

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 19-012)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.65 relating to scheduling of approved cannabidiol drugs.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

Statutory authority: ss. 961.11 (1) and (4g), 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 cannabidiol is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol under this chapter as soon as practically possible but no later than 30 days from the date of publication in the federal register of a final order rescheduling or deleting cannabidiol or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h). 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 rule making is omitted, rescheduling or deleting cannabidiol. [s. 961.11 (4g), Stats.]

Related statute or rule: s. 961.14, Stats.

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

On September 28, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved drug products that contain cannabidiol into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board took affirmative action on October 9, 2018 to similarly treat Food and Drug Administration approved drug products that contain cannabidiol under chapter 961 effective October 15, 2018 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.22 (7), Stats. which adds Food and Drug Administration approved drug products that contain cannabidiol to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Iowa: Iowa scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Michigan: Michigan has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Minnesota: Minnesota scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Summary of factual data and analytical methodologies:

The methodology was to schedule scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances 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 Daniel.Hereth@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, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.65 is created to read:

CSB 2.65 Addition of approved cannabidiol drugs to schedule V. Section 961.22 (7), Stats., is created to read:

961.22 (7) APPROVED CANNABIDIOL DRUGS. A drug product in finished dosage formulation that has been approved by the United States food and drug administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

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)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated May 21, 2019



Chair
Controlled Substances Board