

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING EMERGENCY RULES

ORDER

An order of the Controlled Substances Board to create CSB 2.77 relating to scheduling flualprazolam.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Controlled Substances Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare.

The Controlled Substances Board has received information from the Milwaukee Medical Examiner's Office, Dane County Medical Examiner's Office, Jefferson County Sheriff's Department, Monona Police Department, Jackson Police Department and Jefferson Police Department indicating recent overdose cases, including deaths, that have involved flualprazolam. In at least one of the deaths, the only substance was flualprazolam.

Flualprazolam is an analog of alprazolam (a schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom.

The Controlled Substances Board considered the following factors in making the finding of an imminent hazard to the public safety: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: ss. 961.11 (1), (1m), (1r), and (2) and (4m), and 961.19 (2m), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

In making a determination regarding a substance, the board shall consider the following:

- (a) The actual or relative potential for abuse.
- (b) The scientific evidence of its pharmacological effect, if known.
- (c) The state of current scientific knowledge regarding the substance.
- (d) The history and current pattern of abuse.
- (e) The scope, duration and significance of abuse.
- (f) The risk to the public health.
- (g) The potential of the substance to produce psychological or physical dependence liability.
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The controlled substances board may consider findings of the federal food and drug administration or the drug enforcement administration as prima facie evidence relating to one or more of the determinative factors.

After considering the factors, the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse. [s. 961.11 (1m), (1r), and (2), Stats.]

The controlled substances board may add a substance to schedule IV without making the finding required under sub. (1m) if the substance is controlled under schedule IV of 21 USC 812 (c) by a federal agency as the result of an international treaty, convention or protocol. [s. 961.19 (2m), Stats.]

Related statute or rule: s. 961.20, Stats.

Plain language analysis:

This rule schedules flualprazolam as Schedule IV controlled substances.

Summary of, and comparison with, existing or proposed federal regulation:

Flualprazolam is not currently scheduled under the Controlled Substances Act.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled flualprazolam as a controlled substance.

Iowa: Iowa has not scheduled flualprazolam as a controlled substance.

Michigan: Michigan has not scheduled flualprazolam as a controlled substance.

Minnesota: Minnesota has not scheduled flualprazolam as a controlled substance.

Summary of factual data and analytical methodologies:

Flualprazolam is an analog of alprazolam (a FDA approved schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom. Flualprazolam is a benzodiazepine synthesized and patented in 1970s for research purposes but was never marketed as a medicine. Flualprazolam is not used clinically.

The onset of action due to flualprazolam is reported to be 10-20 minutes after oral use with a duration of action of 6-14 hours. Flualprazolam depresses the central nervous system resulting in sedation, reduced anxiety, and loss of consciousness. Flualprazolam is similar to alprazolam which has demonstrably greater abuse liability compared to diazepam, especially for those with a personal or family substance use disorder history.

The World Health Organization released a critical review report on flualprazolam in October 2019. On March 4, 2020, the United Nations Commission on Narcotic Drugs placed flualprazolam under international control as a Schedule IV. Delaware added several benzodiazepines, including flualprazolam, to Schedule IV due to the serious potential for abuse. Flualprazolam is on several states' law enforcement watchlists or alerts.

In 2019 and 2020, there has been an increased prevalence of flualprazolam in the United States. Law enforcement officers and medical examiners have provided information to the Controlled Substances Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can't be commenced under Wisconsin's analog law (s. 961.25, Stats).

Public health concerns are similar to other benzodiazepines which are higher potency with a relatively fast time of onset. When flualprazolam is combined with opioids, this contributes to increased overdose through benzodiazepine-potentiated opioid-induced respiratory depression. In addition, flualprazolam causes disinhibition and sedation that impair driving. There have been reports of intentionally counterfeit alprazolam product containing flualprazolam entering the drug supply chain in other states.

Flualprazolam has a fast onset of action and similarities to alprazolam and has a relatively high dependence liability.

The Controlled Substances Board considered the following factors in making the determination to add flualprazolam to the controlled substance schedules in ch. 961, Stats.:

- The actual or relative potential for abuse.
- The scientific evidence of its pharmacological effect.
- The state of current scientific knowledge regarding the substance.
- The history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The risk to the public health.
- The potential of the substance to produce psychological or physical dependence liability.

- Whether the substance is an immediate precursor of a substance already controlled under ch. 961, Stats.

The Controlled Substances Board makes a finding that flualprazolam has a potential for abuse.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The rule schedules flualprazolam as a Schedule IV controlled substance which will not have any effect on small business.

Fiscal Estimate:

There is no fiscal impact.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be submitted by the date and time at which the public hearing on these rules is conducted. Information as to the place, date, and time of the public hearing will be published on the Legislature's website and in the Wisconsin Administrative Register.

TEXT OF RULE

SECTION 1. CSB 2.77 is created to read:

CSB 2.72 Scheduling of flualprazolam. Section 961.20 (2) (ef), Stats., is created to read:

961.20 (2) (ef) flualprazolam.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated October 20, 2020



Chair
Controlled Substances Board