

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.77

Relating to: Scheduling Flualprazolam

Rule Type: Both Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only):

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.

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to schedule flualprazolam as a controlled substance.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

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.
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Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death.

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.

The alternative to scheduling flualprazolam as a controlled substance is for it to remain as a substance that is not treated as a controlled substance in Wisconsin. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can not be commenced under Wisconsin's analog law (s. 961.25, Stats).

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.11 (1) 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.

(1m) 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; and
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(1r) 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.

(2) After considering the factors enumerated in sub. (1m), 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.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :

60 hours

6. List with description of all entities that may be affected by the proposed rule :

Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule :

The federal government has not scheduled flualprazolam as a controlled substance.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. This rule is not likely to have a significant economic impact on small businesses.

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Authorized Signature

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Date Submitted