

**Clearinghouse Rule 18-024**

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 )  
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PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.58 relating to excluding from scheduling naldemedine.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

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

**Statutory authority:** ss. 961.11 (1) and (4), 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.]

If 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). [s. 961.11 (4), Stats.]

**Related statute or rule:** s. 961.16, Stats.

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

On September 29, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing naldemedine from the federal Controlled Substances Act.

**Plain language analysis:**

The Controlled Substances Board did not receive an objection to excluding naldemedine as a controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on November 10, 2017 to similarly treat naldemedine under chapter 961 effective November 20, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends s. 961.16 (2) (a) (intro.), Stats. which excludes naldemedine from the controlled substance schedules.

**Comparison with rules in adjacent states:**

**Illinois:** Illinois has not excluded naldemedine from scheduling.

**Iowa:** Iowa has not excluded naldemedine from scheduling.

**Michigan:** Michigan has not excluded naldemedine from scheduling.

**Minnesota:** Minnesota has not excluded naldemedine from scheduling.

**Summary of factual data and analytical methodologies:**

The methodology was to exclude naldemedine from scheduling 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:**

This rule schedules a drug and does not have an effect on small business.

**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 Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by May 9, 2018 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 2.58 is created to read:

**CSB 2.58 Exclusion of naldemedine.** Section 961.16 (2) (a) (intro), Stats., is amended to read: *961.16 (2) (a) (intro) Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, naldemedine, nalmefene, naloxegol, naloxone and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:*

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.

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(END OF TEXT OF RULE)

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