

Notice of Hearing

The Controlled Substances Board announces that it will hold a public hearing on a permanent and emergency rule for CSB 2.77 relating to scheduling flualprazolam at the time and place shown below.

Hearing Information

Date: January 15, 2021

Time: 9:30 AM

Location: Virtual Hearing—Connection information will be posted in advance of the hearing at the following webpage:
<https://dsps.wi.gov/Pages/RulesStatutes/PublicHearingComments.aspx>

Appearances at the Hearing and Submittal of Written Comments

Comments may be submitted to Jon Derenne, 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 shall be received on or before the time of the hearing scheduled for January 15, 2021 at 9:30 AM to be included in the record of rule-making proceedings.

The rule may be reviewed and comments made at:
<http://docs.legis.wisconsin.gov/code/chr/hearings>.

Initial Regulatory Flexibility Analysis

The proposed rule will not have an effect on small businesses, as defined under s. 227.114 (1).

Agency Small Business Regulatory Coordinator

Daniel Hereth, Daniel.Hereth@wisconsin.gov, (608) 267-2435

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED 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.

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 a Schedule IV controlled substance.

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:

Jon Derenne, 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 608-266-0955; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Jon Derenne, 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 received at or before the public hearing to be held on January 15, 2021 at 9:30 AM to be included in the record of rulemaking proceedings.

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. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date November 12, 2020
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.77	
4. Subject Relating to scheduling flualprazolam	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected
7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule 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	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.

The rule was posted on the department's website for 14 days to solicit economic impact comments from businesses, business sectors, associations representing business, local governmental units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.

None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

No impact.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the rule will be to protect Wisconsin residents by scheduling flualprazolam as a Schedule IV controlled substance.

16. Long Range Implications of Implementing the Rule

The long range implication of implementing the rule will be to schedule flualprazolam as a controlled substance in Wisconsin and potentially prevent harm caused by the abuse of flualprazolam.

17. Compare With Approaches Being Used by Federal Government

Flualprazolam is not currently scheduled under the Controlled Substances Act.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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.

19. Contact Name

Jon Derenne

20. Contact Phone Number

(608) 266-0955

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
 - Less Stringent Schedules or Deadlines for Compliance or Reporting
 - Consolidation or Simplification of Reporting Requirements
 - Establishment of performance standards in lieu of Design or Operational Standards
 - Exemption of Small Businesses from some or all requirements
 - Other, describe:
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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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