

Notice of Rulemaking Without Public Hearing

The Controlled Substance Board will adopt the attached rule creating CSB 2.004, relating to Scheduling Zuranolone, without public hearing under the procedure set forth in s. 961.11 (4), Stats.

Submittal of Written Comments

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before September 20, 2024, to be included in the record of rule-making proceedings.

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

Jennifer Garrett, (608) 266-2112, Jennifer.Garrett@wisconsin.gov

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 2.004, relating to scheduling Zuranolone.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:

Section 961.11 (1), Stats. provides that “[t]he 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.”

Section 961.11(4), Stats. provides that “[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30–day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).”

Related statute or rule: s. 961.20, Stats.

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

On October 31, 2023, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register adding Zuranolone to schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 31, 2023.

Plain language analysis:

This rule schedules Zuranolone as a schedule IV controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Zuranolone as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Zuranolone under chapter 961, Stats. by creating the following:

CSB 2.004 Addition of Zuranolone to Schedule IV. Section 961.20 (2) (r), Stats., is created to read:

961.20 (2) (r) Zuranolone.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

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 listed Zuranolone as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210].

Iowa: Iowa has not listed Zuranolone as a schedule IV controlled substance [Iowa Code 124.210].

Michigan: Michigan has not listed Zuranolone as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218].

Minnesota: Minnesota has not listed Zuranolone as a schedule IV controlled substance [Minnesota Statutes 152.02 (5)].

Summary of factual data and analytical methodologies:

The methodology was to schedule Zuranolone to conform with the federal Controlled Substances Act.

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

The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and economic impact analysis is attached.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, 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 by September 20, 2024 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.004 is created to read:

CSB 2.004 Addition of Zuranolone to Schedule IV. Section 961.20 (2) (r), Stats., is created to read:

961.20 (2) (r) Zuranolone.

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 08/07/24
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.004	
4. Subject Scheduling Zuranolone	
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 s. 20.165 (1) (hg)
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 This rule schedules Zuranolone as a schedule IV controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Zuranolone as a schedule IV controlled substance. The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.	
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 public comment on economic impact, including how the proposed rules may affect businesses, local government 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) DSPS estimates no one-time or ongoing costs to implementing this rule.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is that the federal and state controlled substances acts will be uniform to avoid stakeholder confusion.	
16. Long Range Implications of Implementing the Rule The long range implications of implementing the rule are that Zuranolone will be added to Wis. Stat. ch. 961 as a schedule IV controlled substance.	
17. Compare With Approaches Being Used by Federal Government	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

On October 31, 2023, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register adding Zuranolone to schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 31, 2023.

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

Illinois: Illinois has not listed Zuranolone as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210].

Iowa: Iowa has not listed Zuranolone as a schedule IV controlled substance [Iowa Code 124.210].

Michigan: Michigan has not listed Zuranolone as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218].

Minnesota: Minnesota has not listed Zuranolone as a schedule IV controlled substance [Minnesota Statutes 152.02 (5)].

19. Contact Name

Nilajah Hardin, Administrative Rules Coordinator

20. Contact Phone Number

608-267-7139

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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