the Hennepin Regional Poison Center and hundreds of adverse reactions had been reported to poison centers across the country by July of 2010. Severe adverse reactions have been reported, including seizures, comas, severely low potassium levels and hallucinations. This is not surprising given that these drugs have not been studied in human beings and some of them are many times more potent than tetrahydrocannabinol (THC), the main active ingredient in marijuana. Since these drugs have no currently accepted medical use, have a high potential for abuse, a lack of accepted safety for use under medical supervision and have been associated with causing severe adverse reactions, there is clearly a need to place them in Schedule I of the state's controlled substance schedules.

V. REASONABLENESS OF THE RULES

The Board has been contacted by legislators, a county attorney, law enforcement officials, chemical dependency treatment professionals and the parents of individuals who have been hospitalized after using these products, many of whom have requested that the Board act quickly to schedule these drugs. The cities of Duluth and Princeton Minnesota have passed city ordinances banning the sale of such products within city limits. The City of Anoka passed a resolution supporting the Board's plan to add these substances to Schedule I. Numerous reports describing the adverse reactions associated with abuse of these products have appeared in the media. These facts indicate that there is public support for regulating these drugs.

Although the United States Drug Enforcement Administration has not yet placed these drugs into the federal Schedule I, it has listed many of them as "substances of concern". At least a dozen states have regulated synthetic cannabinoids. The North Dakota Board of Pharmacy promulgated emergency rules earlier this year that placed some of these drugs into that state's Schedule I. (Those rules were successfully challenged in court because the ND Board of Pharmacy had not properly followed that state's rule-making procedures). The Iowa Board of Pharmacy promulgated rules that made some of these drugs "imitation controlled substances", making their possession and use illegal in that state. Consequently, Minnesota would not be the only state that has regulated synthetic cannabinoids.

Minnesota Statutes §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. In regards to Schedule I, that subdivision states:

"The Board of Pharmacy shall place a substance in Schedule I if it finds that the substance has: 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".

Since the Board finds that synthetic cannabinoids meet those criteria, it is reasonable for the Board to place them in Schedule I.

The reader should note that the Advisory Council on Controlled Substances mentioned in Minnesota Statutes §152.02, subd. 8 no longer exists. The Legislature repealed Minnesota Statutes §152.02, subd. 11, which required the Board to establish that council, back in 1993 (1993 c 337 s 20). Consequently, there is no longer a requirement for the Board to consult with the Advisory Council before amending the state's schedules of controlled substances. Based on research conducted by Board staff, the Board finds that the synthetic cannabinoids that it proposes to add to Schedule I do have a potential for abuse, since they activate the same receptors activated by THC. The substances listed were developed and studied by researchers, so scientific evidence exists that they are, in fact, cannabinoid receptor agonists. These substances have not been extensively studied in humans, but hundreds of cases of adverse reactions to their abuse have been reported to poison centers across the country. The products that contain these substances are widely available in "head shops", music stores, truck stops and even some convenience stores. Some of these businesses derive a substantial percentage of their revenue from the sale of these products. The wide availability of the products and the number of adverse

events reported to poison centers are indications that these products are probably being abused by a significant number of individuals. Given the significant adverse events that have been linked to these substances, the Board finds that they do pose a risk to the public health. Since they act on cannabinoid receptors, these substances do have a potential for psychological dependency.

VI. REGULATORY ANALYSIS

Minnesota Statutes §14.131 (2009), 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 the Board is proposing to place synthetic cannabinoids in Schedule I, their sale and possession will be illegal in this state. That should lead to decreased abuse of these drugs and a positive impact on the general health and welfare of the public. There should be a decrease in serious adverse reactions related to abuse of these drugs, leading to decreased health care costs. Other than having to treat fewer patients who have abused synthetic cannabinoids, there should be no impact on health care professionals.

Adopting these rule changes would give state law enforcement agencies the ability to take action under state law when these substances are sold or possessed. At present, individuals can legally buy these products at so-called "head shops", music stores and even convenience stores and truck stops. As mentioned above, the Board has been contacted by law enforcement agencies and county attorneys who want synthetic cannabinoids placed in Schedule I. To the extent that law enforcement agencies choose to arrest individuals selling or possessing these drugs, they may have increased costs. The same would hold true for county attorney offices that choose to prosecute those who are arrested for use or possession.

Individuals who sell the products that contain the synthetic cannabinoids will no longer be able to sell them. Similarly, individuals who use the products will no longer be able to legally possess them. Presumably individuals in those classes will view the Board's actions negatively.

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 the Bureau of Criminal Apprehension – to the extent that the BCA is asked to analyze substances in order to determine if they contain synthetic cannabinoids.

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 only option available to the Board is to exercise its authority under Minnesota Statutes §152.02, subs. 7 and 8 to add these substances to Schedule I.

- 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;”**

Except for waiting for the Legislature to take action during the next session, no other methods for achieving the purpose of the proposed rule changes were considered. The only way that the Board can achieve the purpose of this rule, which is to make the sale and possession of these substances illegal, is to exercise its authority under Minnesota Statutes §152.02, subs. 7 and 8 to add these substances to Schedule I. Given the apparent extent of abuse and the severe adverse reactions that have been linked to synthetic cannabinoids, the Board decided to not wait for the Legislature to take action next year.

- 5. “...the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;”**

Individuals involved in the sale of products that contain synthetic cannabinoids will lose all of their sales. However, given the fact that these products are not really used as “incense” and that smoking them is known to cause severe adverse reactions, the Board finds it necessary and reasonable to place synthetic cannabinoids in Schedule I.

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 county attorneys and law enforcement officials, requesting that these proposed rule changes be made. In addition, law enforcement agencies and county attorneys will have discretion in terms of whether to arrest and prosecute individuals found in possession of synthetic cannabinoids.

- 6. the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals**

If these substances are not added to Schedule I, they will most likely continue to be sold and abused. Some of the individuals who abuse synthetic cannabinoids will experience adverse reactions and some may even die. Those who experience adverse reactions may need medical care, which will result in increased costs for health insurers and state-funded health care programs.

- 7. “... 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 place synthetic cannabinoids in schedule I of the state's schedules of controlled substances. The U.S. Drug Enforcement Agency has not yet scheduled these drugs but it has listed them as "substances of concern". Since state laws and rules can be stricter than federal laws and rules (as long as they do not conflict with them), it is not unreasonable for the Board to promulgate these proposed rules. The rules are necessary because people are being adversely affected by synthetic cannabinoids and the Board can act much more quickly than the DEA to schedule them. In order to place a drug or substance in one of the federal schedules, the DEA must consult with the U.S. Food and Drug Administration. That makes the federal process lengthier than the state's process.

8. "... 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."

Adopting these rule changes would give state law enforcement agencies the ability to take action under state law when these dangerous substances are sold or possessed. However, the rule changes would not obligate law enforcement agencies to conduct investigations or county attorneys to prosecute individuals found to be selling or possessing these drugs.

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 or e-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 or e-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 the Minnesota Chiefs of Police Association, the Minnesota Sheriffs' Association and the Minnesota County Attorneys Association and the individuals on the Board's rulemaking list. A notice of the website posting will also be placed on the Board's Facebook page.
4. The Board will make all documents available in alternative formats, as requested.

Although not an official part of the Board's additional notice plan, it should be noted that the Board's intent to schedule synthetic cannabinoids has been widely reported by the media.

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 Michelle L. Fischbach, Chair and Ranking Minority Member, respectively, of the Health and Human Services Budget Division; Representatives Paul Thissen and Jim Abeler, Chair and Lead-GOP, respectively, of the Health Care and Human Services Policy and Oversight Committee; Representatives Karen Clark and Dan Severson, Chair and Lead-GOP, respectively, of the Housing Finance and Policy and Public Health Finance Division and Representatives Thomas Huntley and Matt Dean, Chair and Lead-GOP, respectively, of the Health Care and Human Services Finance 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 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 pursuant to Minnesota Statutes §152.02, subs. 7 and 8, which authorize the Board to add substances to the state's schedules of controlled substances. Given that the synthetic cannabinoids at issue have no currently accepted medical use, have a high potential for abuse, a lack of accepted safety for use under medical supervision and have been associated with causing severe adverse reactions, this proposed rule change is both necessary and reasonable.



Cody Wiberg, Executive Director
Minnesota Board of Pharmacy

10/01/2010

Date