Clearinghouse Rule 22-014

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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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 2.79 relating to scheduling Remimazolam.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, 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. 961.16, Stats.

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

On October 6, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register listing Remimazolam into schedule IV of the federal Controlled Substances Act. The scheduling action was effective October 6, 2020.

Plain language analysis:

This rule schedules Remimazolam as a Schedule IV controlled substance.

The Controlled Substances Board did not receive an objection to similarly treat Remimazolam as a Schedule IV controlled substance under ch. 961, Stats. within 30 days of the date of publication in the Federal Register of the final order designating Remimazolam as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat Remimazolam under ch. 961, Stats. by creating the following:

961.20 (2) (mo) Remimazolam.

The Affirmative Action order, dated November 13, 2020, took effect on November 23, 2020 to allow for 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 scheduled Remimazolam as a controlled substance.

Iowa: Iowa temporarily designated Remimazolam as a Schedule IV controlled substance, via their temporary amendment process, effective May 12, 2021 (<u>ARC 5541C - Iowa Administrative Rules</u>).

Michigan: Michigan has not scheduled Remimazolam as a controlled substance.

Minnesota: Minnesota has not scheduled Remimazolam as a controlled substance.

Summary of factual data and analytical methodologies:

The methodology was to schedule Remimazolam 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 rules were 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:

The Fiscal Estimate and Economic Impact are 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

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; telephone 608-267-7139; 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 March 11, 2022 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.79 is created to read:

CSB 2.79 Scheduling of Remimazolam. Section 961.20 (2) (mo), Stats., is created to read:

961.20 (2) (mo) Remimazolam.

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)