

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	

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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
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20. Contact Phone Number
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ADMINISTRATIVE RULES
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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:

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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