

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE CONTROLLED
PROCEEDINGS BEFORE THE : SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 20-080)

ORDER

An order of the Controlled Substances Board to create CSB 4.03 (2) and 4.08 (4) relating to designating Gabapentin as a monitored drug having a substantial potential for abuse.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385 (1), Stats.

Statutory authority: ss. 961.385 (1) (ag) and (2), Stats.

Explanation of agency authority:

“Monitored prescription drug” means a substance indentified in s. 961.16, 961.18, 961.20, or 961.22 or a drug identified by the board by rule as having a substantial potential for abuse. [s. 961.385 (1) (ag), Stats.]

The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. [s. 961.385 (2) (c), Stats.]

Related statute or rule: s. 961.385, Stats.

Plain language analysis:

Gabapentin is not a scheduled controlled substance. Gabapentin closely resembles pregabalin, a Schedule V controlled substance, in its chemical structure and pharmacological activity.

Gabapentin is a prescription medication approved by the Federal Food and Drug Administration for the treatment of neuropathic pain and epileptic disorders. In recent years however, gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers, and diverted for illicit use. The Researched Abuse, Diversion and Addictive – Related Surveillance (RADARS) indicates an increase in gabapentin diversion. The Drug Abuse Warning Network (DAWN) indicates a rise of emergency department visit rates for gabapentin.

The Controlled Substance Board and the Prescription Drug Monitoring Program (PDMP) staff has received requests by health care practitioners and law enforcement to have gabapentin included in the PDMP. Prescribers have indicated it is beneficial to be aware of a patient having a prescription for Gabapentin prior to prescribing an opioid because when combined with opioids there is an increase risk of respiratory depression and opioid-related mortality increases significantly. Gabapentin is highly sought after for illicit use due to its potentiating opioids affect.

This rule designates Gabapentin as a drug having substantial potential for abuse. This designation would make Gabapentin a monitored drug in the PDMP.

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

There are no federal regulations regarding drugs monitored through state prescription drug monitoring programs. Gabapentin is not a federal controlled substance.

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:

A public hearing on the statement of scope was held on January 10, 2020. No one testified at the hearing, or submitted written comments.

Comparison with rules in adjacent states:

Illinois: Illinois has designated Gabapentin as a monitored drug in the prescription monitoring program.

Iowa: Iowa's prescription monitoring program designates reportable drugs as controlled substances administered or dispensed by a practitioner or opioid antagonist dispensed by a practitioner or administered by a first responder. There is no provision for designating drugs, such as Gabapentin, as a reportable drug. Iowa has not scheduled Gabapentin as a controlled substance.

Michigan: Michigan has scheduled Gabapentin as a Schedule V controlled substance. Michigan's prescription monitoring program requires all Schedule II-V controlled substances to be monitored.

Minnesota: For purposes of the prescription monitoring program, Minnesota includes Gabapentin in the definition of controlled substances and it is a monitored drug. Gabapentin is not scheduled as a controlled substance.

Summary of factual data and analytical methodologies:

The Prescription Drug Monitoring Program received inquiries from prescribers and law enforcement about the inclusion of gabapentin as a monitored drug. The Controlled Substances

Board received information from those testifying at several law enforcement hearings held pursuant to 2017 Executive Order 228 and the Milwaukee Medical Examiners Office regarding the increase of the presence of gabapentin in overdose cases. The Controlled Substances Board reviewed research of the affects of gabapentin. In addition, the Controlled Substances Board took notice of the actions of several sptates, including our surrounding states, to either schedule gabapentin as a controlled substance or to designate it as a monitored drug in the prescription monitoring programs.

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

The rule draft was posted on the department’s website for 14 days to solicit economic impact comments from small businesses. 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Kevyn Radcliffe, 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 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 4.03 (2) is created to read:

CSB 4.03 (2) Gabapentin.

SECTION 2. CSB 4.08 (4) is created to read:

CSB 4.08 (4) A dispenser who is not otherwise required to have a DEA registration number is not required to compile or submit dispensing data when dispensing Gabapentin.

SECTION 3. 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)

Dated 7/9/2021

Agency



Chairperson
Controlled Substances Board