Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD
VIRTUAL/TELECONFERENCE
Virtual, 4822 Madison Yards Way, Madison
Contact: Adam Barr (608) 266-2112
April 16, 2021

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions and deliberations of the Board.

AGENDA

3:00 P.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1)

B. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates

C. Administrative Rule Matters – Discussion and Consideration
1) Affirmative Action Order for CSB 2.81 Scheduling Brorphine as a Schedule I Controlled Substance **(2-3)**
2) Possible Germane Modification to CR 20-080, Relating to Designating Gabapentin as a Monitored Drug **(4-13) Added via Addendum**

ADJOURNMENT

NEXT MEETING: MAY 14, 2021

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. To confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Kevyn Radcliffe, Administrative Rules Coordinator	April 6, 2021 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
April 16, 2021	☒ Yes ☐ No	Affirmative action order for CSB 2.81 scheduling brorphine as a schedule I controlled substance.

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed

Review and consider affirmative action order to schedule brorphine as a schedule I controlled substance.

11) Authorization

Kevyn Radcliffe — April 6, 2021

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	AFFIRMATIVE ACTION ORDER OF THE CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On March 1, 2021, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register listing brorphine into schedule I of the federal Controlled Substances Act. The scheduling action is effective March 1, 2021.

2. The Controlled Substances Board did not receive an objection to similarly listing brorphine as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the interim final order listing brorphine as a schedule I controlled substance.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.15 and omitting the notice of proposed rule making, listing brorphine as a schedule I controlled substance.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats brorphine under chapter 961, Stats. by creating the following:

CSB 2.81 Addition of Brorphine to schedule I. Section 961.14 (2) (er), Stats., is created to read:

961.14 (2) (er) Brorphine.

This order shall take effect on April 26, 2021 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated April 16, 2021

_____
Doug Englebert, Chair
Controlled Substances Board

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Adam Barr, Executive Director	4/15/21
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
4/16/21	☒ Yes ☐ No	Possible Germane Modification to CR 20-080, Relating to Designating Gabapentin as a Monitored Drug

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed:

The Board will discuss the need to either modify the rule or delay adoption.

11) Authorization

Adam Barr — 4/15/21

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
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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 Addivtive – 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 PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE 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 indentifed 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 pharmaceological 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 Addivtive – 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 dispsend by a practitioner o administered by a first responder. There is no provision for designating drugs, such as Gabapentin, as a reportable drug. Iowa has not scheduled Gabapenin 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 Examininers 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

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ 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
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ 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)?
☐ Yes ☒ 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 Addivtive – 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.

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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 dispsend by a practitioner o administered by a first responder. There is no provision for designating drugs, such as Gabapentin, as a reportable drug. Iowa has not scheduled Gabapenin as a controlled substance.

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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	20. Contact Phone Number
Jon Derenne	(608) 266-0955

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

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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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