

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING : NOTICE OF TIME PERIOD
PROCEEDINGS BEFORE THE : FOR COMMENTS FOR THE
CONTROLLED SUBSTANCES BOARD : ECONOMIC IMPACT ANALYSIS

NOTICE IS HEREBY GIVEN of the time period for public comment on the economic impact of this proposed rule of the Controlled Substances Board on CSB 2.004, relating to scheduling Zuranolone, including how this proposed rule may affect businesses, local government units and individuals. The comments will be considered when the Department of Safety and Professional Services prepares the Economic Impact Analysis pursuant to § 227.137. Written comments may be submitted to:

Nilajah Hardin, Administrative Rule Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935
DSPSAdminRules@wisconsin.gov

The deadline for submitting economic impact comments is July 31, 2024.

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 will be 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.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and economic impact analysis will be attached upon completion.

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 (date) 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)
