

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
CONTROLLED SUBSTANCES BOARD : CR 20-080**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

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.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD’S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Controlled Substances Board held a public hearing on January 15, 2021. No comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

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 20-080)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.03 (2) 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) (ag), 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.

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

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 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:

Jon Derenne, 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 608-266-0955; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Jon Derenne, 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 at or before the public hearing to be held on January 15, 2021 at 9:30 AM to be included in the record of rule-making proceedings.

TEXT OF RULE

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

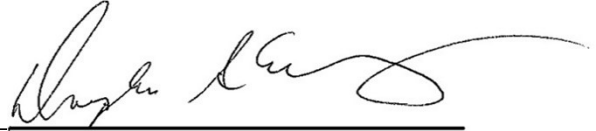
CSB 4.03 (2) Gabapentin.

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 February 1, 2021



Chairperson

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

| | |
|---|--|
| 1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected | 2. Date November 12, 2020 |
| 3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 4 | |
| 4. Subject Relating to designating Gabapentin as a monitored drug having substantial potential for abuse. | |
| 5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S | 6. Chapter 20, Stats. Appropriations Affected |
| 7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget | |
| 8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A) | |
| 9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0 | |
| 10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | |
| 11. Policy Problem Addressed by the Rule 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. | |
| 12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. The rule was posted on the department's website for 14 days to solicit economic impact comments from businesses, business sectors, associations representing business, local governmental units, and individuals. No comments were received. | |
| 13. Identify the Local Governmental Units that Participated in the Development of this EIA. | |

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

No impact.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the rule will be protect Wisconsin residents by including Gabapentin, which has a substantial potential for abuse, as a monitored drug in the prescription drug monitoring program.

16. Long Range Implications of Implementing the Rule

The long range implication of implementing this rule will be to include Gabapentin as a monitored drug in the prescription drug monitoring program, which several of our surrounding states already do, and potentially reduce harm from the abuse of this substance.

17. Compare With Approaches Being Used by Federal Government

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

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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.

19. Contact Name

Jon Derenne

20. Contact Phone Number

(608) 266-0955

This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
 - Less Stringent Schedules or Deadlines for Compliance or Reporting
 - Consolidation or Simplification of Reporting Requirements
 - Establishment of performance standards in lieu of Design or Operational Standards
 - Exemption of Small Businesses from some or all requirements
 - Other, describe:
-

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
-